The treatment of defaecation disorders

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The treatment of defaecation disorders

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PROEFSCHRIFT

ter verkrijging van de graad van doctor
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chapter 1

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GENERAL INTRODUCTION

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PREFACE

Defaecation disorders are difficult to treat and cause serious impairment of quality of life in affected patients.¹ Defaecation disorders can be classified in faecal incontinence and constipation. The different entities and their treatment are described here.

FAECAL INCONTINENCE

Faecal incontinence is defined as recurrent involuntary passage of faecal material or flatus through the anal canal.² There are different scales to describe faecal incontinence, which correlate well with the clinical impression of severity. They serve as a useful instrument to compare patients and treatment modalities. The classification of faecal incontinence by Parks is often used and is pragmatic (**Table 1.1**).³ The classification of Williams is a five point scale, containing the same items as the Parks' scale adding grade 5; always incontinence for solid faeces, grade 4 means always incontinence for liquid faeces, sometimes incontinence for solid faeces.⁴ The classification of Vaizey is more precise and includes the social impact of the disorder (**Table 1.2**).⁵

Table 1.1 Grading faecal incontinence according to Parks.³

Grade 1	Continent
Grade 2	Incontinent of flatus
Grade 3	Incontinent of liquid stool
Grade 4	Incontinent of solid stool

The prevalence of faecal incontinence for solid stools is estimated to be 1.4-5% and up to 19.6% of the population is incontinent for flatus, liquid stools or solid stool.^{2,6,7} The prevalence of faecal incontinence increases with age.⁸ However, due to the underreporting of symptoms by patients, different standardized scoring scales, differences in data collection and variations in the selected populations, true prevalence remains unknown and is hard to establish.⁹

Table 1.2 Faecal incontinence score according to Vaizey (minimum score 0; maximum score 24).⁵

Incontinent	Never	Seldom	Sometimes	Regular	Daily
Solid stool	0	1	2	3	4
Liquid stool	0	1	2	3	4
Flatus	0	1	2	3	4
Change lifestyle	0	1	2	3	4

Never, not in the past four weeks; seldom, once in the past four weeks; sometimes, > once in the past four weeks but < once a week; regular, several times a week; daily, one or more times a day

	No	Yes
Use of sanitary napkins	0	2
Use of constipating medication	0	2
Impossible to postpone defecation 15 minutes	0	4

Continence is the result of coordinated activity of the rectum and anal sphincters.¹⁰ This is determined by many factors. Consistency and volume of stool is important. The most common causes of faecal incontinence are diarrhoea or constipation with overflow incontinence, especially in children and elderly people.¹¹ Diarrhoea can be caused by certain medication, after colon resection, proctitis or secondary overflow diarrhoea as result of faecal impaction. In case of diarrhoea, this has to be treated first by diet or medication. The majority of patients can be diagnosed and treatment initiated in the primary care setting when the physician is well informed about treatment options. Patients who fail to respond within a few weeks need to be referred.¹¹ Then other causes of diarrhoea have to be excluded.¹² Other treatments for faecal incontinence will not succeed in case of diarrhoea. Pelvic floor, anal sphincters, anal and rectal sensitivity, rectal capacity or compliance are other important factors influencing continence.¹⁰ The most common aetiology of incontinence disorders is traumatic childbirth. This can cause a sphincter rupture with or without pudendal neuropathy.^{13,14} Anal surgical procedures, like treatment of perianal fistulas, fissures and haemorrhoids, can cause anal sphincter defects and are a common aetiological factor for incontinence.¹⁵ Decreased anorectal function is influencing faecal continence and can become apparent with increasing age, spinal cord injury, after abdominoperineal resection and in congenital disorders, like anorectal malformations or spina bifida.¹⁶⁻²⁰ Substantial numbers of patients suffer from idiopathic faecal incontinence, in which the

aetiology cannot be identified. **Table 1.3** shows the different aetiologies and their distribution in a study group of 200 patients with faecal incontinence in an university hospital.²¹ The study population has a selection bias, because these patients were tertiary referrals for a dynamic graciloplasty.

Patients with complaints of faecal incontinence have to be evaluated to assess the grade and aetiology of incontinence. Besides this evaluation, a good medical history and physical examination, including rectovaginal examination, are very important.²² Recommended anorectal physiological tests that can be performed are anorectal manometry, rectal sensitivity and capacity tests and endo-anal ultrasonography.²²⁻²⁶ Pudendal nerve terminal motor latency time measurements and defaecography can provide additional information.²⁶ The clinical relevance of these individual anorectal tests is not always evident, but the potential strength comes from combining test results.²⁷ Other investigations like a sigmoidoscopy or colonic transit time are performed when indicated, e.g. when a tumour, proctitis, or overflow incontinence is suspected.^{28,29}

Table 1.3 Aetiologies of faecal incontinence and their prevalences.²¹

Aetiology	Prevalence
Anal trauma/rupture/fistula	49%
Neurogenic	8%
Congenital	14%
Idiopathic	29%
Total	100%

TREATMENT OF FAECAL INCONTINENCE

Conservative

Treatment of faecal incontinence is difficult. The first choice is conservative therapy: medication and diet modifications to reduce colonic motility (loperamide, codeine phosphate, diphenoxylate and bile acid binders) or extraction of fluids from the luminal content (fibres). In case of overflow incontinence, medications, diet modification and bowel habit training to improve colonic motility have to be performed, which is successful in 60%.¹¹ Pelvic Floor Rehabilitation (PFR)³⁰ is pelvic floor

muscle training combined with biofeedback therapy³¹ and sometimes with electrical stimulation.³² Studies investigating treatment with PFR show different success rates. Most patient groups investigated in these studies however are not very large and only a few studies give a long-term follow-up. These studies are difficult to compare because of the difference in investigational methods and follow-up.^{31,33-35} It is thought that patients with weakness of the external sphincter due to injury of the pudendal nerve or impaired rectal sensation caused by injury to the afferent nerve pathway, are most amenable to treatment with biofeedback.³⁶

Anal plugs can be used, giving satisfactory results for some patients, but pelvic floor function is needed to support the plug. Local side-effects like anal irritation, leakage and plug loss prevent its daily use.³⁷ Since the presence of the plug itself causes a desire to defaecate, the ideal indication is a patient with a loss of sensibility.

Retrograde colonic irrigation (RCI) can be considered when other conservative measures are unsuccessful.^{38,39} Irrigation causes massive defaecation of liquid combined with faeces. When the bowel is empty no loss can be expected until new arrival of stool. This will normally take another day. During this time the patient is pseudocontinent. RCI was already performed in the past, but often forgotten in modern times.

Surgery

The surgeon can make the decision to perform a surgical procedure after failed conservative treatment, but the indications are often overlapping. The end-point of surgery should be recovery of faecal continence and the associated quality of life at the price of minimal morbidity and mortality.⁴⁰ The surgical treatment in faecal incontinence gives an overall success in about 50-84%.^{30,41-51}

The postanal repair was introduced by Parks in 1975. An intersphincteric approach was used to sharpen the anorectal angle and thus improve continence in up to 81%.³ A more recent study suggested that there is an immediate benefit of postanal repair, but only 35% profit from a long-term improvement. They recommend that the postanal repair should be offered to selected patients with persistent, severe faecal incontinence despite an anatomically intact external anal sphincter who are not candidates for or refuse all other operative modalities.⁵²

The total pelvic repair described by Deen and colleagues in 1993 is a combination of postanal repair and pre-anal levatorplasty.^{53,54} The

rectopexy or the Delorme procedure are performed in case of rectal prolapse with respect to faecal incontinence, which is successful in 38-69%.^{55,56} In patients with defective anal sphincters an anal repair can be performed. A good sphincter repair produces good results in 70-80% of patients in the short-term.^{47,57,58} The outcome is similar whether direct end-to-end or overlapping repair of a sphincter defect is performed.⁵⁸ In the medium term, deterioration of the continence following sphincter repair occurs; only a few patients are able to maintain full continence and only 50-75% are having improved continence.⁵⁹⁻⁶²

The Sacral Nerve Modulation (SNM) is another procedure that is successful in patients with a structurally intact external anal sphincter in about 55-100% (**Figure 1.1**).^{30,41-46} Electrical stimulation of the sacral nerves has already been used successfully in the treatment of urinary incontinence by Tanagho et al. in 1988.⁶³ The use of SNM in patients with faecal incontinence was first reported by Matzel and colleagues in 1995.⁶⁴ In SNM the nerves and reflexes are probably modulated to provide for example better rectal sensitivity,³⁰ but the precise working mechanism has yet to be elucidated. SNM is nowadays also used in patients with limited external sphincter defects^{45,65} and in patients with constipation.¹ A new percutaneous technique, insertion of a tined lead, is becoming more widely available and allows the implantation to be performed under local anaesthesia.⁶⁶

In case of a small sphincter defect (33% of the circumference) a SNM can be attempted.^{65,67}

Figure 1.1 Sacral Nerve Modulation.

When a sphincter repair gives insufficient results in large external sphincter defects, a second repair can be undertaken. When this second repair fails, SNM can be performed in functional failures, and a replacement of the sphincter has to be performed in structural failures.

Mainly two techniques are available to treat patients with complete destruction of the sphincter complex or when other surgical techniques failed. The non-stimulated gracilis transposition was described first by Pickrell et al. in 1952.⁶⁸ Techniques like the non-stimulated gracilo- and gluteoplasty are seldom used nowadays, because there is early fatigue of the muscles.^{69,70}

The dynamic graciloplasty (DGP) (**Figure 1.2**) and the artificial bowel sphincter (ABS) are the favoured sphincter replacement procedures in case of failing sphincters.^{13,18,21,71-79} Baeten and Williams and colleagues performed the first stimulated graciloplasties in 1991.^{4,80} The results of DGP are reasonable and even after longer follow-up the success rate is 59%.⁸¹ Complications of the DGP are infection, constipation and pain. Most of the time these complications can be treated successfully.^{71,82,83}

Figure 1.2 Dynamic graciloplasty.

The ABS is a modification of the artificial urinary sphincter especially designed for treatment of faecal incontinence by Lehur and Wong and colleagues.^{75,84,85} The prosthesis is composed of three components which are implanted: 1. an inflatable, occlusive cuff; 2. a pressure regulating balloon and 3. a control pump (**Figure 1.3**).⁷⁵ The inflatable cuff is

brought around the anal canal and is connected to the control pump placed in the large labia in women or in the scrotum in men. This pump is connected to the pressure-regulating balloon that is positioned in Retzius' space, dorsal of the pubic bone and ventral of the bladder. The different components are connected by subcutaneous tubes. A review reports a mean success rate of ABS of 45%, but results seem to deteriorate with time.⁸¹ The technical failure rate of the ABS is high and constipation can be a difficult problem.⁸⁶ The biggest risk of the ABS is infection around the peri-anal cuff; this risk is about 17-25%.^{73,75,84,86,87} The new transvaginal approach may reduce the infectious complications, however follow-up for this method is short.⁸⁸

The results of ABS seems comparable with the DGP in the short-term, but the ABS has a higher adverse event rate compared to the DGP and the results of ABS seem to deteriorate with time.^{79,81} However, different studies vary in methods and patient population, so it is preliminary to draw definitive conclusions.⁸¹ Therefore, it is difficult to give an advice in favour of one of the sphincter replacement techniques. In case of a short perineal length, it seems better to perform a DGP to prevent erosion of the cuff in the ABS procedure.⁸⁶

Figure 1.3 Artificial Bowel Sphincter

Additional RCI can be started when the results of surgery are not satisfactory.³⁸ When RCI is insufficient, antegrade irrigation can be performed usually by the Malone antegrade colonic enema (MACE) first described by Malone et al.⁸⁹ In this procedure the appendix is pulled through the abdominal wall and serves as a colonic access for the irrigation tube. In patients with a previous appendectomy the terminal part of the ileum can be used.⁹⁰ The distal side is pulled through the abdominal wall to serve as the irrigation stoma, and the proximal side is anastomosed to the ascending colon in an intussuscepted way. An urinary catheter is placed in the stoma and antegrade colonic irrigation is started. The most common complication is stenosis of the stoma caused by fibrosis, which can be treated by dilatations,⁸⁹⁻⁹² and leakage of the irrigation fluid and faeces through the appendicostomy⁹³ requiring surgical revision. Antegrade colonic irrigation can also be performed by a sigmoidostomy.⁹⁴

The final treatment option in severe faecal incontinence is an end-colostomy. This can be a good alternative for intractable faecal incontinence. The quality of life can improve significantly for these patients.^{95,96} However, a small group of patients cannot adapt to the colostomy and dislike it intensely.⁹⁶

CONSTIPATION

Constipation can be described by different objective criteria: infrequent defaecation less than three times a week, straining during defaecation or a feeling of incomplete evacuation after defaecation.^{97,98} Other symptoms that can be present are abdominal pain and bloating. The Wexner constipation score is a common score ranging from 0 to 30 to assess the severity of constipation in patients and success of treatment (**Table 1.4**).⁹⁹ The Rome II Committee on Functional Gastrointestinal Disorders set forth criteria for the diagnosis of chronic constipation in 1999 (**Table 1.5**).¹⁰⁰

Constipation affects 3-20.3% of the general population.¹⁰¹⁻¹⁰³

Defaecation is based on the coordination between colon, rectum, pelvic floor and anal sphincters. When this coordination fails constipation can develop. Constipation is caused by various factors. The Rome II criteria may permit the classification of chronic constipation into one of three subtypes: colonic inertia (delayed motility), outlet obstruction, and functional constipation.¹⁰⁰ Slow transit constipation (colonic inertia) can

Table 1.4 Wexner constipation score (minimum score 0; maximum score 30).⁹⁹

Score	0	1	2	3	4
Freq. of bowel movement	1-2 times/ 1-2 days	2x/week	1x/week	<1x/week	<1x/month
Straining	Never	Rarely	Sometimes	Usually	Always
Incomplete evacuation	Never	Rarely	Sometimes	Usually	Always
Abdominal pain	Never	Rarely	Sometimes	Usually	Always
Time needed for defaecation (min)	<5	5-10	10-20	20-30	>30
Assistance for defaecation	Without assistance	Laxatives	Digital assist./ enema		
Unsuccessful attempts / day	Never	1-3	3-6	6-9	>9
Duration of constipation (yrs)	0	1-5	5-10	10-20	>20

Table 1.5 ROME II criteria for constipation.¹⁰⁰

Complaints 12 weeks in the previous year, which do not need to be consecutive	
Symptoms	Fewer than three bowel movements per week
(two of which must be present at least 25% of the time)	Hard or lumpy stools
	Straining with defaecation
	A sensation of incomplete evacuation
	A sensation of anorectal obstruction
	The use of manual manoeuvres to assist defaecation

be caused by disturbed motility of the colon.¹⁰⁴⁻¹⁰⁶ Outlet obstruction can be caused by a pelvic floor dyssynergia,^{105,107} but also anatomical obstructions, like carcinoma, rectal prolapse, intussusception, enterocele and rectocele can present as an outlet obstruction.^{108,109} Functional constipation can be caused by different aetiologies. Decreased rectal sensitivity in congenital disorders, like Hirschsprung’s disease, anorectal malformations and spina bifida, cause constipation.¹¹⁰⁻¹¹² A wrong diet or some medications can produce constipation.¹⁰⁹ Further factors are psychosocial disorders,¹¹³ sexual abuse and physical violence.¹¹⁴

Constipation is often seen in patients after urogenital or anal surgery.^{83,15-117} Some patients suffer from idiopathic constipation, in these patients the aetiology of constipation is unknown.¹¹⁸

After thorough medical history and physical examination anorectal physiologic testing is performed in patients with constipation to evaluate the severity and aetiology of the constipation before deciding what treatment is appropriate. The diagnostic methods are about the same as in faecal incontinence: anorectal manometry, rectal sensitivity and capacity measurements, pudendal nerve terminal motor latency time measurements and defaecography.¹¹⁹⁻¹²² Defaecography is important to demonstrate a pelvic floor dyssynergia or a rectal prolapse, intussusception or rectocele.¹²³ In constipated patients a sigmoidoscopy or a colonoscopy is performed when indicated to exclude other causes of constipation.⁹⁷ Additional colonic transit time measurements are done to determine the severity of constipation or location of dysmotility and to assess the therapeutic response.^{122,124-126} Colon transit time can be determined by radio opaque markers, radio isotopes or colon manometry.¹²⁷ In a transit time study with radio opaque markers only a few radiographs will be taken. This investigation is the most accessible and therefore often used as a screening tool.¹²⁸ This is best performed by administration of in total 30 radio-opaque markers during three days; every day ten markers are taken and each day the markers have a different shape. At the fourth day a conventional abdominal radiograph has to be taken. In the literature upper normality limits for total colonic transit time vary from 45 to 62 hours.¹²⁹ Radio isotope ingestion provides more accurate information about the transit through individual colonic regions because of the possibility of frequent observations and the clear delineation of the entire colon, which is important for selection of patients for segmental colectomy.¹²⁴ Colon manometry has developed in recent years. The pan-colonic pressure with its response to waking and meals can be measured during a whole digestive cycle by a capsule with pressure sensor. This may represent a useful tool for the study of physiology and pathology of colonic motor disorders. It is also possible to use solid state catheters, but the maximum number of recording sensors available is notably reduced.¹³⁰ It is important to realize that these tests are not without problems as abnormal results are also found in asymptomatic controls.¹²²

TREATMENT OF CONSTIPATION

Conservative

The treatment of constipation starts with medication and dietary modification (fibre intake) with increasing fluids to achieve a softer consistency of the stool. Laxatives and colonic enemas can be effective.¹⁰⁹ These treatments are often associated with side effects¹³¹ and results are not always satisfactory.¹³² PFR is satisfactory in a number of patients with evidence of pelvic floor dyssynergia.¹³³ Colonic irrigation can be used when other conservative methods are not successful.^{37,134} Retrograde and antegrade irrigation techniques can be used as described by faecal incontinence.

Surgery

The MACE procedure is described in the treatment of faecal incontinence,⁹⁰ but is originally developed for the treatment of constipation.¹³⁵ In patients with a rectocele a posterior colporrhaphy can be performed.¹³⁶ The SNM is another procedure that is successful in constipation.⁹⁷ A study of Holzer et al., including patients with slow transit and pelvic outlet obstruction, reports good results with improved quality of life.¹³⁷ A review suggests that the clinical effect of SNM in idiopathic constipation is improvement of evacuation with decreased straining, increased frequency of defaecation, decreased abdominal pain and bloating, but only a few studies with small numbers of patients, a short length of follow-up and different baseline definitions have been performed.¹ Surgical resections for constipation must be restricted for intractable constipation and strict patient selection is very important.¹³⁸ The patients with outlet obstruction and the patients with irritable bowel syndrome should be excluded, because in these cases there is no indication for colon resection.^{123,139} The indication for a subtotal colectomy with ileorectal anastomosis exists in a selected group of patients with a slow transit constipation.¹²³ The results are reasonable in case of appropriate patient selection, but complaints of abdominal pain and bloating often persist.^{140,141} It is also possible that abdominal pain, faecal incontinence and recurrent constipation develop after surgery, which has a negative impact on quality of life.^{125,142} However, in the study of FitzHarris et al., 93% of the patients reported to undergo the subtotal colectomy again when given a second chance.¹³⁹ The study of

Glia et al. investigated 17 patients with slow transit constipation and concluded a trend towards worse in patients with abnormal antroduodenal manometry.¹⁴¹ So before performing a (sub)total colectomy, antroduodenal manometry should be performed. In patients with isolated segmental slow transit constipation a segmental colectomy can be performed, resulting in the same results with less side-effects like faecal incontinence.¹²³ To decrease the risk of acquired faecal incontinence, a segmental colectomy should be considered in patients with an abnormal sphincter function,¹⁴³ to prevent intractable diarrhoea. Finally, in some patients an end-colostomy can give good results, and is sometimes preferred above colectomy,⁹⁵ especially in wheelchair bound patients.

AIM AND OUTLINE OF THIS THESIS

Defaecation disorders are distressing for patients and affecting their lives severely. A proportion of patient is resistant to medication and dietary modifications.¹⁴⁴ The aim of this thesis is to investigate different conservative and surgical treatment modalities for defaecation disorders. All studies were performed in the period 2001-2007. All but two of the studies described in this thesis were performed only at the Department of Colorectal Surgery of the Maastricht University Medical Centre. The collaborative study described in Chapter 3 was performed in the Maastricht University Medical Centre and the Academic Medical Centre of Amsterdam with patients from 16 hospitals in the Netherlands. The interdisciplinary study described in Chapter 6 was carried out in collaboration with the Department of Neurosurgery, Paediatric Neurology, Urology, Colorectal Surgery and Paediatric Surgery in the Maastricht University Medical Centre.

Retrograde colonic irrigation (RCI) is a treatment that has been used already in the past, but there are only a few studies.^{37,38} The RCI can be a very successful treatment for defaecation disorders before surgery and after unsatisfactory outcome of surgery, but more investigations need to be done to delineate the effect of RCI in faecal incontinence and constipation. **Chapter 2** delineates the success and pitfalls of RCI in patients with defaecation disorders in a prospective study.

PFR can be successful in some patients.³³ However, when PFR and other conservative treatments are failing, surgery can be performed. SNM is the first choice of treatment, because of the minimal invasive nature of the procedure and the fact that a test treatment is possible before the definitive surgical procedure is performed. SNM has been proved to be successful in patients with faecal incontinence, and also in voiding disorders.^{41,45,77,145-149}

Chapter 3 describes patients with faecal incontinence after a failed standardized PFR program,³³ who are treated with SNM. **Chapter 4** describes patients with faecal incontinence and an implantation with SNM that are stimulated with a voltage below the sensitivity threshold. The sensitivity threshold is the threshold voltage that causes a sensation around the anus during stimulation. When having a therapeutic effect of SNM below the sensitivity threshold, this proves that SNM is not working by solely a stimulatory motor effect, but most probably by modulating the rectal and central nerve pathways. The effect of SNM on patients with constipation and in patients with congenital malformations, like spina bifida has only been investigated in a few small

studies.^{41,42,97,150-153} **Chapter 5** assesses SNM in patients with spina bifida.

In patients suffering from faecal incontinence and dysfunction of the anal sphincters, a sphincter replacing operation can be performed: a DGP or an ABS implantation.^{13,18,21,71-77} The success of DGP in patients with an anorectal malformation (ARM) is not as good as in other patients with a DGP. A study with short-term follow-up was performed in the past.⁷² A longer follow-up of patients with an ARM, who were treated with DGP, is presented in **Chapter 6**.

Chapter 7 reports the success of RCI in defaecation disorders after DGP in a cross-sectional study. RCI can be used after all failing surgical procedures. **Chapter 8** reports the results of RCI in patients with faecal incontinence after a Low Anterior Resection for rectal carcinoma.

LITERATURE

1. Jarrett ME, Mowatt G, Glazener CM, Fraser C, Nicholls RJ, Grant AM, Kamm MA. Systematic review of sacral nerve stimulation for faecal incontinence and constipation. *Br J Surg* 2004;91:1559-69.
2. Nelson R, Norton N, Cautley E, Furner S. Community-based prevalence of anal incontinence. *JAMA* 1995;274:559-61.
3. Parks AG. Royal Society of Medicine, Section of Proctology; Meeting 27 November 1974. President's Address. Anorectal incontinence. *Proc R Soc Med* 1975;68:681-90.
4. Williams NS, Patel J, George BD, Hallan RI, Watkins ES. Development of an electrically stimulated neoanal sphincter. *Lancet* 1991;338:1166-9.
5. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. *Gut* 1999;44:77-80.
6. Perry S, Shaw C, McGrother C, Matthews RJ, Assassa RP, Dallosso H, Williams K, Brittain KR, Azam U, Clarke M, Jagger C, Mayne C, Castleden CM; Leicestershire MRC Incontinence Study Team. Prevalence of faecal incontinence in adults aged 40 years or more living in the community. *Gut* 2002;50:480-4.
7. Giebel GD, Lefering R, Troidl H, Blochl H. Prevalence of fecal incontinence: what can be expected? *Int J Colorectal Dis* 1998;13:73-7.
8. Nelson R, Furner S, Jesudason V. Fecal incontinence in Wisconsin nursing homes: prevalence and associations. *Dis Colon Rectum* 1998;41:1226-9.
9. Madoff RD, Parker SC, Varma MG, Lowry AC. Faecal incontinence in adults. *Lancet* 2004;364:621-32.
10. Ganio E, LAR, Clerico G., Trompetto M. Sacral Nerve Stimulation for Treatment of Fecal Incontinence. *Diseases of colon and rectum* 2001;44:619-31.
11. Whitehead WE, Wald A, Norton NJ. Treatment options for fecal incontinence. *Dis Colon Rectum* 2001;44:131-42; discussion 142-4.
12. Wald A. Faecal incontinence in the elderly: epidemiology and management. *Drugs Aging* 2005;22:131-9.
13. Baeten CG, Uludag OO, Rongen MJ. Dynamic graciloplasty for fecal incontinence. *Microsurgery* 2001;21:230-4.
14. Fenner DE, Genberg B, Brahma P, Marek L, DeLancey JO. Fecal and urinary incontinence after vaginal delivery with anal sphincter disruption in an obstetrics unit in the United States. *Am J Obstet Gynecol* 2003;189:1543-9; discussion 1549-50.
15. Wald A. Clinical practice. Fecal incontinence in adults. *N Engl J Med* 2007;356: 1648-55.
16. Ryhammer AM, Laurberg S, Sorensen FH. Effects of age on anal function in normal women. *Int J Colorectal Dis* 1997;12:225-9.
17. Felt-Bersma RJ, Gort G, Meuwissen SG. Normal values in anal manometry and rectal sensation: a problem of range. *Hepatogastroenterology* 1991;38:444-9.
18. Baeten CG, Geerdes BP, Adang EM, Heineman E, Konsten J, Engel GL, Kester AD, Spaans F, Soeters PB. Anal dynamic graciloplasty in the treatment of intractable fecal incontinence. *N Engl J Med* 1995;332:1600-5.
19. Geerdes B, Heineman E, Zoetmulder FAN, Adang EMM, Vos E. Double dynamic graciloplasty: an alternative to colostomy after total loss of the anorectum. *Neth J Med* 1996;140:773-7.
20. Krogh K, Christensen P, Laurberg S. Colorectal symptoms in patients with neurological diseases. *Acta Neurol Scand* 2001;103:335-43.

21. Rongen MJ, Uludag O, El Naggar K, Geerdes BP, Konsten J, Baeten CG. Long-term follow-up of dynamic graciloplasty for fecal incontinence. *Dis Colon Rectum* 2003;46:716-21.
22. Dobben AC, Terra MP, Deutekom M, Gerhards MF, Bijnen AB, Felt-Bersma RJ, Janssen LW, Bossuyt PM, Stoker J. Anal inspection and digital rectal examination compared to anorectal physiology tests and endoanal ultrasonography in evaluating fecal incontinence. *Int J Colorectal Dis* 2007;22:783-90.
23. Dobben AC, Wiersma TG, Janssen LW, de Vos R, Terra MP, Baeten CG, Stoker J. Prospective assessment of interobserver agreement for defecography in fecal incontinence. *AJR Am J Roentgenol* 2005;185:1166-72.
24. Dobben AC, Terra MP, Deutekom M, Bossuyt PM, Felt-Bersma RJ, Stoker J. Diagnostic work-up for faecal incontinence in daily clinical practice in the Netherlands. *Neth J Med* 2005;63:265-9.
25. Baeten C, Bartolo DC, Lehur PA, Matzel K, Pescatori M, Roche B, Williams NS. Consensus conference on faecal incontinence. *Tech Coloproctol* 2007;11:225-33.
26. Felt-Bersma RJ, Cuesta MA. Faecal incontinence 1994: which test and which treatment? *Neth J Med* 1994;44:182-8.
27. Azpiroz F, Enck P, Whitehead WE. Anorectal functional testing: review of collective experience. *Am J Gastroenterol* 2002;97:232-40.
28. Jiang XL, Cui HF. An analysis of 10218 ulcerative colitis cases in China. *World J Gastroenterol* 2002;8:158-61.
29. Munikrishnan V, Gillams AR, Lees WR, Vaizey CJ, Boulos PB. Prospective study comparing multislice CT colonography with colonoscopy in the detection of colorectal cancer and polyps. *Dis Colon Rectum* 2003;46:1384-90.
30. Uludag O, Darby M, Dejong CH, Schouten WR, Baeten CG. Sacral neuromodulation is effective in the treatment of fecal incontinence with intact sphincter muscles; a prospective study. *Neth J Med* 2002;146:989-93.
31. Norton C, Cody JD, Hosker G. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database Syst Rev* 2006;3:CD002111.
32. Hosker G, Norton C, Brazzelli M. Electrical stimulation for faecal incontinence in adults. *Cochrane Database Syst Rev* 2000(2):CD001310.
33. Terra MP, Dobben AC, Berghmans B, Deutekom M, Baeten CG, Janssen LW, Boeckxstaens GE, Engel AF, Felt-Bersma RJ, Slors JF, Gerhards MF, Bijnen AB, Everhardt E, Schouten WR, Bossuyt PM, Stoker J. Electrical stimulation and pelvic floor muscle training with biofeedback in patients with fecal incontinence: a cohort study of 281 patients. *Dis Colon Rectum* 2006;49:1149-59.
34. Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence. *Gastroenterology* 2003;125:1320-9.
35. Norton C, Kamm MA. Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults--a systematic review. *Aliment Pharmacol Ther* 2001;15:1147-54.
36. Diamant NE, Kamm MA, Wald A, Whitehead WE. AGA technical review on anorectal testing techniques. *Gastroenterology* 1999;116:735-60.
37. Cazemier M, Felt-Bersma RJ, Mulder CJ. Anal plugs and retrograde colonic irrigation are helpful in fecal incontinence or constipation. *World J Gastroenterol* 2007;13:3101-5.
38. Briel JW, Schouten WR, Vlot EA, Smits S, van Kessel I. Clinical value of colonic irrigation in patients with continence disturbances. *Dis Colon Rectum* 1997;40:802-5.

39. Gosselink MP, Darby M, Zimmerman DD, Smits AA, van Kessel I, Hop WC, Briel JW, Schouten WR. Long-term follow-up of retrograde colonic irrigation for defaecation disturbances. *Colorectal Dis* 2005;7:65-9.
40. Muller C, Belyaev O, Deska T, Chromik A, Weyhe D, Uhl W. Fecal incontinence: an up-to-date critical overview of surgical treatment options. *Langenbecks Arch Surg* 2005;390: 544-52.
41. Rosen HR, Urbarz C, Holzer B, Novi G, Schiessel R. Sacral nerve stimulation as a treatment for fecal incontinence. *Gastroenterology* 2001;121:536-41.
42. Jarrett ME, Matzel KE, Christiansen J, Baeten CG, Rosen H, Bittorf B, Stösser M, Madoff R, Kamm MA. Sacral nerve stimulation for faecal incontinence in patients with previous partial spinal injury including disc prolapse. *Br J Surg* 2005;92:734-9.
43. Jarrett ME, Matzel KE, Stosser M, Baeten CG, Kamm MA. Sacral nerve stimulation for fecal incontinence following surgery for rectal prolapse repair: a multicenter study. *Dis Colon Rectum* 2005;48:1243-8.
44. Jarrett ME, Varma JS, Duthie GS, Nicholls RJ, Kamm MA. Sacral nerve stimulation for faecal incontinence in the UK. *Br J Surg* 2004;91:755-61.
45. Melenhorst J, Koch SM, Uludag O, van Gemert WG, Baeten CG. Sacral neuromodulation in patients with faecal incontinence: results of the first 100 permanent implantations. *Colorectal Dis* 2007;9:725-30.
46. Leroi AM, Michot F, Grise P, Denis P. Effect of sacral nerve stimulation in patients with fecal and urinary incontinence. *Dis Colon Rectum* 2001;44:779-89.
47. Engel AF, Kamm MA, Sultan AH, Bartram CI, Nicholls RJ. Anterior anal sphincter repair in patients with obstetric trauma. *Br J Surg* 1994;81:1231-4.
48. Engel AF, van Baal SJ, Brummelkamp WH. Late results of postanal repair for idiopathic faecal incontinence. *Eur J Surg* 1994;160:637-40.
49. Yoshioka K, Keighley MR. Sphincter repair for fecal incontinence. *Dis Colon Rectum* 1989;32:39-42.
50. Baig MK, Wexner SD. Factors predictive of outcome after surgery for faecal incontinence. *Br J Surg* 2000;87:1316-30.
51. Osterberg A, Edebol Eeg-Olofsson K, Graf W. Results of surgical treatment for faecal incontinence. *Br J Surg* 2000;87:1546-52.
52. Matsuoka H, Mavrantonis C, Wexner SD, Oliveira L, Gilliland R, Pikarsky A. Postanal repair for fecal incontinence--is it worthwhile? *Dis Colon Rectum* 2000;43:1561-7.
53. Deen KI, Oya M, Ortiz J, Keighley MR. Randomized trial comparing three forms of pelvic floor repair for neuropathic faecal incontinence. *Br J Surg* 1993;80:794-8.
54. Korsgen S, Deen KI, Keighley MR. Long-term results of total pelvic floor repair for postobstetric fecal incontinence. *Dis Colon Rectum* 1997;40:835-9.
55. Lechaux JP, Lechaux D, Perez M. Results of Delorme's procedure for rectal prolapse. Advantages of a modified technique. *Dis Colon Rectum* 1995;38:301-7.
56. McCue JL, Thomson JP. Clinical and functional results of abdominal rectopexy for complete rectal prolapse. *Br J Surg* 1991;78:921-3.
57. Barisic G, Krivokapic Z, Markovic V, Popovic M, Saranovic D, Marsavelska A. The role of overlapping sphincteroplasty in traumatic fecal incontinence. *Acta Chir Iugosl* 2000;47(4 Suppl 1):37-41.
58. Tjandra JJ, Han WR, Goh J, Carey M, Dwyer P. Direct repair vs. overlapping sphincter repair: a randomized, controlled trial. *Dis Colon Rectum* 2003;46:937-42; discussion 942-3.

