Robot-assisted laparoscopic surgery

ROBOT-ASSISTED LAPAROSCOPIC SURGERY

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Cover: Detail from: Mona Lisa (La Gioconda)
Oil on poplar wood, 1503-1506

The painting is thought to be a portrait of Lisa Gherardini, the wife of Francesco del giocondo. Using his famous “sfumato” painting technique, the outlines of the object become less clear, adding to the unusual lively and enigmatic look in her eyes.

Leonardo da Vinci extensively studied human anatomy and fysiology using controversial autopsy on human corpses. The knowledge he obtained resulted in the creation of this renaissance masterpiece, probably the most famous, copied and parodied painting in the world.

Surgical intuitive has been studying human stereoscopy and manipulation. This knowledge resulted in the creation of the daVinci®Surgical System, the only commercially available surgical “robot” at this moment. Scientific proof of the added value of this 1.5 million euro advanced telemanipulator remains controversial.

Robot-assisted Laparoscopic Surgery

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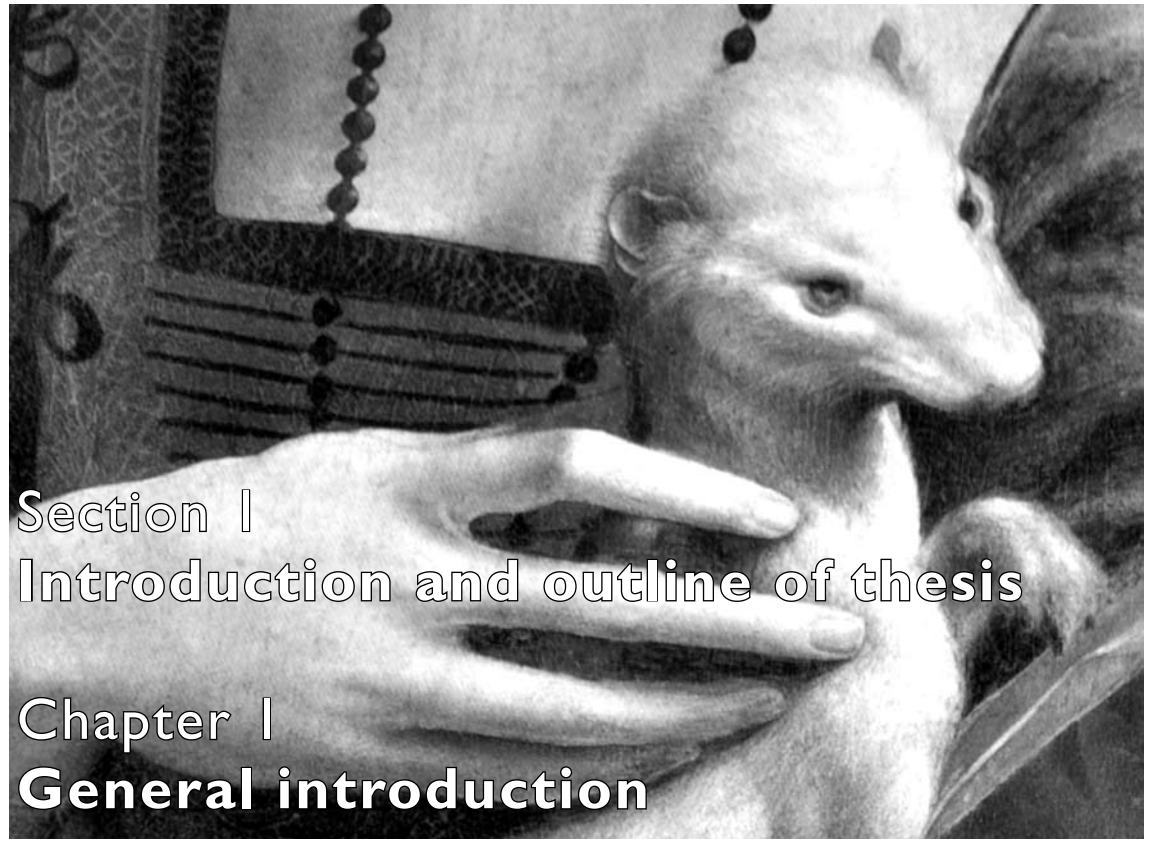

Section I
Introduction and outline of thesis

Chapter I
General introduction

DETAIL FROM: THE LADY WITH AN ERMINE
OIL ON WOODEN PANEL, 1489-1490

The subject of the painting is Cecilia Gallerani, favorite mistress of Ludovico Sforza, Duke of Milan. Using a stoat in its winter coat was a traditional symbol of purity. An ermine was thought to prefer let itself be captured by hunters, than take refuge in a dirty lair, in order not to stain its white coat.

HISTORY OF LAPAROSCOPY

Laparoscopic surgery is one of the major advances in modern surgery. This technique enables surgeons to combine minimal access with maximal results, potentially offering great advantages to our patients. However, conventional laparoscopic surgery is not a new technique. In 1902, Georg Kelling of Dresden, Saxony, performed the first laparoscopic procedure in dogs. In 1910 the first laparoscopic operation on humans has been documented. Early pioneers in the field used instruments and optics that were primitive by today's standards and handling was difficult. In the 60's and 70's of the 20th century diagnostic laparoscopy became more popular, followed by merely gynaecologic therapeutic interventions such as salpingectomy and ovarian cyst enucleation. In the Netherlands, laparoscopic appendectomy was performed in the 60's by De Kok, a surgeon from Gorinchem. There was major scepticism amongst surgeons within the Dutch surgical society as to whether such minimal invasive techniques would be safe enough to introduce in general practise, and whether they should be performed by a surgeon. The first laparoscopic cholecystectomy followed in 1988. Within 10 years, laparoscopic surgery became the treatment of choice for the performance of elective cholecystectomy in The Netherlands.

Technologic advances have made the operations more efficacious, safer and easier to perform. Within a few years, various devices including high-tech energy sources, 3-chip cameras and vascular and gastro-intestinal staplers have allowed surgeons to perform complex minimal invasive operations with improved confidence. However, significant concern arose soon due to a perceived increase in serious and sometimes lethal complications after minimal invasive surgery. Technical drawbacks might have been, at least partially, responsible for some of these complications. This triggered awareness within the surgical community that laparoscopy might offer a promising technique for many surgical problems, but an emphasis on extensive training in meticulous dissection and positive identification of all relevant anatomic structures is as important as ever. After all, "a fool with a tool is merely a fool" (quote: Prof. dr J.J. Jakimowicz).

DRAWBACKS IN LAPAROSCOPY

General surgery requires subtle manipulation of instruments and tissue in a complex three-dimensional environment. The human arm naturally has the ability to move instruments in six degrees of freedom (DOFs) , as illustrated in figure 1:
1. Surging (moving forward and backward over the X-axis)
2. Swaying (moving left and right over the Y-axis)
3. Heaving (moving up and down over the Z-axis)
4. Rolling (tilting side to side around the X-axis)
5. Pitching (tilting forward and backward around the Y-axis)
6. Yawing (rotation left and right around the Z-axis)

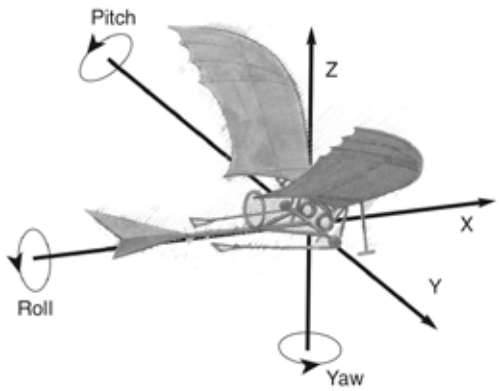

Figure 1

Besides this, instruments can often be opened and closed, sometimes disputably defined as a seventh degree of freedom. Laparoscopic surgery can be demanding owing to several technical drawbacks. This attributes to a longer learning curve and might lead to increased iatrogenic complications. Limitations due to conventional laparoscopic surgery are the following:

1) Limited freedom of movement of the instruments due to the rigid instruments, introduced in the abdomen through fixed abdominal entry points. Heaving and swaying have become impossible. Surging (moving the instrument in and out the trocar) is still possible, just as rolling and pitching over a fixed entry point in the patient's abdominal wall, and yawing around the X-axis. This limitation makes manipulation more demanding, leading to decreased flexibility and manoeuvrability[1].
2) The fulcrum effect is a second effect from this combination of rigid instruments and fixed entry points in the abdominal wall. There is a movement of the tip of the instrument in the opposite direction of the handle of the instrument. Movement is both mirrored and scaled due to the point of rotation of the patient's abdominal wall. This contra-directional movement is known as the fulcrum effect, increasing learning curve and decreasing dexterity, as illustrated in figure 2.
3) The long, inflexible instruments used in laparoscopic surgery magnify the surgeon's natural hand tremor
4 Limited tactile feedback decreases dexterity[2,3].
5) Two-dimensional vision using a conventional monitor jeopardizes a visual perception of depth. Misinterpretation of depth leads to decreased accuracy in performing surgical tasks, potentially leading to non-intentional damage to organs surrounding the surgical target[4,5].
6) Depending on the location of the target organ and the setup of the equipment, there always is a variable disturbance of the natural eye-hand-target axis. This leads to decreased ergonomics and dexterity, subsequently leading to an increased risk of non-intentional damage.
7) Camera instability increases fatigue and degrades surgical performance[6].
8) Limited overview due to the small distance between the camera and the object,

These factors probably all contribute to the relatively long training period before reaching proficiency compared with traditional open surgery[7]. Even after extensive training, dexterity and ergonomics might remain decreased compared to open surgery, potentially leading to more complications. The use of advanced laparoscopic tools, instrument manipulating systems and visual systems might potentially address some of these shortcomings related to conventional laparoscopy, potentially leading to faster, easier, more accurate and safer minimal invasive surgery. They might also lead to a shorter learning curve[8,9].

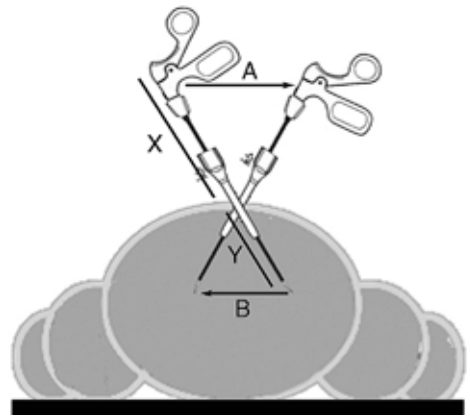

Figure 2

POTENTIAL SOLUTIONS

1) Restoration of the full six degrees of freedom, as available in conventional manipulation, cannot be achieved with conventional laparoscopic rigid instruments. However, advanced handheld instruments, mechanical motorized telemanipulators are being developed in order to optimally restore the freedom of movement. These systems do result in improved dexterity during surgery[10,11].
2) The presence of a fulcrum effect is inherent to the use of conventional laparoscopic long and rigid instruments, inserted to fixed abdominal entry points. Although extensive training of the surgeon leads to faster automation to the fulcrum effect[12,13], only a telemanipulator system is able to fully restore intuitive movement of the instrument's tip in the direction of the surgeon's hand.
3) Automated tremor filtration using conventional laparoscopic tools has not been developed yet. At this moment, only a telemanipulator system has been shown to successfully diminish the increased natural tremor of the surgeon's hand in minimal invasive surgery[10].
4) No commercially available surgical systems have been able to restore the diminished sensitivity in tactile feedback resulting from laparoscopic surgery. In fact, haptic feedback might be significantly less in conventional laparoscopic surgery as compared to open surgery, but is virtually absent in mechanical telemanipulators and totally absent in the motorized telemanipulator systems available. Introduction of such haptic feedback offering motorized systems is not expected soon.
5) A variety of advanced visual systems are being developed. Traditionally, a 60Hz screen refresh rate is used in television systems, resulting in an unsteady, flickering image and increased fatigue of the surgeon. The introduction of an increased screen refresh rate from 60Hz to 120 Hz results in High Definition television (HDTV) with a smoother image in terms of motion rendering and flicker reduction. Previous studies suggest that improved resolution has a beneficial effect on surgical performance[14]. At the moment, this two-dimensional HDTV is considered the standard in contemporary laparoscopic surgery.
However, on the other side of the spectrum, stereoscopic systems are being developed potentially leading to convincing perception of depth. Although at this moment these stereoscopic systems rarely offer convincing depth perception[15], its use has shown to be safe and feasible and it might improve laparoscopic performance[5,16-19].
6) The disturbed eye-hand-target axis is difficult, if not impossible, to restore using conventional laparoscopic equipment. Although ergonomic monitor placement is crucial, the ideal situation positioning the surgeon on the ergonomically perfect spot and projecting the image exactly where the operation takes place is difficult (if not impossible) to achieve without the use of a head-mounted display[20,21].
7) Camera instability due to exhausting camera holding or insufficiently experienced camera holding assistants, can be restored using a variety of rigid or flexible mechanical or motorized camera holding systems.
8) The forced small distance between camera and subject and subsequent limited overview of the entire operative specimen seems inherent on the basis of single-camera video-assisted minimal invasive surgery and will not be easy to overcome.
This manuscript focuses at identification of these technical drawbacks and at defining how these difficulties could best be addressed.

ADVANCED HANDHELD INSTRUMENTS

The efficacy of a surgeon in laparoscopic surgery is highly dependent on his or her dexterity. However, conventional long and rigid laparoscopic instruments result in decreased dexterity due to the fulcrum effect, decreased degrees of freedom, magnification of the natural hand tremor

of the surgeon and diminished haptic feedback as mentioned before. Rigid bend (or bendable) instruments might offer an extra possibility to allow appropriate manipulation and dissection. Recently, The introduction of Single Incision Laparoscopic Surgery (SILS) in laparoscopic surgery has attributed to the increased use of such instruments. However, a real significant improvement in instrument handling requires more than just rigid bend instruments. It requires maximal restoration of the decreased number of degrees of freedom (DOF's) . Various advanced handheld instruments have been developed in order to address some of these shortcomings.

One of these instruments (and probably the most successful one) is the Radius®Surgical System. This instrument has been developed by Tuebingen Scientific Medical GmbH, a spin-off company of Tuebingen University, Germany. The system consists of a manual manipulator with two additional degrees of freedom compared with conventional laparoscopic instruments. Extra opportunities are offered by a flexible and rotatable tip, resulting in faster, more accurate performance of laparoscopic tasks[22,23]. Although a variety of interchangeable instrument tips (or endo effectors) have been developed, there are still some drawbacks in the use of this instrument. Some of these drawbacks are related to the ergonomic design of this specific manipulator and its handling requiring additional training. Other drawbacks seem inherent in the use of mechanical handheld manipulators in laparoscopy such as a persisting fulcrum effect, tremor magnification and limited tactile feedback[2,3].

MOTORIZED INSTRUMENT- OR CAMERA HOLDER

Various companies have tried to develop motorized instrument- or camera holder systems in order to support the surgeon and redress some of the fore-mentioned technical drawbacks. The era of automated assistance in laparoscopic surgery started in 1994 with the introduction of the motorized camera-holder AESOP®. This Automated Endoscopic System for Optimal Positioning has been developed by Computer Motion (Santa Barbara, CA, USA) and consists of a voice-activated and controlled system. It does not perform automated tasks independently, but strictly follows the verbal orders of the controller, as could be expected from an instrument named after an ancient Greek slave. Therefore, the term "motorized camera holder" or "telemanipulator" seems more accurate for this device than the term "Camera Holding Surgical Robot". Potential benefits are the presence of a stable, tremor free image and a non-fatigued camera holding assistant. Use of this device might save on labour costs. However, the lack of active participation of the camera-holding assistant and subsequent suboptimal performance may lead to an increased need for necessary commands and to manual camera corrections, resulting in a loss of comfort as well as time for the operating surgeon[24].

An alternative might be offered by the use of the EndoAssist®or Freehand®Camera Holding System (originally designed by Prosurgics but now further developed by Freehand 2010 Ltd, Guildford, UK) . This motorized camera holder is controlled through a headset-mounted motion axis selection sensor. This might arguably lead to increased accuracy, a shorter learning curve for the surgeon and faster performance of laparoscopic tasks compared to the Aesop[25,26] or conventional assistance[27]. However, these techniques have not been fully developed and there is no convincing evidence supporting the acquisition and use of any of these technically advanced and expensive manipulators[28-30].