59. Engel AF, van Baal SJ, Brummelkamp WH. Late results of anterior sphincter plication for traumatic faecal incontinence. *Eur J Surg* 1994;160:633-6.
60. Halverson AL, Hull TL. Long-term outcome of overlapping anal sphincter repair. *Dis Colon Rectum* 2002;45:345-8.
61. Malouf AJ, Norton CS, Engel AF, Nicholls RJ, Kamm MA. Long-term results of overlapping anterior anal-sphincter repair for obstetric trauma. *Lancet* 2000;355:260-5.
62. Morren GL, Hallbook O, Nystrom PO, Baeten CG, Sjudahl R. Audit of anal-sphincter repair. *Colorectal Dis* 2001;3:17-22.
63. Tanagho EA, Schmidt RA. Electrical stimulation in the clinical management of the neurogenic bladder. *J Urol* 1988;140:1331-9.
64. Matzel KE, Stadelmaier U, Hohenfellner M, Gall FP. Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. *Lancet* 1995;346:1124-7.
65. Conaghan P, Farouk R. Sacral nerve stimulation can be successful in patients with ultrasound evidence of external anal sphincter disruption. *Dis Colon Rectum* 2005;48:1610-4.
66. Spinelli M, Weil E, Ostardo E, Del Popolo G, Ruiz-Cerdá JL, Kiss G, Heesakkers J. New tined lead electrode in sacral neuromodulation: experience from a multicentre European study. *World J Urol* 2005;23:225-9.
67. Melenhorst J, Koch SM, Uludag O, van Gemert WG, Baeten CG. Is a morphologically intact anal sphincter necessary for success with sacral nerve modulation in patients with faecal incontinence? *Colorectal Dis* 2008;10:257-62.
68. Pickrell KL, Broadbent TR, Masters FW, Metzger JT. Construction of a rectal sphincter and restoration of anal continence by transplanting the gracilis muscle; a report of four cases in children. *Ann Surg* 1952;135:853-62.
69. Christiansen J, Hansen CR, Rasmussen O. Bilateral gluteus maximus transposition for anal incontinence. *Br J Surg* 1995;82:903-5.
70. Corman ML. Follow-up evaluation of gracilis muscle transposition for fecal incontinence. *Dis Colon Rectum* 1980;23:552-5.
71. Baeten CG, Bailey HR, Bakka A, Belliveau P, Berg E, Buie WD, Burnstein MJ, Christiansen J, Collier JA, Galandiuk S, LaFontaine LJ, Lange J, Madoff RD, Matzel KE, Pählman L, Parc R, Reilly JC, Seccia M, Thorson AG, Vernava AM 3rd, Wexner S. Safety and efficacy of dynamic graciloplasty for fecal incontinence: report of a prospective, multicenter trial. Dynamic Graciloplasty Therapy Study Group. *Dis Colon Rectum* 2000;43:743-51.
72. Baeten CG, Konsten J, Heineman E, Soeters PB. Dynamic graciloplasty for anal atresia. *J Pediatr Surg* 1994;29:922-4; discussion 925.
73. Christiansen J, Sparso B. Treatment of anal incontinence by an implantable prosthetic anal sphincter. *Ann Surg* 1992;215:383-6.
74. Lehur PA, Roig JV, Duinslaeger M. Artificial anal sphincter: prospective clinical and manometric evaluation. *Dis Colon Rectum* 2000;43:1100-6.
75. Lehur PA, Michot F, Denis P, Grise P, Leborgne J, Teniere P, Buzelin JM. Results of artificial sphincter in severe anal incontinence. Report of 14 consecutive implantations. *Dis Colon Rectum* 1996;39:1352-5.
76. Parker SC, Spencer MP, Madoff RD, Jensen LL, Wong WD, Rothenberger DA. Artificial bowel sphincter: long-term experience at a single institution. *Dis Colon Rectum* 2003;46:722-9.
77. Zhao X, Pasricha PJ. Novel surgical approaches to fecal incontinence: neurostimulation and artificial anal sphincter. *Curr Gastroenterol Rep* 2003;5:419-24.

78. Christiansen J, Rasmussen OO, Lindorff-Larsen K. Long-term results of artificial anal sphincter implantation for severe anal incontinence. *Ann Surg* 1999;230:45-8.
79. Altomare DF, Binda GA, Dodi G, La Torre F, Romano G, Rinaldi M, Melega E. Disappointing long-term results of the artificial anal sphincter for faecal incontinence. *Br J Surg* 2004;91:1352-3.
80. Baeten CG, Konsten J, Spaans F, Visser R, Habets AM, Bourgeois IM, Wagenmakers AJ, Soeters PB. Dynamic graciloplasty for treatment of faecal incontinence. *Lancet* 1991;338:1163-5.
81. Belyaev O, Muller C, Uhl W. Neosphincter surgery for fecal incontinence: a critical and unbiased review of the relevant literature. *Surg Today* 2006;36:295-303.
82. Tillin T, Gannon K, Feldman RA, Williams NS. Third-party prospective evaluation of patient outcomes after dynamic graciloplasty. *Br J Surg* 2006;93:1402-10.
83. Matzel KE, Madoff RD, LaFontaine LJ, Baeten CG, Buie WD, Christiansen J, Wexner S; Dynamic Graciloplasty Therapy Study Group. Complications of dynamic graciloplasty: incidence, management, and impact on outcome. *Dis Colon Rectum* 2001;44:1427-35.
84. Wong WD, Jensen LL, Bartolo DC, Rothenberger DA. Artificial anal sphincter. *Dis Colon Rectum* 1996;39:1345-51.
85. Christiansen J, Lorentzen M. Implantation of artificial sphincter for anal incontinence. *Lancet* 1987;2:244-5.
86. Melenhorst J, Koch SM, van Gemert WG, Baeten CG. The artificial bowel sphincter for faecal incontinence: a single centre study. *Int J Colorectal Dis* 2008;23:107-11.
87. Ruthmann O, Fischer A, Hopt UT, Schrag HJ. Dynamic graciloplasty vs artificial bowel sphincter in the management of severe fecal incontinence. *Chirurg* 2006;77:926-38.
88. Michot F, Tuech JJ, Lefebure B, Bridoux V, Denis P. A new implantation procedure of artificial sphincter for anal incontinence: the transvaginal approach. *Dis Colon Rectum* 2007;50:1401-4.
89. Malone PS, Ransley PG, Kiely EM. Preliminary report: the antegrade continence enema. *Lancet* 1990;336:1217-8.
90. Schell SR, Toogood GJ, Dudley NE. Control of fecal incontinence: continued success with the Malone procedure. *Surgery* 1997;122:626-31.
91. Christensen P, Olsen N, Krogh K, Laurberg S. Scintigraphic assessment of antegrade colonic irrigation through an appendicostomy or a neoappendicostomy. *Br J Surg* 2002;89:1275-80.
92. Darakhshan AA, Williams NS. Recent innovations in the management of fecal incontinence. *Semin Pediatr Surg* 2002;11:83-90.
93. Barqawi A, de Valdenebro M, Furness PD, 3rd, Koyle MA. Lessons learned from stomal complications in children with cutaneous catheterizable continent stomas. *BJU Int* 2004;94:1344-7.
94. Gauderer MW, Decou JM, Boyle JT. Sigmoid irrigation tube for the management of chronic evacuation disorders. *J Pediatr Surg* 2002;37:348-51.
95. Harris R, Daly K, Jones L, Kiff E. Stoma formation for functional bowel disease. *Colorectal Dis* 2004;6:280-4.
96. Norton C, Burch J, Kamm MA. Patients' Views of a Colostomy for Fecal Incontinence. *Dis Col Rectum* 2005;48:1062-9.
97. Kenefick NJ, Nicholls RJ, Cohen RG, Kamm MA. Permanent sacral nerve stimulation for treatment of idiopathic constipation. *Br J Surg* 2002;89:882-8.
98. Whitehead WE. Report of an international workshop on management of constipation. *Gastroenterol Int* 1990;4:99-113.

99. Agachan F, Chen T, Pfeifer J, Reissman P, Wexner SD. A constipation scoring system to simplify evaluation and management of constipated patients. *Dis Colon Rectum* 1996;39: 681-5.
100. Thompson WG, Longstreth GF, Drossman DA, Heaton KW, Irvine EJ, Muller-Lissner SA. Functional bowel disorders and functional abdominal pain. *Gut* 1999;45 Suppl 2:II43-7.
101. Thompson WG, Heaton KW. Functional bowel disorders in apparently healthy people. *Gastroenterology* 1980;79:283-8.
102. Everhart JE, Go VL, Johannes RS, Fitzsimmons SC, Roth HP, White LR. A longitudinal survey of self-reported bowel habits in the United States. *Dig Dis Sci* 1989;34:1153-62.
103. Garrigues V, Galvez C, Ortiz V, Ponce M, Nos P, Ponce J. Prevalence of constipation: agreement among several criteria and evaluation of the diagnostic accuracy of qualifying symptoms and self-reported definition in a population-based survey in Spain. *Am J Epidemiol* 2004;159:520-6.
104. Preston DM, Lennard-Jones JE. Severe chronic constipation of young women: 'idiopathic slow transit constipation'. *Gut* 1986;27:41-8.
105. Pemberton JH, Rath DM, Ilstrup DM. Evaluation and surgical treatment of severe chronic constipation. *Ann Surg* 1991;214:403-11; discussion 411-3.
106. Snape WJ, Jr. Myoelectric and motor activity of the colon in normal and abnormal states. *Scand J Gastroenterol Suppl* 1984;96:55-60.
107. Glia A, Gyllin M, Gullberg K, Lindberg G. Biofeedback retraining in patients with functional constipation and paradoxical puborectalis contraction: comparison of anal manometry and sphincter electromyography for feedback. *Dis Colon Rectum* 1997;40:889-95.
108. Boonjunwetwat D, Sungtong P, Rojanasakul A. Defecography in patients with anorectal disorders: a study in 27 cases. *J Med Assoc Thai* 2001;84:1097-102.
109. Schiller LR. Review article: the therapy of constipation. *Aliment Pharmacol Ther* 2001;15: 749-63.
110. Hanneman MJ, Sprangers MA, De Mik EL, Ernest van Heurn LW, De Langen ZJ, Looyard N, Madern GC, Rieu PN, van der Zee DC, van Silfhout M, Aronson DC. Quality of life in patients with anorectal malformation or Hirschsprung's disease: development of a disease-specific questionnaire. *Dis Colon Rectum* 2001;44:1650-60.
111. van Kuyk EM, Brugman-Boezeman AT, Wissink-Essink M, Severijnen RS, Festen C, Bleijenberg G. Biopsychosocial treatment of defecation problems in children with anal atresia: a retrospective study. *Pediatr Surg Int* 2000;16:317-21.
112. Lie HR, Lagergren J, Rasmussen F, Lagerkvist B, Hagelsteen J, Börjeson MC, Muttillainen M, Taudorf K. Bowel and bladder control of children with myelomeningocele: a Nordic study. *Dev Med Child Neurol* 1991;33:1053-61.
113. Wald A, Hinds JP, Caruana BJ. Psychological and physiological characteristics of patients with severe idiopathic constipation. *Gastroenterology* 1989;97:932-7.
114. Leserman J, Drossman DA. Relationship of abuse history to functional gastrointestinal disorders and symptoms: some possible mediating mechanisms. *Trauma Violence Abuse* 2007;8:331-43.
115. van Dam JH, Gosselink MJ, Drogendijk AC, Hop WC, Schouten WR. Changes in bowel function after hysterectomy. *Dis Colon Rectum* 1997;40:1342-7.
116. Chen GD, Hu SW, Chen YC, Lin TL, Lin LY. Prevalence and correlations of anal incontinence and constipation in Taiwanese women. *Neurourol Urodyn* 2003;22:664-9.

117. Speakman CT, Madden MV, Nicholls RJ, Kamm MA. Lateral ligament division during rectopexy causes constipation but prevents recurrence: results of a prospective randomized study. *Br J Surg* 1991;78:1431-3.
118. Knowles CH, Scott SM, Rayner C, Glia A, Lindberg G, Kamm MA, Lunniss PJ. Idiopathic slow-transit constipation: an almost exclusively female disorder. *Dis Colon Rectum* 2003;46:1716-7.
119. Molnar D, Taitz LS, Urwin OM, Wales JK. Anorectal manometry results in defecation disorders. *Arch Dis Child* 1983;58:257-61.
120. Baldi F, Ferrarini F, Corinaldesi R, Balestra R, Cassan M, Fenati GP, Barbara L. Function of the internal anal sphincter and rectal sensitivity in idiopathic constipation. *Digestion* 1982;24:14-22.
121. Pfeifer J, Salanga VD, Agachan F, Weiss EG, Wexner SD. Variation in pudendal nerve terminal motor latency according to disease. *Dis Colon Rectum* 1997;40:79-83.
122. D'Hoore A, Penninckx F. Obstructed defecation. *Colorectal Dis* 2003;5:280-7.
123. Ripetti V, Caputo D, Greco S, Alloni R, Coppola R. Is total colectomy the right choice in intractable slow-transit constipation? *Surgery* 2006;140:435-40.
124. von der Ohe MR, Camilleri M. Measurement of small bowel and colonic transit: indications and methods. *Mayo Clin Proc* 1992;67:1169-79.
125. de Graaf EJ, Gilberts EC, Schouten WR. Role of segmental colonic transit time studies to select patients with slow transit constipation for partial left-sided or subtotal colectomy. *Br J Surg* 1996;83:648-51.
126. Mollen RM, Claassen AT, Kuipers JH. Measurement of colon transit time useful in the evaluation of functional constipation. *Ned Tijdschr Geneesk* 1998;142:357-61.
127. Wong SW, Lubowski DZ. Slow-transit constipation: evaluation and treatment. *ANZ J Surg* 2007;77:320-8.
128. Lundin E, Graf W, Garske U, Nilsson S, Maripuu E, Karlbom U. Segmental colonic transit studies: comparison of a radiological and a scintigraphic method. *Colorectal Dis* 2007;9: 344-51.
129. Gutierrez C, Marco A, Nogales A, Tebar R. Total and segmental colonic transit time and anorectal manometry in children with chronic idiopathic constipation. *J Pediatr Gastroenterol Nutr* 2002;35:31-8.
130. Zhang WQ, Yan GZ, Yu LZ, Yang XQ. Non-invasive measurement of pan-colonic pressure over a whole digestive cycle: clinical applications of a capsule-style manometric system. *World J Gastroenterol* 2006;12:7690-4.
131. Gattuso JM, Kamm MA. Adverse effects of drugs used in the management of constipation and diarrhoea. *Drug Saf* 1994;10:47-65.
132. Annells M, Koch T. Constipation and the preached trio: diet, fluid intake, exercise. *Int J Nurs Stud* 2003;40:843-52.
133. Bassotti G, Chistolini F, Sietchiping-Nzepa F, de Roberto G, Morelli A, Chiarioni G. Biofeedback for pelvic floor dysfunction in constipation. *BMJ* 2004;328:393-6.
134. Christensen P, Olsen N, Krogh K, Bacher T, Laurberg S. Scintigraphic assessment of retrograde colonic washout in fecal incontinence and constipation. *Dis Colon Rectum* 2003;46:68-76.
135. Kokoska ER, Keller MS, Weber TR. Outcome of the antegrade colonic enema procedure in children with chronic constipation. *Am J Surg* 2001;182:625-9.

136. Sloots CE, Meulen AJ, Felt-Bersma RJ. Rectocele repair improves evacuation and prolapse complaints independent of anorectal function and colonic transit time. *Int J Colorectal Dis* 2003;18:342-8.
137. Holzer B, Rosen HR, Novi G, Ausch C, Hölbling N, Hofmann M, Schiessel R. Sacral nerve stimulation in patients with severe constipation. *Dis Colon Rectum* 2008;51:524-9.
138. Pfeifer J, Agachan F, Wexner SD. Surgery for constipation. *Dis Colon Rectum* 1996;39:444-60.
139. von Flue M. Surgery for idiopathic constipation. The modest role of successful surgery. *Schweiz Med Wochenschr* 2000;130:1766-71.
140. van der Sijp JR, Rasing L, Kamm MA, Akkermans LM, van Vroonhoven TJ. Surgical management of severe idiopathic constipation: a review. *Neth J Surg* 1991;43:29-35.
141. Glia A, Akerlund JE, Lindberg G. Outcome of colectomy for slow-transit constipation in relation to presence of small-bowel dysmotility. *Dis Colon Rectum* 2004;47:96-102.
142. FitzHarris GP, Garcia-Aguilar J, Parker SC, Bullard KM, Madoff RD, Goldberg SM, Lowry A. Quality of life after subtotal colectomy for slow-transit constipation: both quality and quantity count. *Dis Colon Rectum* 2003;46:433-40.
143. Lundin E, Graf W, Karlbom U. Anorectal manovolumetry in the decision making before surgery for slow transit constipation. *Tech Coloproctol* 2007;11:259-65.
144. Mowatt G, Glazener C, Jarrett M. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Cochrane Database Syst Rev* 2007(3):CD004464.
145. Matzel KE, Bittorf B, Stadelmaier U, Hohenberger W. Sacral nerve stimulation in the treatment of faecal incontinence. *Chirurg* 2003;74:26-32.
146. Ganio E, Masin A, Ratto C, Altomare DF, Ripetti V, Clerico G, Lise M, Doglietto GB, Memeo V, Landolfi V, Del Genio A, Arullani A, Giardiello G, de Seta F. Short-term sacral nerve stimulation for functional anorectal and urinary disturbances: results in 40 patients: evaluation of a new option for anorectal functional disorders. *Dis Colon Rectum* 2001;44:1261-7.
147. Baeten CG, Uludag O. Second-line treatment for faecal incontinence. *Scand J Gastroenterol Suppl* 2002;72-5.
148. Vaizey CJ, Kamm MA, Roy AJ, Nicholls RJ. Double-blind crossover study of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum* 2000;43:298-302.
149. Janknegt RA, Hassouna MM, Siegel SW, Schmidt RA, Gajewski JB, Rivas DA, Elhilali MM, Milam DC, van Kerrebroeck PE, Dijkema HE, Lycklama à Nijeholt AA, Fall M, Jonas U, Catanzaro F, Fowler CJ, Oleson KA. Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence. *Eur Urol* 2001;39:101-6.
150. Guys JM, Haddad M, Planche D, Torre M, Louis-Borrione C, Breaud J. Sacral neuromodulation for neurogenic bladder dysfunction in children. *J Urol* 2004;172(4 S1):1673-6.
151. Wallace PA, Lane FL, Noblett KL. Sacral nerve neuromodulation in patients with underlying neurologic disease. *Am J Obstet Gynecol* 2007;197:96 e1-5.
152. Holzer B, Rosen HR, Novi G, Ausch C, Holbling N, Schiessel R. Sacral nerve stimulation for neurogenic faecal incontinence. *Br J Surg* 2007;94:749-53.
153. Pescatori M. Correspondence: Systematic review of sacral nerve stimulation for faecal incontinence and constipation (*Br J Surg*; 912:1559-1569). *Br J Surg* 2004;91:755-61.

chapter 2

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PROSPECTIVE STUDY OF COLONIC IRRIGATION FOR THE TREATMENT OF DEFAECATION DISORDERS

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ABSTRACT

PURPOSE

Retrograde colonic irrigation (RCI) is a possible treatment for defaecation disorders when conservative treatment or surgery has failed. The aim of this prospective study was to investigate its effectiveness.

PATIENTS AND METHODS

Patients were divided into three groups: Those with faecal incontinence (A), constipation (B) or both (C). The Biotrol® Irrimatic pump or the irrigation bag was used for colonic irrigation. Patients completed a questionnaire at baseline and after three months, six months and one year, as well as a Short Form 36 health survey and an American Society of Colon and Rectal Surgery quality of life questionnaire at baseline and after six months.

RESULTS

The study included 39 patients (26 women; mean age 58.0 years). In group A, 11 of 18 patients were pseudocontinent for faeces at three months ($P<0.001$). Parks' incontinence scores decreased for all patients in this group at three months ($P<0.001$), six months ($P=0.036$) and one year ($P=0.005$). In group B, three of ten patients reported a major improvement. The mean score for the feeling of incomplete evacuation decreased at three months ($P=0.007$), six months ($P=0.013$) and one year ($P=0.036$). In group C, six of ten patients became pseudocontinent for faeces ($P=0.009$) and three reported improvement in constipation. The overall quality of life scores improved ($P=0.012$).

CONCLUSION

RCI is an undervalued but effective alternative treatment for intractable defaecation disorders.

INTRODUCTION

Faecal incontinence and constipation are distressing conditions with a great impact on daily life. Faecal incontinence affects approximately 1-4% of the population older than 40 years;¹ it is more common in women and increases with age. Chronic constipation is a common self-reported gastrointestinal problem that affects between 2 and 34% of adults.² About 30% of patients with faecal incontinence also suffer from constipation.^{3,4}

The preferred treatment of these disorders is conservative, with dietary and medical measures and eventually biofeedback therapy. Modification of diet and medication can alter the consistency of stool,⁵ but results are often unsatisfactory.^{6,7} Biofeedback therapy to train the pelvic floor is beneficial in some patients, but the benefits seem to decrease with time.⁸⁻¹² Some recovery may occur after repeated biofeedback.¹³

There remains a group of patients with intractable and incapacitating symptoms, despite conservative measures. Traditionally, surgery is the next step for these patients. However, retrograde colonic irrigation can be considered first.¹⁴⁻¹⁶ Colonic irrigation is also possible as an additional therapy after failed surgery for faecal incontinence and intractable constipation before colostomy, which is considered in most of these patients.¹⁴ Irrigation for constipation alters the consistency of stool and provokes the desire to defaecate, thereby increasing the defaecation frequency. Irrigation for incontinence cleans the bowel and increases the time for arrival of new stool in the rectum resulting in pseudo-incontinence.¹⁷

Colonic irrigation can be performed in different ways: retrograde rectal irrigation, or irrigation through a colostomy, and antegrade irrigation by means of a Malone antegrade colonic enema (MACE), a transverse or sigmoid colostomy.^{14,18-25} Only a few studies have assessed retrograde colonic irrigation (RCI), and all reported a beneficial effect.^{14,16,26-30}

The aim of the present prospective study was to investigate the effectiveness of RCI and its influence on quality of life for the treatment of defaecation disorders.

PATIENTS AND METHODS

All patients were referred to the Department of Colorectal Surgery of the Maastricht University Hospital for the treatment of faecal incontinence, constipation or both. All consecutive patients who started RCI from June

2003 to June 2004 were invited to join the study. The patients received detailed information about the study and gave informed consent before joining. They started RCI after failed conservative treatment or after (partially) unsuccessful surgical treatment for their defaecation disorder. Faecal incontinence was defined as involuntary loss of solid or liquid stool more than once a week. The extent of faecal incontinence was determined using Parks' score, ranging from 1 (complete continence) to 4 (incontinence for solid faeces).³¹ Constipation was defined as less than two bowel movements per week, straining or having had a feeling of incomplete evacuation for more than 50% of bowel movements during the previous year. The patients gave scores for incomplete evacuation, straining, bloating and abdominal pain on defaecation using a scale adapted from the Wexner constipation score: 1 (always, or with every defaecation), 2 (often, more than once a week), 3 (sometimes, more than once in four weeks, but less than once a week) or 4 (never).³²

Patients were divided into three groups: those with faecal incontinence (group A), those with constipation (group B) and those with a combination of faecal incontinence and constipation (group C).

Patients filled out a baseline questionnaire regarding their medical history, defaecation pattern and medication. They completed another questionnaire at three months, six months and one year, which asked them about the time needed for RCI, the amount of water used, the frequency of irrigation and possible side-effects. Most patients irrigated a second time in the same session, and the total amount of water used in one session was assessed. The endpoints were defined as successful RCI for the patients and a significant improvement in quality of life. The RCI was considered successful when patients with faecal incontinence became pseudocontinent and those with constipation no longer had a feeling of incomplete evacuation or straining during defaecation. In the combination group, RCI was considered successful when faecal incontinence, constipation or both ceased.

Secondary endpoints were assessment of irrigation details and side-effects.

A Biotrol[®] Irrimatic pump (B.Braun[®], Melsungen, Germany) or the irrigation bag (B.Braun[®], Melsungen, Germany) was used for RCI,^{29,30} with the patient choosing the more convenient of the two. The pump set consists of a pump, a tube and a cone tip which is introduced in the anal canal. All patients were instructed in the same way by the same physician to sit on the toilet while irrigating and were advised to start the irrigation daily with 500 ml of tap water. Thereafter, the frequency and the amount

of water were adjusted until a satisfactory result was achieved, with a maximum of two litres at once. Eventually, patients could irrigate a second time in the same session to clean the bowel of the remaining faeces. Water used for irrigation was at body temperature, and soap or laxatives were added when necessary. The pump worked on a storage battery and the speed of water ejection could be regulated. The working mechanism of the irrigation bag was similar, except that the water ejection used gravity.

Quality of life

Patients were asked to complete a validated Dutch translation³³ of the Short Form 36 health survey (SF-36; Medical Outcomes Trust, Waltham, Massachusetts, USA[®])^{34,35} and the American Society of Colon and Rectal Surgery (ASCRS) quality of life questionnaire³⁶ at baseline and after six months. The ASCRS questionnaire (29 items) measures quality of life specifically in association with faecal incontinence in four distinct domains: lifestyle, coping and behaviour, depression and self-perception, and embarrassment.³⁶ The SF-36[®] is not disease-specific, using a scale of 1-100 (high score indicates better functioning) in eight domains: physical functioning, role physical, vitality, social functioning, role emotional, pain, general health perception and mental health.^{34,35}

Statistical analysis

Data analysis was performed by SPSS[®] version 14.0 (SPSS, Chicago, Illinois, USA). The Wilcoxon Signed ranks non-parametric test for paired samples was used to test the significance of the overall outcome of colonic irrigation during follow-up compared with baseline values. To test the difference between groups, the Mann-Whitney *U* test for independent samples was used (non-parametric tests because of the small size of the groups). $P \leq 0.050$ was considered significant. Data are given as mean $\pm$ SD.

RESULTS

Thirty-nine patients were included in the study; 26 were women, and the mean age was 58.0 $\pm$ 13.5 years. Group A had 18 patients (12 women) with faecal incontinence and a mean age of 60.8 $\pm$ 12.2 years; group B had 11 patients (seven women) with constipation and a mean age of

55.4±14.6 years; and group C had ten patients (seven women) with a combination of faecal incontinence and constipation, and a mean age of 54.7±16.2 years. The age differences between the groups were not significant.

The baseline mean defaecation frequency per day was significantly higher in group A (5.2±3.2) than groups B (3.9±7.7; *P*=0.009) and C (1.1±1.3; *P*=0.001). The consistency of stool was looser in 17 patients of group A (hard, zero; normal, three; diarrhoea: 11; watery, three) than all patients in group B (hard, four; normal, two; diarrhoea, five; watery, zero) and seven patients of group C (hard, three; normal, one; diarrhoea, three; watery, zero). The other patients of groups A (one) and C (three) reported variable consistency.

Before the start of the irrigation, medication to alter the stool consistency was used in nine of 18 patients in group A, four of 11 in group B and seven of ten in group C. This was psyllium fibres (six patients), mebeverine (one) and loperamide (two) in group A, lactulose (two), bisacodyl (one) and psyllium fibres (one) in group B, and psyllium fibres (four), enemas (two) and magnesium oxide (one) in group C. In total 20 of all 39 patients used medication. **Table 2.1** shows the medical histories in each group.

Table 2.1 Medical histories of 39 patients.

	Group A <i>n</i> =18	Group B <i>n</i> =11	Group C <i>n</i> =10	Total
Hysterectomy	8	2	3	13
Prolapse surgery	7	4	0	11
Recto-sigmoid resection	5	1	2	8
Haemorrhoidectomy	2	3	1	6
Cholecystectomy	2	2	1	5
Nucleus Pulposus Herniation	1	2	1	5
Dynamic graciloplasty	3	0	0	3
Diabetes Mellitus	1	1	1	3
Fistula surgery	0	1	1	2
Anal repair	1	0	1	2
Multiple Sclerosis	0	0	1	1
Spina Bifida	1	0	0	1
Anorectal malformation	1	0	0	1

Overall, six patients used the RCI to treat idiopathic faecal incontinence or constipation, and the other 33 patients used it after failed or partially successful colorectal surgery. Three patients used it as an additional treatment for faecal incontinence after a dynamic graciloplasty (DGP), 11 patients for faecal incontinence, constipation or both after surgery for rectal prolapse, and 19 patients after other miscellaneous surgical procedures (**Table 2.1**).

The results of RCI on defaecation disorders in groups A and B are shown in **Figures 2.1 and 2.2** respectively. At three months, 11 patients from group A were pseudocontinent for faeces ($P<0.001$), and were considered successful. Parks' scores decreased for all incontinent patients in group A from 3.6 ± 0.5 to 2.3 ± 1.0 at three months ($P<0.001$), 2.7 ± 1.3 at six months ($P=0.036$) and 1.6 ± 0.9 at one year ($P=0.005$).

In three of ten patients in group B, the irrigation was successful. In two of ten patients in group B ($n=11$), the feeling of incomplete evacuation ceased. There was a major improvement in five other patients ($P=0.007$). There was a major improvement in straining in one patient and complete cessation in two ($P=0.051$), complete cessation of bloating in two ($P=0.055$), and major improvement in abdominal pain in one and complete cessation in three ($P=0.204$). Mean scores measuring the feeling of incomplete evacuation for patients in group B reduced from 1.6 ± 2.5 at baseline to 2.8 ± 2.4 at three months ($P=0.007$), 3.0 ± 1.7 at six months ($P=0.013$) and 2.8 ± 1.4 at one year ($P=0.036$).

Six patients in group C became pseudocontinent for faeces as a result of the irrigation ($P=0.009$) and three patients reported the feeling of incomplete evacuation was resolved after RCI; these patients also became continent for faeces ($P=0.079$).

The total amount of water used at three months was significantly higher than at one year (1.8 ± 1.5 vs. 1.7 ± 0.8 l., $P=0.014$). Other irrigation parameters did not change during follow-up (**Table 2.2**). **Table 2.3** shows irrigation parameters of groups A, B and C at three months. Analysis for the separate groups was not possible because data for only 20 patients were available at one year.

The mean amount of water used for RCI was significantly higher in group A than in group C (2.4 ± 1.9 vs. 1.3 ± 0.8 l.; $P=0.030$). The frequency of RCI per day in patients in group A (0.9 ± 0.3) was significantly lower than that in patients in group B (1.3 ± 0.5 ; $P=0.007$) and C (0.9 ± 0.2 ; $P=0.042$); and the time needed for the RCI was significantly higher in group A (42.5 ± 20.2 min.) than in groups B (28.6 ± 21.3 min.; $P=0.005$).

Figure 2.1 Success of colonic irrigation for all 18 patients with faecal incontinence (group A) at three months. * $P < 0.001$

Figure 2.2 Success of colonic irrigation for ten patients with constipation (group B) at three months. * $P = 0.007$; † $P = 0.051$; ‡ $P = 0.055$; § $P = 0.204$

or C (25.4 ± 15.6 min.; $P=0.027$). RCI was mostly performed once a day; 26 patients in the morning (16 from group A; six from B; four from C), seven in the evening (one from group A; two from B; four from C), and six irrigated twice a day (one from group A; three from B; two from C).

The nine patients in group A discontinued taking medication to alter the consistency of stool, but another patient started taking psyllium fibres; in group B, two of four patients stopped and another patient started taking psyllium fibres; in group C four of seven patients stopped taking their medication.

The quality of life scores improved on all domains, except vitality in the SF-36[®] which decreased and role physical which remained unchanged. Significance could not be proved for separate domains in the SF-36[®] and ASCRS questionnaires; however, the overall quality of life score improved significantly ($P=0.012$).

Table 2.2 Overall irrigation parameters. Mean values (SD).

	3 months	6 months	1 year	P^*	$P^\dagger$	$P^\ddagger$
Amount of water used (litres)	1.8 (1.5)	2.2 (1.5)	1.8 (0.8)	0.206	0.014	0.263
Frequency of irrigation (per day)	1.0 (0.4)	1.0 (0.4)	1.1 (0.5)	0.550	0.353	0.328
Time needed for RCI in total (min.)	35.3 (20.9)	37.5 (27.8)	36.4 (16.0)	0.376	0.431	0.160

*Three vs. six months; $\dagger$ three months vs. one year; $\ddagger$ six months vs. one year; all Wilcoxon Signed ranks test

Table 2.3 Irrigation parameters of the three groups at three months. Mean values (SD).

	Group A	Group B	Group C	P^*	$P^\dagger$	$P^\ddagger$
Amount of water used (litres)	2.4 (1.9)	1.7 (1.2)	1.3 (0.8)	0.262	0.030	0.214
Frequency of irrigation (per day)	0.9 (0.3)	1.3 (0.5)	0.9 (0.2)	0.007	0.042	0.194
Time needed for irrigation in total (min.)	42.5 (20.2)	28.6 (21.3)	25.4 (15.6)	0.005	0.027	0.401

*Group A vs. group B; $\dagger$ group A vs. group C; $\ddagger$ group B vs. group C; all Mann-Whitney U test

Negative side-effects such as leakage after irrigation, abdominal cramps and bloating were reported by 23 patients (**Figure 2.3**). Nine patients stopped RCI, seven because the result was unsatisfactory and two because the incontinence or constipation improved spontaneously. Two patients changed the irrigation from retrograde irrigation to antegrade irrigation by an appendicostomy.

Table 2.4 shows a summary of the results to enable a comparison with other studies of retrograde colonic irrigation.

DISCUSSION

In this study 11 of 18 patients with faecal incontinence became pseudocontinent for faeces and, in some constipated patients, the straining, incomplete evacuation or both resolved. In addition, ASCRS and SF-36[®] questionnaires showed a significant overall improvement of quality of life.

Defaecation disorders include a broad group of conditions: faecal incontinence, constipation and a combination of both. This study, describing results in all three groups, has a heterogeneous study population and relatively small groups, so the results should be interpreted cautiously.

Figure 2.3 Side-effects of colonic irrigation in 39 patients.

Table 2.4 Summary of results from studies of retrograde colonic irrigation.

Author	Total Faecal incontinence			Constipation		Faecal soiling		Combination		Stopped irrigation
	<i>n</i>	<i>n</i>	Success	<i>n</i>	Success	<i>n</i>	Success	<i>n</i>	Success	
Briel ¹⁴	32	16	38%			16	79%			18%
Gosselink ¹⁶	169	71	41%	37	65%	32	47%	29	79%	55%
Krogh ²⁶	37	9	44%	16	19%			12	91%	
Crawshaw ²⁷	48	33	48%	15	53%					8%
Scholler-Gyure ²⁸	41	11	66%	11				19		
Koch ²⁹	46	24	37%	11	30%			11	29%	16%
Cazemier ³⁰	88	54	87%	34	79%					23%
Present study	39	18	61%	11	30%			10	60%	23%

There have been only a few studies of RCI, but all reported a beneficial effect (**Table 2.4**).^{14,16,26-30} In all but two of the studies the subjective beneficial effect of RCI was considered as success.^{14,16,26,27,30} Only the studies of Scholler-Gyure and co-workers²⁸ and Koch and colleagues²⁹ considered pseudocontinence and resolved constipation as success. In the present study, success was also defined as a resolution of the symptoms of faecal incontinence (pseudocontinence) and constipation. The success rate of 30% (three of ten) for constipation in this study is worse than those reported by Gosselink and co-workers,¹⁶ Crawshaw and colleagues²⁷ and Cazemier et al.,³⁰ but better than those of Krogh and co-workers.²⁶ The differences are probably explained by the differing study designs, populations and outcome measures.

Five studies of irrigation included patients with different aetiologies for their defaecation disorders,^{14,26,27,30} one had children with spina bifida²⁸ and another patients with DGP.²⁹ In the retrospective study of 41 children with spina bifida, 66% (27 children) became pseudocontinent.²⁸ In a cross-sectional study of patients with defaecation disorders after DGP, 37% of patients reached pseudocontinence and 30% had resolved constipation. Seven patients (16%) stopped the irrigation therapy.²⁹

In a cross-sectional study of the long-term feasibility and outcome of RCI in 169 patients with miscellaneous defaecation disorders, RCI, used for a median of 56 months, was reported to be effective and beneficial by 91 patients (54%).¹⁶ Fifty-five per cent of the patients discontinued RCI: all 78 patients in whom RCI was not effective and 15 who did benefit. The overall success rate was 45%. Another cross-sectional study in 25 adults

and 43 children with defaecation disorders found that 87% of patients with faecal incontinence and 79% of patients with constipation were satisfied with their results.³⁰

In these studies, the rate of stopping irrigation therapy varied considerably (**Table 2.4**). In a retrospective study of 16 patients with faecal incontinence and 16 with soiling with a mean follow-up of 18 months, six of 32 patients (19%) discontinued RCI.¹⁴ In another retrospective study of 48 patients with miscellaneous defaecation disorders and a median follow-up of 11 months, four of 48 patients (8%) stopped.²⁷ The study with the highest percentage (50%) of patients stopping RCI had a long follow-up.¹⁶ However, the study with the longest follow-up (the mean duration of use was given as 81.6 months) reported a lower rate of patients stopping RCI (23%).³⁰ In the present study, the rate of patients stopping was also 23% (nine patients); patients stopped mainly because it was not effective. However, the follow-up was only one year, and it is possible that more patients would have stopped the therapy with more time.

RCI can be used as primary therapy after failed conservative treatment or as additional therapy after failed surgical treatment of faecal incontinence or constipation. In the present study, three patients used the RCI as additional therapy after failed DGP and 11 patients after a procedure for rectal prolapse. Rectal prolapse is frequently associated with defaecation disorders. Several surgical techniques have been described and used for the treatment of complete rectal prolapse. Abdominal rectopexy offers the best anatomical results and lowest recurrence rates, but intractable constipation is frequently reported after rectopexy.³⁷ Constipation after abdominal rectopexy is probably associated with the rectal denervation after lateral dissection of the rectum,³⁸ and faecal incontinence can occur when rectopexy is combined with sigmoidectomy.³⁹

A remarkably high number of patients (13; 33%) in the present study had a history of hysterectomy (**Table 2.1**). Previous studies have shown that abdominal hysterectomy is a risk factor for developing faecal incontinence, which is increased further by concomitant bilateral salpingo-oophorectomy.⁴⁰ The onset of constipation after hysterectomy has also been reported.⁴¹

The patients in the present study used normal tap water for irrigation. Electrolyte imbalance, especially hyponatraemia, as a result of irrigation with tap water has been rarely described.⁴² None of the patients had developed hyponatraemia, but periodic evaluation of serum electrolytes could be considered. Tap water is thought to be the safest irrigation fluid,

because other solutions are hypertonic and have a stimulatory effect on the bowel. These hypertonic solutions constitute a much greater risk for electrolyte disturbances.⁴³

CONCLUSION

RCI with tap water is an undervalued but effective alternative for the treatment of intractable defaecation disorders. RCI should be considered before performing surgery for defaecation disorders. It can also be effectively used as an additional or salvage treatment after colorectal surgical procedures for faecal incontinence and constipation.

LITERATURE

1. Perry S, Shaw C, McGrother C, Matthews RJ, Assassa RP, Dallosso H, Williams K, Brittain KR, Azam U, Clarke M, Jagger C, Mayne C, Castleden CM, Leicestershire MRC Incontinence Study Team. Prevalence of faecal incontinence in adults aged 40 years or more living in the community. *Gut* 2002;50:480-4.
2. D'Hoore A, Penninckx F. Obstructed defecation. *Colorectal Dis* 2003;5:280-7.
3. Whitehead WE, Wald A, Norton NJ. Treatment options for fecal incontinence. *Dis Colon Rectum* 2001;44:131-42; discussion 142-4.
4. Norton C, Kamm MA. Outcome of biofeedback for faecal incontinence. *BJS* 1999;86:1159-63.
5. Uludag O, Darby M, Dejong CH, Schouten WR, Baeten CG. Sacral neuromodulation is effective in the treatment of fecal incontinence with intact sphincter muscles; a prospective study. *Neth J Med* 2002;146:989-93.
6. Gattuso JM, Kamm MA. Adverse effects of drugs used in the management of constipation and diarrhoea. *Drug Saf* 1994;10:47-65.
7. Annells M, Koch T. Constipation and the preached trio: diet, fluid intake, exercise. *Int J Nurs Stud* 2003;40:843-52.
8. Bassotti G, Chistolini F, Sietchiping-Nzepa F, de Roberto G, Morelli A, Chiarioni G. Biofeedback for pelvic floor dysfunction in constipation. *BMJ* 2004;328:393-6.
9. Koutsomanis D, Lennard-Jones JE, Roy AJ, Kamm MA. Controlled randomised trial of visual biofeedback versus muscle training without a visual display for intractable constipation. *Gut* 1995;37:95-9.
10. Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence. *Gastroenterology* 2003;125:1320-9.
11. Heymen S, Jones KR, Ringel Y, Scarlett Y, Whitehead WE. Biofeedback treatment of fecal incontinence: a critical review. *Dis Colon Rectum* 2001;44:728-36.
12. Chiotakakou-Faliakou E, Kamm MA, Roy AJ, Storrie JB, Turner IC. Biofeedback provides long-term benefit for patients with intractable, slow and normal transit constipation. *Gut* 1998;42:517-21.
13. Ryn AK, Morren GL, Hallbook O, Sjodahl R. Long-term results of electromyographic biofeedback training for fecal incontinence. *Dis Colon Rectum* 2000;43:1262-6.
14. Briel JW, Schouten WR, Vlot EA, Smits S, van Kessel I. Clinical value of colonic irrigation in patients with continence disturbances. *Dis Colon Rectum* 1997;40:802-5.
15. Christensen P, Olsen N, Krogh K, Bacher T, Laurberg S. Scintigraphic assessment of retrograde colonic washout in fecal incontinence and constipation. *Dis Colon Rectum* 2003;46:68-76.
16. Gosselink MP, Darby M, Zimmerman DD, Smits AA, van Kessel I, Hop WC, Briel JW, Schouten WR. Long-term follow-up of retrograde colonic irrigation for defaecation disturbances. *Colorectal Dis* 2005;7:65-9.
17. Deutekom M, Dobben A. Plugs for containing faecal incontinence. *Cochrane Database Syst Rev* 2005(3):CD005086.
18. Malone PS, Ransley PG, Kiely EM. Preliminary report: the antegrade continence enema. *Lancet* 1990;336:1217-8.
19. Malone PS, Curry JJ, Osborne A. The antegrade continence enema procedure why, when and how? *World J Urol* 1998;16:274-8.
20. Youssef NN, Barksdale Jr E, Griffiths JM, Flores AF, Di Lorenzo C. Management of intractable constipation with antegrade enemas in neurologically intact children. *J Pediatr Gastroenterol Nutr* 2002;34:402-5.
21. Kokoska ER, Keller MS, Weber TR. Outcome of the antegrade colonic enema procedure in children with chronic constipation. *Am J Surg* 2001;182:625-9.

22. Rongen MJ, van der Hoop AG, Baeten CG. Cecal access for antegrade colon enemas in medically refractory slow-transit constipation: a prospective study. *Dis Colon Rectum* 2001; 44:1644-9.
23. Cascio S, Flett ME, De la Hunt M, Barrett AM, Jaffray B. MACE or caecostomy button for idiopathic constipation in children: a comparison of complications and outcomes. *Pediatr Surg Int* 2004;20:484-7.
24. Heriot AG, Tilney HS, Simson JN. The application of percutaneous endoscopic colostomy to the management of obstructed defecation. *Dis Colon Rectum* 2002;45:700-2.
25. Gauderer MW, Decou JM, Boyle JT. Sigmoid irrigation tube for the management of chronic evacuation disorders. *J Pediatr Surg* 2002;37:348-51.
26. Krogh K, Kvitzau B, Jorgensen TM, Laurberg S. Treatment of anal incontinence and constipation with transanal irrigation. *Ugeskr Laeger*. 1999;161:253-6.
27. Crawshaw AP, Pigott L, Potter MA, Bartolo DCC. A retrospective evaluation of rectal irrigation in the treatment of disorders of faecal incontinence. *Colorectal Disease* 2004;6: 185-90.
28. Scholler-Gyure M, Nesselaar C, van Wieringen H, van Gool JD. Treatment of defecation disorders by colonic enemas in children with spina bifida. *Eur J Pediatr Surg* 1996;6 Suppl 1:32-4.
29. Koch SM, Uludag O, El Naggar K, van Gemert WG, Baeten CG. Colonic irrigation for defecation disorders after dynamic graciloplasty. *Int J Colorectal Dis* 2008;23:195-200.
30. Cazemier M, Felt-Bersma RJ, Mulder CJ. Anal plugs and retrograde colonic irrigation are helpful in fecal incontinence or constipation. *World J Gastroenterol* 2007;13:3101-5.
31. Parks AG. Royal Society of Medicine, Section of Proctology; Meeting 27 November 1974. President's Address. Anorectal incontinence. *Proc R Soc Med* 1975;68:681-90.
32. Agachan F, Chen T, Pfeifer J, Reissman P, Wexner SD. A constipation scoring system to simplify evaluation and management of constipated patients. *Dis Colon Rectum* 1996; 39:681-5.
33. Aaronson NK, Muller M, Cohen PD, Essink-Bot ML, Fekkes M, Sanderman R, Sprangers MA, te Velde A, Verrips E. Translation, validation, and norming of the Dutch language version of the SF-36 Health Survey in community and chronic disease populations. *J Clin Epidemiol* 1998;51:1055-68.
34. Brazier JE, Harper R, Jones NM, O'Cathain A, Thomas KJ, Usherwood T, Westlake L. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ* 1992;305:160-4.
35. McHorney CA, Ware JE, Jr., Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med Care* 1993;31:247-63.
36. Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG, Wexner SD, Bliss D, Lowry AC. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum* 2000;43:9-16; discussion 16-7.
37. Speakman CT, Madden MV, Nicholls RJ, Kamm MA. Lateral ligament division during rectopexy causes constipation but prevents recurrence: results of a prospective randomized study. *Br J Surg* 1991;78:1431-3.
38. Scaglia M, Fasth S, Hallgren T, Nordgren S, Oresland T, Hulten L. Abdominal rectopexy for rectal prolapse. Influence of surgical technique on functional outcome. *Dis Colon Rectum* 1994;37:805-13.
39. Madoff RD, Williams JG, Wong WD, Rothenberger DA, Goldberg SM. Long-term functional results of colon resection and rectopexy for overt rectal prolapse. *Am J Gastroenterol* 1992;87:101-4.
40. Altman D, Zetterstrom J, Lopez A, Pollack J, Nordenstam J, Mellgren A. Effect of hysterectomy on bowel function. *Dis Colon Rectum* 2004;47:502-8; discussion 508-9.
41. Weber AM, Walters MD, Schover LR, Church JM, Piedmonte MR. Functional outcomes and satisfaction after abdominal hysterectomy. *Am J Obstet Gynecol* 1999;181:530-5.

42. Chertow GM, Brady HR. Hyponatraemia from tap-water enema. *Lancet* 1994;344:748.
43. Yerkes EB, Rink RC, King S, Cain MP, Kaefer M, Casale AJ. Tap water and the Malone antegrade continence enema: a safe combination? *J Urol* 2001;166:1476-8.

chapter 3

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SACRAL NERVE MODULATION AND OTHER TREATMENTS IN PATIENTS WITH FAECAL INCONTINENCE AFTER UNSUCCESSFUL PELVIC FLOOR REHABILITATION: A PROSPECTIVE STUDY

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ABSTRACT

PURPOSE

Sacral Nerve Modulation (SNM) is a minimally invasive technique for the treatment of faecal incontinence. This study investigates the results of SNM after negative outcome of a standardized pelvic floor rehabilitation (PFR) programme for the treatment of faecal incontinence.

PATIENTS AND METHODS

A prospective cohort study was performed between December 2001 and August 2007. Consecutive patients that visited the outpatient department for faecal incontinence were included in a multicentre study and treated with standardized PFR. Those with an unsuccessful result who were eligible for SNM were included in the present study. Failures at test stimulation or SNM received another treatment. Clinical outcome, Vaizey scores and quality of life (EQ-5D and HAQL) were assessed during follow-up in patients with SNM and in patients with other treatments (OT). Adverse events (AE) were documented.

RESULTS

Thirty-five patients (mean age 59.7 years; 31 females) were included. Twenty-one had a successful test stimulation and 19 patients proceeded to a SNM implant. Incontinence episodes per week decreased significantly from 11.1 ± 11.7 to 1.9 ± 2.6 during test stimulation ($P < 0.0001$) and SNM over 24.1 months follow-up. The overall success rate was 49% (17/35). The patients with unsuccessful test stimulation or SNM received OT. The Vaizey score improved in both SNM (18.2 ± 3.5 vs. 13.7 ± 4.8 ; $P = 0.004$) and other treatment (18.2 ± 3.5 vs. 13.9 ± 6.9 ; $P = 0.019$). The HAQL scale improved significantly during SNM in all subscales ($P < 0.005$), but not in the other treatment group. Eight AE occurred during test stimulation (23%) and six AE after permanent implantation (26%).

CONCLUSION

Sacral nerve modulation improves disease specific quality of life significantly compared with other treatment.

INTRODUCTION

The aetiology of faecal incontinence is multifactorial.¹ Faecal incontinence is initially treated with conservative measures including dietary adjustments or medication. Pelvic Floor Rehabilitation (PFR) is commonly used as the next step in conservative treatment.² This combines pelvic floor muscle training with biofeedback and electrical stimulation.³ An intra-anal electromyography sensor, anal manometry probe or peri-anal surface electromyography electrodes are used to help the patient learn how to exercise the external anal sphincter. A balloon system is used to train the patient to recognize the stimulus of rectal distension, for perception of the sensory threshold and expansion of the rectum to improve the discrimination of smaller rectal volumes.⁴ Success rates vary from 0-100%,⁴⁻⁶ but the benefits of PFR decrease with time.^{3,7-10} Some recovery may occur after repeated biofeedback.¹¹

Surgical treatment is considered when conservative treatment fails. Sacral Nerve Modulation (SNM) is minimally invasive,¹²⁻¹⁵ and its effectiveness can be predicted by peripheral nerve evaluation (PNE), which when successful is followed by a test stimulation period. A successful test stimulation is succeeded by permanent implantation.¹² The reported success rate of SNM ranges from 55 to 100%.^{12,14-17} Precise criteria predicting success of SNM are not yet fully identified.¹⁶

This study investigates the efficiency of SNM for the treatment of faecal incontinence in patients after an unsuccessful standardized PFR program. In addition, in a separate analysis, it investigates the value of the other treatments (OT) after an unsuccessful SNM.

PATIENTS AND METHODS

Patients

The faecal incontinence therapy (FIT) study investigated 281 patients with faecal incontinence from 16 hospitals in the Netherlands in a prospective cohort multicentre study between December 2001 and August 2007.⁶ This was approved by the medical ethics committees in all the hospitals involved. Inclusion criteria included faecal incontinence for at least six months, a Vaizey score¹⁸ of at least 12, and failure of conservative treatment. Patients under the age of 18 years, and patients with an anorectal tumour, chronic diarrhoea, overflow incontinence, proctitis, soiling, previous ileo-anal or colo-anal anastomosis and/or

grade III rectal prolapse, intussusception or rectocele were all excluded. Patients who had received PFR in the previous six months or who were considered to be cognitively unable to undergo PFR were also excluded. Eligible patients were included in the FIT study after a written informed consent.

Diagnostics

Their medical history was recorded, including duration, nature, severity and possible underlying causes of faecal incontinence. The severity of faecal incontinence was assessed with the Vaizey incontinence scoring system, ranging from 0 (complete continence) to 24 (fully incontinent).¹⁸ Manometry was carried out with a four-point solid state catheter (Konigsberg instrument Inc., Pasadena, California, USA), measuring anal resting and squeeze pressures, and anal and rectal pressures during straining and coughing. The recto-anal inhibitory reflex was measured using this catheter with a balloon. Rectal sensitivity and capacity was assessed using a balloon catheter, measuring first rectal sensation volume, first urge sensation volume and the maximum tolerated volume. Each patient underwent endo-anal ultrasonography (7.5 MHz, SDD 2000, Multiview, Aloka, Japan). All external sphincter defects in the entire length of the sphincter were considered as external sphincter defects. Pudendal nerve terminal motor latency times (PNTML) were assessed using a St. Mark's pudendal electrode (Medtronic USA). Pudendopathy was diagnosed when a PNTML was >2.4 ms or an abnormal curve. Defaecography was performed to exclude grade III rectal prolapse, intussusception or rectocele and to assess pelvic floor function.

Pelvic floor rehabilitation

Patients were referred to a specialized physiotherapist for PFR after investigation. The protocol of PFR is described elsewhere.⁶ After the standardized PFR programme patients returned to the outpatient department and Vaizey scores, anorectal manometry and rectal balloon distension were re-assessed.

The PFR programme was considered unsuccessful when the improvement of the Vaizey score was <50%. Consecutive patients with a negative outcome after PFR who wanted further treatment were offered SNM. A PNE was undertaken when faecal incontinence occurred more than once a week.

Sacral nerve modulation

Patients filled out a baseline defaecation diary during three weeks. A temporary PNE electrode was inserted and connected to an external pulse generator.¹⁹ If a three-week test stimulation was successful, a permanent electrode, extension cable and pulse generator were implanted.¹⁹ The test stimulation was considered successful when a decrease of incontinence episodes of >50% was achieved. The patients had the pulse generator switched on during the day only, because they had no faecal incontinence at night.

Follow-up was scheduled at three, six, 12 and 24 months after permanent SNM implantation and included defaecation diary recordings, anorectal manometry, rectal sensitivity and capacity estimations by rectal balloon insufflation. Vaizey scores were determined and any adverse event was recorded.

Patients with unsuccessful test stimulation or a failing SNM were offered OT including retrograde colonic irrigation, anal repair, a sphincter replacement technique (dynamic graciloplasty (DGP) or artificial bowel sphincter (ABS)) or an end-colostomy.

Quality of life

A quality of life-health status questionnaire was used at baseline, after PFR and during SNM or OT. The validated EQ-5D questionnaire and HAQL scales were used.^{20,21} The EQ-5D (EuroQol) questionnaire comprises five dimensions of health including mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension comprises three levels including no problems, some/moderate problems and extreme problems. The score in each dimension can be summarized resulting in a summary utility value which can range from -0.594 (worst imaginable health state) to 1 (optimal health).

The HAQL (Hirschsprung's disease/anorectal malformation quality-of-life) scale is a disease-specific quality of life scale especially developed for patients with Hirschsprung's disease. It is composed of items related to physical, emotional and social functioning, and disease-related symptoms.²¹ The 42 items of the questionnaire were combined to form three subscales including constipation, faecal incontinence and psychosocial functioning. The four response categories, ranging from 'never' to 'very often', were recoded and linearly transformed to a scale from 0 to 100, with higher scores indicating better levels of quality of

life. This scale substantially correlated with selective scales of the SF-36,²² which is an established generic quality-of-life instrument.

Data analysis

Data analysis was performed by using SPSS 14.0 (SPSS release 14.0, SPSS Inc. Chicago, Illinois, USA). The *t*-test for paired and independent samples was used. $P\leq0.050$ was considered statistically significant. Parametric data are given as mean±SD. Analysis was performed according to the intention to treat principle.

RESULTS

Baseline

Thirty-five patients who had failed the PFR program were included. The mean age was 59.7±11.4 years and 31 (89%) were female. The obstetric and other medical history is shown in **Tables 3.1** and **3.2**. The duration of faecal incontinence was a mean of 8.5±8.1 years. Thirteen (37%) patients used constipating medication including loperamide (four) or psyllium fibres with low fluid intake (nine). Twenty-one (60%) patients had a pudendopathy. In 27 (77%) patients a lesion of the anal sphincter was seen on endo-anal ultrasound, including ten (29%) with an external anal sphincter defect and three (9%) with a combined defect of the internal and external anal sphincters. The most severe defect of the external anal sphincter was not more than 17% of the circumference in the entire length of the sphincter. Defaecography revealed a grade I or II rectocele in 16 patients and a grade I or II intussusception and/or grade I or II rectal prolapse in 13 patients. In six patients both entities were present.

Table 3.1 Obstetric history of the 29 female patients.

Obstetric history	Number of patients (%)
Breech delivery	2 (7)
Prolonged labour	11 (38)
Birth weight > 4 kg	11 (38)
Assisted delivery (vacuum/forceps)	4 (14)
Episiotomy	19 (66)
Rupture	18 (62)

Table 3.2 Previous medical history (35 patients).

Medical history	Number of patients (%)
Hysterectomy	16 (46)
Prolapse surgery	7 (20)
Fistula surgery	2 (6)
Haemorrhoidectomy	6 (17)
Anal repair	4 (11)
Maximal anal dilatation	2 (6)
Nucleus Pulposus Herniation	3 (9)
Cholecystectomy	4 (11)

Sacral nerve modulation

A PNE was possible in all but one patient (34) and the test stimulation was successful in 21 (60%). Incontinence days and episodes per week decreased significantly during test stimulation compared with PFR (1.3 ± 1.5 vs. 4.1 ± 1.8 ; $P < 0.0001$ and 1.9 ± 2.6 vs. 11.1 ± 11.7 ; $P < 0.0001$) and these results were maintained during SNM (**Figure 3.1**). Two patients did not want to proceed with permanent implantation. One patient complained of leg pain and the other became continent during the test stimulation and remained so afterwards. All the other 19 patients had a permanent implant. The average time from PNE to implantation was 3.4 ± 3.0 months. The mean follow-up after implantation was 24.1 ± 14.0 months. The mean stimulation voltage was 2.1 ± 0.8 Volts at a follow-up of three months and did not change during follow-up.

In three patients the SNM was stopped owing to an unsatisfactory result. One of these three then had an ABS and two started colonic irrigation. The overall success rate of SNM was 49% (17/35), rating the patient with persisting continence after test stimulation to the successful group.

There were 18 patients who had an unsuccessful PNE or test stimulation and who failed after permanent implantation. These proceeded to OT modalities including retrograde colonic irrigation (RCI) (four), anal sphincter repair (AR) (one), DGP (one), ABS (two), awaiting ABS (one), and end-colostomy (three). Two patients with diarrhoea used loperamide when needed. One patient experienced spontaneous improvement of incontinence one year after the PFR and in two treatments was stopped because it was no longer desired (**Figure 3.2**).

Figure 3.1 Box-and-whisker plot showing median incontinence days and episodes at baseline and during follow-up after SNM. * Statistically significant compared with PFR value. Numbers represent number of patients at follow-up.

Four patients in the SNM group achieved complete continence for faeces and 13 patients reported faeces loss less than once a week. Seven of the 18 patients in the OT group achieved complete continence for faeces, and ten patients reported faeces loss less than once a week compared with two after PFR.

Diagnostics

Pudendopathy was present in 22/35 (63%) of patients. In five this was bilateral. Seven (32%) of the 22 patients with pudendopathy had a successful SNM. Two (25%) of the eight patients with an external sphincter defect had a successful SNM.

The results of anorectal manometry and rectal balloon insufflation at baseline, after PFR and during SNM (one year) are shown in **Table 3.3**.

The rectal pressure during coughing increased significantly after PFR, while the other parameters did not change significantly. There was no significant change in resting and squeeze pressures, first rectal sensation volume and first urge sensation volumes between SNM and PFR (**Figure 3.3**). The maximum tolerated volume decreased significantly during SNM compared with the values after PFR (**Figure 3.4**).

Figure 3.2 Patient flow in the study. FIT, faecal incontinence therapy; PNE, peripheral nerve evaluation; TS, test stimulation; SNM, sacral nerve modulation; OT, other treatment; LOP, loperamide; RCI, retrograde colonic irrigation; AR, anal repair; DGP, dynamic graciloplasty and ABS, artificial bowel sphincter.

Figure 3.3 Box-and-whisker plot showing resting and squeeze pressure after PFR and during SNM. Numbers represent number of patients at follow-up.

Vaizey score and quality of life

The Vaizey scores and quality of life scales EQ-5D and HAQL were assessed at a mean follow-up of 33.4 ± 11.7 months after OT or SNM.

The Vaizey score improved significantly from 20.1 ± 2.6 at baseline to 18.2 ± 3.5 after PFR ($P=0.0005$). This improved further to 13.7 ± 4.8 after successful SNM ($P=0.004$) and after OT to 13.9 ± 6.9 ($P=0.019$). The Vaizey score at baseline was significantly better in the SNM group compared with the OT group (18.9 ± 2.5 vs. 20.9 ± 1.4 ; $P=0.006$).

Thirty-three patients filled out quality of life questionnaires. The quality of life changed significantly during SNM in all subscales of the HAQL scale, while the EQ-5D did not. In the OT group there was no significant change in either scale (**Table 3.4**).

Adverse events

Eight adverse events (AE) in eight patients occurred during test stimulation in 34 patients (0.24 AE per patient). Three had incorrect placement of the temporary electrode, four had dislodgement and in one occurred an electrode break.

After permanent implantation in 19 patients, six AE were recorded in five (0.32 AE per patient). One had pain during stimulation with increasing resistance and decreasing efficacy. SNM was stopped and colonic irrigation instituted. Another required local surgery because of pain at the pacemaker site and subsequently the electrode replaced. One patient complained of pain in the foot during stimulation regardless of the electrode settings. Two patients had an infection of the permanent implant which was treated with antibiotics, one of whom needed a revision.

Figure 3.4 Box-and-whisker plot showing the results of rectal balloon insufflation after PFR and during SNM. FRSV, first rectal sensation volume; FUSV, first urge sensation volume; MTV, maximum tolerated volume. Numbers represent number of patients at follow-up.

Table 3.3 The results of anorectal manometry and rectal balloon insufflation in 28 patients, baseline, after PFR and during SNM (mean values±SD).

Pressure, volumes	Baseline n=28	After PFR n=28	SNM at one n=11	Baseline vs. PFR P-value	PFR vs. SNM P-value
Resting pressure (mmHg)	54.6±20.4	57.3±28.4	67.3±26.35	0.315	0.333
Squeeze pressure (mmHg)	80.6±34.1	88.3±41.3	110.9±57.7	0.114	0.472
Anal pressure during coughing (mmHg)	100.6±20.5	112.8±32.2	-	0.042*	-
Rectal pressure during coughing (mmHg)	86.6±21.1	90.3±28.4	-	0.241	-
Anal pressure during straining (mmHg)	72.4±22.3	72.3±28.6	-	0.486	-
Rectal pressure during straining (mmHg)	80.3±21.0	72.7±31.6	-	0.157	-
First rectal sensation volume (ml)	42.8±33.7	39.2±33.7	42.8±29.9	0.338	0.388
First urge sensation volume (ml)	85.0±43.6	83.9±59.6	91.1±63.6	0.455	0.345
Maximum tolerated volume (ml)	157.7±75.0	166.8±80.4	151.7±70.3	0.307	0.023*

* *P-value* <0.050

Table 3.4 EQ-5D and HAQL: Baseline, after PFR and during SNM/OT (mean values±SD).

	n	Baseline vs. PFR P-value	Baseline n	PFR vs. SNM P-value	SNM n	PFR vs. OT P-value	OT n
EQ-5D	28	0.73±0.22 vs. 0.71±0.24	0.292	0.67±0.27 vs. 0.71±0.20	0.183	0.79±0.16 vs. 0.67±0.25	0.040
HAQL							
Faecal incontinence	30	66.5±18.6 vs. 71.6±19.2	0.022	66.7±21.6 vs. 77.3±14.9	0.005*	77.7±13.6 vs. 80.2±18.2	0.272
Constipation	28	74.2±15.2 vs. 73.4±13.4	0.352	68.7±13.3 vs. 76.6±15.0	0.008*	78.7±9.4 vs. 74.1±19.2	0.275
Psychosocial functioning	31	50.0±27.2 vs. 49.3±27.8	0.413	44.0±26.4 vs. 61.2±25.6	0.003*	48.7±26.9 vs. 41.6±29.5	0.245

* *P-value* <0.050

DISCUSSION

Success after PFR for faecal incontinence has been reported to range from 0 to 100%, but in these studies severity of faecal incontinence differed sometimes considerably.^{4,5,23} A systematic review suggested that biofeedback is helpful and has a role in the treatment of faecal incontinence, but different selection criteria, lack of controls and validated outcome measures create inconsistencies when evaluating these results. The initial 46 studies reviewed varied in the method of biofeedback and criteria for success. Of the 34 studies including a total of 566 patients which fulfilled the entry criteria, 49% achieved satisfactory continence.⁴ In the FIT study a standardized PFR programme was found to be successful in only 13% of patients⁶ but the severity of incontinence was worse compared with most other studies.

A significant improvement in squeeze pressure after PFR and first rectal sensation volume has been reported after PFR.^{24,25} In the present study, however, only a significant increase in anal pressure with coughing was found in the SNM group (**Table 3.3**). Several studies have reported conflicting results of the effect of SNM on squeeze pressure, ranging from no change to a significant increase.^{16,26} Any increase in squeeze pressure is most probably caused by a high stimulation voltage causing a transformation of muscle fibre type. It is also possible to achieve a therapeutic effect by stimulating below the sensitivity threshold as demonstrated in a previous study.²⁷ The clinical significance of these parameters is still not understood.

The population size of the present study is too small to compare anorectal physiological parameters before and after treatment with SNM. Statistical significance was reached only for the decrease of maximum tolerated volume, but this should be interpreted with caution. It is possible that more patients in the multicentre FIT study of Terra et al.⁶ would have been eligible for SNM but were not identified for recruitment.

In patients treated by SNM after failed PFR, the present study has shown success in 49%, which is lower than the mean results reported by other studies. This may be explained by differences in the study populations, which include patients with varying Vaizey scores above 12, and inclusion of patients with variable degrees of sphincter damage.

In the present study, the Vaizey incontinence score has been used as the assessment of clinical incontinence, because it is reproducible and correlates well with the clinical impression.¹⁸ The severity of the score also reflects the impact of faecal incontinence on the quality of life

measured by the EQ-5D.²⁸ The Vaizey score improved significantly in both the SNM and the OT groups. The EQ-5D and HAQL questionnaires were used in this study because they had already been applied in the FIT study.⁶ The HAQL questionnaire had been used in the FIT study²¹ because a validated Dutch version of the ASCRS quality of life scale was not available when the study was initiated.²⁹ The validated EQ-5D scale was also used in the FIT study, because it gives a good representation of the general quality of life.²¹ As expected, the quality of life improved significantly after SNM but surprisingly not after OT although the Vaizey score, which usually correlates well with general quality of life, did so.²⁸ The OT group contains patients who had failed SNM, and these patients already had a significantly lower Vaizey score at baseline. The faecal incontinence and its aetiology were probably more severe in this group. It is noteworthy, however, that the Vaizey score during OT was not significantly different from patients after a successful SNM. A subanalysis of the quality of life and Vaizey scores of the different treatment subgroups included in OT was not possible because of the small number of patients. A randomized study between SNM and other treatments would be difficult because patients prefer the minimally invasive SNM before invasive procedures such as colostomy, ABS and DGP.

A review of SNM for faecal incontinence revealed an AE rate of 0.04 per patient for test stimulation and 0.12 AE per patient for permanent implantation. The most serious complication was infection of the implant requiring removal in three patients.²⁶ Overall, this study recorded an AE rate per patient of 0.24 AE per patient during test stimulation. This seems high compared with the review of Jarret et al., but this did not include wrongly-placed electrodes.²⁶

Sphincter replacement techniques like ABS and DGP are successful in 69-85% of patients,³⁰⁻³⁵ but the indications for this treatment are different from SNM. The present evidence indicates that SNM is the surgical treatment of choice for most patients with faecal incontinence after failed conservative therapy. The minimal invasion, the test stimulation, the complication rate and costs which are lower compared to the DGP, ABS or colostomy are advantages in favour of SNM.³⁶⁻³⁸ A sphincter replacement technique can be considered when the patient is not eligible for SNM or when SNM fails. The end-colostomy is mostly the final treatment option. Retrograde colonic irrigation must not be forgotten as conservative treatment before or after these treatment modalities.³⁹

CONCLUSION

Sacral nerve modulation is successful in about half of patients experiencing an unsuccessful standardized PFR. It improves quality of life and continence. Other treatments for patients who fail after SNM also result in improved continence.