HIGH-DEFINITION AND STEREOSCOPIC VISUAL SYSTEM

A variety of advanced visual systems have been developed. In the ideal situation, the use of direct view by the surgeon through a pure optical stereoscopic system offers high-quality images with an adequate perception of depth. However, this technique is only feasible if the following two conditions are met:
1) the target area is limited and camera relocation is virtually absent, allowing for fixation of the stereoscopic optic to the table, and
2) the anatomy of the patient's body does not prevent positioning of the surgeon at the ergonomically ideal location. For example: in laparoscopic surgery in the lower pelvis such as radical prostatectomy or rectum resection, the optimal location of the surgeon would probably be where the upper abdomen and the thorax of the patient are situated. Since removal of these patient body parts is not a feasible option, alternative positioning of the surgeon has to be accepted, possibly leading to the need of an alternative visual system.
At this moment, these ideal conditions are only met in Transanal Endoscopic Microsurgery (TEM) using the stereoscopic equipment developed by Prof Buess and offered by Richard Wolf GmbH[31].
In conventional abdominal and thoracic minimal invasive surgery, the use of a video camera and screen is unconditional. Traditionally, a mere 60Hz screen refresh rate is used in both medical and consumer home television systems, resulting in an unsteady, flickering image. This leads to increased fatigue and consequently suboptimal performance of the surgeon. The introduction of an increased screen refresh rate from 60Hz to 120 Hz results in High Definition television (HDTV) with a smoother image in terms of motion rendering and flicker reduction.
This two-dimensional HDTV is considered the standard in contemporary laparoscopic surgery[32].
In consumer electronics, the appearance of 240Hz and even 480Hz televisions suggests there might be an advantage of even higher screen refresh rates in order to prevent judder and motion blur. Whether there is a real benefit, or this is just a marketing tool[33], remains unclear[14].

However, on the other side of the spectrum, stereoscopic visual systems are being developed in order to mimic life-like three dimensional (3D) vision, leading to a convincing perception of depth. In order to achieve this, two slightly different images have to be produced on the retina of both eyes. In the case of a stereo endoscope, the object being viewed is captured in two slightly different orientations and, after image processing by the brain, appears as a three-dimensional object. One potential limiting factor of 3D endoscopic systems is that the normal inter-pupillary distance for human vision is approximately 60mm, while the maximum separation of two objective lenses in a 10mm laparoscope is approximately 8mm. However, various endoscopic designs have accounted for this disparity, and were thus able to provide adequate capture and display of 3D images. Three groups of 3D visual systems have been developed: monitor-based systems, head-mounted display systems and console-based systems.

The basic mechanism of 3D visual monitor-based systems consists of two separate images that are captured using a stereoscopic endoscope and alternately transmitted to a monitor at high frequency. There are three different techniques for directing the correct images to its respective eye without the other eye seeing it:
1) Using active eyewear offering two separate images from two offset sources
2) using passive eyewear offering two separate images from one monitor
3) Using an auto stereo display without eyewear.

The first method involves a surgeon wearing active eyewear. One option is the use of a head-mounted display with two separate screens (one in front of each eye) offering slightly different images to the surgeon. Examples of this system are the initial versions of the Viking 3DHD Vision System, originally developed by Viking Systems Inc, Westborough, UK and offering high-quality images with a convincing perception of depth (Figure 3). However, one of the disadvantages of this system is the relatively heavy weight of such a head-mounted display. Another problem is the inability to see anything but the image projected in front of the eyes, blinding the surgeon for other important information in the operating room.

Figure 3

Another possible solution using active headware consists of a head-mounted active shutter system. This system makes use of liquid crystal glasses that receive a signal from the displaying system. The transmitted signal controls the alternate optical shuttering of the glasses to enable the surgeon to receive the two images with the respective eyes. The cerebrum merges the two separate and slightly different images as one composed 3D image. Again, head-mounted active eyewear tends to be rather bulky and heavy, preventing its successful introduction into regular practise. Development of such systems seems to be discontinued and the Viking Company has been sold to ConMed Corporation, shifting its focus to the development of 3D visual systems using passive eyewear.

The second method uses passive eyewear. This can be achieved using a similar shutter system. In this situation, a large liquid crystal shutter is placed in front of the monitor instead of the eye. This shutter changes polarisation and synchronizes with the right and left image signals. The surgeon wears passive eyewear with a right circular polarized lens in the right eye and a left circular polarized lens in the left eye. The right eye then can only perceive a right-image signal, because it is similarly polarized, whereas the left eye can only perceive a left-image signal. Again, the 3D image is composed in the brain by merging the two slightly different images. This technique seems more promising due to its better ergonomics. Several companies are offering such systems, including Conmed and Olympus (Figure 4). The perception of depth is often reasonable or good, although the quality of the images rarely equals the quality offered by a good conventional HD monitor.

Figure 4

Figure 5

Another technique to offer two separate images to the eyes by looking at the same screen with passive eyewear, is the use of coloured glasses (the anaglyph technique) . Generally, one glass is blue whilst the other is red (Figure 5). The image presented consists of two slightly different coloured images of the same object (Figure6), but each eye only receives one image. The anaglyph method has been used in microscopy successfully. However, its use might lead to an unnatural sensation of the colour of the operative images. A significant number of individuals find it visually distressing to receive an image that is one colour in one eye, and an other colour in the other eye[34]. Significant nausea and vertigo are common results of such a " colour bombardment". Due to these drawbacks, anaglyph stereoscopic systems have not become commercially available yet.

The third method uses no eyewear at all but requires an auto stereo display. These displays can basically be divided into either two-viewed, head tracked displays and multi view displays. The former allows for only one viewer to acquire a good stereoscopic image, under the condition that he is wearing a head-tracking device. The main difficulty is the head tracking itself, and adjusting the broadcasted two separate images to both separate eyes. Although some of these systems have shown to produce a reasonable perception of depth, the quality of the image and the fact that only one viewer can see the stereoscopic image makes this method not feasible for daily use.
Using a multi-view display could possibly solve some of the practical drawbacks of auto stereo displaying. However, this technique is still in its infancy and the quality of the image is not nearly adequate enough. Therefore, auto stereoscopy should not be considered a viable option soon.

Despite the development of these different visual systems, the stereoscopic systems available rarely offer a combination of HDTV with a high screen refresh rate and convincing stereoscopic perception of depth[15]. Its use might improve laparoscopic performance performing tasks in a laboratory environment[5,16-19]. If this use of stereoscopy leads to faster, safer or more accurate surgery in daily practise, is subject of debate[18]. Technically, this might in daily practise lead to a trade-off where a pragmatic choice will have to be made between HDTV or Stereoscopic view. Future research will have to clarify whether this offers significant advantages for the surgeon and the patient, potentially leading to a new standard in laparoscopic surgery.

Figure 6

INTEGRATED TELEMANIPULATOR AND VISUAL SYSTEMS

Various companies have tried to develop an integrated system offering both motorized automated manipulator arms and High-Definition stereoscopic view in order to support the surgeon and address some of the fore-mentioned technical drawbacks. Some of these more complex and automated surgical systems have incorrectly been named "robotic" systems. The term "robot" was first used in 1921 by the Czech play writer Karel Capek and is derived from the Czech word "robota" which means forced labour. A robot is defined as "a mechanical contraption which can perform a variety of automated tasks on its own". The integrated systems available at this moment consist of a master-slave unit. The surgeon (master) is seated at a console and his movements of the instrument handles are digitized and imported in a computer. This computer can process these raw data in order to improve precise manipulation. Possible corrections made by the computer are the filtering of the surgeon's innate tremor. Also considerable downscaling occurs, reducing the relatively gross movements of the surgeon's hands. The adjusted information is then translated to relatively small but highly precise and accurate movement of the robotic (slave) arms.
The term "robotic surgery" is currently often used to refer to such telemanipulation technology. However, this might incorrectly give the impression that the system is performing the operation autonomously, suggesting a totally new and original concept. In advertisement, it is used (or abused) as a term suggesting a safer surgical environment, free of potential human errors. Research is being done in order to create a control system based on artificial intelligence, allowing for a real autonomous system performing save and reliable surgery. However, a major obstacle is that surgery per se is not readily formalizable. Therefore, all current systems are designed to merely seamlessly replicate the movement of the surgeon's hands with the tips of micro-instruments, not to make decisions or move without the surgeon's direct input. Automated performance of limited surgical tasks such as taking image-guided biopsies[35] or other interventions in specific surgical fields is still in its infancy and real automated surgery of entire procedures is not expected soon. Therefore, the consequent use of the term "telemanipulator" addressing the current robotic systems would add to clarification of its real nature. However, the term "robot" is being used so frequently by the manufacturer, users and patients alike, that this term has more or less become synonym with such an integrated visual and telemanipulator system. For the sake of readability, we will comply to the current use of the word "robot" and use the terms robot and telemanipulator interchangeable.

The ZEUS-AESOP®Robotic Surgical System was the first integrated and therefore "robotic" system especially designed for laparoscopic surgery by Computer Motion (Santa Barbara, CA, USA) . The system was originally developed under a NASA Small Business Innovation Research (SBIR) contract to invent robots able to perform tasks requiring precise movements that exceed human dexterity. These automated systems were intended to facilitate remotely controlled operations in a hostile environment, for example during space repair missions or in a battlefield. The ZEUS®Robotic Surgical System was developed as a two-armed extension of the AESOP®motorized camera holder. It was first used in experimental surgery in 1998 re-anastomosing fallopian tubes after sterilisation. In 2001 it was cleared by the Food and Drug Administration (FDA) for use by surgeons in a variety of laparoscopic and thoracoscopic procedures. The ultimate proof showing the feasibility of this remotely controlled precise movements, was delivered during the Lindbergh operation in the year 2001. A remote controlled robotic laparoscopic cholecystectomy was performed in a patient with symptomatic cholelithiasis. Surgeons were in New York (USA) while the patient was several thousand miles away in Strasbourg (FR) [36]. Despite this spectacular telesurgical operation and a few cases of telementoring[37], commercial success of the Zeus®Robotic Surgical System was limited.

THE DAVINCI®SURGICAL SYSTEM

In 1999, Intuitive surgical Inc. introduced the da Vinci®Surgical System. This system is described by the manufacturer as being "a sophisticated robotic platform designed to expand the surgeon's capabilities – and for the first time – offer a minimal invasive option for major surgery"[38,39]. Again, the system has been designed to copy the movement of the surgeon, not to perform an operation autonomously. The system combines an ergonomic console based working place for the surgeon with a four-armed motorized instrument and camera holder. Positioning of the camera and instruments is performed by the surgeon's fingers grasping the master controls below the display, allowing an optimal restoration of the eye-hand-target axis. The view offered by the console consists of High-definition stereoscopic vision for the surgeon, allowing for a convincing perception of depth. An extensive technical description of the da Vinci®Surgical System is available in Chapter 2. Operation of this system seems quite intuitive. In the year 2000 it became the first robotic surgical system cleared by the FDA for general laparoscopic surgery. After a period of serious competition with the rival medical robotics company Computer Motion (offering the ZEUS®system) , a variety of lawsuits were filed against Intuitive Surgical Inc. for allegedly infringing on Computer Motion's patents related to robotic technology. In March 2003, Intuitive Motion Inc acquired its principal (if not only) competitor, combining their intellectual potency and their efforts in developing robotic surgical systems.

At this moment, the da Vinci®Surgical System is the only integrated surgical system commercially available, combining advanced High-Definition stereoscopic view with motorized manipulator arms. Since its introduction to the market, Surgical intuitive has expanded impressively. The market for robotic systems is booming and at the time of writing, over 1800 da Vinci®Surgical Systems have been installed in more than 1450 hospital sites world wide where they are being used for a broad variety of cardiac, thoracic, urologic, gynaecologic, colorectal, general surgical and paediatric operations. In the past few years, numerous manuscripts have been published on the advantages and disadvantages of the use of robotic assistance in laparoscopic surgery. Enthusiasts have proclaimed a clear benefit in terms of a shorter learning curve and an increased speed and accuracy performing laparoscopic tasks. This is supposed to result in improved operative results in terms of better functional results and less complications performing actual surgery. However, opponents have stated that the decrease in learning curve is mainly a significant finding in inexperienced individuals[40-43], not in expert surgeons performing actual surgery. The increased speed of performing laparoscopic tasks as found in various laboratory studies[44,45], might not result in an actual reduction of operation time, since installation of the da Vinci®Surgical System can be time consuming and cumbersome. Various studies show the use of robotic assistance is without any doubt feasible in both adults[46-50] and in children[51,52], but whether robotic assistance really leads to significant improved results compared to conventional laparoscopic or even open surgery remains under debate[53-55]. Studies suffering from publication bias might even further blur a clear view on advantages and disadvantages. Advantages might be minimal and certainly not justifying the increased financial costs, working in an era where cost reduction seems to become one of the primary goals in medicine. Critical surgeons have already stated that the da Vinci®Surgical System is an insignificant tool for surgery, but a great tool for marketing purposes. Whether the da Vinci®Surgical System should be categorized as "an invaluable extension of the surgical armamentarium" or as "toys for boys and tools for fools" remains subject to debate.

To clarify the role of advanced surgical systems, a four-armed da Vinci®Surgical System was acquired at Maastricht University Hospital in the year 2003. Since then, various studies have been conducted both in a dry lab environment and in clinical practise. This manuscript describes the studies conducted and the results and conclusions that might be taken. An outline of the thesis can be found in Chapter three.

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Chapter 2
Technical aspects of the da Vinci®Surgical System

DETAIL FROM: VIRGIN OF THE ROCKS
OIL ON PANEL, 1483-1486

The subject of the painting is the Virgin Mary with the Christ child being adored by John the Baptist, Patron Saint of Florence.

TECHNICAL ASPECTS

Robotic system or stereoscopic telemanipulator?
As described before, the da Vinci®Surgical System became the first telesurgical system cleared by the FDA for general laparoscopic surgery in the year 2002. Since the company acquired its principal (if not only) rival competitor in 2003, it is the only company currently offering an integrated visual and telemanipulatory surgical system. In order to comply with the most common used terms, we will use the words "robot" and "telemanipulator" interchangeable, although the system is not able to perform tasks independently. The system merely copies the exact movements of the surgeon and translates them (after downscaling and tremor filtration), to a movement of the manipulator arms. The system combines an ergonomic console based stereoscopic working place for the surgeon with a four-armed motorized instrument and camera holder.

THE SURGEON'S CONSOLE

During surgery, the surgeon is seated in a comfortable ergonomic console, restoring optimal posture and minimizing strain (Figure 1).
His eyes are faced downwards to see the operative field. The positioning of the camera and instruments is performed by the surgeon's fingers grasping the master controls located directly below the display. This allows for an optimal restoration of the eye-hand-target axis where hands and wrists are positioned naturally relative to the surgeon's eyes (Figure 2). Operating this system

Figure 1. The surgeon is seated in an ergonomic console, restoring optimal posture and minimizing strain.

Figure 2. The tips of the instruments are projected on the location where the finger tips of the surgeon are, allowing optimal restoration of the eye-hand-target axis. The controls allow for a natural forceps-like grip.

seems more natural and intuitive compared to conventional laparoscopy, but also compared to the previous joystick-controlled ZEUS®Robotic Surgical System. The da Vinci®system automatically and fully compensates for the so-called fulcrum effect, normally present in minimal access surgery. The intuitive motion potentially leads to easier and faster surgery. The surgeon's fingers are positioned in the manipulators in a quite natural forceps-like grip. Motions performed by the surgeon are detected by sensors and indirectly translated to movement of the tips of the robotic instruments adjusted to the patient side cart.
A double-channel stereoscopic 12mm video-endoscope (Figure 3) contains two lenses approximately 8mm separate from each other. It generates two slightly different images that are transposed through two separate vision canals. After correcting the images for the mean inter papillary distance of 60mm, the images are sent to two separate High-Definition displays in the console.

Figure 3. A double-channel videoscope captures two slightly different images.

Both eyes are offered a slightly different image in the console, allowing for a convincing perception of depth (Figure 4).
The console holds a number of foot pedals (Figure 5). The most lateral left foot pedal is the clutch and allows for control of the position of the master controls without moving the instruments or camera holder. Once pressed, the specially designed robotic instruments are fixed in its current position whilst movement of the manipulators at the tips of the surgeon's fingers allow the surgeon for repositioning his hands and forearms to an ergonomically optimal position. The second pedal allows for camera control. Once pressed, the surgical instruments are fixed in its current position and any movement of the manipulators results in a subsequent movement of the automated camera holder. This allows for a perfectly stable tremor-filtrated view, directed exactly at the location of interest of the surgeon. The middle pedal allows for focus control. The median right foot pedal is reserved for new applications, such as activation of newly designed bipolar or ultrasonic sealing instruments. The lateral right foot pedal controls activation of monopolar diathermy.
Besides these foot pedals and the manipulators, two control panels are integrated in the console. One allows for adjustment of working distance and scaling factor (Figure 6). The indirect translation of the movement of the master control to a movement of the instrument tips, allows for automated downscaling to a preferred scale.

Figure 4. The two separate displays in the console offer the different images to the surgeon.

Figure 5. The console holds a number of foot pedals, allowing for adjustments of the manipulating and visual systems.

Figure 6. Control panel A

Figure 7. Control panel B

This gives the surgeon the opportunity to operate with a precision and dexterity unprecedented by the natural human hand. The last integrated control panel (Figure 7) allows selection and calibration of the stereoscopic High-definition endoscope.