LITERATURE

1. Muller C, Belyaev O, Deska T, Chromik A, Weyhe D, Uhl W. Fecal incontinence: an up-to-date critical overview of surgical treatment options. *Langenbecks Arch Surg* 2005;390: 544-52.
2. Dobben AC, Terra MP, Deutekom M, Bossuyt PM, Felt-Bersma RJ, Stoker J. Diagnostic work-up for faecal incontinence in daily clinical practice in the Netherlands. *Neth J Med* 2005;63:265-9.
3. Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence. *Gastroenterology* 2003;125:1320-9.
4. Norton C, Kamm MA. Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults--a systematic review. *Aliment Pharmacol Ther* 2001;15:1147-54.
5. van Tets WF, Kuijpers JH, Bleijenberg G. Biofeedback treatment is ineffective in neurogenic fecal incontinence. *Dis Colon Rectum* 1996;39:992-4.
6. Terra MP, Dobben AC, Berghmans B, et al. Electrical stimulation and pelvic floor muscle training with biofeedback in patients with fecal incontinence: a cohort study of 281 patients. *Dis Colon Rectum* 2006;49:1149-59.
7. Bassotti G, Chistolini F, Sietchiping-Nzepa F, de Roberto G, Morelli A, Chiarioni G. Biofeedback for pelvic floor dysfunction in constipation. *BMJ* 2004;328:393-6.
8. Koutsomanis D, Lennard-Jones JE, Roy AJ, Kamm MA. Controlled randomised trial of visual biofeedback versus muscle training without a visual display for intractable constipation. *Gut* 1995;37:95-9.
9. Heymen S, Jones KR, Ringel Y, Scarlett Y, Whitehead WE. Biofeedback treatment of fecal incontinence: a critical review. *Dis Colon Rectum* 2001;44:728-36.
10. Chiotakakou-Faliakou E, Kamm MA, Roy AJ, Storrie JB, Turner IC. Biofeedback provides long-term benefit for patients with intractable, slow and normal transit constipation. *Gut* 1998;42:517-21.
11. Ryn AK, Morren GL, Hallbook O, Sjodahl R. Long-term results of electromyographic biofeedback training for fecal incontinence. *Dis Colon Rectum* 2000;43:1262-6.
12. Uludag O, Darby M, Dejong CH, Schouten WR, Baeten CG. Sacral neuromodulation is effective in the treatment of fecal incontinence with intact sphincter muscles; a prospective study. *Neth J Med* 2002;146:989-93.
13. Kenefick NJ, Vaizey CJ, Cohen RC, Nicholls RJ, Kamm MA. Medium-term results of permanent sacral nerve stimulation for faecal incontinence. *Br J Surg* 2002;89:896-901.
14. Rosen HR, Urbarz C, Holzer B, Novi G, Schiessel R. Sacral nerve stimulation as a treatment for fecal incontinence. *Gastroenterology* 2001;121:536-41.
15. Jarrett ME, Varma JS, Duthie GS, Nicholls RJ, Kamm MA. Sacral nerve stimulation for faecal incontinence in the UK. *Br J Surg* 2004;91:755-61.
16. Melenhorst J, Koch SM, Uludag O, van Gemert WG, Baeten CG. Sacral neuromodulation in patients with faecal incontinence: results of the first 100 permanent implantations. *Colorectal Dis* 2007;9:725-30.
17. Leroi AM, Michot F, Grise P, Denis P. Effect of sacral nerve stimulation in patients with fecal and urinary incontinence. *Dis Colon Rectum* 2001;44:779-89.
18. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. *Gut* 1999;44:77-80.
19. Uludag O, Koch SM, van Gemert WG, Dejong CH, Baeten CG. Sacral neuromodulation in patients with fecal incontinence: a single-center study. *Dis Colon Rectum* 2004;47: 1350-7.
20. EuroQol--a new facility for the measurement of health-related quality of life. The EuroQol Group. *Health Policy* 1990;16:199-208.
21. Hanneman MJ, Sprangers MA, De Mik EL, et al. Quality of life in patients with anorectal malformation or Hirschsprung's disease: development of a disease-specific questionnaire. *Dis Colon Rectum* 2001;44:1650-60.

22. Brazier JE, Harper R, Jones NM, et al. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ* 1992;305:160-4.
23. Kairaluoma M, Raivio P, Kupila J, Aarnio M, Kellokumpu I. The role of biofeedback therapy in functional proctologic disorders. *Scand J Surg* 2004;93:184-90.
24. Byrne CM, Solomon MJ, Young JM, Rex J, Merlino CL. Biofeedback for fecal incontinence: short-term outcomes of 513 consecutive patients and predictors of successful treatment. *Dis Colon Rectum* 2007;50:417-27.
25. Norton C, Cody JD, Hosker G. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database Syst Rev* 2006;3:CD002111.
26. Jarrett ME, Mowatt G, Glazener CM, et al. Systematic review of sacral nerve stimulation for faecal incontinence and constipation. *Br J Surg* 2004;91:1559-69.
27. Koch SM, van Gemert WG, Baeten CG. Determination of therapeutic threshold in sacral nerve modulation for faecal incontinence. *Br J Surg* 2005;92:83-7.
28. Deutekom M, Terra MP, Dobben AC, et al. Impact of faecal incontinence severity on health domains. *Colorectal Dis* 2005;7:263-9.
29. Rockwood TH, Church JM, Fleshman JW, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum* 2000;43:9-16; discussion 16-7.
30. Mavrantonis C, Billotti VL, Wexner SD. Stimulated graciloplasty for treatment of intractable fecal incontinence: critical influence of the method of stimulation. *Dis Colon Rectum* 1999;42:497-504.
31. Rongen MJ, Uludag O, El Naggar K, Geerdes BP, Konsten J, Baeten CG. Long-term follow-up of dynamic graciloplasty for fecal incontinence. *Dis Colon Rectum* 2003;46:716-21.
32. Penninckx F. Belgian experience with dynamic graciloplasty for faecal incontinence. *Br J Surg* 2004;91:872-8.
33. Wong WD, Jensen LL, Bartolo DC, Rothenberger DA. Artificial anal sphincter. *Dis Colon Rectum* 1996;39:1345-51.
34. Lehur PA, Michot F, Denis P, et al. Results of artificial sphincter in severe anal incontinence. Report of 14 consecutive implantations. *Dis Colon Rectum* 1996;39:1352-5.
35. Ruthmann O, Fischer A, Hopt UT, Schrag HJ. [Dynamic graciloplasty vs. artificial bowel sphincter in the management of severe fecal incontinence]. *Chirurg* 2006;77(10):926-38.
36. Chapman AE, Geerdes B, Hewett P, et al. Systematic review of dynamic graciloplasty in the treatment of faecal incontinence. *Br J Surg* 2002;89:138-53.
37. Belyaev O, Muller C, Uhl W. Neosphincter surgery for fecal incontinence: a critical and unbiased review of the relevant literature. *Surg Today* 2006;36:295-303.
38. Hetzer FH, Bieler A, Hahnloser D, Lohlein F, Clavien PA, Demartines N. Outcome and cost analysis of sacral nerve stimulation for faecal incontinence. *Br J Surg* 2006;93:1411-7.
39. Koch SM, Uludag O, El Naggar K, van Gemert WG, Baeten CG. Colonic irrigation for defecation disorders after dynamic graciloplasty. *Int J Colorectal Dis* 2008;23:195-200.

chapter 4

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DETERMINATION OF THERAPEUTIC THRESHOLD IN SACRAL NERVE MODULATION (SNM) FOR FAECAL INCONTINENCE

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ABSTRACT

PURPOSE

The aim of the study was to determine the therapeutic response threshold in patients with successful sacral nerve modulation (SNM) for faecal incontinence.

PATIENTS AND METHODS

Patients who had undergone successful permanent SNM implantation and had been followed up for a minimum follow-up of three months were included. The sensitivity threshold and motor threshold were determined and correlated with therapeutic response, determining therapeutic response threshold. Patients went home with the stimulator set at 0.6 V below the sensitivity threshold. Each week the voltage was increased by 0.2 Volts until the sensitivity threshold was reached. The effects on anorectal physiology and continence were recorded.

RESULTS

Eight patients (seven women) with a median age of 58.5 years were included. The median follow-up was 6.3 months. The median sensibility threshold volume was 50 ml, the median urge threshold volume was 140 ml and the median maximum tolerated rectal volume 240 ml. The median incontinence episodes and days per week decreased from 5.0 and 3.8 before operation to 0.7 and 0.7 respectively after follow-up for three months. At anorectal manometry the median resting and squeeze pressures were 57 mmHg and 85 mmHg respectively, and remained constant over time. The therapeutic response threshold was significantly lower than the sensitivity threshold (median 1.6 vs. 1.7 V; $P=0.042$). The median motor threshold was 2.1 V, significantly higher than the sensitivity threshold ($P=0.009$). The stimulation threshold for suboptimal therapeutic response was 1.4 Volts. In five of the eight patients the therapeutic response threshold was the same as the sensitivity threshold.

CONCLUSION

SNM can produce a therapeutic effect below the sensitivity threshold. A lower stimulation voltage increases the lifespan of the pulse generator.

INTRODUCTION

Faecal continence is maintained by a combination of physiological parameters, including functioning anal sphincters, coordinated recto-sigmoid perception and motility, and solid-consistency stool.¹ Incontinence may occur when one or more of these factors alter.

Surgery is necessary when conservative treatment gives unsatisfactory results.

A high success rate is observed in patients with a simple structural defect of the external anal sphincter that can be corrected surgically. However, some patients with an internal anal sphincter muscle defect or a weak, but structurally intact external anal sphincter do not benefit from simple surgical procedures.^{1,2} For these patients therapeutic electrostimulation of the sacral nerves by sacral nerve modulation (SNM) is the treatment of choice.

SNM has been used to treat urinary incontinence and urine retention,³⁻⁵ and has also proven to be a successful treatment for faecal incontinence.^{6,7} The procedure is performed in three stages.^{1,8} Percutaneous neural evaluation (PNE) is first performed to assess the effect of SNM. An electrode is then inserted and a test stimulation is performed over a three-week period. If this test stimulation produces a decrease in incontinence episodes of more than 50%, a permanent electrode, extension cable and pulse generator is implanted. A minimal continuous tingling sensation in the anus, labia or pelvic floor indicates that the stimulation is working. This sensation is continuous during the first few weeks after implantation, but after 4-6 weeks it occurs only shortly after reactivating the pulse generator. During the first 2-3 months the voltage requires adjustment, after which it remains stable.⁷ The mechanism underlying the effect of SNM has not been clarified but probably involves both motor and sensory pathways.⁸ This study investigated whether the perineal sensation is essential for a therapeutic effect.

PATIENTS AND METHODS

Patients with a successful permanent implantation for SNM and a minimum follow-up of three months were included. The SNM procedure has been described previously.^{6,8,9} All patients had undergone preoperative investigations including anorectal manometry with rectal

balloon dilatation, defaecography, endoanal ultrasonography and determination of pudendal nerve motor latency times.

Inclusion criteria were a structurally intact external anal sphincter confirmed by endoanal ultrasonography and faecal incontinence with a frequency of more than once a week. Exclusion criteria were congenital anorectal malformations, rectal surgery in the preceding 12 months or inflammatory skin disease around the sacrum.

The lowest voltage at which the tingling sensation was present around the anus, at the perineum, pelvic floor or labia (in women) or scrotum (in men) determined the best pulse generator setting.⁸ This voltage is called the sensitivity threshold (ST). Sensation at the sacrum, buttock or glans penis was not accepted. To determine the motor threshold (MT), the electrode setting was maintained and the voltage was increased to the lowest level at which a motor response of the anal sphincter was present. In all patients the ST was lower than the MT. Patients went home with the voltage set at 0.6 V below the ST. Each week the voltage was increased by an increment of 0.2 V until the ST was reached. During these four weeks a bowel movement diary was completed. The optimal therapeutic response threshold (TT) was determined. A suboptimal therapeutic response threshold (STT) was a voltage at which an improvement in continence was observed, but not an optimal improvement. The definition for suboptimal improvement was either a strong urge to defaecate, which was not present during treatment with SNM before the study; or a decreased effect of SNM, but still more than 50% improvement in comparison to incontinence episodes before SNM implantation. The therapeutic response threshold was the voltage that produced the optimal effect of SNM. The baseline for optimum was determined according to the result achieved during the preceding treatment with SNM.

Statistical analysis was performed using the Wilcoxon and Mann-Whitney *U* tests for non-parametric samples in SPSS 11.0 (SPSS, Chicago, Illinois, USA). Results are presented as median (range). Statistical significance was set at $P \leq 0.050$.

RESULTS

Eight patients (seven women) with a median age of 58.5 (32.5-66.6) years were studied. Median follow-up was 6.3 (3.2-13.5) months. The

median duration of incontinence before SNM was 7.5 (range 2.0-61.0) years. The aetiology was idiopathic in five patients.

Two patients had a pudendal neuropathy, two had had a hysterectomy and two an obstetric injury. Two other patients had a history of a nucleus pulposus herniation, and one patient had undergone an anal repair and a hysterectomy.

The median sensibility threshold volume of rectal sensation was 50 (30-150) ml. The median urge threshold volume was 140 (90-400) ml and the median maximum tolerated rectal volume was 240 (150-400) ml. The number of incontinence episodes per week and number of days affected by incontinence per week decreased with stimulation (Figure 4.1).

Figure 4.1 Number of incontinence episodes and days affected by incontinence per week, before (baseline) and after implantation with sacral nerve modulation. Horizontal bars, boxes and error bars represent median, interquartile range and range respectively.

Figure 4.2 Resting and squeeze pressures before (baseline) and after implantation with sacral nerve modulation. Horizontal bars, boxes and error bars represent median, interquartile range and range respectively.

Figure 4.3 Suboptimal therapeutic response threshold (STT), therapeutic response threshold (TT), sensitivity threshold (ST) and motoric threshold (MT). Horizontal bars, boxes and error bars represent median, interquartile range and range respectively.

Figure 4.4 Number of incontinence episodes per week recorded before implantation with SNM (baseline), and during week 1 (0.6 Volts below sensitivity threshold), week 2 (0.4 Volts below sensitivity threshold), week 3 (0.2 Volts below sensitivity threshold) and week 4 (stimulation at sensitivity threshold).

Resting and squeeze anal canal pressures remained constant over time (**Figure 4.2**). The TT was significantly lower than the ST (median 1.6 (0.9-2.9) vs. 1.7 (0.9-2.9)V; $P=0.042$). The MT (median 2.1 (1.2-3.1)V) was significantly higher than the ST ($P=0.009$). The STT was 1.4 (1.3-1.4) V (**Figure 4.3**). In five of eight patients the TT was the same as the ST, including both patients with pudendal neuropathy. Examination of the diaries revealed a gradual decrease in incontinence episodes over the four weeks during which the stimulation voltage was increased (**Figure 4.4**).

DISCUSSION

The mechanism underlying the functional improvement provided by SNM is still unknown. It was originally suggested that SNM improved continence by stimulating and strengthening the anal sphincter. In two studies by Ganio et al.^{10,11} stimulation was noted to increase both resting and squeeze pressures. Other studies reported only increased squeeze

pressures,^{1,6,7,12} and Ganio et al.⁹ reported an increase in resting pressure only in another study. Rosen and al. demonstrated increased squeeze and resting pressures in patients with neurogenic incontinence but no increase in patients with idiopathic incontinence.¹³ Other studies have found no significant improvement in resting and squeeze pressures,^{8,14-16} probably because the stimulation voltage applied to achieve a therapeutic effect was low. An analysis of all studies has revealed that those reporting increased resting and/or squeeze pressures used a maximum stimulation amplitude that was comfortable to the patient^{1,9,11} or stimulation adapted according to the patients' perception of muscular contraction.⁶ Studies that did not report increased anal pressures used stimulation voltages just above sensitivity threshold¹⁶ and stimulation voltages adjusted to fine tune continence.¹⁵ Only one study that did not find increased anal pressures reported a stimulation voltage adapted according to the patients' perception of muscular contraction.¹⁴ Voltage data are only available for a few studies and therefore comparison is difficult. However, a stimulation voltage below the motor threshold is apparently sufficient to induce a therapeutic effect.

In the present study the MT was shown to be higher than the ST. Continuous stimulation at the level of the MT probably induces a transformation of type II fatigue-prone to type I fatigue-resistant muscle fibres. This phenomenon is also observed in dynamic graciloplasty, that increases the duration of the contraction and/or anal canal pressures.¹⁷ However, rectal sensitivity and activity, and pelvic floor coordination are just as important in maintaining continence as functioning anal sphincters.¹ Stimulation at the level of the ST or below probably results in a better motor and sensory input and output of the rectum. For this reason the term sacral nerve modulation is preferred over sacral nerve stimulation.

The pelvic floor and anal sphincters receive motor innervation from S2-4. Direct branches of the sacral plexuses, but mostly S3, innervate the levator ani and puborectal muscles. S3 stimulation causes contraction of the pelvic floor musculature, which might slightly raise the anal canal pressure, but primarily decreases the recto anal angle.¹⁸ The maximal rise in anal canal pressure is induced via stimulation of the pudendal nerve. The pudendal nerve derives mainly from S2, although S3 may contribute to varying degrees.

The external anal sphincter contracts voluntarily, but also by reflex action. Reflex contraction is due to a sacral reflex arc.⁸ The Aδ fibres of the sacral plexus are probably stimulated with SNM, and modulate sacral

reflexes. In this way the sacral reflex arc is altered by SNM.¹ The effects of stimulation are likely to be more diverse than a simple effect on the efferent motor supply of the sphincter.¹ The internal anal sphincter is innervated by the sympathetic (hypogastric plexus) and parasympathetic autonomic pathways. Only a few studies report increased resting and squeeze anal canal pressures with SNM.^{10,11} The level of stimulation required to achieve smooth muscle contraction via autonomic myelinated efferent fibres is three to five times higher than the threshold for α -motor neurons, which innervate the striated muscle fibres of the external anal sphincter.

In a mixed nerve the largest fibres are the IA sensory fibres that respond to phasic muscle stretch; these are also the fibres with the lowest stimulation threshold. The mixed nerves modulate the sacral reflexes. The α -motor neurons need a higher level of stimulation than the IA sensory fibres. The level of stimulation required to activate afferent A δ fibres is 1.5 times higher than that for the α -motor neurons.¹

Chronic low-grade stimulation at the sensory threshold or lower causes an insufficient stimulus to raise anal sphincter pressure, but the stimulus may be enough to modulate the A δ reflexes and IA sensory fibres. Modulation of sacral reflexes that serve the rectum may stabilize rectal contractile activity and improve rectal sensation.^{8,13,16,18-20} Several studies support this theory. Voluntary motor pathways involved in pelvic floor control originate in the most medial part of the primary motor cortex, the medial cerebellum and the motor thalamus.²¹ One study provided evidence for a supraspinally mediated site of modulation by SNM, most probably in the sensory cortex.²²

The present study has shown that it is possible to obtain a therapeutic result with stimulation below the ST. This observation supports the hypothesis that the effects of SNM on incontinence are not merely explained by motor responses, but probably involve modulation of sensory responses of the sacral nerve plexus. However, most patients prefer to feel the stimulation because this confirms that the stimulator is working. Stimulating below the ST should extend the life of the pulse generator. There are currently no data on the lifespan of pulse generators in patients with SNM because the follow-up is still too short, but that of pulse generators in patients with a dynamic graciloplasty was reported to be 7.8 years.²³ Pulse generator used for SNM should last longer, because the stimulator may be turned off at night, as during sleep involuntary faecal loss is rare.

LITERATURE

1. Vaizey CJ, Kamm MA, Turner IC, Nicholls RJ, Woloszko J. Effects of short term sacral nerve stimulation on anal and rectal function in patients with anal incontinence. *Gut* 1999; 44:407-12.
2. Baeten CG, Uludag O. Second-line treatment for faecal incontinence. *Scand J Gastroenterol Suppl* 2002(236):72-5.
3. Janknegt RA, Hassouna MM, Siegel SW, Schmidt RA, Gajewski JB, Rivas DA, Elhilali MM, Milam DC, van Kerrebroeck PE, Dijkema HE, Lycklama à Nijeholt AA, Fall M, Jonas U, Catanzaro F, Fowler CJ, Oleson KA. Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence. *Eur Urol* 2001;39:101-6.
4. Schmidt RA, Jonas U, Oleson KA, Janknegt RA, Hassouna MM, Siegel SW, van Kerrebroeck PE. Sacral nerve stimulation for treatment of refractory urinary urge incontinence. Sacral Nerve Stimulation Study Group. *J Urol* 1999;162:352-7.
5. Jonas U, Fowler CJ, Chancellor MB, Elhilali MM, Fall M, Gajewski JB, Grünewald V, Hassouna MM, Hombergh U, Janknegt R, van Kerrebroeck PE, Lycklama à Nijeholt AA, Siegel SW, Schmidt RA. Efficacy of sacral nerve stimulation for urinary retention: results 18 months after implantation. *J Urol* 2001;165:15-9.
6. Matzel KE, Stadelmaier U, Hohenfellner M, Gall FP. Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. *Lancet* 1995;346:1124-7.
7. Matzel KE, Stadelmaier U, Hohenfellner M, Hohenberger W. Chronic sacral spinal nerve stimulation for fecal incontinence: long-term results with foramen and cuff electrodes. *Dis Colon Rectum* 2001;44:59-66.
8. Uludag O, Darby M, Dejong CH, Schouten WR, Baeten CG. Sacrale neuromodulatie effectief bij fecale incontinentie en intacte kringsspieren; een prospectieve studie. *Ned Tijdschr Geneesk* 2002;146:989-93.
9. Ganio E, LAR, Clerico G., Trompetto M. Sacral Nerve Stimulation for Treatment of Fecal Incontinence. *Diseases of colon and rectum* 2001;44:619-31.
10. Ganio E, Masin A, Ratto C, Altomare DF, Ripetti V, Clerico G, Lise M, Doglietto GB, Memeo V, Landolfi V, Del Genio A, Arullani A, Giardiello G, de Seta F. Short-term sacral nerve stimulation for functional anorectal and urinary disturbances: results in 40 patients: evaluation of a new option for anorectal functional disorders. *Dis Colon Rectum* 2001; 44:1261-7.
11. Ganio E, Ratto C, Masin A, Luc AR, Doglietto GB, Dodi G, Ripetti V, Arullani A, Frascio M, BertiRiboli E, Landolfi V, DelGenio A, Altomare DF, Memeo V, Bertapelle P, Carone R, Spinelli M, Zanollo A, Spreafico L, Giardiello G, de Seta F. Neuromodulation for fecal incontinence: outcome in 16 patients with definitive implant. The initial Italian Sacral Neurostimulation Group (GINS) experience. *Dis Colon Rectum* 2001;44:965-70.
12. Matzel KE, Stadelmaier U, Bittorf B, Hohenfellner M, Hohenberger W. Bilateral sacral spinal nerve stimulation for fecal incontinence after low anterior rectum resection. *Int J Colorectal Dis* 2002;17:430-4.
13. Rosen HR, Urbarz C, Holzer B, Novi G, Schiessel R. Sacral nerve stimulation as a treatment for fecal incontinence. *Gastroenterology* 2001;121:536-41.
14. Leroi AM, Michot F, Grise P, Denis P. Effect of sacral nerve stimulation in patients with fecal and urinary incontinence. *Dis Colon Rectum* 2001;44:779-89.
15. Malouf AJ, Vaizey CJ, Nicholls RJ, Kamm MA. Permanent sacral nerve stimulation for fecal incontinence. *Ann Surg* 2000;232:143-8.
16. Kenefick NJ, Vaizey CJ, Cohen RC, Nicholls RJ, Kamm MA. Medium-term results of permanent sacral nerve stimulation for faecal incontinence. *Br J Surg* 2002;89:896-901.
17. Baeten CG, Konsten J, Spaans F, Visser R, Habets AM, Bourgeois IM, Wagenmakers AJ, Soeters PB. Dynamic graciloplasty for treatment of faecal incontinence. *Lancet* 1991; 338:1163-5.

18. Matzel KE, Schmidt RA, Tanagho EA. Neuroanatomy of the striated muscular anal continence mechanism. Implications for the use of neurostimulation. *Dis Colon Rectum* 1990;33:666-73.
19. Ripetti V, Caputo D, Ausania F, Esposito E, Bruni R, Arullani A. Sacral nerve neuromodulation improves physical, psychological and social quality of life in patients with fecal incontinence. *Tech Coloproctol* 2002;6:147-52.
20. Vaizey CJ, Kamm MA, Roy AJ, Nicholls RJ. Double-blind crossover study of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum* 2000;43:298-302.
21. Blok BF. Central pathways controlling micturition and urinary continence. *Urology* 2002; 59(5 Suppl 1):13-7.
22. Braun PM, Baezner H, Seif C, Boehler G, Bross S, Eschenfelder CC, Alken P, Hennerici M, Juenemann P. Alterations of cortical electrical activity in patients with sacral neuromodulator. *Eur Urol* 2002;41:562-6; discussion 566-7.
23. Rongen MJ, Adang EM, Van Der Hoop AG, Baeten CG. One-step vs two-step procedure in dynamic graciloplasty. *Colorectal Dis* 2001;3:51-7.

chapter 5

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SACRAL NERVE MODULATION FOR DEFAECATION AND MICTURITION DISORDERS IN PATIENTS WITH SPINA BIFIDA

Submitted

ABSTRACT

PURPOSE

Sacral Nerve Modulation (SNM) is a well accepted method for the treatment of defaecation and voiding disorders. Results vary and depend on the underlying disease. Results of SNM in patients with spinal cord lesions are not well assessed, but preliminary results look poor. Therefore, the purpose of this study was to assess the use of SNM in patients with spina bifida and defaecation and micturition disorders.

PATIENTS AND METHODS

Consecutive patients with spina bifida suffering from a myelomeningocele and combined defaecation and voiding disorders that were tested with a peripheral nerve evaluation were included in the study.

Patient history and medication was noted and diagnostics were performed. A peripheral nerve evaluation was performed and when successful followed by a test stimulation for a period of three weeks. A permanent implantation was performed after successful test stimulation. Follow-up data including anorectal manometry and rectal balloon insufflation were scheduled at one, three, six and 12 months.

RESULTS

Between February 2003 and December 2006, ten patients (four females) were included in this study with a median age of 26.4 years. In two patients the peripheral nerve evaluation was unsuccessful and consequently eight patients underwent a test stimulation. The median incontinence days and episodes per three weeks decreased significantly during test stimulation ($P=0.033$), but only three of ten (30%) patients had a more than 50% improvement and proceeded to SNM implantation. All patients had a malformed sacrum. Patients with an absent pudendal nerve terminal motor latency times were technically more difficult to stimulate, but successful peripheral nerve evaluation and/or test stimulation was not excluded in these patients.

CONCLUSION

SNM can be successful in a subgroup of spina bifida patients with combined defaecation and voiding disorders.

INTRODUCTION

The affected spinal cord in spina bifida patients suffering from a myelomeningocele (SB) may lead to profound motor, sensory and autonomic disorders in the lower limbs, bladder and bowel, depending on the level and the pattern of the cord lesion.¹

Faecal incontinence, constipation, urinary incontinence and retention are major impairments affecting the quality of life and social integration of patients with SB.² Lack of bowel control is found to be as stressful as bladder dysfunction and even more stressful as the impairment of motor function.³ Several studies report successful treatment of defaecation and voiding disorders with sacral nerve modulation (SNM). But only a few reports about the use of SNM in SB patients exist in the literature and preliminary results look poor.⁴⁻⁹

The purpose of this study was to assess the effectiveness of SNM for the treatment of combined defaecation and voiding disorders in patients with SB. Also selection criteria for successful result of SNM in SB patients were assessed.

PATIENTS AND METHODS

Patients

Consecutive SB patients with combined defaecation and micturition disorders who were tested with a PNE were included in the study. Inclusion criteria were age above eight years, not or only partially wheelchair bound, a structurally intact external anal sphincter and failed conservative therapy including colonic irrigation. Exclusion criteria were severe grade III/IV pelvic prolapse, rectal prolapse, cystocele, urethrocele, enterocele, rectocele, chronic inflammatory bowel diseases, chronic diarrhoea, anatomic obstructive voiding disorders and stress incontinence for urine.

Patients completed a baseline defaecation diary during three weeks. Faecal incontinence was defined as incontinence for solid or liquid stool more than once a week on average. Constipation was defined as less than two bowel movements per week, difficulty in emptying the rectum or feeling of incomplete evacuation for more than 50% of the bowel movements during the previous year. Urinary incontinence was defined as incontinence associated with or without overactive detrusor function during cystometric evaluation. Urinary retention or voiding dysfunction

was defined as hesitancy or intermittency due to an acontractile detrusor or obstruction due to urethral sphincter overactivity resulting in incomplete voiding or retention (>100 cc residual).

Diagnostics

Information on history and medication was collected and anorectal manometry, pudendal nerve terminal motor latency time measurement, endo-anal ultrasonography and X-ray of the sacrum were collected. In patients having voiding disorders as major complaint a micturition cystogram was performed.

Diagnostic measurements were performed starting with anorectal manometry using a four point solid state catheter (Konigsberg instrument Inc., Pasadena, CA) measuring resting and squeeze pressures, anal and rectal pressures during straining and coughing. The recto-anal inhibitory reflex (RAIR) was assessed using this catheter together with a balloon. Rectal sensitivity and capacity was assessed with a balloon catheter; measurement of first rectal sensation volume (FRSV), first urge sensation volume (FUSV) and the maximal tolerated volume (MTV) was performed by rectal balloon insufflation. Each patient underwent an endo-anal ultrasonography (7.5 MHz, SDD 2000, Multiview, Aloka, Japan). Pudendal nerve terminal motor latency times (PNTML) were assessed using a St. Marks pudendal electrode (Medtronic USA). Pudendopathy was diagnosed in case of a PNTML of >2.4 ms or the presence of an abnormal curve. In case of an abnormal curve, the PNTML was recorded as absent.

Sacral Nerve Modulation

Patient history and symptoms, results of anorectal and urodynamic physiologic testing and a sacral neuromodulation screening period determined whether a patient was a candidate for permanent implantation with SNM. The first step is the peripheral neural evaluation (PNE) which is considered successful in case of a good motoric response, achieved by a contraction of the anal sphincter or a plantar flexion of the great toe and/or a sensory response characterized by a continuous tingling sensation around the anus, pelvic floor, labia or scrotum. Only the motoric response was assessed in children, because the PNE was performed under general anaesthesia in the paediatric group. An electrode was positioned in the foramina of S2 to S4, but preferably in the third sacral foramen and connected to an external test stimulator after

a successful PNE for a three-week evaluation period (trial screening). The test stimulation (TS) period was successful if there was an improvement of 50% in one of the defaecation disorders (incontinence days or episodes, straining, abdominal pain, bloating abdomen and incomplete evacuation) or micturition disorders (spontaneous voiding, number of voids, number of urinary leakages and catheterized volume), objectivated by a diary. SNM was indicated after successful TS.

The implantable components of the sacral nerve stimulation system (Medtronic®) include an implantable pulse generator (IPG), a connection wire and a lead with quadripolar electrodes. The electrode is positioned in one of the sacral foramina by an open procedure under general anaesthesia, attaching the electrode to the fascia of the sacrum, typically at the level of S3. The IPG is implanted subcutaneously in the buttock. The physician uses an external programmer to adjust the parameters of the electrical stimulation produced by the IPG. The patient uses a hand-held programmer to turn the IPG on or off.

Follow-up data were collected at one month, three months, six months, 12 months postoperatively and yearly thereafter. Anal manometry was performed at three, six, and 12 months. Rectal balloon insufflation was performed at three and six months.

Data analysis

Statistical analysis was performed with SPSS 14.0 (SPSS release 14.0, SPSS Inc. Chicago). The Wilcoxon non-parametric test for paired samples was used to test the statistical significance of overall SNM outcome during follow-up compared to baseline values. Data were expressed as median values and range. Statistical significance was set at $P \leq 0.050$.

RESULTS

Baseline

Ten patients (four females) were included in the study between February 2003 and December 2006 with a median age of 26.4 (11.1-41.0) years. Medical diagnosis, defaecation and micturition disorders are described in **Table 5.1**. The results of anorectal manometry and rectal balloon insufflation are shown in **Table 5.2**. PNMTL was bilaterally normal in only one patient, while all other (eight of nine) patients had a

pudendopathy; two patients had bilaterally absent PNMTL. In one patient PNMTL were not assessed. Endo-anal ultrasound showed ventral atrophy of the external anal sphincter in one patient and scarring in another patient, other patients had no structural abnormalities. An X-ray showed lumbo-sacral anomalies in all patients with gradations from an open lamina to a totally abnormal sacrum.

Sacral nerve modulation

The PNE was successful in eight of the ten included patients. These eight patients subsequently had a TS. The median incontinence days and episodes per 21 days during TS decreased from 6.0 (2-19) to 3.5 (1.3-8) ($P=0.030$) and 8.5 (2-35) to 3.5 (1.3-8) ($P=0.033$) respectively in six patients with faecal incontinence. The median defaecation frequency per day decreased significantly from 3.5 (1.0-5.0) to 2.0 (0.4-3.0) during TS ($P=0.022$). Three of the total ten included (30%) Patients fulfilled the criteria of successful TS and proceeded to SNM implantation. Two patients with faecal incontinence improved more than 50%. One patient (patient 6) improved from 19.0 to 1.3 incontinence days per 21 days and from 35.0 to 1.3 incontinence episodes per 21 days. Another patient (patient 9) improved from 7.0 to 2.0 incontinence days per 21 days and from 12.0 to 2.0 incontinence episodes per 21 days. The urinary retention improved in a third patient (patient 1): spontaneous voiding per day improved from 10 ml to 150 ml, the number of voids per day improved from 0.2 to 1.3 and the number of urinary leakages per day decreased from 0.4 to 0.0. The catheterized volume however did not improve. This patient also had constipation: the abdominal pain improved from 24% to 14% of the days, and bloating abdomen improved from 19% to 5%. The percentage of straining and incomplete evacuation did not improve. In one patient (patient 6) the implantation was technically impossible, because the motoric response was absent under general anaesthesia. A tined lead procedure¹⁰ under local anaesthesia is planned for this patient.

Anorectal physiologic testing

All three patients with successful PNE had a malformed sacrum and pudendopathy; one patient had bilaterally absent PNMTL. Two of three patients had a normal RAIR baseline.

Table 5.1 Patient characteristics.

Patient	Age	Medical history	Faecal incontinence	Constipation	Urinary incontinence	Urinary retention
1 [#]	15	Tethered cord	-	+	+	+
2	20	Durasac L5	+	+	+	+
3	11	Tethered cord	-	+	+	-
4	17	Ileocystoplasty DGP, rectovaginal fistula	+	+	-	+
5*	26	Heart operation	+	-	+	+
6 [#]	41	Hydrocephalus, VP drain, Indiana pouch	+	-	-	+
7	40	Monokidney, bricker urostomy	+	+	Na	Na
8*	40	Operation spina bifida	+	+	-	+
9 [#]	37	Tethered cord	+	-	-	+
10	27	Tethered cord	+	+	+	-

* No reaction with PNE. [#] Successful TS

Table 5.2 The results of anorectal manometry and rectal balloon distension baseline.

n=10	Median (range)	Normal values
Resting pressure in mmHg	55 (42-121)	35 - 70
Squeeze pressure in mmHg	84 (53-144)	140 - 220
Anal pressure during coughing in mmHg	109 (63-175)	anal pressure > rectal pressure
Rectal pressures during coughing in mmHg	90 (57-119)	anal pressure > rectal pressure
Anal pressures during straining in mmHg	81 (60-193)	anal pressure < rectal pressure
Rectal pressures during straining in mmHg	97 (71-179)	anal pressure < rectal pressure
RAIR	present in 7/10 patients	
FRSV in ml	88 (10-240)	10 - 30
FUSV in ml	125 (30-380)	60 - 150
MTV in ml	190 (75-400)	150 - 250

RAIR, recto-anal inhibition reflex; FRSV, first rectal sensation volume; FUSV, first urge sensation volume; MTV, maximal tolerable volume.

Results of anal manometry and rectal balloon insufflation in the two implanted patients did not significantly change during follow-up and are shown in **Figure 5.1** and **5.2**.

Figure 5.1 The result of anal manometry (mmHg) in the two patients with successful implantation.

Figure 5.2 The result of rectal sensitivity and capacity (ml) in the two patients with successful implantation.