THE PATIENT-SIDE CART

The patient is situated on the operating table. A patient-side cart (Figure 8) with four telemanipulator arms is positioned next to the table, allowing the arms to reach the operating area. It is imperative to choose the position of the cart in relation to the operating table well, in order to prevent clashes of robotic arms. The camera-arm is connected to the 11mm endoscope and a 12mm trocar. The three other robotic arms are connected to the robotic instruments and to specially designed robotic trocars. Once the trocars have been inserted into the patient's body and are well connected to the patient side cart, robotic surgery can begin. Control of the operation can be switched from the surgeon standing next to the operating table to the surgeon sitting in the console. This console can be located at considerable distance from the operative field, potentially at the other side of the globe. The tableside surgeon and the rest of the attending surgical team can follow the progress of the operation looking at a conventional monitor, located on a video cart. This video cart holds the standard accessories for conventional laparoscopy, including an insufflator, light source and camera controls.

The motions of the surgeon's fingers are indirectly translated to motion of the tips of the specially designed robotic instruments (Figure 9), allowing for downscaling and tremor filtration. Despite the limitations of minimal access surgery, the use of "endowrist" instruments allows for a full six degrees of freedom and an impressive dexterity and range of motion. A wide selection of specially designed instruments allows for a broad range of surgical procedures. New energised robotic instruments are being developed allowing the use of monopolar and bipolar cautery, ultrasonic and advanced bipolar dissection and sealing, and even laser surgery.

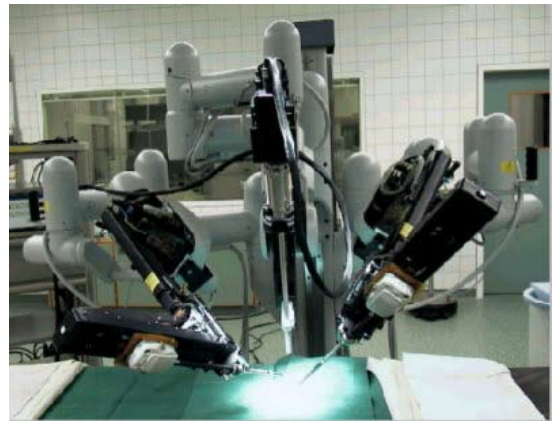
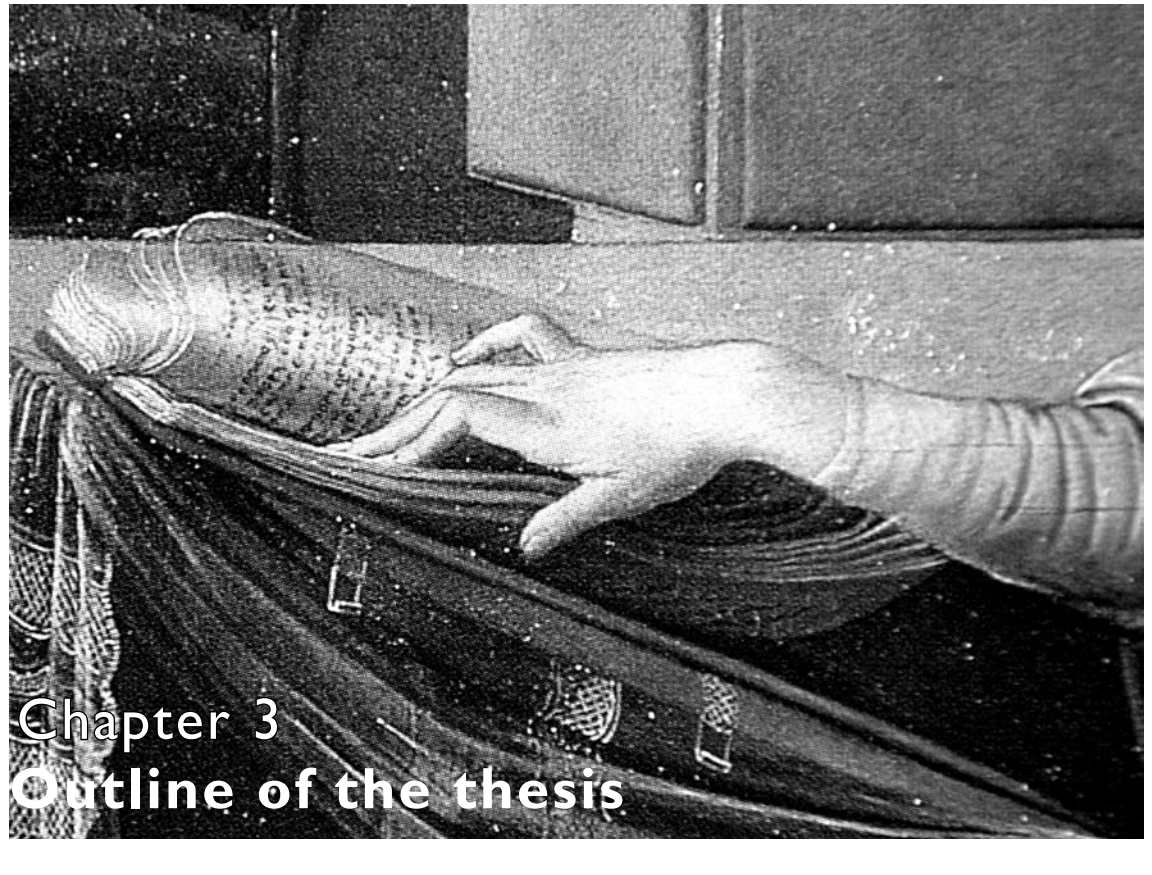


Figure 8. The patient-side cart holds one arm for the visual system and three arms for manipulation

Figure 9. The specially designed robotic instrument tips offer six degrees of freedom and allow for intuitive manipulation.



Chapter 3
Outline of the thesis

DETAIL FROM: ANNUNCIATION
OIL AND TEMPERA ON WOODEN PANEL

Madonna receives the annunciation of her immaculate conception. Her right hand on the marble table probably quotes the tomb of Piero and Giovanni de'medici in the Basilica of San Lorenzo, Florence, which Verrocchio had sculpted during this same period.

OUTLINE OF THE THESIS

1 In order to clarify the role of advanced surgical systems, a four-armed da Vinci®Surgical System was acquired at Maastricht University Hospital in the year 2003. Since then, various studies have been conducted both in a dry lab environment and in clinical practise. This manuscript describes the studies conducted and the results and conclusions that might be taken.

2 The questions that were attempted to answer in this thesis are
Is it possible to use the da Vinci®Surgical system as a research tool in order to clarify whether this integrated system really facilitates the performance of laparoscopic tasks. Is it possible to differentiate what part of this integrated system offers clear benefits? Is it the stereoscopic 3-dimensional view? Is it due to the high-definition image? Is it the restoration of the eye-hand-target-axis or the intuitive movement of the instruments with 6 degrees of freedom?

3 In Chapter four of this thesis we focus on the advantages (and disadvantages) of these separate parts of the da Vinci®telemanipulator in the performance of laparoscopic tasks in a dry lab environment.

4 Is there a difference in learning curve between conventional laparoscopy and robot-assisted laparoscopy? A significant part of medical complications and mistakes is caused during the learning curve of the surgeon or surgical resident. If use of the da Vinci®Surgical System would lead to a significant shorter learning curve, this could lead to safer medical care.
In Chapter five of this thesis we focus on the learning curves of inexperienced individuals, learning how to perform laparoscopic tasks using conventional laparoscopy or Robot-assisted laparoscopy. Looking at the time needed to perform a certain laparoscopic task and the accuracy or number of technical mistakes while performing this task, we try to determine whether there is a significant difference in learning curve between both groups.

5 Is the use of robotic assistance feasible in actual laparoscopic surgery? Does it lead to advantages for the patient such as a decreased operating time? Does it lead to advantages to the health care system such as a decrease in costs involved?

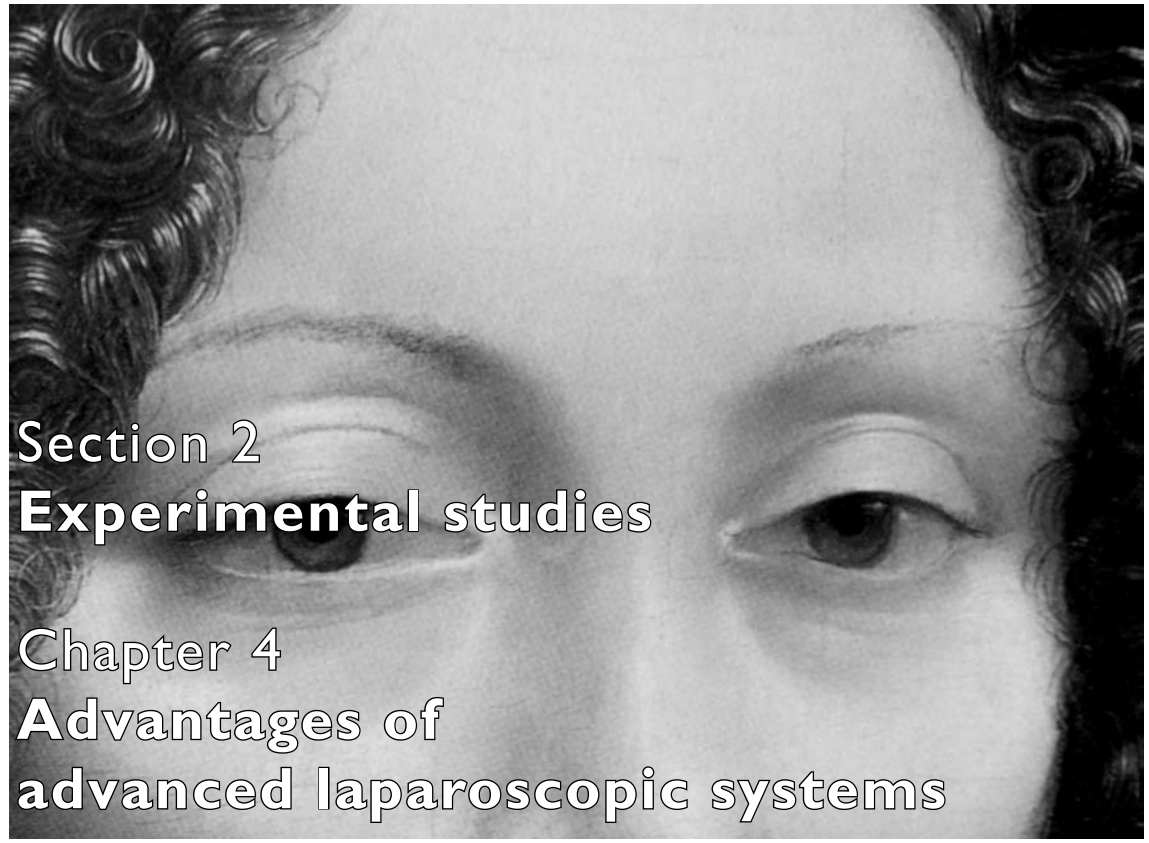
6 In Chapter six, seven and eight, we evaluated the role of this telemanipulator system while performing actual laparoscopic surgery. We selected a variety of frequently-performed laparoscopic operations. Chapter six focuses on cholecystectomy, Chapter seven focuses on Nissen fundoplication and Chapter eight focuses on rectopexy. Secondary end points in these studies were operative complications and duration of admission.

7 Does the use of robotic assistance lead to advantages for the patient such as an improved functional result or a lower recurrence rate?
In Chapter nine we focus on the long-term results and recurrence rates after conventional open, conventional laparoscopic and robot-assisted laparoscopic rectopexy.

8 Does the use of robotic assistance lead to a more ergonomic working situation? Does it lead to less mental strain with the surgeon and therefore to less exhaustion, less potentially harmful operative mistakes and less stress-induced illnesses with the surgeon?
This is a quite uncommon focus for medical research. The effects of newly developed surgical techniques are generally measured mainly (if not exclusively) by their direct effects on the patient (in terms of post-operative pain and complications, tissue damage, time-to-recovery, functional and aesthetic results, Quality Of Life and chance of recurrence) or they are focused on the impact on the health system (in terms of costs, operative time and duration of admission). However, we know that newly developed, minimal invasive techniques might be advantageous for our patients but may be quite demanding, exhausting and harmful to the surgeon. Increased mental strain to the minimal invasive surgeon is closely associated with decreased heart rate variability (HRV), impaired health and limited life expectancy. Although adverse health effects to the surgeon are difficult to measure, the physical effects of mental strain can be measured as a precursor for stress-induced health risk.

9 Chapter 10 focuses on the question whether the use of “robotic” assistance during laparoscopic surgery does actually lead to increased HRV and therefore diminished mental strain as compared to conventional laparoscopic performance of these same operation.

10 In Chapter 11 we will summarize the conclusions of the previous separate studies performed. A critical discussion on these conclusions and a systematic review to evaluate the current status of robotic assistance in a variety of surgical fields is the subject of Chapter 12. In this Chapter we will also focus on future perspectives.



Section 2
Experimental studies

Chapter 4
Advantages of advanced laparoscopic systems

Previously published as:
Advantages of advanced laparoscopic systems
Heemskerk J, Zandbergen HR, Maessen JG, Greve JWM, Bouvy ND.
Surg Endosc 2006;20:730-733

DETAIL FROM: GINEVRA DE' BENCI
OIL ON WOODEN PANEL, 1474-1478

A young, sad looking woman is being depicted in front of juniper tree, symbol of sorrow, loss and pain. The subject might be Ginevra de'Benci, wife of Amerigo de'Benci. Other sources suggest the woman depicted is Fioretta Gorini, the widow of the murdered Giuliano de'Medici.

ABSTRACT

Background: Conventional laparoscopy offers great benefits to our patients, but suffers from major technical drawbacks. Advanced laparoscopic systems are being developed addressing some of these drawbacks.

Methods: We performed a training-box based study, performing laparoscopic tasks using conventional laparoscopy and advanced laparoscopic systems in order to assess the influence of these technical drawbacks in order to predict where the biggest advantages of newly developed surgical systems can be expected.

Results: The most significant technical drawbacks were two-dimensional vision, disturbed eye-hand-target axis and (possibly to a lesser extent) the rigid instruments with a limited four degrees of freedom.

Conclusion: Major advances in advanced laparoscopy might only be expected using console-based robot-arm manipulated systems like the da Vinci®Surgical System, or a combination of a high-quality 3-dimensional vision system, restoration of the eye-hand-target axis and the use of an advanced handheld instrument offering six degrees of freedom such as the Radius®Surgical System.

INTRODUCTION

Minimal invasive surgery is one of the great advances in medicine in recent decades, aiming at maximal reduction of surgical trauma. However, laparoscopic surgeons sacrifice dexterity to provide patients with less invasive surgery. The following are major drawbacks of laparoscopy:

1 Two-dimensional (2D) vision using a conventional monitor reduces perception of depth.
2 A disturbed eye-hand-target axis decreases ergonomics and dexterity.
3 The long, inflexible instruments used in laparoscopic surgery magnify the surgeon's natural hand tremor.
4 The rigid instruments with four degrees of freedom limit the surgeon's natural range of motion, decreasing dexterity.
5 Fixed abdominal entry points result in limited freedom of motion and movement of the tip of the instrument to the opposite direction of the outer pat of the instrument, a technical drawback known as the fulcrum effect.
6 Camera instability increases fatigue.
7 Limited tactile feedback decreases dexterity.

These factors probably all contribute to the relatively long learning curve in laparoscopic surgery[1]. Advanced stereoscopic and instrument manipulating surgical systems are being developed in order to address some of the shortcomings related to conventional laparoscopy, potentially leading to faster and more accurate laparoscopy[2,3]:

A variety of stereoscopic systems are being developed. Although stereoscopy rarely offers convincing depth perception[4], its use might improve laparoscopic performance[5-9].
The disturbed eye-hand-target axis is difficult to restore using conventional laparoscopic equipment. Although ergonomic monitor placement is crucial, the ideal situation of projecting the image exactly where the operation takes place is difficult to achieve without a console-based surgical system[10,11]. Tremor can be diminished using a robot arm manipulated system with tremor filtration[12]. Both handheld and console-based surgical systems offer the full six degrees of freedom, increasing dexterity[12,13]. The fulcrum effect is difficult to address using conventional laparoscopic instruments. Although extensive training leads to faster automation to the fulcrum effect[14,15], only robot arm manipulated systems can restore intuitive movement of the instrument's tip in the direction of the surgeon's hand, increasing dexterity. Camera instability due to exhausting camera holding can be restored using a variety of mechanical or robot arm manipulated systems. No commercially available surgical systems have been able to restore normal sensitivity in tactile feedback.

We performed a training box-based study, describing time consumption and accuracy in both inexperienced users and expert laparoscopic surgeons performing laparoscopic tasks using conventional laparoscopy, the Radius®Surgical System (Tuebingen Scientific, Tuebingen, Germany) and the da Vinci®Surgical System (Intuitive Surgical, Mountain View, CA, USA) in a variety of settings. The aim of the study was to assess the significance of the previously described technical drawbacks for laparoscopic surgery in order to predict where the major advantages of newly developed surgical systems can be expected.

MATERIAL AND METHODS

Participants

Ten inexperienced and 10 experienced volunteers were selected to perform laparoscopic tasks using various laparoscopic systems. The inexperienced group consisted of 10 volunteers without any previous laparoscopic experience. The experienced group consisted of 10 expert laparoscopic and thoracoscopic surgeons from the Departments of Surgery and Cardio-thoracic Surgery of Maastricht University Hospital. All of them had extensive experience in laparoscopy or thoracoscopy, having performed more than 100 laparoscopic or thoracoscopic procedures.

Conventional laparoscopy

All conventional laparoscopic tasks were performed using a pelvic trainer with one 12mm video port and two 12mm trocar ports (Versaport, US Surgical Corporation, Norwalk, CT, USA). A 10mm 0° digital video camera (Endoeye, Olympus, Hamburg, Germany) was used, and the image was displayed on a 14-inch high-resolution 100Hz monitor. Camera handling was done using a simple rigid standard. Manual laparoscopic drills were performed using disposable 5mm laparoscopic instruments (Endo Clinch II, Autosuture, Norwalk, CT, USA) and a 5mm laparoscopic needle driver (Storz 26173SC laparoscopic needle driver, Karl Storz Endoskope, Tuttlingen, Germany).

Radius®Surgical System

All radius-assisted laparoscopic tasks were performed in the same pelvic trainer using the same trocars described previously. The Radius®handheld manipulator (Radius Surgical Systems, Tuebingen Scientific Medical GmbH, Tuebingen, germany) was used instead of conventional laparoscopic instruments. This laparoscopic instrument enables the surgeon to perform laparoscopic tasks offering a full six degrees of freedom instead of the four degrees of freedom on conventional laparoscopy, potentially increasing dexterity and improving performance. Unfortunately, the tip of the Radius instrument was not suitable to grasp the beads used in task 1. therefore, this task was not done using the Radius®Surgical System.

da Vinci®Surgical System

All da Vinci®-assisted laparoscopic tasks were performed in the same pelvic trainer as described previously using a 12mm video port and two 7mm trocars. We used three arms of the four-armed da Vinci®Surgical System. This robotic surgical system consists of a surgeon's console, patient side cart, Endowrist®instruments and InSite®Vision System. The surgeon's console offers an ergonomic position to the surgeon, translating the surgeon's intuitive movements into precise, real-time movements of the instruments. The patient side cart offers four robot arms, executing the surgeon's commands while offering tremor filtration and movement downscaling if desired. The Endowrist®instruments attached to the patient side cart offer the full six degrees of freedom. The InSite®Vision System provides high-quality stereoscopic stable vision, projecting the tip of the instruments where the fingertips of the surgeon are located.
Three arms of the four-armed da Vinci®system were used. One arm handled the camera and the other two arms manipulated two Endowrist®laparoscopic Debakey forceps. The da Vinci®tasks were performed using the da Vinci®Surgical System in stereoscopic 3D InSite®vision, in 2D InSite®vision, and in a conventional monitor-viewed modus.

Tasks

Three laparoscopic tasks were devised to test dexterity, two-handed coordination, and suturing. Each participant was instructed about the main features of the endoscopic tasks to be performed and on how to use the surgical systems. The participants were allowed to manipulate each surgical system for five minutes become familiar with the controls and setup. Questions were allowed before and during the tests, but no assistance was provided. The same order of tasks was performed for every participant, but the sequence of the use of the different surgical systems changed in order to prevent a learning curve from interfering with the results.

Task 1: pick up and drop

A comparable laparoscopic drill was used in other studies[16-18], in which a receptacle (40mm opening and 10mm high) containing five beads was used. The task was to pick up a bead from the receptacle with the right-handed instrument and transfer it halfway to a second receptacle. The bead had to be taken over with the left-handed instrument and dropped into the second receptacle. Time was recorded from starting position with the instrument in focus but outside the initial receptacle to the fifth bead dropped into the final receptacle. Inaccuracy was defined as 10 points for every bead accidentally dropped outside the receptacle. The task was performed eight times – twice per suitable instrument. The tip of the Radius®instrument was unfit for this task.

Task 2: cap the needle

This task was performed as described previously[15] using a 19-gauge x 1,5-inch aspiration needle with Luer Lock (Terumo Europe NV, Leuven, Belgium) and its cap. The task was to cap the needle after grasping both pieces from the floor of the training box, keeping both cap and needle above the box floor. Time was recorded from starting position with the instruments in focus but 5cm from the needle and its cap to the moment when te needle and cap were securely coupled and held by one instrument. Inaccuracy was defined as 10 points for every cap or needle accidentally dropped or touching the box floor. The task was performed 10 times – twice per instrument.

Task 3: suturing and knot tying

This task was previously described[16,18,19], and it consists of using a size eight latex glove and a Vicryl 3-0 polyglactin suture with FS-1 24mm 3/8 circular needle (Johnson&Johnson, New Brunswick, NJ, USA). The task was to pass the needle through two separated five mm dots on the glove and then tie a double knot. Time was recorded from starting position with the instruments in focus but five cm away from the needle to the moment when the suture was securely tied. Inaccuracy was defined as 10 points per mm distance between the black dot and the needle entry through the glove. Twenty points was added if the knot was too loose or the suture broke. The task was performed 10 times – twice per setup.

Statistical analysis

Data were stored in an Excel XP database (Microsoft, Redmond, WA, USA) and analysed using SPSS version 11.0.1 (SPSS, Chicago, IL, USA). Comparison of groups was done using Pearson's chi-square test. Comparison of two related samples was done using a non-parametric Wilcoxon signed rank test. A p value ≤ 0.05 was defined as statistically significant.

RESULTS

Study population

The median age of the study population was 32 years (range, 21-52), 36 years in the experienced group (range, 32-52) and 23 years in the inexperienced group (range, 21-35). In total, 20 participants performed two tasks twice using five different setups. One task was performed twice using four setups, leading to a total of 560 tasks. Performing every task, time consumption, and accuracy were registered, leading to a total of 1,120 analyzable data points.

Time and accuracy

Time consumption was compared by performing different tasks using various instruments and setups. Inexperienced participants took significantly more time to complete a task than the experienced surgeons. Conventional laparoscopy was most time-consuming, whereas the daVinci®system with stereoscopy was the fastest. Task 3 was far more time-consuming than tasks 1 and 2. The benefit of using advanced surgical systems seemed less for experienced users compared to inexperienced users. Accuracy was compared using the different surgical systems. Higher numbers of failures and mistakes resulted in higher inaccuracy scores. Inexperienced participants had higher inaccuracy scores than expert surgeons. Conventional laparoscopy and the use of the da Vinci®system with monitor-viewed vision resulted in the highest inaccuracy scores, whereas use of the daVinci®system with stereoscopic InSite®vision resulted in the lowest inaccuracy scores and thus the best results. Table 1 shows mean time consumption and inaccuracy scores for the total group and for the inexperienced and experienced subgroups separately.

Table 1. Mean time consumption and inaccuracy scores in the total group (inexperienced, experienced subgroups)

	Task	Conventional	Radius	daVinci 3-D	daVinci 2-D	daVinci-M
Time	Task 1, first trial	171 (233,108)	—	85 (108,62)	96 (111,82)	140 (189,90)
	Task 1, second trial	121 (167,74)	—	65 (74,56)	92 (107,76)	118 (143,94)
	Task 2, first trial	138 (220,55)	100 (156,43)	40 (44,35)	64 (74,55)	105 (121,89)
	Task 2, second trial	103 (158,49)	62 (80,44)	55 (40,70)	64 (52,77)	109 (137,80)
	Task 3, first trial	332 (500,164)	304 (477,132)	122 (165,79)	158 (192,124)	182 (238,127)
	Task 3, second trial	323 (515,132)	240 (335,148)	87 (105,69)	155 (200,110)	186 (251,120)
Inaccuracy	Task 1, first trial	18 (28,7)	—	9 (13,4)	10 (16,3)	24 (44,4)
	Task 1, second trial	11 (17,5)	—	6 (6,5)	9 (16,2)	14 (26,2)
	Task 2, first trial	23 (37,9)	14 (20,8)	15 (10,20)	23 (21,24)	30 (26,34)
	Task 2, second trial	16 (27,4)	9 (9,8)	17 (12,22)	24 (19,28)	37 (37,36)
	Task 3, first trial	23 (44,2)	27 (41,13)	0 (0,0)	4 (7, 1)	7 (11, 2)
	Task 3, second trial	27 (46,7)	24 (45,2)	2 (3,0)	5 (9,0)	12 (24,0)

Comparing instruments

Using the Radius®Surgical System, two tasks were performed twice each, describing time consumption, accuracy, and score. This resulted in 12 data samples. Using a non-parametric Wilcoxon signed rank test, related samples could be compared in order to assess significant superiority of one setup or the other. Results are depicted in table 2.

Table 2. Number of significantly better results comparing first instrument versus second instrument (number of camparing data samples)

	Total Group	Inexperienced	Experienced
Conventional vs Radius	0 vs 1 (8)	0 vs 2 (8)	0 vs 0 (8)
Conventional vs da Vinci 3-D	0 vs 9 (12)	0 vs 10 (12)	0 vs 1 (12)
Conventional vs da Vinci 2-D	0 vs 5 (12)	0 vs 8 (12)	1 vs 0 (12)
Conventional vs da Vinci M	1 vs 0 (12)	0 vs 2 (12)	2 vs 0 (12)
Radius vs da Vinci 3-D	0 vs 5 (8)	0 vs 7 (8)	0 vs 2 (8)
Radius vs da Vinci 2-D	1 vs 4 (8)	0 vs 5 (8)	1 vs 0 (8)
Radius vs da Vinci M	1 vs 1 (8)	1 vs 1 (8)	3 vs 0 (8)
da Vinci 3-D vs da Vinci 2-D	5 vs 0 (12)	3 vs 0 (12)	4 vs 0 (12)
da Vinci 3-D vs da Vinci M	12 vs 0 (12)	10 vs 0 (12)	6 vs 0 (12)
da Vinci 2-D vs da Vinci M	5 vs 0 (12)	4 vs 0 (12)	0 vs 0 (12)

DISCUSSION

Conventional laparoscopy suffers from seven technical drawback as described previously. This study was conducted in order to assess these drawbacks.

The role of 2D vision was assessed by comparing results of da Vinci®in 2D InSite®vision mode with daVinci®in stereoscopic InSite®mode. The daVinci®system in 3D mode seemed faster and more accurate in all 12 data samples (table 1). This difference was significant in 5 of 12 data samples (table 2), suggesting stereoscopic vision does indeed lead to faster and better performance of laparoscopic tasks. The role of the disturbed eye-hand-target axis was assessed by comparing the results of da Vinci®in the 2D InSite®vision mode with daVinci®in the monitor-viewed mode. Two-dimensional InSite®vision seemed faster and more accurate in all 12 data samples (table 1). This difference was significant in five of 12 data samples (table 2), suggesting restoration of the disturbed eye-hand-target axis does improve performance of laparoscopic tasks.

The role of limited degrees of freedom in conventional laparoscopy was assessed by comparing conventional laparoscopy with the Radius®Surgical System. Although the tip of the Radius®instrument was not fit for task 1, the other tasks seemed to be performed faster and more accurate using the radius®instrument in seven of eight data samples (table 1). This suggests that offering six degrees of freedom might improve laparoscopic performance.

The roles of tremor enhancement, fulcrum effect, and limited tactile feedback could not be assessed separately in this study. However, comparing the radius®system, which suffers from tremor enhancement, fulcrum effect, and limited tactile feedback, with the da Vinci®system in monitor-viewed mode, no significant difference was present (tables 1 and 2). This suggests these three drawback do not play a crucial role and might not require a technical solution.

The role of camera instability was not assessed in this study, since camera holding was done by a rigid standard or robot arm.

Analysis of the experienced and inexperienced subgroups showed a more significant advantage of the use of advanced laparoscopic systems in the inexperienced group. This suggests that extensive training in laparoscopy may reduce the need for advanced stereoscopic or manipulating laparoscopic systems.

We conclude that the most significant improvements with regard to the previously mentioned technical drawbacks in conventional laparoscopy are high-definition 3D vision, restoration of the disturbed eye-hand-target axis and (possibly to a lesser extent) the use of instruments offering the full six degrees of freedom. Major improvements in laparoscopic surgery may only be expected from either a console-based surgical system, such as the da Vinci®Surgical System, or a combination of a high-definition 3D vision system with ergonomic monitor placement (or a head-mounted display), with a handheld, six degrees of freedom instrument, such as the Radius®Surgical System.

Advanced laparoscopic surgery is still in its infancy, and major improvements in the availability of specifically designed surgical systems are expected soon, offering great opportunities for the future. However, more research is needed in order to develop affordable and feasible instruments offering high-quality 3D vision, a restoration of the eye-hand-target axis, and six degrees of freedom.

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Chapter 5

Learning curves in robot-assisted laparoscopic surgery

Previously published as:

Learning curves of Robot-assisted Laparoscopic Surgery Compared With Conventional Laparoscopic Surgery
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DETAIL FROM: ST. JOHN THE BAPTIST
OIL ON WOODEN PANEL 1513-1516

This piece depicts St John in isolation. The pointing gesture towards heaven suggests the importance of salvation through baptism. Others suggest an esoteric symbolique referring to the first principle of the Emerald Table of Alchemy.

ABSTRACT

Background: Laparoscopic surgery can be demanding, resulting in a longer operating time and a longer time before reaching proficiency compared with open surgery. Robotic assistance allows stereoscopic vision and improves dexterity; potentially leading o faster and safer laparoscopic surgery and a shortening of the learning curve.

Methods: Duration and accuracy were measured in inexperienced participants, performing basic and advanced laparoscopic tasks using both conventional laparoscopy and the da Vinci®Surgical System.

Results: Eight participants performed 176 laparoscopic tasks. Robotic assistance resulted in faster and more accurate performance of laparoscopic tasks. However, conventional laparoscopy showed faster skill acquisition.

Conclusion: Robotic assistance resulted in faster and more accurate performance of laparoscopic tasks. However, learning curve favored conventional laparoscopy. These data suggest robotic assistance might be most beneficial in inexperienced subjects. The relatively flat learning curve in robot-assisted laparoscopy suggests robotic assistance might be less (or marginally) beneficial in experienced surgeons. This could explain why robotic assistance has failed to show clear benefit in several clinical studies. Extensive conventional laparoscopic training might lead to faster, safer and less expensive surgery, further marginalizing the role for robotic assistance in laparoscopic surgery.

INTRODUCTION

Laparoscopic surgery offers great advantages to our patients but can be demanding owing to several technical drawbacks. Limitations include 2-dimensional vision jeopardizing visual perception of depth, disturbance of the eye-hand-target axis, fulcrum effect, rigid instruments with limited degrees of freedom and limited tactile feedback. These factors might attribute to the required relatively long training period before reaching proficiency compared with traditional open Surgery[1].
Robotic assistance improves dexterity and offers stereoscopic vision in combination with a restored eyehand-target axis, allowing complex laparoscopic tasks to be performed faster and more accurate compared with conventional laparoscopy[2-6]. Disadvantages of robot-assisted laparoscopy are higher costs, longer preparation time, complex technology, and lack of tactile feedback. In several clinical studies, the use of robotic assistance in laparoscopic surgery has been proven safe and feasible, but failed to offer major advantages over standard laparoscopic surgery[7-10]. Data comparing learning curves of participants performing laparoscopic tasks are limited, possibly favoring robot-assisted surgery[11].
We performed a training-box-based study, describing speed and accuracy in volunteers performing basic and complex laparoscopic tasks using both conventional laparoscopy and using the da Vinci®Surgical System. Aim of the study was to assess differences in both performance and in skill acquisition of inexperienced users using both conventional and robotic laparoscopy.

MATERIAL AND METHODS

Participants

To obtain reliable learning curves, eight medical students with no experience in conventional laparoscopic surgery or robot-assisted laparoscopic surgery performed four laparoscopic tasks, using both conventional laparoscopy (CL) and robot-assisted laparoscopy (RL) in randomized order.

Materials

All CL tasks were performed using a pelvic trainer with two 10-mm trocar ports (Versaport, United States Surgical Corporation, Norwalk, CT, USA) and a 10-mm video port. A lOmm 0-degree 1-chip video camera (Karl Storz Endoscopy, Tuttlingen, Germany) was used, and the image was displayed on a 14-inch monitor. Conventional laparoscopic drills were performed using disposable 5mm laparoscopic instruments (Endo Clinch II, AutoSuture, Norwalk, CT, USA). The CL suturing task was performed using a 5mm laparoscopic needle driver (Storz 26173SC laparoscopic needle driver, Karl Storz Endoscopy, Tuttlingen, Germany).
All RL tasks were performed using a pelvic trainer with two 7mm trocar ports and a 12-mm video port. We used 3 arms of the 4-armed da Vinci®Surgical System (Intuitive surgical, Mountain view, CA). One arm handled the 0-degree video camera and the other two manipulated laparoscopic Debakey forceps. Standardized instructions about the use of instruments and the endoscopic tasks to be performed, were given to the participants on an individual basis. The participants were allowed to manipulate both systems for two minutes to become familiar with its controls and setup. However, no time was allowed to practice any of the tasks.