Complications

Patient 9 had an erosion of the pacemaker in the buttock and had his pacemaker replaced to the abdomen.

DISCUSSION

Treatment of SB patients

The treatment of defaecation and voiding disorders in SB patients mainly consists of conservative therapy; medication to alter consistency of stool, diet modification and colonic irrigation in case of faecal incontinence or constipation. Anticholinergics, antibiotics in case of associated urinary tract infection and intermittent catheterization are used for the treatment of micturition disorders.⁴ Surgical procedures for constipation and faecal incontinence in SB patients are usually an Malone antegrade continence enema (MACE) using the appendix, caecum, sigmoid or descending colon.¹¹ Surgical procedures for urinary incontinence and retention in SB patients are peri-urethral injection of bulking agents, bladder neck reconstruction, bladder augmentation, and artificial urinary sphincter implantation.⁴ SNM may be an alternative minimally invasive technique to treat defaecation and voiding disorders. Another advantage is the test stimulation which is performed before proceeding to definitive SNM implantation.

Exclusion criteria

Patients bound to the wheelchair were excluded from this study. Although it is technically possible to treat these patients with surgical techniques such as SNM or dynamic graciloplasty, we advise patients who are fully wheelchair bound to refrain from these treatment options. These treatments usually improve the postponement capacity, but mostly not enough for these patients to reach the toilet in a reasonable time and make a proper transfer. This patient group is therefore better off with a colostomy which deals with the incontinence issue and increases their independency.

Only a few cases of SNM treatment in SB patients are described in the literature (**Table 5.3**).^{4-9,12} All but one of these studies presents the results of a selected SB group. Tanagho reported 27 children with voiding dysfunction including 19 children with meningomyelocele.¹² Rosen et al.

studied a population of 20 patients with faecal incontinence in which two patients with SB were included.⁷ Ganio et al. reported 23 patients with various aetiologies, including one patient with SB, having an improvement of 50%.¹³ Holzer et al.⁶ reported 36 patients with faecal incontinence including the 15 patients reported already in the study of Rosen et al.,⁷ of which four patients were SB patients.⁶ Guys et al. performed a study in 21 children with neurogenic bladder dysfunction including 13 patients with SB. Enrolment in the study was possible after a positive PNE, however the number of patients with unsuccessful PNE was not stated. Comparison with other studies including the present study is difficult because the criteria for success were not defined in that study.⁴ Wallace et al. describe 33 patients with lower urinary tract dysfunction and neurological disease, including two patients with SB.⁵ Pescatori reported one patient with SB.⁹ Jarrett et al.⁸ report 13 patients with partial spinal injury, including one patient with SB.⁸ In the present study ten SB patients were included with combined defaecation and voiding disorders. In the entire literature including the present study a total of 53 SB patients have been reported. Because the data of Guys et al.⁴ are not available, only 30 patients could be evaluated, resulting in 23 of 40 patients (58%) with successful TS (**Table 5.3**).

Anaesthesia technique

In this study, the PNE was mostly performed under local anaesthesia assessing the sensory and motoric response, except in two children (patient 1 and 3). Most studies relied on the motoric response and used general anaesthesia.^{4,6,7} The authors believe a PNE should be performed under local anaesthesia, as the patient is aware of the sensation caused by the stimulation, whereas under general anaesthesia only the motoric response can be assessed. Unpublished data of the authors suggest that patients with faecal incontinence and only a sensory response during PNE have the same probability of a successful TS and SNM compared to patients with (also) a motoric response. This would implicate that a potential successful group with only sensory responses are missed when PNE is performed under general anaesthesia (unpublished data). The implantation however was performed by an open procedure under general anaesthesia in all three patients. One of these (patient 6) had no motoric response and therefore the system could not be implanted. Nevertheless, in cases without motoric response, it is possible to place a

percutaneous placed tined lead under local anaesthesia,¹⁴ when the sacral foramina are intact.

Technique of implantation

In case of malformed sacral foramina the authors prefer to perform an open procedure to prevent accidental damage to the nerves. In the study of Holzer et al., the permanent electrode was sutured directly to the nerve by an open procedure.⁶ Jarrett et al. also reported one patient with an absent posterior wall with a migration of the electrode which was replaced during an open procedure.⁸

Table 5.3 Review of success percentages and complications in studies treating SB patients with SNM. The present study is mentioned under Koch.

Author	n	Faecal incontinence	Constipation	Urinary incontinence	Urinary retention	Positive PNE	Success	Complications
Tanagho 1992 ¹²	19			19		11	11/19	?
Rosen 2001 ⁷	2	2				1	1/2	1 infection causing explantation
Ganio 2001 ¹³	1	1			1	1	1/1	?
Guys 2004 ⁴	13	+	+	13	13	13	?	?
Pescatori 2004 ⁹	1		1	1		1	1/1	?
Jarret 2005 ⁸	1	1				1	1/1	1 lead migration after implantation
Holzer 2007 ⁶	4	4	?	?		3	3/4	1 infection causing explantation 1 lead migration after implantation
Wallace 2007 ⁵	2			1	1	2	2/2	-
Koch	10	8	7	5	7	8	3/10	1 erosion of the pacemaker
Total	52					41	23/40	

Although all patients had sacral malformations, it was possible to stimulate the majority of them. It is important to investigate the caudal end of the thecal sac to prevent puncturing the dura, risking meningitis. In this study all thecal sacs ended above S2 and whenever in doubt, the neurosurgeon was consulted preoperatively.

Other techniques of electrical stimulation are described in the literature. Holmes described six children with SB and faecal soiling with external electrical stimulation at S2-S3, achieving continence in three of six patients.¹⁵ Binnie et al. reported seven patients with spinal cord injury and constipation implanted with the Brindley stimulator. After a lumbo-sacral laminectomy the appropriate anterior sacral nerve roots were placed within the electrodes. These patients had a significant increase in the defaecation frequency. This procedure however is complex and hazardous for the sacral nerves, and infection of the implant is a major threat.¹⁶

Rectal sensitivity

Constipation and faecal incontinence are common in patients with spina bifida affecting about 78%.^{3,17} Motility is impaired in the distal colon, rectal sensation and anal sphincter pressures are reduced.^{2,18} The present study confirms the reduced rectal sensitivity in patients with SB (**Table 5.2**). The results of rectal sensitivity and capacity in different studies are shown in **Table 5.4**. The studies are divided in studies including patients with and without neurological disease. The studies with neurological disease included patients suffering from various neurological congenital or acquired disorders: spinal cord trauma, spinal cord surgery, spinal stroke, multiple sclerosis, syringomyelia, SB. The FRSV in patients with a neurological disorder is much higher compared to other patient groups (**Table 5.4**).¹⁹⁻²⁴ The FRSV is higher in studies that also included patients with neurological disorders,^{6,7,13} except in a study of Jarrett et al., reporting 46 patients including two patients with spinal trauma.²⁴ Rosen et al. studied 16 patients, including 14 patients with neurological disease.⁷ Ganio et al. studied 23 patients and included ten patients with neurological disease.¹³ The study of Holzer et al. consisted of 36 patients, included 17 patients after spinal cord surgery, 11 patients with spinal cord trauma and four SB patients.⁶ In this study, a transient decrease in FRSV, FUSV and MTV during SNM was seen. Most studies report a decreased FRSV during SNM.^{7,13,19,21,23-25} A few studies report an increased FRSV.^{6,22,26} FUSV decreased in most

studies,^{6,13,19,21,24,25} but increased in some other studies.^{22,23,26} The MTV decreased in some studies^{7,19,21,24,25} and increased in other studies.^{6,22,23,26} The changes in rectal sensation suggest modification of the afferent sensory nerves.²¹ In conclusion, the results of the different studies are controversial and no definitive conclusion can be drawn about rectal sensitivity. One may expect decreased FRSV and FUSV and increased MTV in these cases where SNM influences rectal sensitivity.

Table 5.4 Review of rectal capacity in different studies treating patients with SNM. Volumes in ml. All volumes in median and range except for Melenhorst et al. (mean with range), Jarrett et al. (mean and SD).

Author	<i>n</i>	FRSV (normal 10-30ml)	FUSV (normal 60-150ml)	MTV (normal 150-250 ml)
Neurological disease				
Koch	10	88	125	190
Rosen 2001 ⁷	16	90	100	220
Ganio 2001 ¹³	23	67	115	-
Holzer 2007 ⁶	36	66	110	148
Jarrett 2004 ²⁴	46	41	92	129
No neurological disease				
Vaizey 1999 ²²	12	45	73	95
Malouf 2000 ²³	5	45	70	95
Kenefick 2002 ²¹	5	53	83	143
Dudding 2008 ²⁰	69	45	81	141
Melenhorst 2007 ¹⁹	100	50	107	175

FRSV, first rectal sensation volume; FUSV, first urge sensation volume; MTV, maximal tolerable volume.

Pudendopathy

As expected, a high rate of pudendopathy was seen in the present study group. It is well-known that pudendopathy is apparent in most patients with spinal cord injury.² Some previous studies showed that patients with a bilateral absent PNMTL had no benefit of SNM.^{13,27} In the studies of Ganio et al., successful PNE proved possible in two of three patients with spinal cord injury and absent PNMTL. However, the TS failed in these patients.^{13,27} Wallace et al. reported that the outcome of PNMTL was not predictive for success or failure of SNM in patients with neurological disease.⁵ One patient in the present study had bilateral absent PNMTL and

nevertheless had a good result on TS. Three patients had an unsuccessful PNE; one of these patients had absent PNMTL bilaterally and one patient bilaterally pudendopathy. It appears that the probability of successful PNE or TS is lower in patients with an absent PNMTL, although success is not precluded.

The authors conclude SNM is successful in a selected group of SB patients, but proper selection criteria are missing. Dudding et al. reported 81 patients with faecal incontinence and observed that only a low threshold to obtain a motor response during temporary lead insertion was associated with improved outcome of TS.²⁰ Larger prospective studies should be performed to determine selection criteria for SNM, especially in this population.

CONCLUSION

SNM for the treatment of defaecation and voiding disorders may be successful in a selected group of SB patients. Further studies are warranted to determine the prognostic factors for success.

LITERATURE

1. Behrman R.E. KRM, Jenson H.B. Textbook of Paediatrics. Chapter 14: Disorders of the central nervous system: WB Saunders Company; 2000.
2. Tjandra JJ, Ooi BS, Han WR. Anorectal physiologic testing for bowel dysfunction in patients with spinal cord lesions. *Dis Colon Rectum* 2000;43:927-31.
3. Lie HR, Lagergren J, Rasmussen F, Lagerkvist B, Hagelsteen J, Börjeson MC, Muttillainen M, Taudorf K. Bowel and bladder control of children with myelomeningocele: a Nordic study. *Dev Med Child Neurol* 1991;33:1053-61.
4. Guys JM, Haddad M, Planche D, Torre M, Louis-Borrione C, Breaud J. Sacral neuromodulation for neurogenic bladder dysfunction in children. *J Urol* 2004;172(4 S 1):1673-6.
5. Wallace PA, Lane FL, Noblett KL. Sacral nerve neuromodulation in patients with underlying neurologic disease. *Am J Obstet Gynecol* 2007;197:96 e1-5.
6. Holzer B, Rosen HR, Novi G, Ausch C, Holbling N, Schiessel R. Sacral nerve stimulation for neurogenic faecal incontinence. *Br J Surg* 2007;94:749-53.
7. Rosen HR, Urbarz C, Holzer B, Novi G, Schiessel R. Sacral nerve stimulation as a treatment for fecal incontinence. *Gastroenterology* 2001;121:536-41.
8. Jarrett ME, Matzel KE, Christiansen J, Baeten CG, Rosen H, Bittorf B, Stösser M, Madoff R, Kamm MA. Sacral nerve stimulation for faecal incontinence in patients with previous partial spinal injury including disc prolapse. *Br J Surg* 2005;92:734-9.
9. Pescatori M. Correspondence: Systematic review of sacral nerve stimulation for faecal incontinence and constipation (*Br J Surg*; 912:1559-1569). *Br J Surg* 2004;91:755-61.
10. Van Voskuilen AC, Oerlemans DJ, Weil EH, van den Hombergh U, van Kerrebroeck PE. Medium-term experience of sacral neuromodulation by tined lead implantation. *BJU Int* 2007;99:107-10.
11. Lemelle JL, Guillemin F, Aubert D, Guys JM, Lottmann H, Lortat-Jacob S, Moscovici J, Mouriquand P, Ruffion A, Schmitt M. A multicentre study of the management of disorders of defecation in patients with spina bifida. *Neurogastroenterol Motil* 2006;18:123-8.
12. Tanagho EA. Neuromodulation in the management of voiding dysfunction in children. *J Urol* 1992;148(2 Pt 2):655-7.
13. Ganio E, LAR, Clerico G., Trompetto M. Sacral Nerve Stimulation for Treatment of Fecal Incontinence. *Diseases of colon and rectum* 2001;44:619-31.
14. Spinelli M, Weil E, Ostardo E, Del Popolo G, Ruiz-Cerdá JL, Kiss G, Heesakkers J. New tined lead electrode in sacral neuromodulation: experience from a multicentre European study. *World J Urol* 2005;23:225-9.
15. Holmes G. EM, Montiel viesca F., Rosenbloom L. Anorectal Electrical Stimulation in the treatment of Children with faecal soiling - A preliminary study. *Eur J Pediatr Surg* 1994; 4:43.
16. Binnie NR, Smith AN, Creasey GH, Edmond P. Constipation associated with chronic spinal cord injury: the effect of pelvic parasympathetic stimulation by the Brindley stimulator. *Paraplegia* 1991;29:463-9.
17. Krogh K, Nielsen J, Djurhuus JC, Mosdal C, Sabroe S, Laurberg S. Colorectal function in patients with spinal cord lesions. *Dis Colon Rectum* 1997;40:1233-9.
18. Krogh K, Christensen P, Laurberg S. Colorectal symptoms in patients with neurological diseases. *Acta Neurol Scand* 2001;103:335-43.
19. Melenhorst J, Koch SM, Uludag O, van Gemert WG, Baeten CG. Sacral neuromodulation in patients with faecal incontinence: results of the first 100 permanent implantations. *Colorectal Dis* 2007;9:725-30.
20. Dudding TC, Pares D, Vaizey CJ, Kamm MA. Predictive factors for successful sacral nerve stimulation in the treatment of faecal incontinence: a 10-year cohort analysis. *Colorectal Dis* 2008;10:249-56.

21. Keneflick NJ, Vaizey CJ, Nicholls RJ, Cohen R, Kamm MA. Sacral nerve stimulation for faecal incontinence due to systemic sclerosis. *Gut* 2002;51:881-3.
22. Vaizey CJ, Kamm MA, Turner IC, Nicholls RJ, Woloszko J. Effects of short term sacral nerve stimulation on anal and rectal function in patients with anal incontinence. *Gut* 1999;44:407-12.
23. Malouf AJ, Vaizey CJ, Nicholls RJ, Kamm MA. Permanent sacral nerve stimulation for fecal incontinence. *Ann Surg* 2000;232:143-8.
24. Jarrett ME, Varma JS, Duthie GS, Nicholls RJ, Kamm MA. Sacral nerve stimulation for faecal incontinence in the UK. *Br J Surg* 2004;91:755-61.
25. Sheldon R, Kiff ES, Clarke A, Harris ML, Hamdy S. Sacral nerve stimulation reduces corticoanal excitability in patients with faecal incontinence. *Br J Surg* 2005;92:1423-31.
26. Michelsen HB, Buntzen S, Krogh K, Laurberg S. Rectal volume tolerability and anal pressures in patients with fecal incontinence treated with sacral nerve stimulation. *Dis Colon Rectum* 2006;49:1039-44.
27. Ganio E, Masin A, Ratto C, Altomare DF, Ripetti V, Clerico G, Lise M, Doglietto GB, Memeo V, Landolfi V, Del Genio A, Arullani A, Giardiello G, de Seta F. Short-term sacral nerve stimulation for functional anorectal and urinary disturbances: results in 40 patients: evaluation of a new option for anorectal functional disorders. *Dis Colon Rectum* 2001;44:1261-7.

chapter 6

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DYNAMIC GRACILOPLASTY IN PATIENTS BORN WITH ANAL ATRESIA

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ABSTRACT

PURPOSE

The aim of this study was to compare long-term results for patients born with an anorectal malformation and faecal incontinence treated with a dynamic graciloplasty (DGP) with those for the total group of patients undergoing a DGP.

PATIENTS AND METHODS

Consecutive patients with faecal incontinence after surgical treatment of an anorectal malformation and treated with a DGP were included in this study. Preoperative assessment was performed. Postoperative follow-up consisted of anorectal manometry and registration of defaecation frequency, continence scores and postponement time of defaecation.

RESULTS

Twenty-eight patients with a median age of 25.5 years were included in the study. The median follow-up was 4.0 years. A high anorectal malformation was present in 89% of patients. Conventional graciloplasty had been previously performed in 36%. All patients were incontinent for faeces. Median frequency of defaecation was 4.0 times/day. Median postponement time of defecation was 0 minutes. Rectoanal inhibition reflex was present in 17% of patients. Median preoperative sensory threshold during balloon distention was 30 ml and median maximum urge threshold was 165 ml. Satisfactory continence was reached in 35% of patients, however, 7% of patients gained this continence score by additional bowel irrigation. Twenty-nine percent of patients were incontinent for liquid stool, 36% were incontinent for solid stool. Satisfactory continence was achieved in only 18% of patients with a high anorectal malformation, compared with 100% in patients with a low anorectal malformation. In the total group of patients with a DGP, satisfactory continence was obtained in 76%. The sensitivity threshold in patients with a successful DGP was lower than that in patients with a failing DGP (45 vs. 24 ml, $P=0.060$). When we compared median preoperative rectal sensitivity threshold in our study group with that in the total patient group with a DGP, statistical difference was established ($P=0.008$). Postponement time (0 vs. 20 min.) and anal squeeze pressure (81 vs. 120 mmHg) increased significantly after surgery. Patients with an anorectal malformation had significantly lower resting and stimulation pressure than that of the total group of patients, but the difference between resting and stimulation pressure in both groups was not significantly different ($P=0.330$). The difference between resting and stimulation pressure was not significantly different between anorectal malformation patients with a failing DGP and patients with a successful DGP. Complications were noted in 57% of patients. Explantation of the DGP was necessary in 32% of patients, mainly because of infection of the implant.

CONCLUSION

Results of DGP for faecal incontinence are reasonable for this specific group of patients with limited treatment options. Despite functional DGP, the results are worse than those for the total group of patients with DGP. Rectal sensitivity and type of malformation are prognostic factors for outcome and can be used to select patients for treatment with DGP, thereby improving treatment outcome.

INTRODUCTION

The incidence of congenital anorectal malformations (ARM) is about 1 in 5000 live births, with a predominance of male children.¹ ARM can be divided in low and high anorectal anomalies. Classification is based on the level of the blind ending rectal pouch in relation to the levator ani musculature.² High lesions occur in 40% of patients and are characterized by the rectal pouch being above the levator muscle and can have a connection (fistula) to the vagina, bladder, or prostatic urethra. Rectum and internal sphincter are usually absent as is the neurovascular system.³ Associated malformations are present in 65%.⁴ In low lesions, the rectum and the anal sphincters are normally present. A narrow fistula between the anorectal cul-de-sac and nearby skin (scrotal, vulvar, or perineal) is often present. In 30% of these cases associated malformations can be found.⁴

Surgical correction of low ARM results in normal bowel control in almost 100% of cases. However, a high percentage of these patients have constipation.⁵ In patients with a high ARM, incontinence varies from 8 to 46% after abdominoperineal or perineal operations. Mostly, posterior sagittal anorecto-plasty as described by Pena is performed.^{1,6-8}

A significant number of children suffer from faecal incontinence or constipation, urinary incontinence, and sexual inadequacy after correction of ARM.⁵ The persistence of functional bowel problems can be explained by the somatic and psychological disabilities inherent to the congenital bowel anomaly. A different faecal consistency and diminished control over flatus in addition to the lack of a normal urge sensation and an inadequately functioning sphincter mechanism can interfere with sanitary training.⁴ It is important to teach children adequate defaecation behaviour and eventually familiarize them with enemas or colonic irrigation.⁹ When children have diarrhoea they should eat more fibre to thicken the faeces.⁵

Conventional graciloplasty is the most commonly performed procedure in patients with persistent faecal incontinence after abdominoperineal operations. Conventional graciloplasty has been used since 1952 in children with ARM. However, the gracilis muscle can only contract voluntarily and is not able to maintain contraction for more than one minute. Therefore, dynamic graciloplasty (DGP) was developed to create continuous contraction of the gracilis muscle by electrical stimulation.^{1,3,10-16} Successful DGP improves the independence and autonomy of these patients. When the gracilis muscle is used for

reconstruction of the anal sphincter, most activities of daily life and even sports are possible.^{3,12}

In this study, long-term results of DGP for treatment of faecal incontinence in patients after correction of an ARM were investigated and compared with those for the total group of DGP patients.

PATIENTS AND METHODS

Included in this study were all consecutive patients, from November 1986 to February 2001, with faecal incontinence after correction of ARM. Age at surgery, type of ARM, associated malformations, and incontinence score were recorded. Faecal incontinence was scored according to the Williams continence score.¹⁷ Preoperative anorectal manometry was performed with a Konigsberg[®] catheter (Konigsberg Instrument inc., Pasadena, CA, USA) connected with a polygraph (Synectics medical, Stockholm, Sweden). Rectal sensibility was measured with rectal balloon dilation.

The DGP procedure has been previously described in detail.³ In short, the gracilis muscle is freed in the upper leg; the neurovascular bundle is left intact to keep the gracilis muscle vital. Then the muscle is wrapped around the anus. The gracilis muscle is electrically stimulated by two intramuscular electrodes, which are connected to a pulse generator (IPG, Medtronic[®], Minneapolis, MN, USA) in the lower abdomen. The stimulation of the gracilis muscle is started four weeks postoperatively. The frequency of stimulation is increased gradually over two months to get sustained tonic contraction of the gracilis muscle. The stimulation has to be turned off by the patient with a remote control or a magnet during defaecation. The remote control has some advantages above the magnet such as use of a beeping sound, which is heard when it is touched and it can be used to increase or decrease the voltage.

Postoperative follow-up consisted of registration of continence scores, defaecation frequency, postponement of defaecation, and anorectal manometry. The patient group with ARM was compared with the total group of patients with a DGP, a large series of 200 patients.^{3,18}

Statistic analysis was performed by use of Wilcoxon's rank-sum test and Mann-Whitney *U* test for non-parametric samples in SPSS 11.0 (SPSS Inc., Chicago, IL, USA). Statistical significance was set at $P \leq 0.050$. Data are expressed as median values and range.

RESULTS

Twenty-eight patients (83% male) with a median age of 25.5 years (12.4-49.1) were included. The median follow-up was 4.0 (0.2-15.5) years. All patients underwent surgical correction of ARM after birth. A high ARM was present in 25 of 28 (89%) patients. In 52% (13) of these patients an associated malformation was noted – ten patients with urogenital, eight patients with skeletal, two patients with intestinal, and two patients with miscellaneous malformations.

The patients with a low ARM did not exhibit any associated malformations.

Twenty-nine percent of patients had previously undergone treatment with biofeedback therapy. A conventional graciloplasty has been performed in ten of 28 (36%) patients.

All patients were incontinent for solid stools (Grade 4 or 5, Williams' continence score). Median frequency of defaecation was 4.0 (0.3-23) times/day. Median postponement time of defaecation was 0 (0-5) minutes.

Figure 6.1 Postoperative continence scores after dynamic graciloplasty in patients with anorectal malformations.

Figure 6.2 Comparison of postoperative continence scores in patients with anorectal malformations after dynamic graciloplasty (DGP) and the total patient group with DGP.

The recto-anal inhibition reflex (RAIR) was present in three of 18 (17%) patients, in ten other patients the RAIR was not determined. Median sensory threshold during balloon distension was 30 (10-100) and median maximum urge threshold was 165 (30-600) ml.

After DGP, 35% of patients gained continence for faeces (Grade 1 or 2). Twenty-nine percent of patients were incontinent for liquid stools (Grade 3), and 36% were still incontinent for solid stools (Grade 4 or 5) after DGP (**Figure 6.1**). The continence score remained stable over time. After DGP, nine patients were explanted because of infection of the implant (seven), pain during stimulation (one), or wound dehiscence (one); seven of these patients had a continence score of 4 to 5. Satisfactory continence was achieved in only 18% of patients with a high ARM, compared with 100% in patients with a low ARM. The presence of associated malformations was not predictive of outcome in patients with a high ARM.

The success rate of patients with ARM (35%) was much lower than that of the total patient group with DGP (76%) (**Figure 6.2**).³

Fifty-seven percent of patients who had undergone previous treatment with biofeedback were continent for stool, compared with 29% of patients who had no previous biofeedback therapy. Among patients who had undergone previous conventional graciloplasty a continence score of 1 and 2 was found in 40%, a continence score of 3 in 10%, and Grade 4 or 5 incontinence in 50%, compared with 33%, 40%, and 27%, respectively, in patients who had not previously undergone conventional graciloplasty.

Patients with a successful DGP demonstrated a higher preoperative rectal capacity than that of patients with a failed DGP, although this difference did not reach statistical significance (236 vs. 163 ml; $P=0.180$). The sensitivity threshold in patients with a successful DGP was lower than that in patients with a failing DGP. This difference tended toward statistical significance (45 vs. 24 ml; $P=0.060$). When we compared median preoperative rectal sensitivity threshold (30 vs. 40 ml) and capacity (165 vs. 150 ml) in our study group with that in the total patients group with DGP, statistical difference could be established for sensitivity threshold ($P=0.008$) but not for capacity ($P=0.240$).

Figure 6.3 Time of postponement of defaecation for patients with successful dynamic graciloplasty and patients with failed dynamic graciloplasty.

Additional bowel irrigation with an irrigation pump was used in four of 28 (14%) patients postoperatively; two of 28 (7%) patients gained continence for stools (Grade 1 and 2), whereas the other two of 28 (7%) patients were still incontinent for loose stools (Grade 3).

The median frequency of defaecation postoperatively was 2.0 (0.3-20) times/day.

The median time of postponement was two (0-60) minutes, which was a significant improvement compared with the preoperative time of postponement ($P=0.001$). When the time of postponement in patients with satisfactory continence (Grade 1 or 2 incontinence) was compared with that in patients with a failing DGP (Grade 4 or 5 incontinence), median postponement for successful treatment was 20 (1-60) minutes and for failing treatment, 0 (0-30) minutes ($P=0.009$) (**Figure 6.3**).

Figure 6.4 Median preoperative and postoperative resting pressures in DGP, stimulation pressures after start with electrical stimulation of the gracilis transposition.

Median resting pressure did not alter after DGP (40 vs. 42 mmHg before; $P=0.350$). However, voluntary squeeze pressure increased significantly as a result of gracilis transposition (120 vs. 81 mmHg; $P=0.020$). Median

pressure during stimulation was 75 (27-286) mmHg; resting, and stimulation pressures in time are shown in **Figure 6.4**.

When we compared resting pressure and stimulation pressure in patients with successful DGP against the same values for patients with failing DGP, the difference in resting pressure was significant ($P=0.045$), but the difference in stimulation pressure was not significant ($P=0.150$). The difference between resting and stimulation pressures was also not significant. ($P=0.430$) (**Figure 6.5**). When resting and stimulation pressures of the ARM patients were compared with values for the total group of patients, the patients with ARM had significant lower resting pressure and stimulation pressure ($P<0.001$ vs. $P<0.030$) (**Figure 6.6**). However, the difference in resting pressure and stimulation pressure between both groups was not significantly different ($P=0.330$).

Complications were noted in 53% of patients (**Table 6.1**). Explantation of the DGP was necessary in nine of 28 (32%) of the patients, mainly because of infection of the implant (18%). Failure of the DGP because of insufficient contraction of the gracilis muscle was present in 14% of patients, which included patients with an infection of the implant.

Two other common complications were displacement of the IPG (11%) and constipation (7%).

DISCUSSION

In this study the results of DGP in patients with ARM were not as good as in the total group of patients with faecal incontinence treated with DGP (76%);³ 35% of all patients gained satisfactory continence. Eighteen percent of patients with a high ARM achieved satisfactory continence compared with 100% in patients with a low ARM. These results can be explained by abnormalities in the neurovascular supply and bowel of patients with an ARM. Patients with a high ARM have low success rates, probably because a high ARM is accompanied by more severe anorectal and/or neurovascular abnormalities. It is well known that several anatomic and physiologic entities are essential for continence: the anal sphincters, mucosal wall of the anorectum, transitional epithelium of the anal canal, rectal capacity, bowel motility, anorectal sensitivity for discrimination of its filling and a positive RAIR.⁹

ARM patients with successful DGP had an almost significantly lower sensitivity threshold than patients with failing DGP. Median

preoperative sensitivity threshold in the total patient group with DGP was significantly lower than that in the ARM patient group. A positive RAIR was present in three of 18 (17%) patients. An absent RAIR was not related to a failing DGP. Preoperative resting pressure was subnormal as was the squeeze pressure. The results in rectal capacity and anal resting and squeeze pressures correspond with the results of Hedlund et al.¹⁹ However, our rate of positive RAIR is far lower in comparison to their rate (30%).¹⁹ Hedlund et al.¹⁹ included all patients after a posterior sagittal anorectoplasty procedure for ARM.⁸ The fact that we only included the posterior sagittal anorectoplasty failures in our present study probably explains the lower rate of positive RAIR. Furthermore, the RAIR was not determined in ten patients in the present study.

This study showed that it was possible to create a higher stimulation pressure than resting pressure in all patients—a functional neosphincter. The resting and stimulation pressure in the patients with ARM was significantly lower than those in the total group, but the difference between resting and stimulation pressure was not significant. The same difference was present in a comparison between patients with an ARM with a successful DGP versus those with a failing DGP. The fact that most of the patients did not reach satisfactory continence while the DGP was technically functioning well, demonstrates that a functioning sphincter is not the sole determinant for faecal continence. The multifactorial nature of faecal continence is further reflected by rectal sensitivity and type of malformation being prognostic factors for outcome in terms of faecal continence after DGP. The worse outcome of DGP in patients with a high ARM is explained by the malformed neurologic, pelvic and sphincter structures resulting in a lack of normal rectal sensation and decreased rectal capacity.^{3,4}

In this study, 14% of the patients used bowel irrigation with an irrigation pump postoperatively and were continent for solid stool (Grade 2 or 3).²⁰ When patients experience an acceptable social life with the use of enemas, colonic irrigation, and medication, results after surgical correction of ARM are considerably good or fair.^{1,9}

Complications were noted in 53% of the patients. However, the most serious complication was infection of the implant, requiring explantation. Displacement of the IPG (11%) was seen in the first years of the study, when the IPG was placed subcutaneously. Thereafter, the IPG was placed just under the rectus fascia, which resolved the problem of displacement.

Figure 6.5 Median resting and stimulation pressures in anorectal malformation patients with successful dynamic graciloplasty and in anorectal malformation patients with a failing dynamic graciloplasty.

Figure 6.6 Median resting and stimulation pressures of patients with anorectal malformations (ARM) and of total patient group with dynamic graciloplasty.

Some patients with anal atresia suffer from constipation in conjunction with faecal incontinence. In our study three of 28 (11%) patients suffered from constipation preoperatively. Postoperative constipation developed in two more patients. This is a common complication after DGP.¹⁰ The aetiology is not yet elucidated, but it is possible that nervous tissue around the anus sustains damage during the operation. It is also plausible that constipation is not experienced by patients with faecal incontinence. When an adequate closing mechanism (DGP) is performed, the pre-existing constipation becomes clinically apparent.

A complication rate of 53% seems high in comparison with a success rate of 35%. However, the patients in this group have had other failing treatment before. So this is one of the last treatment options before a colostomy.

Table 6.1 Complication rate.

Complication	Patients <i>n</i> (%)	Intervention	Number of patients
Infection implant	5 (18)	Explantation (1 re-implant, 1 ABS, 2 colostomy)	5
Failure contracting gracilis (all also infection)	4 (14)		
Displacement IPG	3 (11)	Subfascial placement	3
Constipation	2 (7)	Colostomy	1
Displacement lead	2 (7)	Revision lead	2
Prolapse	2 (7)	Resection	2
Pain during stimulation	2 (7)	Explantation	1
Wound-infection	1 (3.6)	Antibiotic treatment	1
Too loose wrap	1 (3.6)	Tightening of the gracilis	1
Wound dehiscence	1 (3.6)	Explantation	1
Total complications	32		
Total patients with complications	15 (53%)		

ABS, artificial bowel sphincter; IPG, implantable pulse generator.

More recent treatment options for faecal incontinence are sacral nerve modulation or placement of artificial bowel sphincter (ABS).²¹⁻³² However, sacral nerve modulation is experimental in this patient population. Other treatment modalities are a Malone antegrade colonic enema or a definitive colostomy.³³⁻³⁵

Five patients in this study received an alternative treatment after a failed DGP: artificial bowel sphincter (two), colostomy (two) and Malone antegrade colonic enema (one).

CONCLUSION

Results of DGP for faecal incontinence are reasonable for this specific group of patients with limited treatment options. Functional DGP was possible in almost all patients but led to continence in only 35%. Associated malformations were no determinant for outcome. Rectal sensitivity and type of malformation are prognostic factors for outcome and can be used to select patients for DGP treatment, thereby improving the treatment outcome.