Tasks

A variety of tasks were devised to test dexterity, two-handed coordination and suturing. Using a cross-over technique, participants started alternating using CL or the da Vinci®system. The same order of tasks was followed for every participant. The same robotic tools were always used for a given task. Two basic laparoscopic tasks were used and two advanced laparoscopic tasks.

Task 1 (Pick up and Drop)

This basic laparoscopic drill was comparable to the tasks described previously by Prasad et al. An initial receptacle (40mm opening, 10mm high) contained five beads (2 x 4mm). The task involved picking up the beads with the right-handed instrument, one at a time, and then transferring them to the second receptacle. Upon successful transfer, participants were asked to reverse the transfer using the left handed instrument, and return the beads one at a time to the first receptacle. The total time for the exercise was recorded, starting from a position with the instruments in focus but outside the first receptacle, and finishing when the last bead was returned to the final receptacle. Accuracy was defined as the number of beads accidentally dropped outside the receptacle or damaged owing to excessive force. The task was performed six times: three times by CL, and three times by RL.

Task 2 (Give Over the Bead)

In this exercise, the same receptacle and beads were used as described before. The initial receptacle contained five beads. Participants were asked to pick up the beads with the right handed instrument, one at a time, and transfer them halfway to the final receptacle. Then they had to be taken over with the left handed instrument and dropped inside a second receptacle. Time and accuracy were recorded as in the previous task. The task was performed six times: three times by CL and three times by RL.

Task 3 (Cap the Needle)

This advanced laparoscopic drill was comparable to the needle capping task as described by Garcia-Ruiz et al. A 19 Gauge x 1.5-inch aspiration needle with luer lock (Terumo Europe NV, Leuven, Belgium) and its cap were used. The purpose was to cap the needle after grasping both pieces from the floor of the training box. The 0nly requirement was to cap the needle above the box floor. Time was recorded from starting position with the instruments in focus and 5mm from the needle and its cap to the moment when needle and cap were securely coupled and held by one instrument. Accuracy was defined as the number of accidental needle or cap droppings. The task was performed six times: three times by CL and three times by RL.

Task 4 (Suturing and Knot Tying)

This suturing task was comparable to tasks described before by others.[1-5]. In this exercise, participants were asked to suture and tie a double knot on a latex glove size 8 using a Vicryl 3-0 polyglactin suture with a FS-1 24.0mm 3/8 circular needle (Johnson & Johnson, New Brunswick). The suture had to pass through two separated 5mm dots on the glove. Time was recorded from a starting position with the instruments in focus and 5mm away from the needle to the moment the suture was securely tied. Accuracy was defined as number of times the suture broke owing to excessive force, or was tied too loose. Task 4 was performed three times in the RL-group. Owing to limited availability of equipment, the task could not be performed three times in the CL-group. For comparison of RL versus CL, only the first trial of robot-assisted laparoscopic suturing was compared with the first trial of conventional laparoscopic suturing.

Statistical Analysis

Data were analyzed using SPSS version 11.0.1 (SPSS, Inc). A multivariate analysis of variance for repeated measures was used. A p value of ≤0.05 was defined as being statistically significant.

RESULTS

Eight inexperienced participants, four men and four women aged between 22 and 26 years, performed in total 176 laparoscopic tasks.

Time and Accuracy Scores

Time and accuracy score were compared performing laparoscopic tasks using CL and the da Vinci®Surgical System (RL). RL performed all four tasks faster than CL, reaching statistical significance in three out of four tasks. Accuracy scores favored RL over CL in three out of four exercises, reaching statistical significance in two of them. Results are shown in table 1.

Table 1.
Time and Accuracy performing laparoscopic tasks using both robot assisted and conventional laparoscopy

	Robot	Conventional	p
Time			
Task 1	92.10	147.80	<0.001*
Task 2	62.20	253.67	<0.001*
Task 3	49.20	83.80	0.009*
Task 4	306.00	441.10	NS
Accuracy			
Task 1	0.25	0.29	NS
Task 2	0.21	1.67	<0.001*
Task 3	0.38	1.75	<0.001*
Task 4	0.75	0.00	NS

* p value < 0.05 was considered statistically significant

Learning curve

To assess an effect of repetition on time necessary to perform a task, a comparison was made between the first, second and third time a task was performed. The first time a task was performed always took more time than the second or third time. However, a multivariate analysis of variance did not show a significant difference between different runs in speed (p=0.438) or in accuracy (p=0.082). Results are shown in Figures 1 and 2.

DISCUSSION

Conventional laparoscopy can be quite demanding owing to several technical drawbacks. In this study, robotic assistance allowed laparoscopic tasks to be performed faster and more accurately than CL as described before.[2-6] Other variables potentially representing the extent of proficiency and/or skill acquisition, such as electromyogram or efficiency of movement,[11] have not been measured in our study. Both CL and RL seemed to show improvement after repetition in speed and accuracy score. This improvement was not always statistically significant, which probably

reflects our limited sample size. Learning curves in time and accuracy for CL and RL were not comparable for all exercises. In some drills, eg, task 1, both curves seemed to run parallel, indicating a continuous persistent advantage of robotic assistance independent of training. In other exercises, for example, task 2, the learning curve for CL seemed to run more steeply, approaching and possibly reaching the learning curve for RL after further training. Subgroup analysis by task was not performed to prevent type 2 error. These results are contradictory to the findings of Chang et al,[13] favoring the learning curve in robotic surgery. However, their study used participants with extensive experience in conventional laparoscopy, but without experience in robot-assisted surgery, making their differences in learning curves more of a challenge to interpret. The declining advantage of robotic assistance after repetition, found in our study, could be owing to the initial inferior performance of our study objects using CL. Those participants who make a slow or inaccurate start to the technically more demanding CL have significant room for improvement, and thus are more likely to demonstrate a steeper learning curve. Those who initially perform well on RL have minimal room for subsequent improvement. One interpretation of the steeper learning curve in conventional laparoscopy might be that robotic assistance is advantageous mainly in inexperienced subjects as suggested before by Sarle et al[3] and Scott et al[14]. This could explain why most clinical studies have not been able to show the benefit from the use of robotic assistance in terms of time or costs, as could be expected from various training-box-based studies[2-6]. Adequate and extensive conventional laparoscopic training might lead to faster, better, and less expensive laparoscopy, further marginalizing the advantages of robotic assistance. The advantages of RL over CL, including improved dexterity, tremor filtration, and stereoscopic vision, resulting in increased accuracy and technical feasibility, may be more pronounced in more complex laparoscopic procedures. More research is required to assess the advantages and disadvantages of the use of robotic assistance by experienced laparoscopic surgeons performing complex laparoscopic surgery, ultimately leading to the creation of clear guidelines for the appropriate use of robotic assistance in laparoscopic surgery.

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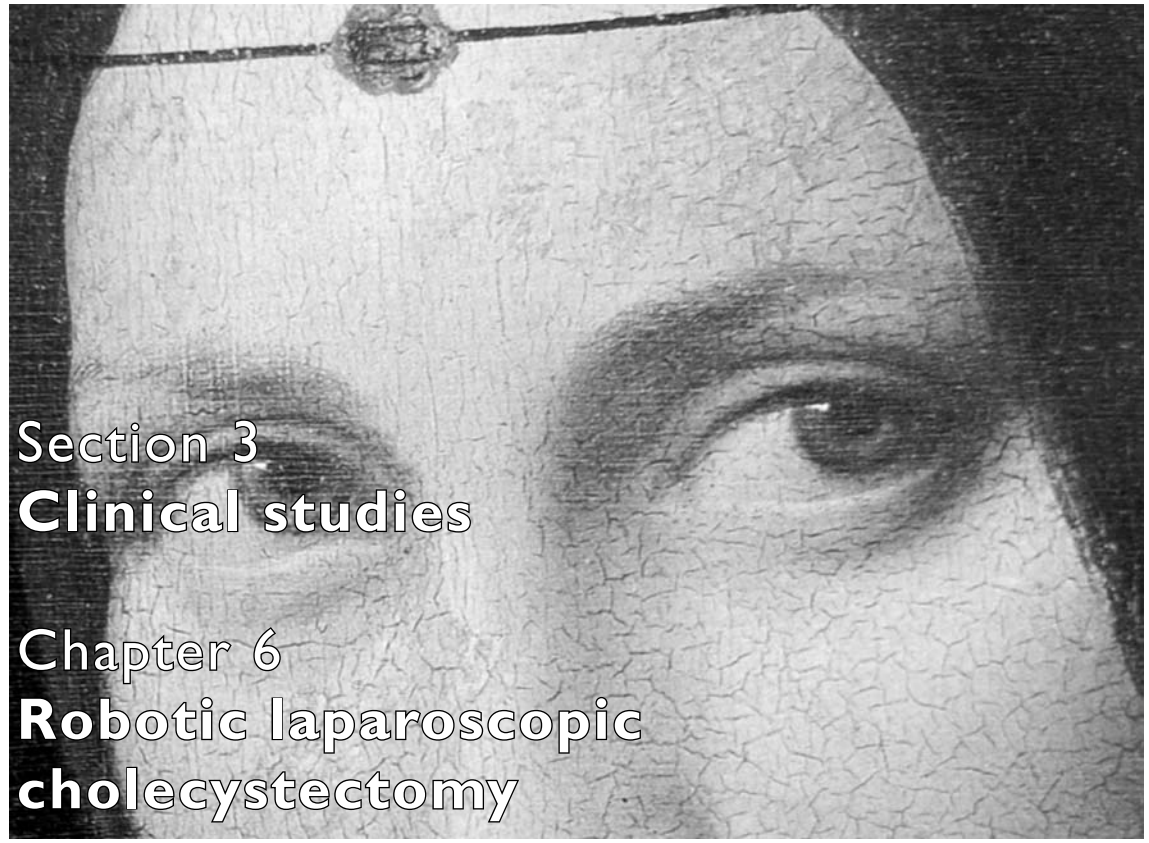

Section 3
Clinical studies

Chapter 6
Robotic laparoscopic cholecystectomy

Previously published as:

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DETAIL FROM: LA BELLE FERRONNIÈRE.

The painting's title discreetly alludes to a reputed mistress of king Francis I of France. She was the unfaithful wife of an ironmonger (a ferronnier). When the aggrieved husband found this out, he took revenge by intentionally infecting himself with syphilis, indirectly passing it through his wife to the king.

ABSTRACT

Background: Laparoscopic cholecystectomy offers less post-operative pain, less complications, and faster recovery compared with open cholecystectomy. However, laparoscopic surgery can be demanding because of several technical drawbacks. Robotic surgery allows dexterity skills to be performed faster and shortens the learning curve, possibly leading to faster and safer laparoscopic surgery.

Methods: In this paper, we report the results of our first 12 cases of fully robotic laparoscopic cholecystectomy using the da Vinci®Surgical System, comparing them with 12 cases of conventional laparoscopic cholecystectomy. Using a fourth arm in robotic laparoscopy enables the surgeon to perform surgery without the use of a tableside assistant, leading to non-tiring, tremblefree assistance and reducing salary costs. Primary end points are operating time and costs. Secondary end points are operative complications and duration of admission.

Results: Fully robotic cholecystectomy was completed in all 12 cases without increased complication rate and without conversions. However, robotic assistance results in an increased overall operating room stay.

Conclusion: Fully robotic laparoscopic cholecystectomy is safe and feasible but seems more expensive and time consuming at this moment.

INTRODUCTION

Laparoscopic cholecystectomy has become the standard treatment for symptomatic and complicated cholelithiasis[1,2] and for acute cholecystitis[3], leading to less complications and faster recovery compared with traditional cholecystectomy[4,5]. However, the benefits for the patient might be smaller than expected and might not justify the additional costs[6,7]. Conventional laparoscopic surgery can be demanding, potentially attributing to the relatively long learning curve[8]. Robotic assistance in laparoscopy enables stereoscopic vision, improves dexterity[9,10], and has been proven safe and feasible in a wide variety of surgical procedures including cholecystectomy[11-15]. However, whether robotic surgery leads to increased costs or time loss remains unclear[16-18].
We describe our first cases of fully robotic laparoscopic cholecystectomy using the four-armed da Vinci®Surgical System. The use of an additional fourth instrumentation arm has proven useful in anti-reflux surgery[19], potentially diminishing the need for a tableside assistant. Our results are compared with conventional laparoscopic cholecystectomies, performed during the same period. Primary end points are operating time and costs. Secondary end points are post-operative complications and duration of hospital stay.

MATERIAL AND METHODS

Patients

Between 1 September 2003 and 1 February 2004, 12 fully robotic laparoscopic cholecystectomies were performed and matched with 12 conventional laparoscopic cholecystectomies. No specific criterion was used selecting patients for fully robotic surgery other than availability of the da Vinci®Surgical System and an experienced laparoscopic surgeon. The indication for cholecystectomy was symptomatic cholecystolithiasis, defined as one or more episodes of colic pain in the right upper abdomen in the presence of cholelithiasis objectivated by ultrasound. Exclusion criterion was the presence of acute cholecystitis.

Procedures

Conventional laparoscopic cholecystectomy (LC) was performed after open introduction of a 10mm trocar at the level of the umbilicus for insufflation. A 10mm 0°three-chip video camera (Karl Storz Endoscopy, Tuttlingen, Germany) was introduced, followed by a second 10mm trocar under the xyphoid. Additionally, two 5mm trocars were used for introduction of 5mm instruments (Endo Grasp, Auto-Suture, Norwalk, CT, USA) to retract and manipulate the gallbladder. Dissection started at the neck of the gallbladder using a curved Maryland dissector. After dissection of Calot's triangle and clear identification of the cystic duct and artery, both were clipped (Hemoclip, Auto-Suture, Norwalk, CT, USA) and cut using 5mm Endo Shears (Auto-Suture). After this, both blunt and diathermic dissection was performed to free the gallbladder from the liver bed. The gallbladder was removed through the sub-umbilical port. If there were signs of cholecystitis or operative bile spill, the gallbladder was inserted into a disposable plastic bag (Medinorm, Quierschied, Germany) before removal. In case of intra-abdominal spill of bile, suction was used and irrigation if deemed necessary.
The operating team for LC consisted of one operating surgeon or surgical resident performing the dissection, one assisting surgeon or surgical resident handling the camera and retracting the gallbladder through the most lateral trocar, and a scrub nurse.
Robotic Cholecystectomy (RC) was performed after open introduction of a 12mm trocar at the level of the umbilicus. A second 12mm trocar was introduced in the paramedian left region of the epigastric space. Additionally, two 7mm trocars were inserted at the standard trocar sites. The

trocars were connected to the four-armed da Vinci® Surgical System patient side cart (Intuitive Surgical, Mountain View, CA, USA) and the surgeon was seated behind the da Vinci® console. Dissection, removal of the gallbladder, and wound closure were performed in the same manner as was done in LC.
The operating team consisted of one operating surgeon and a scrub nurse. No assisting surgeon or surgical resident was used during this stage of surgery. The assisting scrub nurse replaced instruments and placed clips during cholecystectomy. Although all RC procedures were performed by experienced surgeons in general surgery, none of them had extensive experience in RC. The number of previously performed robotic cholecystectomies ranged between zero and three.

Measurements

Discharge criteria were identical for all patients. Patients were discharged one day after surgery if sufficiently recovered and if pain and nausea had resided. All patients were seen for examination and reassessment at the outpatient clinics two weeks after surgery. Laboratory tests were only performed on indication.
Primary endpoints were operating time and costs. Operating time was recorded separately for different stages of surgery. The overall operating room stay was defined as the total time a patient was in the operating room. This was divided in pre-operative anesthesia induction time (from arrival in the operating room until the end of anesthesia induction), preparation time (from the end of anesthesia induction until the first incision) and real operating time (from incision until placement of the last closing suture). In the RC group, real operating time could be divided into operating time previous to robotic assistance, operating time with robotic assistance, and wound closure time.
Costs per patient were calculated using costs of hospital stay, costs for diagnostic tests, material costs for laparoscopic cholecystectomy, accessory costs for sterile draping and robotic instruments if applicable, salary costs (wages per hour for attending surgeons, residents and nurses, multiplied by overall operating room stay), and outpatient clinics pre-operative assessment and post-operative follow-up.
Secondary endpoints were length of hospital stay and complications.

Statistical analysis

Data were stored in an Excel 97 database (Microsoft Corporation, Redmond, WT, USA) and analysed using SPSS version 11.0.1 (SPSS Inc., Chicago, Ill, USA). The results were analysed by the intention to treat principle. No conversions were performed in this study population. Groups were compared using Pearson's X^2 test for nominal differences. Age, Laboratory test results, and duration of operation of both groups were compared using a Mann-Whitney U non-parametric test for independent samples or a Spearman's rank correlation test for non-parametric correlations. A p –value ≤ 0.05 was defined as statistically significant.

Results

Pre-operative patient characteristics

Twelve consecutive patients undergoing fully RC were matched for age and gender with 12 patients undergoing a standard LC in the same hospital during the same period. The total study population was 24 patients.
The indication for surgery was symptomatic cholecystolithiasis without acute cholecystitis or previous biliary complications in 23 cases (96%). One patient in the RC group underwent cholecystectomy "à froid" four months after an episode of acute cholecystitis without cholestasis. None of the patients met the criteria of acute cholecystitis at the time of hospital admission. Pearson's X^2 test for nominal differences showed no difference between both groups in sex, indication for operation, or indicators for acute cholecystitis or cholestasis. However, there was a significant difference in the consistence of the operating team. In the RC group, all operations were performed by an experienced general surgeon, assisted by a scrub nurse. Experience in robotic surgery was limited in all six individual surgeons. None of them had experienced more than three RC procedures and one of them had no previous experience in laparoscopic cholecystectomy at all. In the LC group, only one cholecystectomy was performed by an experienced general surgeon. The other 11 operations were performed by a surgical resident. The Mann-Whitney U test showed no significant difference between both groups in age and pre-operative laboratory results. Pre-operative characteristics of the study population are displayed in table 1.

Intra-operative complications

No major intra-operative complications occurred. There were no cases of intra-operative bleeding, bile duct damage, or conversion. Nine patients had per-operative intra-abdominal bile spill, four in the CC group and five in the RC group. Pearson's X^2 test showed no difference between both groups.

Table 1. Pre-operative characteristics of the study population

	Total study Group (n=24)	LC (n=12)	RC (n=12)	p value
Sex, % male	4	8	0	0.307
Mean age, years	47.8	48	47.7	0.977
Median age, years (range)	45.5 (19-77)	46.5 (19-77)	45 (24-73)	0.977
Operated by surgeon %	54	8	100	<0.001*
Pre-op abd tenderness, %	0	0	0	0.680
Pre-op leucocytosis	7.7 (5.3-11.4)	7.7 (5.3-11.4)	7.6 (5.4-9.0)	0.862
Pre-op CRP	5 (1-195)	8.4 (2-195)	3.2 (1-16)	0.056
Pre-op bilirubine	12.4 (7.3-24)	13.5 (10.1-24.0)	12 (7.3-23.0)	0.174
Pre-op Alk. phosphatase	84 (53-152)	94 (64-138)	75 (53-152)	0.009*
Pre-op GGT	22 (7-126)	32 (9-126)	19 (7-64)	0.078
Cholelithiasis on US, %	100	100	100	1.000
Thick wall on US, %	17	17	17	1.000
Pericystic oedema on US%	4	8	0	0.320

p value < 0.05 was considered statistically significant

Duration of the operation

The duration of the overall operating room stay was significantly longer in the RC group compared with the LC group (2:30 vs. 1 :59). No significant difference could be found between the groups in anesthesia induction time, preparation time, or real operating time.
Time consumption of different stages of RC was compared with the number of previously performed robotic procedures in our hospital as an indicator for our experience with the robotic system. In the group of 12 patients, no significant correlation could be found between our previous robotic laparoscopic experience and anesthetic induction time (p = 0.23), preparation time (p = 0.12), operating time previous to robotic assistance (p = 0.31), operating time with robotic assistance (p = 0.51), or wound closure time (p = 0.76) using Spearman's test for non-parametric correlations. Therefore, no statistical significant decrease in operating time due to a progression in learning curve could be shown at the moment.

Post-operative recovery

Four patients developed post-operative complications. Three of them (all in the RC group) had a superficial wound infection. One patient in this group developed urinary bladder retention. Admission was 2.5 days (range 2-4), i.e. 2.7 days versus 2.3 days for the RC and CC groups respectively (p = 0.21). Pathologic examination of resected gallbladder showed no difference between both groups.

Costs

Total costs per patient were calculated. In our total study group, mean costs of admission were € 1,402.17, accessory costs € 567.47, and wage costs € 274.17. Added to the costs of outpatient clinics (€ 47.80) and, if applicable, the costs of the da Vinci®Surgical System (€ 889.18 excluding acquisition and maintenance of the robotic system), the total costs were € 2,738.76 per patient. Using a Mann-Whitney U non-parametric test for independent samples, no statistically significant difference in costs of hospital admission, outpatient clinics, accessory diagnostics, or operation theatre rent and materials used, excluding specific da Vinci®instruments, were present between both groups.

Salary costs of the LC group were calculated adding the salary costs of one surgeon, one surgical resident, and two theatre nurses, multiplied by the overall operating room stay. This resulted in costs of € 137.39 per hour during 1:59h and therefore in a total of € 273.74. Using the da Vinci®robotic system with a fourth arm, there was no need for an assisting surgical resident. Salary costs were calculated adding only the costs of one surgeon and two nurses, multiplied by the overall operating room stay. This resulted in costs of € 113.31 per hour during 2:30h and therefore in a total of € 274.57. Consequently, total salary costs for LC and RC were equal, despite a significant longer overall operating room stay in the latter group. Including the extra material costs of the specific da Vinci®Surgical System instruments (€ 889.18), this resulted in significantly higher total costs (€ 3,329.07 versus € 2,148.45; p < 0,001) compared with LC, with a difference of € 1,180.62. Characteristics of both groups are displayed in table 2.

No correlation could be found between complications and costs.

Table 2. Operative and post-operative characteristics of the study population

Total study Group	LC (n=24)	RC (n=12)	p value (n=12)
Overall operating room stay (range)	2:14 (1:09-3:14)	1:59 (1:09-3:14)	2:30 (1:24-3:10) 0.042*
Anesthesia induction	0:11	0:13	0:09 0.280
Preparation time	0:13	0:15	0:10 0.760
Real operating time	1:43	1:30	1:55 0.170
Bile spill, %	38	33	42 0.673
Wound infection, %	12	0	25 0.064
Duration of admission, days	2.5	2.3	2.7 0.208
Costs for hospital stay	€ 1,402.17	€ 1,308.83	€ 1,495.50 0.219
Costs for accessory tests	€ 567.47	€ 552.01	€ 582.92 0.567
Costs for da Vinci®System	€ 444.59	€ 0.00	€ 889.18 <0.001*
Salary costs	€ 274.16	€ 273.74	€ 274.57 0.980
Outpatient follow-up	€ 47.80	€ 47.80	€ 47.80 1.00
Total Costs	€ 2,738.76	€ 2,148.45	€ 3,329.07 <0.001*

p value < 0.05 was considered statistically significant

DISCUSSION

Robotic laparoscopic surgery provides multiple potential advantages over conventional laparoscopy. We compared our first 12 cases of fully robotic laparoscopic cholecystectomy with 12 conventional laparoscopic cholecystectomies performed during the same period in the same hospital. Primary end points were duration of the operation and costs.

Statistical analysis showed that robotic laparoscopic cholecystectomy, at this moment, is relatively time consuming. A faster operating time in the robotic group could be expected due to the potentially beneficial aid of the robotic system and the use of experienced laparoscopic surgeons in comparison with several relatively inexperienced residents in the conventional laparoscopic group. However, despite improved three-dimensional optics, improved camera stability, and increased dexterity, the use of robotics in laparoscopic surgery lead to a significant increased time consumption of 31 min compared with conventional laparoscopy in our study. Increased time consumption was described before by Ruurda et al[16] and Delaney et al[17]. whereas a beneficial effect of robotic assistance on time consumption was previously described by Sarle et al[18]. Probably, part of this increase in time consumption is due to the relative extensive effort exchanging robotic instruments, the increased time necessary to position the bulky patient-side cart, and due to our relative limited experience with robotic surgery at the moment.

Robotic assistance in laparoscopic cholecystectomy results in accessory costs of € 1,180.62 per patient. The real costs might be even higher, since increased wage costs for the anesthesiologist during this time consuming operation were not taken into account. Using the fourth robotic arm of the da Vinci®Surgical System enabled us to perform surgery with one assistant less, thereby decreasing salary costs per hour compared with the three armed robotic systems. Whether the absence of a surgeon at the operating room table side is a potential hazard in case of acute complications remains subject to debate. However, absence of a tableside surgeon (or resident) did lead to decreased salary costs per hour. Consequently, salary costs for conventional laparoscopic cholecystectomy and for robot-assisted laparoscopic cholecystectomy were similar, despite a significantly longer overall operating room time in the robotic group. Since financial resources in contemporary medicine are limited, a comparative assessment of costs and benefits should be made. Therefore, clear benefits for the patient should be indicated in order to warrant the additional costs. In more complex laparoscopic surgery, the benefits of robotic assistance may result in faster and safer performance of laparoscopic tasks[18], potentially leading to decreased operating room stay, less complications, faster recovery after surgery, and shorter admission. Eventually, these improvements may lead to decreased costs.

Secondary end points were peri-operative complications and hospital stay. In our study group, complications were rare and no differences were found between LC and RC. Hospital admission was similar in both groups. Therefore, RC using the four armed da Vinci®Surgical System was a

safe and feasible procedure that could be performed by general surgeons with limited experience in robotic surgery. However, no convincing benefits of robotic assistance were identified that could justify the associated increased costs and increased consumption of time. Safety and feasibility were described before by other authors in a variety of robotic and robot-assisted laparoscopic procedures[11-13,17]. However, to the best of our knowledge, no previous study has been reported describing the results of fully robotic laparoscopic cholecystectomy using the four-armed da Vinci®Surgical System.

The advantages of three-dimensional optics and increased dexterity offered by the robot to, for example, intra-corporal suturing and micro-suturing are not required for laparoscopic cholecystectomy. In more complex laparoscopic surgery, these advantages may result in more technical possibilities, less complications, and decreased time consumption. Therefore, in complex procedures, robot-assisted laparoscopic surgery is more likely to become cost-effective than in relatively simple procedures such as laparoscopic cholecystectomy. In our opinion, fully robotic laparoscopic cholecystectomy should be considered as a learning tool for complex robot-assisted procedures, not as a potential standard operative procedure for symptomatic cholelithiasis. Contemporary robotic and robot-assisted laparoscopic surgery is still in its infancy, and major improvements in the availability of tactile feedback and specifically designed instruments are expected soon, offering great opportunities for the future. However, more research needs to be done in order to define exact indications for robotic assistance in order to justify the increased costs and increased time consumption compared with standard laparoscopic surgery.

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Chapter 7

Robot-assisted laparoscopic Nissen Fundoplication

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DETAIL FROM: VIRGIN OF THE ROCKS
OIL ON PANEL, 1483-1486

The Christ child sits towards the front of the picture, and raises his right hand in a sign of benediction towards the kneeling John the Baptist.

ABSTRACT

Background: Laparoscopic Nissen fundoplication offers clear benefits for our patients, but requires advanced laparoscopic skills. Robotic assistance in laparoscopic antireflux surgery improves dexterity skills and shortens learning curve, possibly leading to faster, more precise, and safer laparoscopic surgery.

Methods: We review our first 11 cases of robot-assisted laparoscopic Nissen fundoplication using the 4-armed da Vinci®Surgical System, comparing them with patients who underwent conventional laparoscopic Nissen fundoplication for gastroesophageal reflux disease in the same period.

Results: Robot-assisted laparoscopic Nissen fundoplication did not result in more complications. However, the use of robotic assistance took an extra 47 minutes to complete the operation and costs were raised with an accessory €987.47.

Conclusion: The use of robotic assistance in laparoscopic antireflux surgery is safe and feasible, but results in longer operating time and higher costs compared with conventional laparoscopic surgery without proven benefit at this moment.

INTRODUCTION

Since Dallemagne et al[1] first described minimal invasive antireflux surgery, laparoscopy has become the golden standard for the surgical treatment of gastroesophageal reflux disease with good-to-excellent quality of life and functional results after long-term follow-up[2,3]. laparoscopic Nissen fundoplication results in comparable functional results[4] but faster convalescence and less postoperative pain compared with open Nissen fundoplication[5,6], allowing antireflux surgery in day care[7].
However, laparoscopic fundoplication requires advanced laparoscopic skills, probably attributing to the relatively long learning curve[8]. Robotic assistance in laparoscopic surgery allows dexterity skills to be performed faster and shortens the learning curve in simple laparoscopic tasks[9-13], possibly leading to faster and safer laparoscopic surgery. Robot-assisted antireflux surgery has been proven safe and feasible[14-16], but has up until now failed to show convincing benefits over conventional laparoscopy[17-19].
In this retrospective study we describe our first 11 cases of robot-assisted laparoscopic Nissen fundoplication (RF), comparing our results with historical data of patients undergoing conventional laparoscopic Nissen fundoplication (LF) in the same hospital and in the same period.

Material and methods

Patients

Between the first of September 2003 and the first of July 2004, 22 patients underwent minimal invasive Nissen fundoplication for gastroesophageal reflux disease. Patients were non-randomly assigned to Robot-assisted surgery (RF) or conventional laparoscopic surgery (LF). Groups were matched for age and sex. The indication for Nissen fundoplication was gastroesophageal reflux, objectivated by gastroscopy, esophageal manometry, and 24-hour pH monitoring. Exclusion criterion was age under 18 years or Nissen fundoplication for esophageal disrupture (Boerhave syndrome or iatrogeneous rupture during endoscopy).

Procedures

Conventional LF was performed using a 5-trocar technique as described by Dallemagne[1,20]. A slight modification was used, placing the 12mm subcostal trocar at the right midclavicular line instead of the left midclavicular line. The operating team consisted of one surgeon, two assisting residents, and a scrub nurse. RF was performed using a similar 5-trocar technique. The operating team consisted of one surgeon, one assisting resident, and a scrub nurse. Using a four-armed da Vinci®robotic system (Intuitive Surgical, Inc, CA, USA), there was no need for a second assistant. A 12mm trocar was placed in the midline on 2/3 from the xyphoid to the umbilicus for insertion of the 30-degree da Vinci®camera with stereoscopic vision. A second 12mm trocar just below the right subcostal margin in the anterior axillary line was used for insertion of a conventional laparoscopic liver retractor. A 7mm trocar just below the right subcostal margin in the midclavicular line was used for insertion of an atraumatic grasper and instruments for dissection. A second 7mm trocar was placed in the epigastrium, just below the xyphoid. A third 7mm trocar below the left subcostal margin was used for insertion of the needle and hemostatic clips, and introduction of dissecting and suturing devices including the 5mm handheld Atlas Ligasure®vessel sealing system (Valleylab, Tyco Healthcare Group, Boulder, CL, USA). All trocars except the right subcostal 12mm trocar containing the liver retractor were connected to the da Vinci®Surgical System. After positioning the patient in mild anti-trendelenberg position, the surgeon was seated behind the console and performed the operation, controlling the camera and three instruments. Manipulation of the liver retractor was done by the assistant. Replacement of instruments was done by the scrub nurse.

After mobilization and retraction of the left liver lobe, the gastric fundus was pulled to the left. The gastrohepatic ligament was divided along the lesser curvature of the stomach thus providing exposure of the right crus of the diaphragm. After identification of the anterior edge of the right diaphragmatic crus, the overlying peritoneum was incised. The incision was continued anterior to the esophagus to the left crus. The right crus was detached from the esophagus, leaving the posterior vagal nerve attached to the esophagus. After totally dissecting the gastroesophageal junction and the distal esophagus up into the mediastinum, a window was made by blunt dissection, inferior to the right crus. The distal esophagus was encircled using a rubber tube to manipulate the esophagus without the risk of further trauma. Dissection of the short gastric vessels was performed using the Atlas®instrument, inserted through the left subcostal trocar. The hiatal crura were approximated using two to four 2-0 prolene non-absorbable sutures. A 56 Fr gastric tube was kept in the esophagus during approximation of the hiatal crura to prevent accidental critical narrowing of the hiatus.
The gastric fundus was pulled through the window behind the esophago-gastric junction to produce a floppy 360-degree wrap. The wrap was secured with three 2-0 prolene non-absorbable sutures using the da Vinci®needle driver. After completion of the fundoplication and control of hemostasis, closure of the abdominal wall was done using vicryl polyglactin absorbable suture (Johnson&Johnson healthcare, Piscataway, NY, USA). Skin closure was done intracutanously.

Measurements

Discharge criteria were identical for all patients. Patients were discharged two days after surgery if sufficiently recovered. All patients were seen for examination and reassessment at the out-patient clinics two weeks after surgery. Accessory laboratory tests, endoscopy, or radiologic examinations were only performed on indication.
Primary end points were length of hospital stay and complications. Secondary end points were operating time and costs. Operating time was recorded separately for different stages of surgery. The overall operating room stay was defined as the total time a patient was in the operating room. This was divided into preoperative anesthesia induction time, preparation time, real operating time, and postoperative recovering time. Setup of the da Vinci®Surgical System was performed during both preoperative anesthesia induction time and preparation time. Costs per patient were calculated using costs of hospital admission and treatment, material costs for open, laparoscopic, or robot-assisted surgery and salary costs (wages per hour for attending surgeons, residents, and nurses, multiplied by total operating room stay).