LITERATURE

1. Baeten CG, Konsten J, Heineman E, Soeters PB. Dynamic graciloplasty for anal atresia. *J Pediatr Surg* 1994;29:922.
2. McHugh K. The role of radiology in children with anorectal anomalies; with particular emphasis on MRI. *Eur J Radiol* 1998;26:194-9.
3. Baeten CG, Uludag O, Rongen MJ. Dynamic graciloplasty for fecal incontinence. *Microsurgery* 2001;21:230-4.
4. van Kuyk EM, Brugman-Boezeman AT, Wissink-Essink M, Severijnen RS, Festen C, Bleijenberg G. Biopsychosocial treatment of defecation problems in children with anal atresia: a retrospective study. *Pediatr Surg Int* 2000;16:317-21.
5. Pena A, Hong A. Advances in the management of anorectal malformations. *Am J Surg* 2000;180:370-6.
6. Mulder W, de Jong E, Wauters I, Kinders M, Heij HA, Vos A. Posterior sagittal anorectoplasty: functional results of primary and secondary operations in comparison to the pull-through method in anorectal malformations. *Eur J Pediatr Surg* 1995;5:170-3.
7. Pena A. Anorectal malformations. *Semin Pediatr Surg* 1995;4:35-47.
8. deVries PA, Pena A. Posterior sagittal anorectoplasty. *J Pediatr Surg* 1982;17:638-43.
9. Pena A, Guardino K, Tovilla JM, Levitt MA, Rodriguez G, Torres R. Bowel management for fecal incontinence in patients with anorectal malformations. *J Pediatr Surg* 1998;33:133-7.
10. Baeten CG, Bailey HR, Bakka A, Belliveau P, Berg E, Buie WD, Burnstein MJ, Christiansen J, Collier JA, Galandiuk S, LaFontaine LJ, Lange J, Madoff RD, Matzel KE, Pahlman L, Parc R, Reilly JC, Seccia M, Thorson AG, Vernava AM 3rd, Wexner S. Safety and efficacy of dynamic graciloplasty for fecal incontinence: report of a prospective, multicenter trial. *Dynamic Graciloplasty Therapy Study Group. Dis Colon Rectum* 2000;43:743-51.
11. Wexner SD, Baeten C, Bailey R, Bakka A, Belin B, Belliveau P, Berg E, Buie WD, Burnstein M, Christiansen J, Collier J, Galandiuk S, Lange J, Madoff R, Matzel KE, Pahlman L, Parc R, Reilly J, Seccia M, Thorson AG, Vernava AM 3rd. Long-term efficacy of dynamic graciloplasty for fecal incontinence. *Dis Colon Rectum* 2002;45:809-18.
12. Chapman AE, Geerdes B, Hewett P, Young J, Eysers T, Kiroff G, Maddern GJ. Systematic review of dynamic graciloplasty in the treatment of faecal incontinence. *Br J Surg* 2002;89:138-53.
13. Baeten C, Spaans F, Fluks A. An implanted neuromuscular stimulator for fecal continence following previously implanted gracilis muscle: report of a case. *Dis Colon Rectum* 1988;31:134-7.
14. Konsten J, Baeten CG, Spaans F, Havenith MG, Soeters PB. Follow-up of anal dynamic graciloplasty for fecal continence. *World J Surg* 1993;17:404-9.
15. Mander BJ, Wexner SD, Williams NS, Bartolo DC, Lubowski DZ, Oresland T, Romano G, Keighley MR. Preliminary results of a multicentre trial of the electrically stimulated gracilis neoanal sphincter. *Br J Surg* 1999;86:1543-8.
16. Sieleznoff I, Malouf AJ, Bartolo DC, Pryde A, Douglas S. Dynamic graciloplasty in the treatment of patients with faecal incontinence. *Br J Surg* 1999;86:61-5.
17. Williams NS, Patel J, George BD, Hallan RI, Watkins ES. Development of an electrically stimulated neoanal sphincter. *Lancet* 1991;338:1166-9.
18. Rongen MJ, Uludag O, El Naggar K, Geerdes BP, Konsten J, Baeten CG. Long-term follow-up of dynamic graciloplasty for fecal incontinence. *Dis Colon Rectum* 2003;46:716-21.
19. Hedlund H, Pena A, Rodriguez G, Maza J. Long-term anorectal function in imperforate anus treated by a posterior sagittal anorectoplasty: manometric investigation. *J Pediatr Surg* 1992;27:906-9.
20. Briel JW, Schouten WR, Vlot EA, Smits S, van Kessel I. Clinical value of colonic irrigation in patients with continence disturbances. *Dis Colon Rectum* 1997;40:802-5.
21. Leroi AM, Michot F, Grise P, Denis P. Effect of sacral nerve stimulation in patients with fecal and urinary incontinence. *Dis Colon Rectum* 2001;44:779-89.

22. Ganio E, Masin A, Ratto C, Altomare DF, Ripetti V, Clerico G, Lise M, Doglietto GB, Memeo V, Landolfi V, Del Genio A, Arullani A, Giardiello G, de Seta F. Short-term sacral nerve stimulation for functional anorectal and urinary disturbances: results in 40 patients: Evaluation of a new option for anorectal functional disorders. *Dis Colon Rectum* 2001;44:1261-7.
23. Ganio E, Ratto C, Masin A, Luc AR, Doglietto GB, Dodi G, Ripetti V, Arullani A, Frascio M, BertiRiboli E, Landolfi V, DelGenio A, Altomare DF, Memeo V, Bertapelle P, Carone R, Spinelli M, Zanollo A, Spreafico L, Giardiello G, de Seta F. Neuromodulation for fecal incontinence: outcome in 16 patients with definitive implant. The initial Italian Sacral Neurostimulation Group (GINS) experience. *Dis Colon Rectum* 2001;44:965-70.
24. Matzel KE, Stadelmaier U, Hohenfellner M, Gall FP. Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. *Lancet* 1995;346:1124-7.
25. Matzel KE, Stadelmaier U, Hohenfellner M, Hohenberger W. Chronic sacral spinal nerve stimulation for fecal incontinence: long-term results with foramen and cuff electrodes. *Dis Colon Rectum* 2001;44:59-66.
26. Uludag Ö, Darby, M., Dejong CH, Schouten WR, Baeten CG. Sacrale neuromodulatie effectief bij fecale incontinentie en intacte kringsspieren; een prospectieve studie. *Sacral neuromodulation: effective in the treatment of faecal incontinence with intact sphincter muscles. A prospective study.* *ned tijdsch geneesk* 2002;146:989-93.
27. Vaizey CJ, Kamm MA, Roy AJ, Nicholls RJ. Double-blind crossover study of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum* 2000; 3:298-302.
28. Vaizey CJ, Kamm MA, Turner IC, Nicholls RJ, Woloszko J. Effects of short term sacral nerve stimulation on anal and rectal function in patients with anal incontinence. *Gut* 1999; 44:407-12.
29. Wong WD, Jensen LL, Bartolo DC, Rothenberger DA. Artificial anal sphincter. *Dis Colon Rectum* 1996; 39:1345-51.
30. Altomare DF, Dodi G, La Torre F, Romano G, Melega E, Rinaldi M. Multicentre retrospective analysis of the outcome of artificial anal sphincter implantation for severe faecal incontinence. *Br J Surg* 2001;88:1481-6.
31. Christiansen J, Sparso B. Treatment of anal incontinence by an implantable prosthetic anal sphincter. *Ann Surg* 1992;215:383-6.
32. Lehur PA, Roig JV, Duinslaeger M. Artificial anal sphincter: prospective clinical and manometric evaluation. *Dis Colon Rectum* 2000;43:1100-6.
33. Malone PS, Ransley PG, Kiely EM. Preliminary report: the antegrade continence enema. *Lancet* 1990;336:1217-8.
34. Kokoska ER, Keller MS, Weber TR. Outcome of the antegrade colonic enema procedure in children with chronic constipation. *Am J Surg* 2001;182:625-9.
35. Youssef NN, Barksdale E Jr, Griffiths JM, Flores AF, Di Lorenzo C. Management of intractable constipation with antegrade enemas in neurologically intact children. *J Pediatr Gastroenterol Nutr* 2002;34:402-5.

chapter 7

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COLONIC IRRIGATION FOR DEFAECATION DISORDERS AFTER DYNAMIC GRACILOPLASTY

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ABSTRACT

PURPOSE

Dynamic graciloplasty (DGP) improves faecal continence and quality of life for most patients. However, in some patients, DGP fails and faecal incontinence is unsolved or only partially improved. Constipation is also a significant problem after DGP, occurring in 13-90%. Colonic irrigation can be considered as an additional or salvage treatment for defaecation disorders after unsuccessful or partially successful DGP. In this study the effectiveness of colonic irrigation for the treatment of persistent faecal incontinence and/or constipation after DGP is investigated.

PATIENTS AND METHODS

Patients with defaecation disorders after DGP visiting the outpatient clinic of the University Hospital Maastricht were selected for colonic irrigation as additional therapy or salvage therapy in the period between January 1999 and June 2003. The Biotrol[®] Irrimatic pump or the irrigation bag was used for colonic irrigation. Relevant physical and medical history was collected. The patients were asked to fill out a detailed questionnaire about colonic irrigation.

RESULTS

Forty-six patients were included in the study with a mean age of 59.3 ± 12.4 years (80% female). On average the patients started the irrigation 21.4 ± 38.8 months after the DGP. Eight patients started irrigation before the DGP. Fifty-two percent of the patients used the irrigation as additional therapy for faecal incontinence, 24% for constipation and 24% for both. Irrigation was usually performed in the morning. The mean frequency of irrigation was 0.90 ± 0.40 times per day. The mean amount of water used for the irrigation was 2.27 ± 1.75 litres with a mean duration of 39 ± 23 minutes.

Four patients performed antegrade irrigation through a colostomy or appendicostomy, with good results. Overall, 81% of the patients were satisfied with the irrigation. Thirty-seven percent of the patients with faecal incontinence reached (pseudo)continence and in 30% of the patients the constipation completely resolved. Side-effects of the irrigation were reported in 61% of the patients: leakage of water after irrigation, abdominal cramps, and distended abdomen. Seven (16%) patients stopped the retrograde colonic irrigation.

CONCLUSION

Colonic irrigation is an effective alternative for the treatment of persistent faecal incontinence after DGP and/or recurrent or onset constipation additional to unsuccessful or (partially) successful DGP.

INTRODUCTION

Dynamic graciloplasty (DGP) is a proven effective treatment for faecal incontinence. Success rates vary from 42-92%.¹⁻⁵ Comparison of results is difficult because the outcome of this method seems to be influenced by the aetiology of faecal incontinence, pre-existing stoma, length of follow-up, method of stimulation and the surgeon's experience.^{1,6} DGP significantly improves quality of life and faecal continence for most patients.² Quality of life and patient satisfaction scores correlate significantly with continence scores.^{7,8} However, in some patients faecal incontinence is unsolved or only partially improved after DGP.

Morbidity rates are high after DGP: complications associated with the technique can often be prevented or treated, but other complications like reduced sensitivity of the rectum by destruction of sensory nerves can be very hard to treat and often result in DGP failure.^{4,8,9} Morbidity rates are lower and success rates higher in the hands of surgeons experienced in the technique.^{3,10}

Constipation is a significant problem after graciloplasty, occurring in 13-90% of the patients after DGP.^{6-8,11,12} Constipation due to technical failure, like a gracilis wrap that is too tight, can be treated by revisional surgery. Other causes of constipation can first be treated with dietary measures and medication. In case of pelvic floor dysfunction, biofeedback training can be started.⁹ When this first line treatment is unsuccessful, retrograde colonic irrigation (RCI) can be considered. Colonic irrigation can also be used as an additional therapy or salvage therapy for persistent faecal incontinence after failed or partially failed surgery.¹³ Not much is known about the success rate of RCI, as there is only a limited number of published studies.^{13,14}

Antegrade irrigation through a colostomy or appendico-caecostomy is another technique for colonic irrigation, with a reasonable success rate of 64-85%.¹⁵⁻¹⁷

In this study, the effectiveness of colonic irrigation for the treatment of persistent faecal incontinence and/or constipation after DGP was investigated.

PATIENTS AND METHODS

Patients with DGP and postoperative defaecation disorders were selected for colonic irrigation between January 1999 and June 2003. The patients

were offered colonic irrigation as additional or salvage therapy, as a colostomy was the final option for these patients. The inclusion criteria were invalidating faecal incontinence and/or constipation after DGP and a signed informed consent; exclusion criteria were patients not willing to perform the irrigation because of either embarrassment or wish for colostomy or patients physically and/or mentally not capable of performing irrigation.

All patients visited the outpatient clinic of the University Hospital Maastricht. Relevant physical and medical history was collected. The patients could be divided in six groups according to the aetiology of faecal incontinence before DGP: congenital, trauma (rupture/anal surgery), pudendopathy (PNTML >2.4 ms), spinal cord lesion, cancer (abdominoperineal resection in rectal carcinoma), and prolapse. The patients were asked to fill out a questionnaire. This questionnaire contained questions concerning the method of irrigation, the time needed for irrigation, the amount of water used, the frequency of irrigation, added substances to the irrigation water and side-effects of colonic irrigation. The end-point was defined that irrigation had to be successful and satisfying for the patients. Successful irrigation was defined as reaching continence for faeces (pseudocontinence) and/or complete resolution of straining, feeling of incomplete evacuation, bloating abdomen and abdominal pain during irrigation.

The patient was considered satisfied when he or she indicated that the colonic irrigation rendered a major improvement of the quality of life. The improvement of quality of life was measured by a visual analogue scale/specific questions within the questionnaire. The irrigation was performed in most patients as RCI; only four patient performed antegrade irrigation through an appendico-caecostomy or a colostomy. Patients with faecal incontinence can gain continence as a result of colonic irrigation. This is called pseudocontinence, because these patients are only continent, as there is no faecal filling of the rectum and distal colon. The definition of resolved constipation was no straining and no feeling of incomplete evacuation after defaecation. Defaecation occurred during irrigation in most of these patients.

The Biotrol[®] Irrimatic pump (Braun[®]) (**Figure 7.1A**) or the irrigation bag (Braun[®]) (**Figure 7.1B**) was used for colonic irrigation. The Irrimatic pump is an irrigation pump using a flexible tube with a cone-shaped end. The tube is introduced either in the anal canal in case of RCI or placed in an appendico-caecostomy or colostomy in case of antegrade irrigation. The pump can hold a maximum of two litres. The patients were

instructed to start the irrigation daily with 500 ml of water. Thereafter, the frequency and the amount of water were adjusted until a satisfactory result was achieved. Water used for irrigation was at body temperature; too cold water can cause abdominal cramps or collapse and too hot water can cause burns. Soap or laxatives could be added if necessary. The pump works on a storage battery and the speed of water ejection can be regulated. The working mechanism of the irrigation bag is similar, except for the water ejection, which is induced by gravity.

Data analysis was performed by using SPSS 14.0 (SPSS release 14.0, SPSS Inc. Chicago, USA), with the Mann-Whitney *U* test. $P \leq 0.050$ was considered statistically significant. Data are given as the mean values with the standard deviation.

RESULTS

The questionnaire was sent to 74 patients. Fourteen patients did not wish to participate in the study for various reasons, and 14 patients did not return the questionnaire. Forty-six patients (62%) could be included for analysis of which 37 were female (80%), and these patients had an overall mean age of 59.3 ± 12.4 years. Complications of the DGP occurred in 23 (50%) patients of which ten patients had two or more complications. Twenty-two patients suffered from constipation, 35 patients were still incontinent for faeces and seven patients had pain in the IPG pocket, leg or anus.

Figure 7.1 A. Biotrol® Irrimatic pump (Braun®), B. Irrigation bag (Braun®).

The medical history besides the DGP is mentioned in **Table 7.1**. On average the patients started the irrigation 21.4 ± 38.8 months after the DGP. Eight patients already used irrigation before DGP.

Twenty-four (52%) patients used irrigation as an additional therapy for faecal incontinence in partially failing DGP. Eleven (24%) patients used irrigation for constipation and 11 (24%) patients for both. Most patients (91%) used the irrigation pump. Three patients added soap and one patient an enema to the water to achieve a better result. These were patients with constipation or a combination of faecal incontinence and constipation.

Irrigation was usually performed in the morning (70%) and sometimes in the evening (16%). The frequency of irrigation was 0.9 ± 0.4 times per day. The amount of water used for irrigation was 2.3 ± 1.8 litres with duration of 39 ± 23 minutes. Seventy-four percent of the patients with faecal incontinence irrigated in the morning, 17% in the evening and 9% twice a day. For the patients with constipation these numbers are respectively 45, 18 and 36%. Ninety percent of the patients with a combination of defecation disorders used the colonic irrigation in the morning.

There was no significant difference in the frequency of irrigation between patients with faecal incontinence and patients with constipation (0.9 vs. 1.0/day; $P=0.108$). The amount of water used for irrigation was higher in patients with faecal incontinence compared to patients with constipation, but this difference was not significant (2.3 vs. 1.9 l.; $P=0.484$). There was no significant difference in the time needed for irrigation between patients with faecal incontinence and those with constipation (40.8 vs. 32.9 min.; $P=0.154$).

Table 7.1 Medical history.

Medical history	Number of patients (%)
Anal rupture during delivery	13 (28%)
Anal repair	14 (30%)
Prolapse surgery	19 (41%)
Hysterectomy	17 (37%)
Abdominoperineal resection for rectal carcinoma	8 (17%)
Sigmoid resection for sigmoiditis	2 (9%)
Cholecystectomy	8 (17%)
Anus atresia	1 (2%)

Overall, 81% of the patients were satisfied with the irrigation; 80% of the patients with faecal incontinence, 90% of the patients with constipation and 72% of the patients with a combined defaecation disorder. Thirty-seven percent of the patients with faecal incontinence reached (pseudo)continence, and in 30% of the patients the constipation completely resolved (**Figure 7.2**). In 29% of the patients with a combined defaecation disorder the constipation resolved and they were (pseudo)continent. Overall, satisfaction was related with symptomatic improvement. Only one patient with good symptomatic improvement was not satisfied because he felt that the irrigation was time-consuming and not practical.

Four patients, two with faecal incontinence, one with constipation and one with both, performed antegrade irrigation through a (3) colostomy or an (1) appendico-caecostomy with good results and all indicated that the irrigation improved their quality of life.

Figure 7.2 Success of colonic irrigation for defaecation disorders.

Table 7.2 Success of colonic irrigation in different aetiologies for faecal incontinence before DGP

Aetiology	<i>n</i>	Success (%) during irrigation
Congenital	1	1 (100)
Trauma	14	3 (21)
Pudendopathy	16	5 (31)
Spinal cord lesion	5	3 (60)
Abdominoperineal resection for rectal carcinoma	8	3 (37)
Prolapse	2	0 (0)
Total	46	15 (33)

The patients could be divided in six groups according to the underlying cause of faecal incontinence before DGP (**Table 7.2**). When the different aetiologies before DGP were compared with the result during irrigation, the patients with a rupture or anal surgery had the worst results of irrigation. The patients with a spinal cord lesion seemed to have the best results.

Side-effects of the irrigation were reported in 61% of the patients: leakage of water after irrigation (43%), abdominal cramps (17%), and distended abdomen (17%). Twenty-four (52%) patients changed the irrigation method during their course to improve the results. Seven (15%) patients stopped the colonic irrigation: in five patients the result was unsatisfactory; two other patients did not need the irrigation anymore because the complaints resolved completely. Finally, two patients received a permanent stoma.

DISCUSSION

Colonic irrigation can be used effectively to treat defaecation disorders when other conservative treatments fail or in addition to unsuccessful or partially successful surgical treatment.¹⁸

Colonic irrigation is usually forgotten as an alternative conservative treatment for defaecation disorders, although many health care takers are familiar with colonic irrigation, particularly, for its use as peroperative colonic cleansing.^{19,20}

RCI is performed through the anorectum or via a colostomy. Only a few publications addressed to RCI are found in literature. Briel et al.¹³ found a success rate of 38% of RCI for faecal incontinence and a significant

improvement in quality of life. Recently, another study reported a success rate of 41% in patients with faecal incontinence and 65% in patients with constipation.¹⁸ The success rate is based on patient satisfaction. Although patient satisfaction is the primary goal of treatment, it is a subjective measure. In future research this should be combined with objective measures such as validated quality of life questionnaires in a prospective study design.

Antegrade colonic irrigation is especially known for the treatment of evacuation disorders in small children and can be performed through an appendico-caecostomy (MACE) or a caecostomy button.^{16,21-23} Alternative enteral access is a sigmoid tube or transverse colonic conduit for patients with a left colonic evacuation disorder.²⁴⁻²⁶ The most common problems of MACE are stoma stenosis and leakage.^{16,17} The results in our hospital of antegrade irrigation by an appendico-caecostomy were described earlier.²³ In this study four patients performed antegrade irrigation via a colostomy or a MACE with good results. O'Bichere et al. performed an experimental study investigating the effect of retrograde versus antegrade colonic irrigation in pigs. That study demonstrates that colonic emptying is more efficient with antegrade irrigation compared to RCI.²⁷ Although a reasonable success rate can be achieved with antegrade irrigation (64-85%),¹⁵⁻¹⁷ RCI is preferred above antegrade irrigation as initial treatment because of its non-invasive nature and benign complications.

The amount of water used for irrigation was higher in patients with faecal incontinence compared to patients with constipation. This can be explained by the difficulty of retaining water in the rectum in case of faecal incontinence. Theoretically, the amount of water retained in the rectum is higher in patients with constipation. The grade of colonic emptying by irrigation in constipated patients by means of scintigraphy was investigated by Christensen et al.¹⁴ The effect of RCI was significantly better in idiopathic faecal incontinence compared to idiopathic constipation and its effect correlated with the extent to which the irrigation fluid had entered the colorectum.

Surgical treatment of faecal incontinence gives an overall success of 50-84%, depending on the aetiology of faecal incontinence and type of surgical procedure.²⁸⁻³² Success percentages in DGP vary from 42-92%.¹⁻⁵ The success rate of 80% of colonic irrigation is comparable to the success rate of surgical treatment for faecal incontinence. Sixty-one percent of the patients that received the questionnaire completed it. Even when we assume that the patients who did not complete the questionnaire

were dissatisfied with the treatment (bad case scenario), the success rate in the present study would still be 50%. It is important to realize that this is a selected group of patients with persistent incontinence and/or constipation after DGP. Regarding the faecal incontinence, this group of patients represents the 8-58% (assuming 42-92% success after DGP) with insufficient results of DGP.¹⁻⁵

Regarding the different underlying causes for faecal incontinence before DGP, the patients with a trauma to the anal sphincter have the lowest success rate and the patients with a spinal cord lesion have the highest success rate. It is not possible to draw conclusions about the statistical significance of these results because of the limited group size.

Previous studies already reported an increased incidence of constipation after DGP.^{3,6,8,11,12}

In this study we included 22 patients that were constipated after DGP, of which 11 patients had constipation in combination with persistent faecal incontinence. It is important to realize that many patients are incontinent for faeces after periods of severe evacuation problems. These evacuation problems are present again after treatment of the faecal incontinence. Its aetiology is not well understood, but is likely to be multifactorial.^{33,34} This is known after all surgical procedures for faecal incontinence.³⁵ Constipation can be due to technical problems such as a tight graciloplasty, which can be solved by revision of the DGP. It is also possible that nerve tissue around the anus sustains damage during the operation, causing pudendopathy which cannot be treated by revisional surgery. Previous surgery in the pelvis like an abdominoperineal resection (eight patients in this study), is known to have a very high rate of obstructed defaecation, probably due to reduced rectal sensitivity and pelvic floor dysfunction.³⁶ Constipation related to physical impairment, like a disturbed sensation and/or motility because of a congenital cause or degeneration, is difficult to treat.⁹ These patients are usually served well with colonic irrigation.

Surgical treatment of constipation is troublesome and only indicated in a selected group of patients with intractable constipation. The defaecation frequency usually increases, but abdominal pain and bloating persists in most patients.³⁷ In this study, 90% of the patients were satisfied with the irrigation and in 30%, the constipation resolved with colonic irrigation.

The final step of treatment after the colonic irrigation in the patients of this study would be a colostomy or ileostomy. In the study of Norton et al., the majority of the patients with faecal incontinence managed by a colostomy reported to be positive about the stoma. However, a few could

not adapt to the stoma and disliked it intensely.³⁸ Harris et al. investigated patients with faecal incontinence or constipation managed with a stoma. Many of these patients reported that lifestyle restrictions were imposed by the stoma, and almost half of the patients felt stigmatized. Up to a third of these patients had significant depression, especially the younger women.³⁹ Cultural issues also have an important impact on the acceptance of a stoma.⁴⁰ Keeping these disadvantages of a definitive stoma in mind, colonic irrigation offers an attractive alternative which is worthwhile trying before proceeding to a definitive stoma.

CONCLUSION

Colonic irrigation is an effective alternative for the treatment of persistent faecal incontinence after DGP and/or recurrent or onset constipation additional to unsuccessful or (partially) successful DGP. Colonic irrigation is an undervalued and often forgotten treatment option, which deserves its rightful place among the other treatment modalities.

LITERATURE

1. Mavrantonis C, Billotti VL, Wexner SD. Stimulated graciloplasty for treatment of intractable fecal incontinence: critical influence of the method of stimulation. *Dis Colon Rectum* 1999;42:497-504.
2. Wexner SD, Baeten C, Bailey R, Bakka A, Belin B, Belliveau P, Berg E, Buie WD, Burnstein M, Christiansen J, Collier J, Galandiuk S, Lange J, Madoff R, Matzel KE, Pahlman L, Parc R, Reilly J, Seccia M, Thorson AG, Vernava AM 3rd. Long-term efficacy of dynamic graciloplasty for fecal incontinence. *Dis Colon Rectum* 2002;45:809-18.
3. Baeten CG, Bailey HR, Bakka A, Belliveau P, Berg E, Buie WD, Burnstein MJ, Christiansen J, Collier JA, Galandiuk S, LaFontaine LJ, Lange J, Madoff RD, Matzel KE, Pahlman L, Parc R, Reilly JC, Seccia M, Thorson AG, Vernava AM 3rd, Wexner S. Safety and efficacy of dynamic graciloplasty for fecal incontinence: report of a prospective, multicenter trial. Dynamic Graciloplasty Therapy Study Group. *Dis Colon Rectum* 2000;43:743-51.
4. Chapman AE, Geerdes B, Hewett P, Young J, Evers T, Kiroff G, Maddern GJ. Systematic review of dynamic graciloplasty in the treatment of faecal incontinence. *Br J Surg* 2002;89:138-53.
5. Penninckx F. Belgian experience with dynamic graciloplasty for faecal incontinence. *Br J Surg* 2004;91:872-8.
6. Ortiz H, Armendariz P, DeMiguel M, Solana A, Alos R, Roig JV. Prospective study of artificial anal sphincter and dynamic graciloplasty for severe anal incontinence. *Int J Colorectal Dis* 2003;18:349-54.
7. Baeten CG, Geerdes BP, Adang EM, Heineman E, Konsten J, Engel GL, Kester AD, Spaans F, Soeters PB. Anal dynamic graciloplasty in the treatment of intractable fecal incontinence. *N Engl J Med* 1995;332:1600-5.
8. Thornton MJ, Kennedy ML, Lubowski DZ, King DW. Long-term follow-up of dynamic graciloplasty for faecal incontinence. *Colorectal Dis* 2004;6:470-6.
9. Geerdes BP, Heineman E, Konsten J, Soeters PB, Baeten CG. Dynamic graciloplasty. Complications and management. *Dis Colon Rectum* 1996;39:912-7.
10. Madoff RD, Rosen HR, Baeten CG, LaFontaine LJ, Cavina E, Devesa M, Rouanet P, Christiansen J, Faucheron JL, Isbister W, Köhler L, Guelinckx PJ, Pahlman L. Safety and efficacy of dynamic muscle plasty for anal incontinence: lessons from a prospective, multicenter trial. *Gastroenterology* 1999;116:549-56.
11. Matzel KE, Madoff RD, LaFontaine LJ, Baeten CG, Buie WD, Christiansen J, Wexner S; Dynamic Graciloplasty Therapy Study Group. Complications of dynamic graciloplasty: incidence, management, and impact on outcome. *Dis Colon Rectum* 2001;44:1427-35.
12. Rosen HR, Urbarz C, Novi G, Zoch G, Schiessel R. Long-term results of modified graciloplasty for sphincter replacement after rectal excision. *Colorectal Dis* 2002;4:266-9.
13. Briel JW, Schouten WR, Vlot EA, Smits S, van Kessel I. Clinical value of colonic irrigation in patients with continence disturbances. *Dis Colon Rectum* 1997;40:802-5.
14. Christensen P, Olsen N, Krogh K, Bacher T, Laurberg S. Scintigraphic assessment of retrograde colonic washout in fecal incontinence and constipation. *Dis Colon Rectum* 2003;46:68-76.
15. Kokoska ER, Keller MS, Weber TR. Outcome of the ante grade colonic enema procedure in children with chronic constipation. *Am J Surg* 2001;182:625-9.
16. Cascio S, Flett ME, De la Hunt M, Barrett AM, Jaffray B. MACE or caecostomy button for idiopathic constipation in children: a comparison of complications and outcomes. *Pediatr Surg Int* 2004;20:484-7.
17. Schell SR, Toogood GJ, Dudley NE. Control of fecal incontinence: continued success with the Malone procedure. *Surgery* 1997;122:626-31.
18. Gosselink MP, Darby M, Zimmerman DD, Smits AA, van Kessel I, Hop WC, Briel JW, Schouten WR. Long-term follow-up of retrograde colonic irrigation for defaecation disturbances. *Colorectal Dis* 2005;7:65-9.

19. Wolters U, Keller HW, Sorgatz S, Raab A, Pichlmaier H. Prospective randomized study of preoperative bowel cleansing for patients undergoing colorectal surgery. *Br J Surg* 1994;81: 598-600.
20. Vincent MV, Marven SS. Intraoperative colonic lavage in infants using a Replogle tube. *Pediatr Surg Int* 2004;20:562-3.
21. Malone PS, Ransley PG, Kiely EM. Preliminary report: the ante grade continence enema. *Lancet* 1990;336:1217-8.
22. Malone PS, Curry JJ, Osborne A. The ante grade continence enema procedure why, when and how? *World J Urol* 1998;16:274-8.
23. Rongen MJ, van der Hoop AG, Baeten CG. Cecal access for ante grade colon enemas in medically refractory slow-transit constipation: a prospective study. *Dis Colon Rectum* 2001;44:1644-9.
24. Gauderer MW, Decou JM, Boyle JT. Sigmoid irrigation tube for the management of chronic evacuation disorders. *J Pediatr Surg* 2002;37:348-51.
25. Heriot AG, Tilney HS, Simson JN. The application of percutaneous endoscopic colostomy to the management of obstructed defecation. *Dis Colon Rectum* 2002;45:700-2.
26. Hughes SF, Williams NS. Continent colonic conduit for the treatment of faecal incontinence associated with disordered evacuation. *Br J Surg* 1995;82:1318-20.
27. O'Bichere A, Sibbons P, Dore C, Green C, Phillips RK. Experimental study of faecal continence and colostomy irrigation. *Br J Surg* 2000;87:902-8.
28. Vaizey CJ, Kamm MA, Roy AJ, Nicholls RJ. Double-blind crossover study of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum* 2000;43:298-302.
29. Matzel KE, Stadelmaier U, Hohenfellner M, Gall FP. Electrical stimulation of sacral spinal nerves for treatment of faecal incontinence. *Lancet* 1995;346:1124-7.
30. Uludag O, Darby M, Dejong CH, Schouten WR, Baeten CG. Sacral neuromodulation is effective in the treatment of fecal incontinence with intact sphincter muscles; a prospective study. *Neth J Med* 2002;146:989-93.
31. Rotholtz NA, Wexner SD. Surgical treatment of constipation and fecal incontinence. *Gastroenterol Clin North Am* 2001;30:131-66.
32. Uludag O, Koch SM, van Gemert WG, Dejong CH, Baeten CG. Sacral neuromodulation in patients with fecal incontinence: a single-center study. *Dis Colon Rectum* 2004;47:1350-7.
33. Koch SM, Uludag O, Rongen MJ, Baeten CG, van Gemert WG. Dynamic graciloplasty in patients born with anal atresia. *Dis Colon Rectum* 2004;47:1711-9.
34. Mander BJ, Wexner SD, Williams NS, Bartolo DC, Lubowski DZ, Oresland T, Romano G, Keighley MR. Preliminary results of a multicentre trial of the electrically stimulated gracilis neoanal sphincter. *Br J Surg* 1999;86:1543-8.
35. Geerdes BP, Konsten J, Baeten CG. Constipation After Dynamic graciloplasty. *Dis Colon Rectum* 1996;39:943.
36. Christiansen J, Rasmussen O, Lindorff-Larsen K. Dynamic graciloplasty for severe anal incontinence. *Br J Surg* 1998;85:88-91.
37. Pfeifer J, Agachan F, Wexner SD. Surgery for constipation. *Dis Colon Rectum* 1996;39: 444-60.
38. Norton C, Burch J, Kamm MA. Patients' Views of a Colostomy for Fecal Incontinence. *Dis Col Rectum* 2005;48:1062-9.
39. Harris R, Daly K, Jones L, Kiff E. Stoma formation for functional bowel disease. *Colorectal Dis* 2004;6:280-4.
40. Black P. Psychological, sexual and cultural issues for patients with a stoma. *Br J Nurs* 2004;13:692-7.

chapter 8

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RETROGRADE COLONIC IRRIGATION FOR FAECAL INCONTINENCE AFTER LOW ANTERIOR RESECTION

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ABSTRACT

PURPOSE

To evaluate the therapeutic effect of retrograde colonic irrigation in patients with faecal incontinence after a low anterior resection for a rectal carcinoma.

PATIENTS AND METHODS

Patients with a previous low anterior resection, who were selected for treatment with retrograde colonic irrigation for faecal incontinence between 2005 and 2008, were included in the study. The data from the patients were gathered by chart research and an interview by phone.

RESULTS

Thirty patients were included in the study. Three patients died and one patient was not able to answer questions due to a cognitive disorder. The data of the remaining 26 patients were analysed. Five patients had already stopped with the retrograde colonic irrigation treatment due to side-effects.

Twelve of the 21 patients (57%) who still performed RCI became completely (pseudo)continent, three patients (14%) were incontinent for flatus and six patients (29%) were still incontinent for liquid stool.

CONCLUSION

Retrograde colonic irrigation is an effective method to treat patients with faecal incontinence after a low anterior resection for rectal carcinoma. Retrograde colonic irrigation is not invasive and has only mild side-effects.

INTRODUCTION

A Low Anterior Resection (LAR) combined with preoperative radio(chemo)therapy is a frequently used treatment for rectal carcinoma. Preoperative radiotherapy has shown to decrease the local recurrence rate.¹ Also neo-adjuvant chemoradiation in case of a locally advanced rectal carcinoma has gained wide acceptance.² However, up to 40-60% of the patients suffer from faecal incontinence after surgery.³⁻⁵ Faecal incontinence is more likely in patients with a resection less than 6 to 8cm from the anal verge. The mechanism is multifactorial.⁶ This type of faecal incontinence is difficult to treat and the outcome of regular surgical treatment is poor. The results of Sacral Nerve Modulation (SNM), Dynamic Graciloplasty (DGP), and Artificial Bowel Sphincter (ABS) are disappointing in this category of patients. A substantial part of these patients ends up with a permanent colostomy.⁷⁻⁹ The study of Gosselink et al. showed an effective treatment with retrograde colonic irrigation (RCI) in 45% of the patients with all kinds of defaecation disorders.¹⁰ In 1989, Iwama et al. described the use of RCI in a group of ten patients with faecal incontinence after LAR.¹¹

The authors have a wide experience with RCI in clinical practice^{12,13} and observed good results with RCI in patients after LAR for rectal carcinoma. The aim of this study was to assess the effect of RCI in patients with faecal incontinence after LAR for rectal carcinoma.