Statistical Analysis

Data were stored in an Excel 97 database (Microsoft Corporation, Redmond, USA) and analysed using SPSS version 11.0.1 (SPSS, Inc, Chicago, Ill, USA). The results were analysed by the intention to treat principle. Groups were compared using Pearson's X^2 test for nominal differences. Age, laboratory test results, duration of operation, and costs were compared using a Mann-Whitney U non-parametric test for independent samples. A p value ≤0.05 was defined as being statistically significant.

RESULTS

Preoperative Characteristics

Twenty-two patients with symptomatic gastroesophageal reflux were non-randomly assigned to undergo either LF or RF. Patients were matched for age and sex. Preoperative patient characteristics are listed in table 1. One patient in the LF had previously undergone transabdominal uterus extirpation. Previous abdominal surgery in the robot-assisted group consisted of laparoscopic cholecystectomy (one patient) and conventional open appendectomy (twice). No intra-operative complications, bleeding, or conversion to another technique occurred.

Postoperative Period

In total, six patients developed postoperative complications. No wound infections occurred. One patient in the da Vinci®group developed an intestinal pseudo-obstruction due to motility dysfunction under high-dose morfinomimetics. After reduction of the analgesics, motility returned and further recovery was uncomplicated. Two patients developed early dysphagia, improving under conservative therapy. Three patients developed late dysphagia or bloating after surgery, one after RF and two after LF. One of them required surgical intervention: the LF was converted to a partial posterior Toupet's fundoplication.

Table 1
Patient pre-operative characteristics, showing the total study population (Total), the conventional laparoscopic group (LF) and the robot-assisted Group (RF)

	Total (n=22)	LF (n=11)	RF (n=11)
Age, median (range)	40 (22-65)	41 (22-58)	39 (26-65)
Sex, % male	64	64	64
Weight, mean in kg	79	77	80
Length, mean in cm	172	175	170
Pre-op reflux of food	90	82	100
Pre-op heartburn	100	100	100
Previous abdominal surgery	4	1	3

There were no significant differences between these groups

Total operating room stay was divided in preoperative anesthesia induction time (Anesth Ind Time), preparation time (Prep Time), real operating time (Operating Time), and post-operative anesthesia recovering time (Anesth Recov Time). No significant differences were found between the two different groups in preparation time, operating time, or recovering time. However, total operating room stay was significantly longer in the robot assisted group (220 vs. 173 min; p =0.028). Total costs for each group were calculated adding costs for hospital admission, postoperative diagnostic tests, material costs for surgery and salary costs of attending surgeon, assistant, and nurses. RF resulted in higher material costs than LF. Although RF could be performed with one assistant less than LF, the longer total operating room stay resulted in marginally higher salary costs, attributing to higher total costs (€ 4,363.82 vs. € 3,376.35; p = 0.033). Therefore, LF is not only the fastest, but also the most economical option. Results are shown in Table 2. When we compare our first five cases of RF with our last five cases, total operating room stay decreased from 266 to 197 minutes (p = 0.115) and operating time decreased from 222 to 150 minutes (p = 0.059), both being not significantly different.

Table 2
Patient post-operative characteristics, showing the total study population (Total), the conventional laparoscopic group (LF) and the robot-assisted Group (RF)

	Total	LF (n=22)	RF (n=11)	p - value (n=11)
Days of admission	4	4	4	0.928
No. of complications	6	3	3	0.901
Early dysphagia	2	1	1	0.867
Late dysphagia	3	2	1	0.893
Anesth Ind time	13	10	16	0.210
Prep time	18	20	15	0.166
Operating time	156	135	176	0.094
Anest rec time	11	8	13	0.236
Total time	197	173	220	0.028*
Admission costs	€ 2,244.00	€ 2,244.00	€ 2,244.00	0.405
Diagnostics costs	€ 22.36	€ 21.87	€ 22.84	0.430
Materials costs	€ 1,272.50	€ 780.00	€ 1,765.00	<0.001*
Wage costs	€ 331.23	€ 330.48	€ 331.98	0.669
Total costs	€ 3,870.09	€ 3,376.35	€ 4,363.82	0.033*

Complications are listed in absolute numbers, anesthesia insuction time, preparation time, operating time, anesthesia recovery time and Total time are noted in minutes. Costs are noted in Euros.
*p value < 0.05 was considered statistically significant

DISCUSSION

Robotic assistance in advanced laparoscopy potentially attributes to safety and feasibility. In this study, we compared conventional laparoscopic with robot-assisted laparoscopic Nissen fundoplication. Statistical analysis showed pre-operative characteristics, duration of admission, and complication rate were comparable in both groups, suggesting RF is safe and feasible. However, group size was limited and complications were rare, making it impossible to find a statistically significant decrease in complication rate.
The use of robotic assistance in antireflux surgery led to a significant increased time consumption of 47 minutes compared with standard conventional laparoscopy in our study. Increased time consumption was described before by other authors in advanced laparoscopy[17-19], in contrast to the beneficial effect of robotic assistance on time consumption in the performance of laparoscopic training drills as described before by us and by others[11,13].
Probably, part of this increase in time consumption is due to the relative extensive effort exchanging robotic instruments and due to our relative limited experience with robotic surgery at this moment. Comparing our first and our last five cases of RF showed a possible decrease in operating time and total operating room stay, although this difference was not statistically significant. Possibly, operating time will decrease further after gaining more extensive experience in robot-assisted surgery.
Robotic assistance in minimal invasive Nissen fundoplication results in accessory material costs of € 985.00 during surgery. However, using the fourth robotic arm of the da Vinci® robotic system enabled us to perform surgery with one assistant less, thereby decreasing salary costs with € 24.08 per hour as compared with conventional laparoscopy and three-armed robotic systems. This resulted in total accessory costs for the four-armed surgical system of € 987.47.

Gaining increasing experience in robot-assisted surgery and extending indications for robotic assistance might probably lead to a decrease of these accessory costs due to either decreased material costs as a result of cheaper instruments, or decreased salary costs due to faster and more efficient routine surgery leading to a shorter operating room stay.
We conclude that at this moment, robotic assistance in minimal invasive Nissen fundoplication is safe and feasible, but results in a significantly longer operating time and higher costs compared with conventional laparoscopic surgery, without proven benefit. However, we describe our first 11 cases of RF at the beginning of our learning curve. Gaining increased experience, both costs and time consumption are likely to decrease, thereby making robot-assisted surgery more cost effective. Further prospective comparative trials are needed to assess the role of robotic assistance in laparoscopic surgery.
Contemporary robotic and robot-assisted laparoscopic surgery is still in its infancy, and major improvements in the availability of tactile feedback and specifically designed instruments are expected soon, offering great opportunities for the future. More research needs to be done to define exact indications for robotic assistance to justify the increased costs and increased time consumption compared with standard laparoscopic surgery.

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Chapter 8

Robot assisted laparoscopic rectopexy

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Dis Colon rectum 2007;50(11):1825-30

DETAIL FROM: THE LADY WITH AN ERMINE
OIL ON WOODEN PANEL, 1489-1490

Cecilia Gallerani was neither wealthy nor noble. At the time the portrait was painted, she was about 16 years old and renowned for her beauty, het scholarship and her poetry. She was betrothed at the age of 10 to a young nobleman of the house of Visconti, but the marriage was called off. Cecilia became the mistress of Lodovica Sforza, Duke of Milan and bore him a son, but he chose to marry a woman from a nobler family, Beatrice d'Este.

ABSTRACT

Background: Laparoscopic rectopexy has become one of the most advocated treatments for full-thickness rectal prolapse, offering good functional results compared with open surgery and resulting in less postoperative pain and faster convalescence. However, laparoscopic rectopexy can be technically demanding. Once having mastered dexterity, with robotic assistance, laparoscopic rectopexy can be performed faster. Moreover, it shortens the learning curve in simple laparoscopic tasks. This may lead to faster and safer laparoscopic surgery. Robot-assisted rectopexy has been proven safe and feasible; however, until now, no study has been performed comparing costs and time consumption in conventional laparoscopic rectopexy vs. robot-assisted rectopexy.

Methods: Our first 14 cases of robot-assisted laparoscopic rectopexy were reviewed and compared with 19 patients who underwent conventional laparoscopic rectopexy in the same period.

Results: Robot-assisted laparoscopic rectopexy did not show more complications. However, the average operating time was 39 minutes longer, and costs were € 557,29 higher.

Conclusion: Robot-assisted laparoscopic rectopexy is a safe and feasible procedure but results in increased time and higher costs than conventional laparoscopy.

INTRODUCTION

Since Edmond Delorme first described a perineal mucosal-stripping procedure to treat rectal procidentia in 1899[1], controversy exists regarding the preferred surgical technique for the treatment of rectal prolapse. Not a single procedure has been considered a standard, because all treatment modalities show failures. In all studies, patient groups are heterogeneous and therefore incomparable, and, often, long-term recurrence has not been observed in adequate numbers. However, most authors agree that perineal procedures might be less invasive than abdominal procedures, offering successful treatment in frail elderly patients with extensive comorbidity[2-5]. A transabdominal procedure is generally considered more effective in healthy patients[6-8] and can be combined with uteropexy or colpopexy when necessary. Laparoscopic repair[9-11] seems as effective as open surgery and results in faster convalescence and less postoperative pain[12-15]. Therefore, this approach has been advocated by many authors as probably the preferred technique. Whether standard sigmoid resection should be performed to prevent constipation remains debatable[16-20]. Division of the lateral ligaments should be avoided to prevent rectal dysfunction[21]. Whether anterior rectopexy leads to better functional results than posterior rectopexy, and mesh repair results in better effect and fewer complications than suture repair, remains unclear[22].
Laparoscopic rectopexy, irrespective of the technique used, can be technically demanding. Robotic assistance in laparoscopic surgery may shorten the operating time as well as the learning curve in simple laparoscopic tasks[23-26]. Robot-assisted rectopexy has been proven safe and feasible[27-28], but until now, no study has been performed comparing costs and time consumption in conventional laparoscopic rectopexy vs. robot-assisted rectopexy.

MATERIAL AND METHODS

Patients

From January 1, 2004 through May 1, 2006, 33 patients underwent laparoscopic rectopexy for rectal procidentia. They were non-randomly assigned to conventional laparoscopic (LR) or robot-assisted (RR) laparoscopic surgery, using the four-armed da Vinci® surgical system if available. The indication for rectopexy was full-thickness rectal prolapse in all cases. Exclusion criteria were: younger than aged 18 years, patients unfit to undergo laparoscopic surgery, or "hostile abdomen" meaning patients with a medical history of extensive abdominal surgery, probably with multiple adhesions, which make them less accessible for laparoscopic surgery. Previous simple abdominal surgery was not considered a contraindication per se, nor was previous antiprolapse surgery. Both LR and RR were performed by the same surgical team.

Procedure

In the first 11 cases, a laparoscopic Wells'[29] posterior sling procedure was performed. Since July 1, 2004, general policy in our department shifted toward performing a minimal invasive d'Hoore's procedure[10] in order to minimize postoperative constipation. This change in technique was used irrespectively of the use of LR vs. RR. In LR, a five-trocar technique was used. The rectosigmoid junction was retracted to the left and a peritoneal incision was made over the right side of the sacral promontory and extended in an inverted J-form along the rectum. The right hypogastric nerve was left undamaged while opening Denonvillier's fascia in male patients or the rectovaginal septum in females. No lateral mobilization or lateral dissection was performed to maximally preserve rectal innervation. In Wells' procedure, a piece of polypropylene mesh (Dacron®) vascular prosthesis is stapled to the sacral promontory using the Endopath® EMS tacker (Ethicon

Endo-Surgery, Norderstedt, Germany) and wrapped at two sides around the lifted rectum where it is fixed on the anterolateral side, using GORE-TEX®sutures. In females with coexisting vaginal vault prolapse, the top of the vagina is fixed to the Dacron®mesh and the peritoneum is closed over the mesh. In d'Hoore's rectopexy, a 3cm x 17cm strip of Dacron®is fixed to the sacral promontory by using an endofascial tacker device (Endopath®EMS) and then sutured to the ventral aspect of the distal rectum. The posterior vagina fornix is elevated and sutured to the anterior aspect of the mesh, closing the rectovaginal septum. The peritoneum is closed over the mesh.
In RR, the same procedure is performed by using the four-armed da Vinci®Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA). The patient is positioned in a French steep Trendelenburg position. The four-armed robotic cart is positioned between the legs of the patient. Port placement is similar to that in LR, using a 12-mm robotic camera port in the infra-umbilical position and three 7mm robotic ports controlled by the surgeon from behind the console. Another 12mm trocar is placed supra-pubically to allow the assistant to retract the bladder and use the EMS stapler to fix the mesh to the promontory. Dissection and fixation is done as described in LR.

Measurements

Discharge criteria were identical for all patients. Patients resumed oral feeding within 24 hours if tolerated. They were discharged two days after surgery if sufficiently recovered and normal defecation had occurred. Laxatives were given when indicated. Accessory laboratory and radiologic examinations were only performed on indication. Primary end points were procedure time, hospital stay, and costs. Costs were calculated by using costs for hospital admission and treatment, material costs during surgery, salary costs (wages per hour for attending surgeons, anesthesiologists, residents and nurses, multiplied by the time spent in the operating room). Secondary end points were morbidity and mortality.
Statistical analysis was performed by using SPSS®12 (SPSS Inc., Chicago, Ill, USA). Pearson's X^2 test was used to compare nominal data between groups. A Mann-Whitney U non-parametric test for two independent samples was used to compare age, time, and costs. A $p \leq 0.05$ was defined as being statistically significant.

RESULTS

Preoperative characteristics

Thirty-three patients (22 females) with symptomatic full-thickness rectal prolapse were non-randomly assigned to undergo LR or RR. In the LR group, 19 patients were included; 7 underwent a Wells' procedure and 12 underwent a d'Hoore's rectopexy. In the RR group, a Wells' rectopexy was performed in four patients and a d'Hoore's procedure in ten patients. Pre-operative, operative and post-operative characteristics are listed in tables 1 and 2. In the d'Hoore's rectopexy group, eight patients had undergone previous uterus extirpation vs. none in the Wells rectopexy group.

Table 1.
Conventional laparoscopic versus Robot-assisted Rectopexy

	Total (n=33)	LR (n=19)	RR (n=14)	p - value
Pre-op characteristics				
Gender, % male	33%	29%	37%	0.618
Mean age, yrs	52 yrs	47 yrs	55 yrs	0.021*
Previous abdominal surgery	58%	71%	47%	0.167
Previous prolapse surgery	21%	29%	16%	0.375
Previous uterus extirpation	24%	36%	16%	0.187
ASA-classification	1.6	1.6	1.6	0.307
Operative characteristics				
Operating time	135 min	113 min	152 min	0.040*
Conversion	3%	0%	5%	0.383
Post-op characteristics				
Admission, days	3.9	4.3	3.5	0.527
First post-op defaecation, days	1.9	1.9	1.8	0.857
Post-op constipation > 5 days	15%	14%	16%	0.905
Incontinence Gr 0	88%	93%	84%	0.635
Incontinence Gr 1	3%	0%	5%	
Incontinence Gr 2	9%	7%	11%	
Procedure, % d'Hoore	67%	71%	63%	0.618
Costs				
Costs (salary)	€ 463.22	€ 386.35	€ 519.87	0.040*
Costs (instruments)	€ 780.00	€ 780.00	€ 780.00	1.000
Costs (use of da Vinci®)	€ 511.95	€ 0.00	€ 889.18	<0.005*
Costs (lab/X-ray etc)	€ 18.44	€ 18.04	€ 18.73	0.700
Costs (outpatient clinic)	€ 47.80	€ 47.80	€ 47.80	1.000
Costs (admittance)	€ 1,615.00	€ 1,883.36	€ 1,417.26	0.441
Costs (total)	€ 3,436.41	€ 3,115.55	€ 3,672.84	0.012*

ASA = American Society of Anesthesiologists score
* p value < 0.05 was considered statistically significant.

Operative and postoperative characteristics

Preoperative and postoperative complication rates were similar in the LR and RR groups, and also in the d'Hoore's and Wells' rectopexy group. However, average operation time is longer in robotic-assisted rectopexy (152 vs. 113 minutes) compared with conventional laparoscopy. D'Hoore's rectopexy is faster than Wells' procedure (122 vs. 162 minutes). When comparing the costs of the procedures, it is clear that RR is more expensive than LR, both in salary and robot-associated costs, leading to higher total costs (€ 3,672.84 vs. € 3,115.55; p = 0.012). When comparing Wells' procedure vs. d'Hoore's rectopexy, the salary costs are higher in Wells' procedure (€ 555.12 vs. € 417.27; p = 0.039), but the total costs remain unchanged (€ 3,446.61 vs. € 3,431.32; p = 0.620).
Postoperative constipation was defined as the inability to pass stool more than five days after surgery. Postoperative incontinence was measured using the Parks-Browning classification for fecal incontinence. Grade 1 is full continence. Grade 2 is incontinence to flatus, Grade 3 is incontinence to liquid stool, and Grade 4 is incontinence to solid stool. Operative and postoperative characteristics are shown in tables 1 and 2.