MATERIAL AND METHODS

A list with all patients who received an irrigation pump for RCI between 2005 and 2008 was used for this study. Patients for this study were selected from this list. Inclusion criteria for this study were faecal incontinence after LAR for rectal carcinoma. After informed consent was obtained, an interview and a questionnaire were completed with the patient by phone. The questionnaire has been used before in two other studies.^{12,13} In this questionnaire, the severity of faecal incontinence was assessed using the Williams incontinence scale, ranging from 1, which is normal continence, to 5, meaning complete incontinence for solid stool (**Table 8.1**).¹⁴ The technique of the irrigation was also assessed: frequency of irrigation, time needed for irrigation and the amount of water used for the irrigation. The side-effects of RCI were noted. Other data were gathered by chart review.

The Biotrol® Irrimatic pump (Braun®) was used for RCI. The Irrimatic pump is an irrigation pump using a flexible tube with a cone shaped end. The cone is introduced in the anal canal. The patients were instructed to start the irrigation daily with 500 ml of water. Thereafter, the frequency and the volume of water were adjusted until a satisfactory result was achieved. Water used for irrigation was at body temperature. The pump works on a storage battery and the speed of water ejection can be regulated. When the patients went for holidays, most of them temporarily used the irrigation bag (Braun®). The working mechanism of the bag is similar to the pump, except for the water ejection which is induced by gravity.¹³ When the patient experiences difficulty in keeping the cone in place in the anus, it is possible to irrigate with a balloon catheter in the rectum.

Data analysis was performed by using SPSS 14.0 (SPSS release 14.0, SPSS Inc. Chicago, USA). For paired variables the Wilcoxon Signed ranks test was used. Data are given as the mean values with the standard deviation. $P \leq 0.050$ was considered statistically significant.

Table 8.1 Williams' incontinence scale.¹⁴

Level	Gas	Williams' score	
		Liquid stool	Solid stool
I	Continent	Continent	Continent
II	Incontinent	Continent	Continent
III	Incontinent	Occasionally incontinent	Continent
IV	Incontinent	Frequently incontinent	Occasionally incontinent
V	Incontinent	Frequently incontinent	Frequently incontinent

RESULTS

Thirty patients were included in the study. Three patients died and one patient had too many cognitive problems to answer the questions. Twenty-six patients (21 men, 81%) with a mean age of 67.6 ± 7.4 years were available for data analysis. The classification of the rectal carcinoma was T₁₋₃N₀₋₂ M₀. The mean follow-up was 4.7 ± 3.5 years after LAR. Patients started RCI 1.6 ± 1.1 years before entering this study. Thus, the mean time between LAR and the start of RCI was 3.1 ± 3.1 years. The mean Williams' score before RCI was 4.4 ± 0.7 . Most patients (18)

reported to have liquid stools, three patients had hard stools, three patients had a normal faecal consistency, and two patients had varying faecal consistency. The frequency of defaecation was continuous in nine patients, 15-20 times/day in four patients, 10-15 times/day in six patients, 5-10 times/day in four patients, and <5 times/day in three patients.

Patients performed the irrigation usually in the morning (73%). The reason for performing the RCI in the evening was mostly related to work. The volume of water used for RCI was 1.5 ± 0.6 litres, with a frequency of 1.8 ± 0.7 times/day. The time needed for the inflow of water was 7.3 ± 5.5 minutes, the total time needed for irrigation and defecation was 43.9 ± 27.3 minutes.

Fourteen patients (54%) changed their irrigation process during the treatment. Seven patients decreased the frequency of irrigation because the continence improved. One patient reduced the volume of water used for RCI and one patient increased the frequency of irrigation resulting in a better effect. Five patients (19%) discontinued the irrigation: one patient because the faecal continence improved and RCI was no longer necessary. The other four patients were not satisfied with RCI. One of these patients received an end-colostomy. In most cases, the result of RCI was satisfactory, but the irrigation was found to be too time-consuming, not practical or painful.

The 21 patients who still performed the RCI had a significant improvement of the Williams' score from 4.5 ± 0.6 to 1.7 ± 0.9 ($P < 0.0001$). Twelve patients (57%) were (pseudo)continent, three patients (14%) were incontinent for flatus and six patients (29%) were incontinent for liquid stools (**Figure 8.1**). They all used pads or a small inlay. Three patients (14%) used loperamide on occasion.

One or more side-effects were experienced by 16 of 26 patients (62%): seven patients had abdominal cramps, six patients had leakage after the irrigation and two patients felt the irrigation was too time-consuming. Eight patients had other side-effects, varying from pain when inserting the cone to nausea.

Figure 8.1 Scatter/dot chart presenting faecal incontinence expressed in the Williams' incontinence scale¹⁴ in 21 patients before and during RCI. * $P < 0.0001$

DISCUSSION

Faecal incontinence is a major problem for many patients. The lack of ability to withhold stool is experienced as very invalidating.¹⁵ The cause of faecal incontinence after LAR is multifactorial; probably caused by loss of the rectal reservoir, by iatrogenic lesions of the anal sphincter or damage to the autonomic nerves. Pietsch et al. showed a significant reduction of resting and squeeze pressures in patients after a LAR caused by innervation problems and fibrosis.¹⁶ Intractable diarrhoea after LAR can contribute to the faecal incontinence, as also seen in this group of patients.

Binkley described the use of colonic irrigation already in 1952.¹⁷ In 1989, as mentioned earlier, the use of colonic irrigation was described in patients with faecal incontinence after a LAR.¹¹

Different other conservative and surgical treatments have been used for faecal incontinence after LAR for rectal carcinoma. A recent study investigated the effect of PFR in this patient group and reported improvement in some patients.¹⁸ Ratto et al. used SNM for the treatment of faecal incontinence following LAR for rectal carcinoma in four patients with successful results in all patients during the test stimulation, and successful result in three patients after implantation.⁶ Jarrett et al. reported three patients with SNM after a LAR for rectal carcinoma, but only two had a successful result of a test stimulation of ten days and after

implantation.¹⁹ Melenhorst et al. reported SNM in three patients with LAR for rectal carcinoma, nevertheless without a successful result of the test stimulation.⁷ Holzer et al. reported treatment with SNM for faecal incontinence after LAR in a retrospective study of seven patients. The indication for LAR was rectal carcinoma in six patients and one patient suffered from Crohn's disease. They found promising results during the test stimulation in all patients and after implantation with SNM in six patients.²⁰ Matzel et al. reported one patient with SNM after LAR for rectal carcinoma. Unilateral stimulation after implantation was unsatisfactory, but bilateral stimulation resulted in successful outcome. Their conclusion was that the effect of SNM on rectal motility, mediated by sacral reflex arcs is not likely, because in this patient with LAR a denervation of the neorectum must be presumed.²¹ Holzer et al. and Ratto et al. noted a change in neo-rectal parameters during SNM.^{6,20} Thus, SNM is successful in a selected group of patients after LAR with a neurogenic impairment. Therefore, proper selection is important.⁶ Results of sphincter replacements techniques for the treatment of faecal incontinence after LAR, like the DGP or ABS, have never been described in the literature. In patients after abdominoperineal resection the DGP can be considered after an abdominoperineal pull through.²² However, many of these patients regain only pseudocontinence with the addition of RCI.¹³ Theoretically, as in patients with anal atresia,²³ it is probable this techniques will not give satisfying results. The sphincter apparatus is anatomically intact in these patients, except for some decreased function.¹⁶ Especially, the rectal sensitivity and capacity is impaired, so a sphincter replacement is not logical in these patients. In some patients a colonic J pouch is performed to create a neo-rectum. This leads to better bowel function and similar rates of postoperative complications in comparison to the straight coloanal anastomosis. The side-to-end anastomosis, with its ease of construction, is a good alternative to the colonic J pouch. It has similar functional outcomes in four randomized trials, but further investigation is necessary.²⁴ In the present study, the authors had no information about the type and level of the anastomosis. The average delay between LAR and start of the RCI was 3.1 years in this study. Many of these patients suffered unnecessarily during this period. The irrigation pump is largely underutilized, because health care workers are usually not informed about this treatment option or because they assume that RCI is too time-consuming.²⁵ In this study population the mean time needed for RCI was 43.9 minutes. All but five of the patients took the required time and experienced side-effects as

acceptable. Patients pointed out that prior to RCI they did not dare to move out of the house, they could not work and their social contacts were lost. The care related to their faecal incontinence also took a lot of time. The use of RCI improved their quality of life; they started to work again and took part in social activities.

One of the side-effects is that the patients experience difficulty in keeping the cone in place in the anus. It is possible to irrigate with a balloon catheter in this situation. There is also a possibility to use antegrade irrigation through an appendicostomy, a Malone Antegrade Colonic Enema (MACE). This is more effective compared to retrograde irrigation, but this treatment also causes more serious complications.^{26,27}

When patients are not satisfied with the irrigation, the choice for a permanent colostomy remains available. Although the ultra-low anastomosis has been partially associated with functional problems like faecal incontinence and sexual dysfunction, it is widely accepted that patients have a significantly better quality of life without a permanent colostomy.^{28,29}

In these kinds of studies, the subjective experience of patients is used as the most important outcome measure. The severity of incontinence can be assessed by validated scores, but eventually it is the subjective experience of the patients that matters the most and is used as outcome measure. A prospective study is necessary with anorectal manometry, rectal sensitivity and capacity measurements to gain more mechanistic insight and to confirm the results of the present study.

CONCLUSION

RCI is an effective treatment for patients with faecal incontinence after LAR for rectum carcinoma. A large group of patients can be treated with this relatively cheap and simple treatment, without major side-effects.

LITERATURE

1. Kapiteijn E, Marijnen CA, Nagtegaal ID, Putter H, Steup WH, Wiggers T, Rutten HJ, Pahlman L, Glimelius B, van Krieken JH, Leer JW, van de Velde CJ; Dutch Colorectal Cancer Group. Preoperative radiotherapy combined with total mesorectal excision for resectable rectal cancer. *N Engl J Med* 2001;345:638-46.
2. Sauer R, Fietkau R, Wittekind C, Rödel C, Martus P, Hohenberger W, Tschmelitsch J, Sabitzer H, Karstens JH, Becker H, Hess C, Raab R; German Rectal Cancer Group. Adjuvant vs. neoadjuvant radiochemotherapy for locally advanced rectal cancer: the German trial CAO/ARO/AIO-94. *Colorectal Dis* 2003;5:406-15.
3. Williams N, Seow-Choen F. Physiological and functional outcome following ultra-low anterior resection with colon pouch-anal anastomosis. *Br J Surg* 1998;85:1029-35.
4. Lange MM, den Dulk M, Bossema ER, Maas CP, Peeters KC, Rutten HJ, Klein Kranenburg E, Marijnen CA, van de Velde CJ; Cooperative Clinical Investigators of the Dutch Total Mesorectal Excision Trial. Risk factors for faecal incontinence after rectal cancer treatment. *Br J Surg* 2007;94:1278-84.
5. Fichera A, Michelassi F. Long-term prospective assessment of functional results after proctectomy with coloanal anastomosis. *J Gastrointest Surg* 2001;5:153-7.
6. Ratto C, Grillo E, Parello A, Petrolino M, Costamagna G, Doglietto GB. Sacral neuromodulation in treatment of fecal incontinence following anterior resection and chemoradiation for rectal cancer. *Dis Colon Rectum* 2005;48:1027-36.
7. Melenhorst J, Koch SM, Uludag O, van Gemert WG, Baeten CG. Sacral neuromodulation in patients with faecal incontinence: results of the first 100 permanent implantations. *Colorectal Dis* 2007;9:725-30.
8. Belyaev O, Muller C, Uhl W. Neosphincter surgery for fecal incontinence: a critical and unbiased review of the relevant literature. *Surg Today* 2006;36:295-303.
9. Tan EK, Vaizey C, Cornish J, Darzi A, Tekkis PP. Surgical strategies for faecal incontinence--a decision analysis between dynamic graciloplasty, artificial bowel sphincter and end stoma. *Colorectal Dis* 2008;10:577-86.
10. Gosselink MP, Darby M, Zimmerman DD, Smits AA, van Kessel I, Hop WC, Briel JW, Schouten WR. Long-term follow-up of retrograde colonic irrigation for defaecation disturbances. *Colorectal Dis* 2005;7:65-9.
11. Iwama T, Imajo M, Yaegashi K, Mishima Y. Self washout method for defecational complaints following low anterior rectal resection. *Jpn J Surg* 1989;19:251-3.
12. Koch SM, Melenhorst J, van Gemert WG, Baeten CG. Prospective study of colonic irrigation for the treatment of defaecation disorders. *Br J Surg* 2008;95:1273-9.
13. Koch SM, Uludag O, El Naggar K, van Gemert WG, Baeten CG. Colonic irrigation for defecation disorders after dynamic graciloplasty. *Int J Colorectal Dis* 2008;23:195-200.
14. Williams NS, Patel J, George BD, Hallan RI, Watkins ES. Development of an electrically stimulated neoanal sphincter. *Lancet* 1991;338:1166-9.
15. Crowell MD, Schettler VA, Lacy BE, Lunsford TN, Harris LA, DiBaise JK, Jones MP. Impact of anal incontinence on psychosocial function and health-related quality of life. *Dig Dis Sci* 2007;52:1627-31.
16. Pietsch AP, Fietkau R, Klautke G, Foitzik T, Klar E. Effect of neoadjuvant chemoradiation on postoperative fecal continence and anal sphincter function in rectal cancer patients. *Int J Colorectal Dis* 2007;22:1311-7.
17. Binkley GE. Construction and care of abdominal colostomy. *Am J Surg* 1952;83:807-11.
18. Pucciani F, Ringressi MN, Redditi S, Masi A, Giani I. Rehabilitation of Fecal Incontinence After Sphincter-Saving Surgery for Rectal Cancer: Encouraging Results. *Dis Colon Rectum* 2008;48:2094-9.
19. Jarrett ME, Matzel KE, Stosser M, Christiansen J, Rosen H, Kamm MA. Sacral nerve stimulation for faecal incontinence following a rectosigmoid resection for colorectal cancer. *Int J Colorectal Dis* 2005;20:446-51.

20. Holzer B, Rosen HR, Zaglmaier W, Klug R, Beer B, Novi G, Schiessel R. Sacral nerve stimulation in patients after rectal resection-preliminary report. *J Gastrointest Surg* 2008;12:921-5.
21. Matzel KE, Stadelmaier U, Bittorf B, Hohenfellner M, Hohenberger W. Bilateral sacral spinal nerve stimulation for fecal incontinence after low anterior rectum resection. *Int J Colorectal Dis* 2002;17:430-4.
22. Geerdes BP, Zoetmulder FA, Baeten CG. Double dynamic graciloplasty and coloperineal pull-through after abdominoperineal resection. *Eur J Cancer* 1995;31A:1248-52.
23. Baeten CG, Konsten J, Heineman E, Soeters PB. Dynamic graciloplasty for anal atresia. *J Pediatr Surg* 1994;29:922-4; discussion 925.
24. Brown CJ, Fenech DS, McLeod RS. Reconstructive techniques after rectal resection for rectal cancer. *Cochrane Database Syst Rev* 2008(2):CD006040.
25. O'Bichere A, Sibbons P, Dore C, Green C, Phillips RK. Experimental study of faecal continence and colostomy irrigation. *Br J Surg* 2000;87:902-8.
26. Malone PS, Ransley PG, Kiely EM. Preliminary report: the antegrade continence enema. *Lancet* 1990;336:1217-8.
27. Rongen MJ, van der Hoop AG, Baeten CG. Cecal access for antegrade colon enemas in medically refractory slow-transit constipation: a prospective study. *Dis Colon Rectum* 2001;44:1644-9.
28. Renner K, Rosen HR, Novi G, Holbling N, Schiessel R. Quality of life after surgery for rectal cancer: do we still need a permanent colostomy? *Dis Colon Rectum* 1999;42:1160-7.
29. Sprangers MA, Taal BG, Aaronson NK, te Velde A. Quality of life in colorectal cancer. Stoma vs. nonstoma patients. *Dis Colon Rectum* 1995;38:361-9.

chapter 9

GENERAL DISCUSSION

COLONIC AND ANORECTAL FUNCTION TESTS

The anorectal function and anatomy is assessed before the decision for a certain treatment is made. **Table 9.1** shows the different tests and their use in daily practice in different hospitals in the Netherlands for evaluation in patients with faecal incontinence.¹

Table 9.1 Different investigations to assess colonic and anorectal function. Percentages of Dutch hospitals that use the different investigations in the work-up of patients with faecal incontinence.¹

Investigation	Function assessed	Information provided	Use in hospital ¹
Anorectal manometry	Resting and squeeze pressures Pressures during straining and coughing RAIR	Anal sphincter function Pelvic floor function Rectal nerve supply	51%
Rectal balloon dilation	RAIR	Hyposensitivity	22%
PNTML	Rectal sensitivity and capacity Pudendal nerve function	Hypersensitivity Pudendopathy	20%
Endo-anal ultrasound	Imaging of anorectum	Imaging of IAS en EAS and puborectalis and assessment of integrity and degeneration Detection of tumour, fistulas	58%
Defaecography	Dynamic assessment of anorectum	Continence Retention Anorectal angle Pelvic floor function Recto-enterocele Intussusception Rectal prolapse	56%
MRI	Anorectal anatomy	Imaging of IAS, EAS and puborectalis and assessment of integrity and degeneration Tumours Fistulas	13%
Antroduodenal manometry ¹⁸	Gastric peristalsis Small bowel peristalsis	Gastric dysmotility Small bowel dysmotility Chronic pseudo-obstruction syndrome Chronic intestinal pseudo-obstruction	
Colonic transit times	Colonic transit time	Segmental colon denervation Pelvic outlet obstruction Total slow-transit colon	
Sigmoidoscopy +biopsy	Visualisation rectosigmoid	Tumour Proctitis Colitis Hirschsprung	64%

A relation of clinical presentation of faecal incontinence to abnormalities of anorectal physiology or anatomy is hypothesized in several studies. Colorectal function is very important in cases of constipation,² and can facilitate the work-up of patients with faecal incontinence and constipation.^{3,4} Anal inspection and digital rectal examination can give information about internal and external sphincter function but are inaccurate for sphincter defects less than 90 degrees.⁵ Also other abnormalities like rectal prolapse can be assessed,² and anal or rectal carcinoma can be detected. Colorectal and anorectal function tests are performed to assess the aetiology of defaecation disorders. However, there is overlap with normal controls, especially in faecal incontinence.^{6,7} Anorectal manometry gives accurate information about anal sphincter function, but does not differentiate between traumatic sphincter damage or atrophy.² Incontinent patients have lower resting and squeeze pressures compared to continent patients.^{6,7} Tjandra et al. reported lower resting and squeeze pressures in patients suffering from defaecation disorders with spinal cord injury, however some of them overlapped with the normal range.⁸ Significant lower resting and squeeze pressures were correlated with passive incontinence compared to patients with urge incontinence in the study of Deutekom et al. Patients had resting pressures and squeeze pressures below normal in 29% and 75% respectively, so the other patients had normal pressures.⁴ Molnar et al. reported higher resting and squeeze pressures in children with soiling or constipation in comparison to controls.⁹ Paradoxically, increased anal pressure during straining is readily detected in patients with pelvic floor dyssynergia, a common cause of constipation.¹⁰

The recto-anal inhibition reflex (RAIR) is assessed by balloon insufflation in the rectum followed by a decrease of the resting pressure of 10 mmHg. Tjandra et al. reported an absent RAIR in patients with spinal cord injury.⁸ In patients with anal atresia the RAIR is absent in most patients.¹¹

Rectal balloon distension measurement can be performed by rectal balloon insufflation or a barostat system.² In this thesis, the rectal balloon insufflation was used, because of easier clinical practice and planning. The advantage of barostat above the rectal balloon insufflation is that the rectal wall tension can be measured with a non-elastic bag delivering constant pressures, giving a measure of rectal compliance.¹²

With the rectal balloon distension measurement, first rectal sensation volume, first urge sensation volume and the maximal tolerated volume can be determined. It is known that the type of inflation (phasic vs.

continuous), the speed of continuous inflation and additionally the size and shape of the balloon affects the first rectal sensation volume.² In this thesis, rectal balloon insufflation with phasic inflation of 50ml or air with a syringe was performed. In incontinent patients the maximal tolerated volume is lower.⁶ Constipated patients have a higher rectal sensitivity threshold, which signifies a decreased rectal sensitivity.^{9,13} In patients with congenital anorectal disorders, like anal atresia or spina bifida, the rectal sensation is mostly decreased.^{8,14}

Endo-anal ultrasonography is very accurate in differentiating between sphincter defects and atrophy and correlates well with findings at surgery.^{15,16} The ultrasonography is also used for the detection of fistulas and anorectal carcinomas.¹⁶

Pudendal nerve terminal motor latency times (PNTML) are assessed in our studies with a glove mounted electrode measuring the conduction of this nerve. In this thesis pudendopathy is defined as PNTML >2.4 ms.

The measurement is operator dependent, and does not correlate with anal sphincter pressures.² PNTML increases physiologically with age and this must therefore be taken in consideration.¹⁷ PNTML measures only the fastest conducting fibres in the pudendal nerve, with the result that a damaged nerve may nevertheless show a normal conduction time as long as some fast-conducting fibres remain.² Pudendopathy can be caused by spinal cord injury,⁸ after prolonged straining, rectal prolapse, pelvic floor dysfunction, colorectal, urological or gynaecological procedures.¹⁹⁻²²

Defaecography is a dynamic assessment of the process, the rate and completeness of rectal evacuation. It is of value in diagnosing intussusception, enterocele, rectocele, rectal prolapse or impaired function of the pelvic floor.² Additionally, it is a good technique to detect pelvic floor dyssynergia.¹⁰

Sigmoidoscopy is necessary to exclude organic disease in patients with defaecation disorders.² Colonic transit times are important to diagnose slow transit constipation of the whole colon or a segment. It is important to ensure normal small bowel peristalsis by antroduodenal manometry before a subtotal colectomy is considered.¹⁸

In conclusion, decreased anorectal function and structure can cause faecal incontinence or constipation. The aetiology is usually multifactorial. Analysis of anorectal function and anatomy is therefore important to come to a more precise diagnosis to guide the treatment upon.

It is clear that there is no single objective investigation considered as the definitive test for anorectal function.²³ Anorectal manometry, rectal

sensitivity and capacity tests and endo-anal ultrasonography are the recommended anorectal function tests for patients with faecal incontinence. These tests have a direct clinical impact. PNTML measurements and defaecography can provide additional information.²⁴ The clinical relevance of the individual anorectal tests is not always evident, but the potential strength comes from combining the test results.²⁵ In case of constipation anorectal manometry, rectal sensitivity and capacity tests are important as well as defaecography and colonic transit times.² Therefore, it is important to assess the medical history of the patient to reveal the aetiology of the defaecation disorder. Possible aetiologies are mentioned in **Table 9.2** separating constipation and faecal incontinence, however many aetiologies are overlapping.

Table 9.2 Different aetiologies of faecal incontinence and constipation and their underlying disorders.

Aetiology	Underlying disorder		
	Faecal incontinence	Combination	Constipation
Congenital		Anal atresia Spina bifida M. Hirschsprung	
Trauma	Obstetric injury Anal impalement Pelvic fracture	Anorectal surgery Colorectal surgery Gynaecologic surgery Urologic surgery	
Pelvic outlet obstruction		Recto-anal(vaginal) prolapse Pelvic floor dyssynergia Intussusception	Solitary rectal ulcer
Neurologic/endocrine disorder	Hyperthyroidism	Diabetes mellitus Multiple sclerosis Dementia Parkinson Myasthenia gravis Multiple system atrophy Spinal cord injury	Hypothyroidism
Functional disorder	Malabsorption IBD Laxative abuse	Psychiatric disorder	Low residue diet Low fluid intake Slow-transit colon

TREATMENT OF FAECAL INCONTINENCE

The aim of treatment of faecal incontinence is to restore continence and improve quality of life with minimal morbidity and mortality.²³ The majority of patients benefit from conservative measures, like diet modifications, medication and pelvic floor rehabilitation (PFR). PFR has successful results in some patients.²⁶ Also retrograde colonic irrigation (RCI) is a satisfactory treatment for many patients.²⁷

Surgical procedures are considered in selected patients. Anal sphincter repair is best suited for patients with an anterior sphincter defect. The short-term results are good, but in the long-term many patients have recurrent faecal incontinence. This is thought to be caused by breakdown of the sphincteroplasty in the short-term, aging, scarring and progressive pudendal neuropathy related to the initial injury or caused by the sphincter repair in the long-term.²³ A test stimulation (TS) with Sacral Nerve Modulation (SNM) can be performed in patients with minor sphincter defects. The advantage of SNM that it can be tested before the definitive implant must be emphasized. Therefore, we advice to perform a TS before proceeding to other invasive treatment modalities. In case of failing anal repair in a disrupted sphincter, sphincter replacement techniques like ABS and DGP are used as the last treatment option for many patients, before performing an end-colostomy. **Figure 9.1** shows the use of DGP, ABS and SNM in the Maastricht University Medical Centre in years, showing an increased incidence of SNM compared to DGP and ABS. This will probably be the trend in the future, but the DGP and ABS will remain necessary in a selected group of patients. Furthermore, the amount of patients with an ABS is increasing in comparison to the DGP. This is explained that the patients eligible for both, can choose for either DGP or ABS. In the past, only the DGP was available. The initial results of DGP and ABS are very good,²⁸⁻³⁰ in the long-term results reveal complications and deterioration in some patients with a high rate of onset constipation, but still 60% of these patients have good results in the long-term.^{31,32}

After failing surgery, retrograde or antegrade colonic irrigation (ACI) should not be forgotten before proceeding to an end-colostomy.

Predictors of outcome for different surgical procedures for faecal incontinence are difficult to assess. The indications for the different surgical treatments are often overlapping.²³ Few studies tried to define predictors for successful outcome of surgery. Glasgow et al. reported significantly improved faecal continence after perineal proctectomy for

rectal prolapse in patients with resting pressures $>60\text{mmHg}$.³³ In the study of Dudding et al. there were no significant differences between patients with successful TS and unsuccessful TS in terms of preoperative results of anorectal manometry or rectal balloon insufflation.³⁴ Altomare et al. reported in a study with 82 patients that anal sphincter electromyography can predict the outcome of PNE in SNM, in contrary to PNTML, which does not contribute to the prediction of outcome.³⁵ The flow sheet for recommendation of treatment of faecal incontinence is presented in **Figure 9.2**.

Figure 9.1 Percentages of SNM, ABS and DGP in years.

TREATMENT OF CONSTIPATION

The treatment of constipation has a lot of overlap with faecal incontinence. Most constipated patients have a lack of dietary fibre and respond to simple measures, often without a physician.³⁶ In case of failing dietary modifications PFR can be successful in patients with pelvic floor dyssynergia.^{10,37} RCI is often successful in patients with constipation of different aetiologies.³⁸ When these treatments are failing and there is no suspicion of an underlying carcinoma or IBD, colorectal physiology testing is performed. This can classify the constipation of patients which is followed by the decision for different treatments. In a series of 277 highly selected patients from a tertiary referral centre with intractable constipation only 29% had an objectivated abnormality.³⁹

Figure 9.2 A schematic overview of the treatment of faecal incontinence. PFR, pelvic floor rehabilitation; RCI, retrograde colonic irrigation; LAR, low anterior resection; SNM, sacral nerve modulation; AR, anal repair; DGP, dynamic graciloplasty; ABS, artificial bowel sphincter; ACI, antegrade colonic irrigation.

SNM can be performed in case of slow transit constipation, pelvic floor dyssynergia, spina bifida or idiopathic constipation and RCI can be used in all cases, except in patients with severe rectal prolapse, rectocele, enterocele or intussusception. In case of slow transit constipation, a (sub)total colectomy can be performed in total slow transit and a segmental colectomy in case of a segmental slow transit.⁴⁰ In case of

Figure 9.3 A schematic overview of the treatment of constipation. PFR, pelvic floor rehabilitation; RCI, retrograde colonic irrigation; SNM, sacral nerve modulation; ACI, antegrade colonic irrigation.

failing RCI, and this can especially happen in patients with slow transit constipation, ACI can be attempted,⁴¹ but the patient has to be well informed about the complications. An end-colostomy is satisfying for some patients.⁴² The flow sheet for recommendation of treatment for constipation is presented in **Figure 9.3**.

COMPLICATIONS OF SURGICAL PROCEDURES

A review of SNM for faecal incontinence revealed an adverse event (AE) rate of 0.04 per patient for the PNE and 0.12 AE per patient for the permanent implantation. The most serious complication was an infection of the implant, requiring removal in three patients.⁴³ In this review wrongly placed electrodes were not mentioned. It is not clear if this was not recognized as an AE or not recorded.⁴³ The AE rate of the permanent implantation is also high (0.12 event per patient), but lower compared to the DGP, ABS or end-colostomy. Constipation is a common complication after surgical procedures for faecal incontinence,^{29,31,32,44} but until now was not reported in SNM.^{43,45}

Two reviews studying the complications of DGP revealed 0.82-1.1 AE per patient.^{46,47} One review of the ABS reported 1.68 AE per patient.⁴⁷ In both reviews the most serious complication was infection of the implant.^{46,47} Another review describing AE of the end-colostomy reported 0.51 event per patient.⁴⁶

COSTS

The five-year cumulative costs for conservative treatment in faecal incontinence is 3234 euro.⁴⁸ The estimated five-years cumulative cost for the irrigation pump is 573 euro and for the irrigation bag 527 euro, additionally the catheters cost 370 euro in five years. The cost for an anterior anal sphincter repair is 5327 euro, but a symptomatic recurrence rate of up to 50% in the long-term is described. The costs for PNE and test stimulation are 4.053 euro. The five-years cumulative cost for a SNM is 22.150 euro, compared to 33.996 euro for an end-colostomy, and 31.590 euro for a DGP.⁴⁸

The cost of an ABS and DGP is compared in another study, giving five-years cumulative costs of an ABS of 29.740 euro.⁴⁹

PRESERVE THE UTERUS

Many patients revealed a hysterectomy in the different studies of this thesis, this seems remarkable. In Chapter 2, 13 (33%) patients had a previous hysterectomy, in Chapter 3, 16 (46%) had undergone a hysterectomy and in Chapter 7, 17 (37%) patients had a medical history with a hysterectomy. However, 40% of females will have undergone a

hysterectomy at the age of 60 years in the United States.^{50,51} In the studies, the mean age of patients was 58.0 years in Chapter 2, 59.0 years in Chapter 3 and 59.3 years in Chapter 7, so the ages of the patients correlate well with the rate of hysterectomy in these studies.

The prospective study of Mann et al. compares 382 patients awaiting hysterectomy with 130 healthy controls. Women awaiting hysterectomy reported abnormal urinary symptoms and more faecal incontinence than the age-matched group.⁵² A prospective study of Forsgren et al. reported a group of 120 patients undergoing hysterectomy for benign conditions. Symptoms of faecal incontinence increased significantly one year after abdominal hysterectomy and three years after vaginal hysterectomy. A reported history of obstetric sphincter injury and increasing age were correlated to an increased risk of developing post-hysterectomy faecal incontinence. Concomitant bilateral salpingo-oophorectomy with the abdominal hysterectomy was a risk factor for faecal incontinence at a follow-up of one year, but this was not present at a follow-up of three years.⁵³ Abdominal hysterectomy was also a risk factor for developing faecal incontinence which was further increased by concomitant bilateral salpingo-oophorectomy in a study including 120 patients with benign conditions of the uterus with a follow-up of one year.⁵⁴ There were no statistically significant changes in urinary or bowel symptoms before and after abdominal hysterectomy in 43 women for benign gynaecologic conditions. The preoperative symptoms resolved in some women after surgery and developed in others. New laxative use was reported after hysterectomy.⁵⁵

The complaints after hysterectomy are most probably caused by nerve damage after hysterectomy and/or prolapse after hysterectomy. The bilateral inferior hypogastric plexus provide (para)sympathetic innervations to the lower pelvic viscera and are located in close proximity to the proximal vagina and distal rectum. The pelvic floor and anal sphincters are innervated by the pudendal nerve. Hysterectomy involves dissection of the paracervical tissues in close proximity to the hypogastric plexus, probably causing damage to these nerve fibres.⁵⁶

In conclusion, defaecation disorders can improve, worsen or develop after hysterectomy. Preservation of the uterus should be considered in every patient referred to the gynaecologist for benign and malign disorders of the uterus.

LITERATURE

1. Dobben AC, Terra MP, Deutekom M, Bossuyt PM, Felt-Bersma RJ, Stoker J. Diagnostic work-up for faecal incontinence in daily clinical practice in the Netherlands. *Neth J Med* 2005;63:265-9.
2. Diamant NE, Kamm MA, Wald A, Whitehead WE. AGA technical review on anorectal testing techniques. *Gastroenterology* 1999;116:735-60.
3. Vaizey CJ, Kamm MA, Bartram CI. Primary degeneration of the internal anal sphincter as a cause of passive faecal incontinence. *Lancet* 1997;349:612-5.
4. Deutekom M, Dobben AC, Terra MP, et al. Clinical presentation of fecal incontinence and anorectal function: what is the relationship? *Am J Gastroenterol* 2007;102:351-61.
5. Dobben AC, Terra MP, Deutekom M, Gerhards MF, Bijnen AB, Felt-Bersma RJ, Janssen LW, Bossuyt PM, Stoker J. Anal inspection and digital rectal examination compared to anorectal physiology tests and endoanal ultrasonography in evaluating fecal incontinence. *Int J Colorectal Dis* 2007;22:783-90.
6. Felt-Bersma RJ, Klinkenberg-Knol EC, Meuwissen SG. Anorectal function investigations in incontinent and continent patients. Differences and discriminatory value. *Dis Colon Rectum* 1990;33:479-85; discussion 485-6.
7. Salvioi B, Bharucha AE, Rath-Harvey D, Pemberton JH, Phillips SF. Rectal compliance, capacity, and rectoanal sensation in fecal incontinence. *Am J Gastroenterol* 2001;96:2158-68.
8. Tjandra JJ, Ooi BS, Han WR. Anorectal physiologic testing for bowel dysfunction in patients with spinal cord lesions. *Dis Colon Rectum* 2000;43:927-31.
9. Molnar D, Taitz LS, Urwin OM, Wales JK. Anorectal manometry results in defecation disorders. *Arch Dis Child* 1983;58:257-61.
10. Bassotti G, Chistolini F, Sietchiping-Nzepa F, de Roberto G, Morelli A, Chiarioni G. Biofeedback for pelvic floor dysfunction in constipation. *BMJ* 2004;328:393-6.
11. Hedlund H, Pena A, Rodriguez G, Maza J. Long-term anorectal function in imperforate anus treated by a posterior sagittal anorectoplasty: manometric investigation. *J Pediatr Surg* 1992;27:906-9.
12. Uludag O, Morren GL, Dejong CH, Baeten CG. Effect of sacral neuromodulation on the rectum. *Br J Surg* 2005;92:1017-23.
13. Baldi F, Ferrarini F, Corinaldesi R, Balestra R, Cassan M, Fenati GP, Barbara L. Function of the internal anal sphincter and rectal sensitivity in idiopathic constipation. *Digestion* 1982;24:14-22.
14. van Kuyk EM, Brugman-Boezeman AT, Wissink-Essink M, Severijnen RS, Festen C, Bleijenberg G. Biopsychosocial treatment of defecation problems in children with anal atresia: a retrospective study. *Pediatr Surg Int* 2000;16:317-21.
15. Hill K, Fanning S, Fennerty MB, Faigel DO. Endoanal ultrasound compared to anorectal manometry for the evaluation of fecal incontinence: a study of the effect these tests have on clinical outcome. *Dig Dis Sci* 2006;51:235-40.
16. Felt-Bersma RJ. Endoanal ultrasound in perianal fistulas and abscesses. *Dig Liver Dis* 2006;38:537-43.
17. Lefaucheur J, Yiou R, Thomas C. Pudendal nerve terminal motor latency: age effects and technical considerations. *Clin Neurophysiol* 2001;112:472-6.
18. Glia A, Akerlund JE, Lindberg G. Outcome of colectomy for slow-transit constipation in relation to presence of small-bowel dysmotility. *Dis Colon Rectum* 2004;47:96-102.
19. Sultan AH, Kamm MA, Hudson CN. Pudendal nerve damage during labour: prospective study before and after childbirth. *Br J Obstet Gynaecol* 1994;101:22-8.
20. Everaert K, De Muynck M, Rimbaut S, Weyers S. Urinary retention after hysterectomy for benign disease: extended diagnostic evaluation and treatment with sacral nerve stimulation. *BJU Int* 2003;91:497-501.

21. Lefaucheur JP, Yiou R, Salomon L, Chopin DK, Abbou CC. Assessment of penile small nerve fiber damage after transurethral resection of the prostate by measurement of penile thermal sensation. *J Urol* 2000;164:1416-9.
22. Bellicini N, Molloy PJ, Caushaj P, Kozlowski P. Fecal incontinence-a review. *Dig Dis Sci* 2008;53:41-6.
23. Muller C, Belyaev O, Deska T, Chromik A, Weyhe D, Uhl W. Fecal incontinence: an up-to-date critical overview of surgical treatment options. *Langenbecks Arch Surg* 2005;390: 544-52.
24. Felt-Bersma RJ, Cuesta MA. Faecal incontinence 1994: which test and which treatment? *Neth J Med* 1994;44:182-8.
25. Azpiroz F, Enck P, Whitehead WE. Anorectal functional testing: review of collective experience. *Am J Gastroenterol* 2002;97:232-40.
26. Terra MP, Dobben AC, Berghmans B, Deutekom M, Baeten CG, Janssen LW, Boeckxstaens GE, Engel AF, Felt-Bersma RJ, Slors JF, Gerhards MF, Bijnen AB, Everhardt E, Schouten WR, Bossuyt PM, Stoker J. Electrical stimulation and pelvic floor muscle training with biofeedback in patients with fecal incontinence: a cohort study of 281 patients. *Dis Colon Rectum* 2006;49:1149-59.
27. Gosselink MP, Darby M, Zimmerman DD, Smits AA, van Kessel I, Hop WC, Briel JW, Schouten WR. Long-term follow-up of retrograde colonic irrigation for defaecation disturbances. *Colorectal Dis* 2005;7:65-9.
28. Altomare DF, Dodi G, La Torre F, Romano G, Melega E, Rinaldi M. Multicentre retrospective analysis of the outcome of artificial anal sphincter implantation for severe faecal incontinence. *Br J Surg* 2001;88:1481-6.
29. Lehur PA, Zerbib F, Neunlist M, Glemain P, Bruley des Varannes S. Comparison of quality of life and anorectal function after artificial sphincter implantation. *Dis Colon Rectum* 2002;45:508-13.
30. Baeten CG, Bailey HR, Bakka A, Belliveau P, Berg E, Buie WD, Burnstein MJ, Christiansen J, Collier JA, Galandiuk S, LaFontaine LJ, Lange J, Madoff RD, Matzel KE, Pahlman L, Parc R, Reilly JC, Seccia M, Thorson AG, Vernava AM 3rd, Wexner S. Safety and efficacy of dynamic graciloplasty for fecal incontinence: report of a prospective, multicenter trial. Dynamic Graciloplasty Therapy Study Group. *Dis Colon Rectum* 2000;43:743-51.
31. Altomare DF, Binda GA, Dodi G, La Torre F, Romano G, Rinaldi M, Melega E. Disappointing long-term results of the artificial anal sphincter for faecal incontinence. *Br J Surg* 2004;91:1352-3.
32. Rongen MJ, Uludag O, El Naggar K, Geerdes BP, Konsten J, Baeten CG. Long-term follow-up of dynamic graciloplasty for fecal incontinence. *Dis Colon Rectum* 2003;46:716-21.
33. Glasgow SC, Birnbaum EH, Kodner IJ, Fleshman JW, Dietz DW. Preoperative Anal Manometry Predicts Continence After Perineal Proctectomy for Rectal Prolapse. *Dis Colon Rectum* 2006;49:1052-8.
34. Dudding TC, Pares D, Vaizey CJ, Kamm MA. Predictive factors for successful sacral nerve stimulation in the treatment of faecal incontinence: a 10-year cohort analysis. *Colorectal Dis* 2008;10:249-56.
35. Altomare DF, Rinaldi M, Petrolino M, Ripetti V, Masin A, Ratto C, Trerotoli P, Monitillo V, Lobascio P, De Fazio M, Guglielmi A, Memeo V. Reliability of electrophysiologic anal tests in predicting the outcome of sacral nerve modulation for fecal incontinence. *Dis Colon Rectum* 2004;47:853-7.
36. Camilleri M, Thompson WG, Fleshman JW, Pemberton JH. Clinical management of intractable constipation. *Ann Intern Med* 1994;121:520-8.
37. Chiarioni G, Whitehead WE, Pezza V, Morelli A, Bassotti G. Biofeedback is superior to laxatives for normal transit constipation due to pelvic floor dyssynergia. *Gastroenterology* 2006;130:657-64.
38. Cazemier M, Felt-Bersma RJ, Mulder CJ. Anal plugs and retrograde colonic irrigation are helpful in fecal incontinence or constipation. *World J Gastroenterol* 2007;13:3101-5.

39. Pemberton JH, Rath DM, Ilstrup DM. Evaluation and surgical treatment of severe chronic constipation. *Ann Surg* 1991;214:403-11; discussion 411-3.
40. Lundin E, Karlbom U, Pahlman L, Graf W. Outcome of segmental colonic resection for slow-transit constipation. *Br J Surg* 2002;89:1270-4.
41. Hirst GR, Arumugam PJ, Watkins AJ, Mackey P, Morgan AR, Carr ND, Beynon J. Antegrade continence enema in the treatment of obstructed defaecation with or without faecal incontinence. *Tech Coloproctol* 2005;9:217-21.
42. Harris R, Daly K, Jones L, Kiff E. Stoma formation for functional bowel disease. *Colorectal Dis* 2004;6:280-4.
43. Jarrett ME, Mowatt G, Glazener CM, Fraser C, Nicholls RJ, Grant AM, Kamm MA. Systematic review of sacral nerve stimulation for faecal incontinence and constipation. *Br J Surg* 2004;91:1559-69.
44. McCue JL, Thomson JP. Clinical and functional results of abdominal rectopexy for complete rectal prolapse. *Br J Surg* 1991;78:921-3.
45. Mowatt G, Glazener C, Jarrett M. Sacral nerve stimulation for faecal incontinence and constipation in adults. *Cochrane Database Syst Rev* 2007(3):CD004464.
46. Chapman AE, Geerdes B, Hewett P, Young J, Evers T, Kiroff G, Maddern GJ. Systematic review of dynamic graciloplasty in the treatment of faecal incontinence. *Br J Surg* 2002;89:138-53.
47. Belyaev O, Muller C, Uhl W. Neosphincter surgery for fecal incontinence: a critical and unbiased review of the relevant literature. *Surg Today* 2006;36:295-303.
48. Hetzer FH, Bieler A, Hahnloser D, Lohlein F, Clavien PA, Demartines N. Outcome and cost analysis of sacral nerve stimulation for faecal incontinence. *Br J Surg* 2006;93:1411-7.
49. Tan EK, Vaizey C, Cornish J, Darzi A, Tekkis PP. Surgical strategies for faecal incontinence - a decision analysis between dynamic graciloplasty, artificial bowel sphincter and end stoma. *Colorectal Dis* 2008;10:577-86.
50. Pokras R, Hufnagel VG. Hysterectomy in the United States, 1965-84. *Am J Public Health* 1988;78:852-3.
51. Farquhar CM, Steiner CA. Hysterectomy rates in the United States 1990-1997. *Obstet Gynecol* 2002;99:229-34.
52. Mann CH, Radley SC, Begum G, Gkoutzioulis F, Jordan JA, Callender R, Radley S. Constipation, faecal incontinence and urinary symptoms in women awaiting hysterectomy. *J Obstet Gynaecol* 2000;20:530-2.
53. Forsgren C, Zetterstrom J, Lopez A, Nordenstam J, Anzen B, Altman D. Effects of hysterectomy on bowel function: a three-year, prospective cohort study. *Dis Colon Rectum* 2007;50:1139-45.
54. Altman D, Zetterstrom J, Lopez A, Pollack J, Nordenstam J, Mellgren A. Effect of hysterectomy on bowel function. *Dis Colon Rectum* 2004;47:502-8; discussion 508-9.
55. Weber AM, Walters MD, Schover LR, Church JM, Piedmonte MR. Functional outcomes and satisfaction after abdominal hysterectomy. *Am J Obstet Gynecol* 1999;181:530-5.
56. Aigner F, Zbar AP, Ludwikowski B, Kreczy A, Kovacs P, Fritsch H. The rectogenital septum: morphology, function, and clinical relevance. *Dis Colon Rectum* 2004;47:131-40.

chapter S

SUMMARY AND CONCLUSIONS

SUMMARY

The aim of this thesis was to investigate different conservative and surgical treatment modalities for defaecation disorders.

Colonic irrigation for the treatment of defaecation disorders can be considered after failing diet modifications or medication, but also after failed surgical treatment. **Chapter 2** describes the success and pitfalls of retrograde colonic irrigation (RCI) in patients with defaecation disorders in a prospective study. The 39 patients with a mean age of 58.0 ± 13.5 years included in this prospective study were divided into three groups: patients with faecal incontinence (group A), patients with constipation (group B) and patients with a combination of faecal incontinence and constipation (group C). The Biotrol® Irrimatic pump (Braun®) and the irrigation bag (Braun®) were used for colonic irrigation. At a follow-up of three months, 59% of the patients of group A ($n=18$) were (pseudo)continent for faeces ($P<0.001$). The Parks' score reduced for all incontinent patients from group A at three months, six months and one year ($P=0.0005$, $P=0.036$, $P=0.005$). In 20% of the patients of group B ($n=11$) the feeling of incomplete evacuation, straining and bloating disappeared ($P=0.007$, $P=0.051$ and $P=0.055$). The overall quality of life score improved significantly ($P=0.012$).

Pelvic floor rehabilitation (PFR), another conservative treatment, can be successful in some patients. However, when PFR and other conservative treatments are failing, anorectal investigations can be performed to reveal the possible aetiology of the defaecation disorders. Sacral nerve modulation (SNM) is a minimal invasive technique for the treatment of defaecation disorders, and also the only surgical procedure that can be tested before the definitive surgical procedure. In **Chapter 3** the results of SNM after negative outcome of PFR for the treatment of faecal incontinence are investigated in a prospective multicentre cohort study. Thirty-five patients with a mean age of 59.7 ± 11.4 years were included: 21 had a successful test stimulation (TS) and 19 patients proceeded to a SNM implant. Incontinence decreased significantly during TS and SNM for a mean of 24.1 months follow-up ($P<0.001$). The overall success rate was 49% (17/35). The 18 patients with unsuccessful TS or SNM received other treatments (OT). The Vaizey score improved in both SNM ($P=0.004$) and OT ($P=0.019$). The disease specific quality of life scale (HAQL scale) improved significantly during SNM in all subscales ($P<0.008$), but not in the OT group. Eight adverse events (AE) occurred

during TS (0.24 AE per patient) and six AE after permanent implantation (0.32 AE per patient).

The exact working mechanism of SNM is still unclear. A placebo effect is excluded when a therapeutic effect can be induced below the sensitivity threshold. It also implies that the working mechanism of SNM is not (only) a direct motoric effect on the anal sphincter, but more likely a modulating effect on the neural network. **Chapter 4** describes eight patients with a median age of 58.5 (32.5-66.6) years with faecal incontinence and successful implantation with SNM with a median follow-up of 6.3 months. The sensitivity threshold (ST) (patients feels the stimulation) and motor threshold (MT) (anal sphincter response on stimulation) were determined. The patients went home with a voltage of 0.6 Volts below the ST. Every week the voltage was increased with 0.2 Volts until the ST was reached. In this way the suboptimal (STT) and optimal therapeutic response threshold (TT) could be determined. The TT (median 1.6 Volts) was significantly lower than the sensitivity threshold (median 1.7 Volts) ($P=0.042$). The median MT was 2.1 Volts and significantly higher than the ST ($P=0.009$). The STT was 1.4 Volts. In five of eight patients the TT was the same as the ST.

Faecal incontinence, constipation, urinary incontinence and retention, are major impairments affecting the quality of life and social integration of patients with spina bifida (SB). **Chapter 5** assesses SNM in patients with SB for the treatment of defaecation and voiding disorders. Ten patients were included in this study with a median age of 26.4 (11.1-41.0) years. In two patients the peripheral nerve evaluation (PNE) was unsuccessful and consequently eight patients underwent a TS. The median incontinence days and episodes per 21 days decreased significantly during TS ($P=0.033$), but only three of ten (30%) patients had a more than 50% improvement and proceeded to SNM implantation. All patients had a malformed sacrum. Patients with absent pudendal nerve terminal motor latency times (PNMTL) were technically more difficult to stimulate, but successful PNE and/or TS was not excluded in these patients.

Patients born with an anorectal malformation (ARM) have usually a surgical correction at a young age. Nevertheless, some of these patients suffer from faecal incontinence in later life resulting in a severely impaired quality of life. In patients suffering from faecal incontinence, with failing anal sphincters, a sphincter replacing operation can be performed: a dynamic graciloplasty (DGP) or an artificial bowel sphincter (ABS). A DGP is a surgical treatment modality offering an

opportunity for independence and autonomy in patients with an ARM. **Chapter 6** assesses the long-term results of patients born with an ARM and faecal incontinence treated with DGP. Twenty-eight patients were included with a median age of 25.5 (12.4-49.1) years and a median follow-up of 4.0 years. A high ARM was present in 25/28 (89.3%) patients. Conventional graciloplasty was already performed in ten of 28 (36%). All patients were incontinent for faeces (Grade 4 or 5 in Williams' continence score). Continence for faeces was reached in 35% of the patients, 29% was incontinent for liquid stool and 36% was still incontinent for solid stool. Satisfactory continence was only achieved in 18% of the patients with a high ARM, compared to 100% of the patients with a low ARM. Patients with a successful DGP demonstrated a higher preoperative rectal capacity compared to patients with a failed DGP (236 versus 163 ml, $P<0.180$). The median postponement time improved significantly from 0 (0-5) to 2 minutes (0-60) ($P=0.001$). Complications were noted in 53% of the patients. Explantation of the DGP was necessary in nine of 28 (32%) of the patients, mainly due to infection of the implant.

Colonic irrigation can be used after all failing surgical procedures. **Chapter 7** reports the success of colonic irrigation as an additional or salvage treatment for defaecation disorders after unsuccessful or partially successful DGP in a cross-sectional study. The 46 patients who were included were asked to fill out a detailed questionnaire about colonic irrigation. The patients had a mean age of 59.3 ± 12.4 years. On average, the patients started the RCI 21.4 ± 38.8 months after DGP. Eight patients started RCI before the DGP. Fifty-two percent of the patients used the RCI as additional therapy for faecal incontinence, 24% for constipation and 24% for both. Overall, 81% of the patients were satisfied with the RCI. Thirty-seven percent of the patients with faecal incontinence reached (pseudo)continence and in 30% of the patients the constipation completely resolved. Side-effects of the RCI were reported in 61% of the patients: leakage of water after irrigation, abdominal cramps and abdominal bloating. Seven (15%) patients stopped the RCI.

Chapter 8 evaluates the results of RCI in patients with faecal incontinence after a Low Anterior Resection for rectal carcinoma. Thirty patients were selected and 26 patients were available for the study. Data were gathered by chart research and a telephone interview with a questionnaire. Five patients stopped with the treatment due to side-effects. Twelve of the 21 (57%) patients who still performed RCI became

completely (pseudo) continent, three (14%) patients were incontinent for flatus and six (29%) patients were still incontinent for liquid stool.

CONCLUSIONS

1. RCI is an undervalued but effective alternative for the treatment of intractable defaecation disorders as primary conservative treatment, but also after failing surgical treatment or side-effects like onset constipation after surgical treatment for faecal incontinence. RCI is minimal invasive and has only mild side-effects.
2. SNM is successful in about half of the patients with faecal incontinence after unsuccessful standardized PFR. SNM improves disease specific quality of life significantly compared to OT.
3. It is possible to have a therapeutic effect of SNM below the ST. This excludes a placebo effect of SNM. A lower stimulation voltage means a longer longevity of the pulse generator.
4. SNM can be successful in a subgroup of SB patients with combined defaecation and voiding functional disorders. A malformed sacrum or an absent PNMTL does not exclude a successful SNM.
5. Results of DGP for faecal incontinence are reasonable for patients with ARM. Rectal function and type of malformation are prognostic factors for outcome and can be used to select the patients for DGP treatment, thereby improving the results.

chapter S

SAMENVATTING EN CONCLUSIES

SAMENVATTING

De studies in deze thesis betreffen verschillende conservatieve en chirurgische behandelingsmogelijkheden van defecatiestoornissen: fecale incontinentie en obstipatie.

Na falende dieetmaatregelen en medicamenteuze behandeling, kan retrograde colon irrigatie (RCI) worden overwogen voor de behandeling van defecatiestoornissen, maar RCI is ook een optie na falende chirurgische behandeling. **Hoofdstuk 2** beschrijft het succes en de neveneffecten van RCI bij 39 patiënten met defecatiestoornissen in een prospectieve studie (gem. lftd 58.0 ± 13.5 jaar). De patiënten werden verdeeld in drie groepen: patiënten met fecale incontinentie (groep A), obstipatie (groep B) of gecombineerde fecale incontinentie of obstipatie (groep C). De Biotrol® Irrimatic spoelpomp (Braun®) en de irrigatie zak (Braun®) werden gebruikt voor RCI. Bij een follow-up van 3 maanden waren 59% van de patiënten uit groep A ($n=18$) (pseudo)continent voor ontlasting ($P<0.001$). De Parks' score (1-4) verbeterde voor alle patiënten in groep A bij 3, 6 en 12 maanden ($P<0.001$, $P=0.036$, $P=0.005$). In 20% van de patiënten van groep B ($n=11$) verdween het gevoel van onvolledige evacuatie, persen en opgeblazen gevoel ($P=0.007$, $P=0.051$ and $P=0.055$). De totale kwaliteit van leven score verbeterde significant ($P=0.012$).

Biofeedbacktherapie (PFR), een andere conservatieve behandeling is succesvol voor sommige patiënten. Bij falen van de PFR en andere conservatieve behandelingen, kunnen anorectale onderzoeken worden uitgevoerd om de mogelijke etiologie van de defecatiestoeornis te achterhalen. Sacrale neuromodulatie (SNM) is een minimaal invasieve techniek om defecatiestoornissen te behandelen. Daarnaast is het ook de enige chirurgische techniek die een proefbehandeling kent, voordat de definitieve chirurgische procedure wordt uitgevoerd. In **Hoofdstuk 3** worden de resultaten van SNM na het falen van een gestandaardiseerd PFR programma voor de behandeling van fecale incontinentie onderzocht in een prospectieve multicenter cohort studie. 35 Patiënten met een gemiddelde leeftijd van 59.7 ± 11.4 jaar werden geïncludeerd: 21 patiënten hadden een succesvolle teststimulatie (TS) en 19 patiënten werden geïmplant met SNM. Fecale incontinentie verbeterde significant gedurende TS en SNM gedurende een gemiddelde follow-up van 24.1 maanden ($P<0.001$). Het totale succespercentage was 49% (17/35). De 18 patiënten zonder succesvolle TS of SNM kregen andere behandelingen (OT). De Vaizey score verbeterde gedurende SNM

($P=0.004$) en OT ($P=0.019$). De ziektespecifieke kwaliteit van leven score (HAQL) verbeterde significant gedurende SNM in alle subscores ($P<0.008$), echter niet tijdens OT. Er traden acht complicaties op gedurende TS (0.24 complicatie per patiënt) en zes complicaties na permanente implantatie met SNM (0.32 complicatie per patiënt).

Het precieze werkingsmechanisme van SNM is nog steeds onduidelijk. Een placebo-effect kan uitgesloten worden wanneer een therapeutisch effect kan worden geïnduceerd bij een stimulatievoltage lager dan de drempel waarbij de patiënt de stimulatie waarneemt (sensitiviteitsdrempel). Het impliceert dat het werkingsmechanisme van SNM niet of nauwelijks wordt bepaald door een direct motorisch effect op de anale sfincter, maar door een modulerend effect op het neurale netwerk. **Hoofdstuk 4** beschrijft acht patiënten met een mediane leeftijd van 58.5 (32.5-66.6) jaar, die succesvol behandeld waren voor fecale incontinentie met een SNM implantatie gedurende een mediane follow-up van 6.3 maanden. De sensitiviteitsdrempel (ST) en motorische drempel (MT) (anale sfincter respons op stimulatie) werden bepaald. De patiënten gingen naar huis met een voltage 0.6 Volt lager dan de ST. Elke week werd het voltage verhoogd met 0.2 Volt totdat de ST werd bereikt. Op deze manier konden ook de suboptimale (STT) en optimale therapeutische responsdrempel (TT) worden bepaald. De TT (mediaan 1.6 Volt) was significant lager dan de ST (mediaan 1.7 Volts) ($P=0.042$). De mediane MT was 2.1 Volt en significant hoger dan de ST ($P=0.009$). De STT was 1.4 Volt. In vijf van de acht patiënten was de TT gelijk aan de ST.

Fecale incontinentie, obstipatie, urine incontinentie en retentie, zijn ziektebeelden die de kwaliteit van leven en sociale integratie van patiënten met spina bifida (SB) verslechteren. In **Hoofdstuk 5** wordt het resultaat van SNM in patiënten met SB voor de behandeling van hun defecatiestoornissen en mictiestoornissen onderzocht. Tien patiënten werden geïncludeerd in deze studie met een mediane leeftijd van 26.4 (range 11.1-41.0) jaar. In twee patiënten was de perifere neurale evaluatie (PNE) niet mogelijk en dus kregen acht patiënten een TS. De mediane incontinentiedagen en episodes per 21 dagen verbeterden significant gedurende TS ($P=0.033$), echter slechts drie van tien (30%) patiënten had een verbetering van meer dan 50% en kregen een SNM implantatie. Alle patiënten hadden een afwijkend sacrum. Patiënten met een afwezige nervus pudendus geleidingstijd (PNMTL) waren technisch moeilijker te stimuleren, maar een succesvolle PNE en/of TS was niet uitgesloten in deze patiëntengroep.

Patiënten geboren met een anorectale malformatie (ARM), worden meestal op jonge leeftijd geopereerd. Toch hebben sommige patiënten fecale incontinentie in hun latere leven wat resulteert in een ernstige verslechtering van de kwaliteit van leven. Bij patiënten met een falende, defecte anale sfincter kan een sfincter-vervangende operatie worden uitgevoerd: Dynamische gracilisplastiek (DGP) of een artificial bowel sphincter implantatie. Een DGP is een chirurgische behandeling die patiënten met een ARM een mogelijkheid geeft tot onafhankelijkheid en autonomie. In **Hoofdstuk 6** worden de lange termijn resultaten bestudeerd van patiënten geboren met een ARM en fecale incontinentie, die behandeld waren met een DGP. 28 Patiënten werden geïncludeerd met een mediane leeftijd van 25.5 jaar en een mediane follow-up van 4.0 jaar. Een hoge ARM was aanwezig in 25/28 (89.3%) patiënten. Continentie voor ontlasting werd bereikt in 35% van de patiënten, 29% van de patiënten waren incontinent voor diarree en 36% van de patiënten waren nog incontinent voor vaste ontlasting. De continentie was naar tevredenheid in slechts 18% van de patiënten met een hoge ARM, in vergelijking met 100% van de patiënten met een lage ARM. Patiënten met een succesvolle DGP hadden een hogere preoperatieve rectale capaciteit in vergelijking met patiënten met een slecht resultaat van de DGP (236 versus 163 ml, $P<0.180$). De mediane tijd voor het uitstellen van de ontlasting verbeterde significant van 0 (0-5) tot twee minuten (0-60). Complicaties waren aanwezig in 53% van de patiënten. Explantatie van de DGP was vereist in 32% van de patiënten, meestal als gevolg van infectie van het implantaat.

Colon irrigatie kan worden toegepast na alle falende chirurgische procedures. **Hoofdstuk 7** rapporteert het succes van colon irrigatie als een additionele behandeling voor defecatiestoornissen na niet of onvoldoende succesvolle DGP in een cross-sectionele studie. De 46 geïncludeerde patiënten werden gevraagd om een gedetailleerde vragenlijst in te vullen over het gebruik van colon irrigatie. De patiënten hadden een gemiddelde leeftijd van 59.3 ± 12.4 jaar. De patiënten startten de irrigatie gemiddeld 21.39 ± 38.77 maanden na de DGP. Acht patiënten startten de irrigatie vóór de DGP. Tweeënvijftig procent van de patiënten gebruikten de irrigatie als additionele therapie voor fecale incontinentie, 24% voor obstipatie en 24% voor beiden. In totaal waren 81% van de patiënten tevreden met de irrigatie. (Pseudo)continentie werd bereikt in 37% van de patiënten met fecale incontinentie en in 30% van de patiënten verdwenen de klachten van obstipatie volledig. Neveneffecten van de irrigatie waren aanwezig in 61% van de patiënten: lekkage van

water na de irrigatie, buikkrampen en een opgeblazen buik. Zeven (15%) patiënten stopten met irrigeren.

Hoofdstuk 8 evalueert de resultaten van RCI in patiënten met fecale incontinentie na een Low Anterior Resectie voor een rectumcarcinoom. Dertig patiënten werden geselecteerd, waarvan 26 patiënten beschikbaar waren voor de studie. Data werden verzameld door dossieronderzoek en een telefonisch interview met vragenlijst. Vijf patiënten stopten met de irrigatie vanwege neveneffecten. Twaalf van de 21 (57%) patiënten die de RCI continueerden werden volledig (pseudo)continent, drie (14%) patiënten waren incontinent voor flatus en zes (29%) patiënten waren nog incontinent voor diarree.

CONCLUSIES

1. RCI is een ondergewaardeerd, maar effectief alternatief voor de behandeling van onbehandelbare defecatiestoornissen als primaire conservatieve behandeling. Echter ook na falende chirurgische behandeling voor fecale incontinentie of neveneffecten zoals obstipatie na een behandeling voor fecale incontinentie. RCI is minimaal invasief en heeft slechts milde neveneffecten.
2. SNM is succesvol in ongeveer de helft van de patiënten met fecale incontinentie na falende gestandaardiseerde PFR. SNM verbetert ziektespecifieke kwaliteit van leven significant in vergelijking met andere behandelingen.
3. Het is mogelijk een therapeutisch effect van SNM te realiseren onder de sensitiviteitsdrempel. Dit sluit een placebo-effect van SNM vrijwel uit. Een lager stimulatie voltage betekent een langere levensduur van de pacemaker.
4. SNM kan succesvol zijn in een subgroep van SB patiënten met gecombineerde functionele defecatie- en mictiestoornissen. Een afwijkend sacrum of afwezige PNMTL sluit een succesvolle SNM niet uit.

5. Resultaten van DGP voor fecale incontinentie zijn redelijk voor patiënten met een ARM. Rectale functie and type malformatie zijn prognostische factoren voor resultaat en kunnen gebruikt worden om patiënten voor een behandeling met DGP te selecteren, waardoor de resultaten verbeteren.

chapter L

LIST OF ABBREVIATIONS

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ABS	Artificial Bowel Sphincter
ASCRS questionnaire	American Society of Colon and Rectal Surgery quality of life questionnaire
ARM	Anorectal Malformation
DGP	Dynamic Graciloplasty
EQ-5D	EuroQol quality of life questionnaire
FRSV	First rectal sensation volume
FUSV	First urge sensation volume
HAQL	Hirschsprung's disease/anorectal malformation quality of life
IPG	Implantable pulse generator
MACE	Malone Antegrade Colonic Enema
MT	Motor Threshold
MTV	Maximal tolerated volume
OT	Other Treatment
PFR	Pelvic Floor Rehabilitation
PNE	Peripheral Nerve Evaluation
PNTML	Pudendal Nerve Terminal Motor Latency Times
RAIR	Recto-anal inhibitory reflex
RCI	Retrograde Colonic Irrigation
SB	Spina bifida
SF-36	Short Form 36 health survey
SNM	Sacral Nerve Modulation
ST	Sensitivity Threshold
STT	Suboptimal Therapeutic response Threshold
TS	Test stimulation
TT	Therapeutic response Threshold

chapter L

LIST OF PUBLICATIONS

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Koch SM, Kumar S, Cremers CW. A Family With Autosomal Dominant Inherited Dysmorphic Small Auricles, Lip pits, and Congenital Conductive Hearing Impairment. *Arch Otolaryng Head Neck Surg* 2000;126:639-44.

Kemperman MH, Koch SM, Joosten FB, Kumar S, Huygen PL, Cremers CW. Inner-ear anomalies, frequent but non-obligatory features of the Branchio-oto-renal syndrome. *Arch Otolaryng Head Neck Surg* 2002;128:1033-8.

Koch SMP, Baeten CGMI: Sphincterersatzplastiken, *Chirurg* 2003;74:15-9.

Kemperman MH, Koch SM, Kumar S, Huygen PL, Joosten FB, Cremers CW. Evidence of progression and fluctuation of hearing impairment in branchio-oto-renal syndrome. *Int J Audiol* 2004;43:523-32.

Koch SM, Uludag O, Rongen MJ, Baeten CG, van Gemert W. Dynamic graciloplasty in patients born with anal atresia. *Dis Colon Rectum* 2004;47:1711-9.

Baeten CGMI, Slors JFM, Koch SMP. Fecal Incontinence: Surgical Aspects. *Integrated Medical and Surgical Gastroenterology* 2004; 381-7.

Uludag O, Koch SM, van Gemert WG, Dejong CH, Baeten CG. Sacral Neuromodulation in patients with faecal incontinence, a single centre study. *Dis Colon Rectum* 2004;47:1350-7.

Koch SM, van Gemert WG, Baeten CG. Determination of therapeutic threshold in Sacral Nerve Modulation (SNM) for faecal incontinence. *Br J Surg* 2005;92:83-7.

Uludag O, Koch SM, Dejong CH, van Gemert WG, Baeten CG. Sacral Neuromodulation; does it affect colonic transit time in patients with faecal incontinence? *Colorectal Dis* 2006;8:318-22.

Melenhorst J, Koch SM, Uludag O, van Gemert WG, Baeten CG. Sacral neuromodulation in patients with faecal incontinence: results of the first 100 permanent implantations. *Colorectal Dis* 2007;9:725-30.

Melenhorst J, Koch SM, Uludag O, van Gemert WG, Baeten CG. Is a morphologically intact anal sphincter necessary for success with sacral nerve modulation in patients with faecal incontinence? *Colorectal Dis* 2008;10:257-62.

Melenhorst J, Koch SM, van Gemert WG, Baeten CG. The artificial bowel sphincter for faecal incontinence: a single centre study. *Int J Colorectal Dis* 2008;23:107-11.

Koch SM, Uludag O, El Naggar K, van Gemert WG, Baeten CG. Colonic irrigation for defaecation disorders after dynamic graciloplasty. *Int J Colorectal Dis* 2008;23:195-200.

Koch SM, Melenhorst J, van Gemert WG, Baeten CG. Prospective study of colonic irrigation for the treatment of defaecation disorders. *Br J Surg* 2008;95:1273-9.

Koch SM, Melenhorst J, Uludag O, Deutekom M, Stoker J, van Gemert WG, Baeten CG. The role of Sacral Nerve Modulation and other treatments in patients with fecal incontinence after unsuccessful pelvic floor rehabilitation: a prospective study. *Colorectal Dis.* 2009 Feb 7.

Lansen-Koch SMP, Rietveld MP, Govaert B, van Gemert WG, Baeten CGMI. Retrograde Colonic Irrigation for faecal incontinence after low anterior resection. *Int J Colorectal Dis.* Accepted for publication.

Koch SM, Govaert B, Oerlemans D, Melenhorst J, Vles H, Cornips E, Weil EHJ, van Heurn E, Baeten CGMI, van Gemert WG. Sacral Nerve Modulation for defaecation and micturition disorders in patients with spina bifida. Submitted.

chapter D

DANKWOORD

DANKWOORD

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chapter

C

CURRICULUM VITAE

CURRICULUM VITAE

Sacha Koch was born on June 7th 1975, in Tegelen, the Netherlands. She attended secondary school at the Collegium Marianum in Venlo from 1987 to 1993. The same year she started Medical School at the University of Nijmegen. She served as student research assistant for the department of Otorhinolaryngology (Prof. dr. C. W.R.J. Cremers) of the University Medical Centre St. Radboud in Nijmegen. During her internships she fulfilled her last internship in the Holy Family Hospital of Berekum in Ghana. She obtained her medical degree in August 2001. From September 2001 to July 2002 she worked as a resident in the Department of Surgery of Viecuri Medical Centre in Venlo. In July 2002 she started as research fellow on the research project "Treatment of defaecation disorders" at the Department of Colorectal Surgery in the University Medical Centre in Maastricht that resulted in this thesis. In July 2004 she started her training as a surgical resident at the Department of Surgery in the University Medical Centre in Maastricht (Prof. dr. J.W.M Greve). She continued her training in July 2006 in the Viecuri Medical Centre in Venlo (dr. H.M. Janzing). She is married to Berry Lansen and they have a twin daughter and son, Britta and Sven (July 21st, 2008).