Table 2.
Wells' versus d'Hoore's laparoscopic Rectopexy

	Total (n=33)	Wells' (n=11)	d'Hoore (n=22)	p - value
Pre-op characteristics				
Gender, % male	33%	45%	27%	0.296
Mean age, yrs	52 yrs	51 yrs	52 yrs	0.985
Previous abdominal surgery	58%	55%	59%	0.803
Previous prolapse surgery	21%	9%	27%	0.228
Previous uterus extirpation	24%	0%	36%	0.022*
ASA-classification	1.6	1.4	1.7	0.084
Operative characteristics				
Operating time	135 min	162 min	122 min	0.039*
Conversion	3%	0%	5%	0.473
Post-op characteristics				
Admission, days	3.9	3.6	4.0	0.938
First post-op defaecation, days	1.9	2.0	1.8	0.344
Post-op constipation > 5 days	15%	18%	14%	0.731
Incontinence Gr 0	88%	82%	91%	0.355
Incontinence Gr 1	3%	0%	5%	
Incontinence Gr 2	9%	18%	5%	
Procedure, % da Vinci®	58%	64%	55%	0.618
Costs				
Costs (salary)	€ 463.22	€ 555.12	€ 417.27	0.039*
Costs (instruments)	€ 780.00	€ 780.00	€ 780.00	1.000
Costs (use of da Vinci®)	€ 511.95	€ 565.84	€ 485.01	0.624
Costs (lab/X-ray etc)	€ 18.44	€ 18.84	€ 18.24	0.923
Costs (outpatient clinic)	€ 47.80	€ 47.80	€ 47.80	1.000
Costs (admittance)	€ 1,615.00	€ 1,479.00	€ 1,683.00	0.984
Costs (TOTAL)	€ 3,436.41	€ 3,446.61	€ 3,431.32	0.620

ASA = American Society of Anesthesiologists score
* p value < 0.05 was considered statistically significant

DISCUSSION

Robotic assistance in advanced laparoscopy leads to high-definition stereoscopic vision and intuitive tremor-filtrated movement of instruments, potentially attributing to safety and feasibility. In this study, we compared conventional laparoscopic vs. robot-assisted rectopexy. Statistical analysis showed that pre-operative characteristics, admissions, and complication rates were similar between both groups, suggesting robot-assisted laparoscopic rectopexy is safe and feasible. However, the group size is limited, making it impossible to show a statistically significant decrease in complication rate. A follow-up study assessing functional results and complications is being performed, and results are expected soon. If robotic assistance does lead to a lower complication rate or better functional results, this could result in higher cost-effectiveness.
Robotic assistance in laparoscopic rectopexy results in a significantly increased operating time of 39 minutes. Increased time consumption in robot-assisted advanced laparoscopy was described previously[30-32] in contrast to the beneficial effect of robotic assistance on time consumption in the performance of laparoscopic excercises[23,24,26]. Probably, part of this increase in time is caused by the relatively laborious effort to change robotic instruments and to the limited experience with robotic surgery at this moment.

The use of robotic assistance leads to increased salary costs (caused by increased time consumption) and increased material costs, which results in a total increase of €557.29 compared with LR. Along with the increasing experience with robotic surgery, the time needed to perform the operation is expected to decrease, resulting in diminished salary costs. Whether material costs will decrease in time remains unclear.
The Wells' procedure seemed more time consuming than the slightly less complex modified D'Hoore's rectopexy. However, because the Wells' rectopexy was performed before July 1, 2004, whereas d'Hoore's rectopexy was performed after this date, the decreased operating time also might partly be a result of the proficiency curve. We did not find a statistically significant decreased number of patients with postoperative constipation performing d'Hoore's rectopexy compared with Wells' rectopexy, as might have been expected[22].

CONCLUSIONS

Robotic assistance in laparoscopic rectopexy is a safe and feasible procedure but leads to a longer operating time and higher costs compared with conventional laparoscopy. Although robotic assistance has excellent vision and intuitive manipulation of instruments during surgery, this study did not show objective arguments to support the routine use of robotic assistance at this time. A follow-up study that assesses functional results and recurrences after robot assisted vs. conventional laparoscopic rectopexy is being conducted, and results are expected in a few months. Further prospective comparative trials are needed to assess the role of robotic assistance in laparoscopic surgery.

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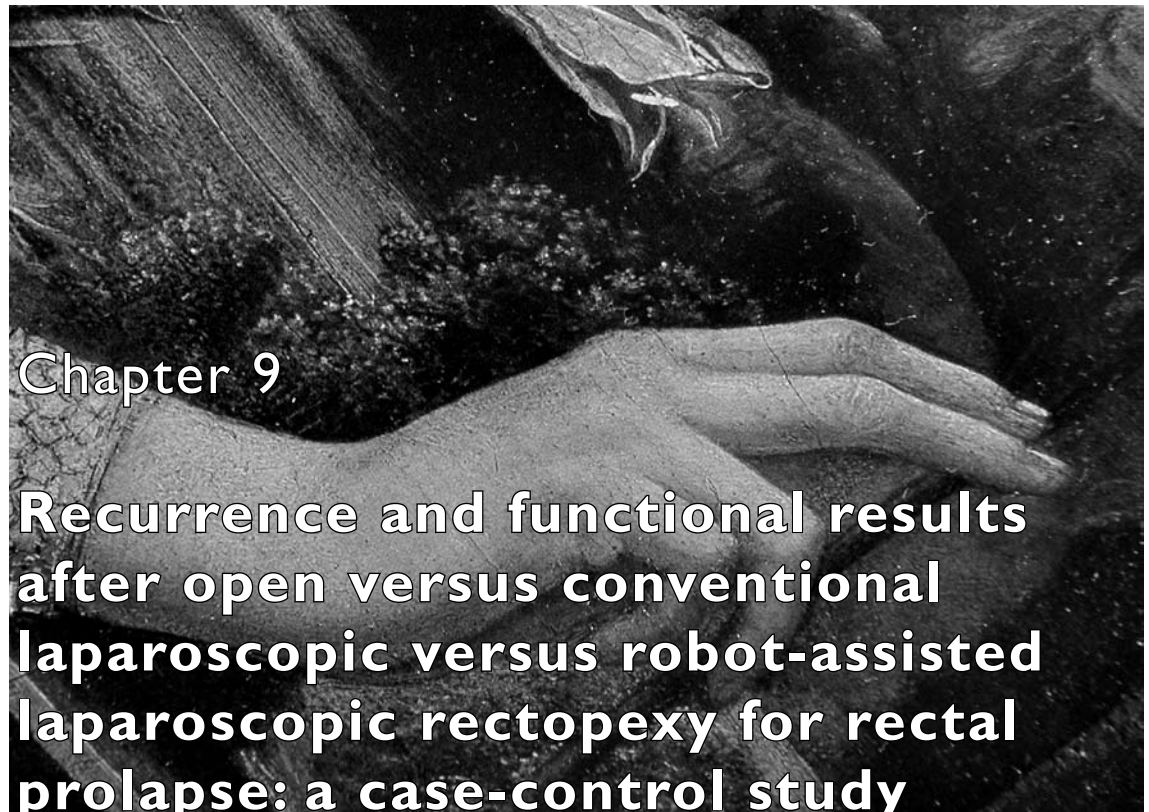

Chapter 9

Recurrence and functional results after open versus conventional laparoscopic versus robot-assisted laparoscopic rectopexy for rectal prolapse: a case-control study

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DETAIL FROM: ANNUNCIATION
OIL AND TEMPERA ON WOODEN PANEL

The angel holds a Madonna lily, a symbol of Mary's virginity and of the city of Florence.

ABSTRACT

Background: This study was designed to evaluate recurrence and functional outcome of three surgical techniques for rectopexy: open (OR), laparoscopic (LR), and robot-assisted (RR). A case-control study was performed to study recurrence after the three operative techniques used for recta l procidentia. The secondary aim of this study was to examine the differences in functional results between the three techniques.

Methods: All consecutive patients who underwent a rectopexy between January 2000 and September 2006 enrolled in this study. Peri-operative data were collected from patient records and functional outcome was assessed by telephonic questionnaire.

Results: Eighty-two patients (71 females, mean age 56.4 years) underwent a rectopexy for rectal procidentia. Nine patients (11%) had a recurrence; one (2%) after OR, four (27%) after LR, and four (20%) after RR. RR showed significantly higher recurrence rates when controlled for age and follow-up time compared to OR , (p=0.027), while LR showed near significant higher rates (p =0.059). Functional results improved in all three operation types, without a difference between them.

Conclusion: LR and RR are adequate procedures but have a higher risk of recurrence. A RCT is needed assessing the definitive role of (robotic assistance in) laparoscopic surgery in rectopexy.

INTRODUCTION

Rectal procidentia frequently occurs in older women. The male-to-female ratio is 1:6 with a peak incidence between 50 and 60 years of age[1]. Patients usually present with obstructed defecation or fecal incontinence.
Controversy exists regarding the preferred surgical technique for the treatment of rectal procidentia. The transabdominal procedure is generally considered more effective in healthy patients compared to perineal procedures[2-5] . Laparoscopic repair seems as effective as open surgery[6-9] with possible advantages such as faster recovery, less blood loss, lower medical costs, and less post-operative pain[10-13]. Therefore, many authors have advocated this approach as the preferential technique[10,11,14].
At our hospital robot-assisted laparoscopic rectopexy (RR) has been performed since 2003. The daVinci®robot combines the advantages of the laparoscopic technique, such as faster recovery and less post-operative pain, with the advantages of open surgery, namely the high-quality three-dimensional vision, restoration of the eye-hand-target axis and the use of an advanced instrument offering a full six degrees of freedom in handling[15-17]. However, there is a suspicion of a higher recurrence rate in the minimal invasive procedure as compared to the conventional procedure most likely due to the differences in fixation of the rectum to the promontory. This study was performed to investigate the effectiveness of laparoscopic rectopexy (LR) and RR compared to open rectopexy (OR) in terms of recurrence rates. The secondary goal was to determine the difference in functional outcome. This was done by measuring differences between these procedures in terms of constipation, fecal incontinence, and the impact on the patients' daily life.

MATERIAL AND METHODS

Patients

Eighty-two patients underwent a rectopexy for rectal procidentia at Maastricht University Medical Center between January 2000 and September 2006. They were non randomly assigned to open, conventional laparoscopic, or robot-assisted rectopexy. The inclusion criterion for rectopexy was full thickness rectal prolapse in all cases. Exclusion criteria for the study were age under 18 or patient unfit for surgery. Patients with a "hostile abdomen" after extensive abdominal surgery were excluded from the study as they were deemed eligible for an OR only. Previous abdominal surgery was not considered a contra-indication for LR or RR per se, nor was previous anti-prolapse surgery. All operations were performed by the same team with all extensive experience in advanced minimal invasive techniques, including laparoscopic d'Hoore's rectopexy. Patients were post-operatively asked to participate in a structured interview. Results of the questionnaire were used for analysis after informed consent was obtained.

Procedure

In the first 42 patients, a Wells' procedure was performed. After rectal mobilization a posterior mesh rectopexy was performed (first described by Wells in 1959)[18]. Since July 2004, the general policy in our department shifted from a modified Wells' procedure towards a d'Hoore's ventral mesh rectopexy in order to minimize the risk for autonomic neural damage and therefore post-operative constipation6. Ventral mobilization of the rectum was performed with fixation of the mesh to the promontory through suture or staple. The mesh was then sutured on the ventral side of the stretched rectum. In females, this procedure included fixation of the mesh to the top of the vagina or uterus.
LR and RR were performed as previously described by our unit[19]. In RR, we used the four-

armed da Vinci®Surgical System (Intuitive Surgical Inc., CA, USA). The patient is positioned in a French steep Trendelenburg position. The four-armed robotic patient-side cart is positioned between the legs of the patient. The port placement is similar in LR and RR. A 12mm port is placed in the infra-umbilical position for the camera. Three 5mm ports are placed in LR, and 7mm robotic ports are placed in RR and controlled by the surgeon from behind the console. Another 12mm trocar is placed supra-pubic to allow the assistant to retract the bladder and use a tacker (Endopath®EMS tacker, Ethicon Endo-Surgery, Norderstedt, Germany) to fix the mesh (polypropylene mesh, Dacron®) to the promontory. Dissection and fixation is done as described by d'Hoore[6].
Discharge criteria were equal for all patients. Patients resumed oral feeding within 24h if tolerated. Laxatives were given when indicated. Discharge was only approved after sufficient recovery, no intravenous analgesia, defecation, and adequate oral intake.

MEASUREMENTS

The primary outcome of the study was the recurrence rate after the various surgical techniques. Secondary outcome parameters were complications, post-operative recovery, functional results, and quality of life. The standardized Wexner constipation score was used to investigate the level of constipation before and after the operation[20]. The Parks-Browning classification was used to grade fecal incontinence[21].
The impact of the surgical procedures on daily life as judged by the patient was scored on an ordinal scale (0 is unbearable/maximally incapacitated to 10 which is no impact at all), further referred to as the IDL score.

STATISTICS

Metric data, if normally distributed, are presented as means and standard deviations and categorical data as frequencies and percentages. To test for normality of distributions the Kolmogorov-Smirnov test is used. In univariate statistics for recurrence loglikelihood chisquares, odds ratios and its 95% confidence intervals (95% CI) are presented for (risk) factors and variables examined in the study (table 1). A multivariate logistic regression analysis is used to search for statistical significance of effects belonging to these risk factors and variables. Backward elimination technique and change in loglikelihood chi-squares is used to find the best-fitting model. The final model for recurrence containing only statistically significant effects is presented as a table with net odds ratios and 95% CI (table 2). To test for differences in operating time between the three types of operations the Univariate overall analysis of variance (ANOVA) F ratio is used, and p values for separate t tests are Bonferroni-adjusted in multiple comparisons. To test for differences in post-operative hospital stay between the three types of operations the Kruskal-Wallis (K-W) test is used. For the analysis of (differences in) pre-operative and postoperative Wexner-scores (or IDL scores) paired t tests and repeated measures ANOVA were done and F ratios, df's and p -values are presented. Statistical analysis was performed using SPSS 15 (SPSS Inc., Chicago, USA). A p -value < 0.05 was defined as being statistically significant.

RESULTS

A total of 82 patients (71 females, 87%) with a mean age of 56.4 years (range, 21-88) were included and underwent OR (n=47, 57%), LR (n=15, 18%), or RR (n=20, 24%) for rectal procidentia. Eighty-two patients were eligible for follow-up. Seventy-two (90%) patients answered the questionnaire (M:F=10:62). Reasons for not taking part were: inaccessibility (four),

psychological illness (three), and unwillingness to participate (one). Two patients died during follow-up as a result of non-related causes.

Pre-operative characteristics

Forty-one (50%) patients had fecal incontinence (including grade 4 incontinence in 35 patients). Other complaints were constipation (n=29, 35%). Fifty-one of the 71 women (72%), have had a hysterectomy. Indication for previous hysterectomy was prolapse of the uterus in 25 patients (35%).

Operative characteristics

Mean operation time was 77±33 min in OR, 119±31 min in LR, and 154±47 min in RR (ANOVA F=33.37 by 2 and 79 df; p<0.001). Bonferroni-adjusted p -values for multiple tests are: OR-LR p=0.001, OR-RR p<0.001, LR-RR p=0.020. Median follow-up time in the study was 1.95 years (mean 2.6; range 0.2-8.0). There was no statistical significant difference in operation time between the Wells' and the d'Hoore's rectopexy (99 versus 107 min; p=0.192).
Thirty-five patients had a rectopexy through EMS fixation. Five patients (14.3%) in this group had a recurrence. Three out of five (60%) had documented failure of the fixation. In contrast, four out of 47 patients (8.5%) in the sutured group had a recurrence. None was documented as a release of the suture from the promontorium.

Post-operative characteristics

Patients were discharged from the hospital after a median of three days (range 1-30, SD 3.94). Mean length of stay per operation type were: OR 5.7 days (range 2-30), LR 3.5 days (range 1-14), and RR 2.6 days (range 1-6; p<0.001). After surgery, there was a large number of complications (42.7%): urine retention (3.7%), cystitis (20.7%), wound infection (4.9%), bowel obstruction (6.1%), and incisional hernia (2.4%).

Recurrences

Nine (11%) of the 82 patients developed a recurrence. Recurrences (Table 1) were more frequent after both minimal invasive rectopexy types compared to open surgery (respectively LR 27% and RR 20% versus OR 2%; p =0.008). Recurrence occurs significantly more often in younger patients in childbearing age (p=0.003), especially below the age of 40 (50% vs. 6% above the age of 60; p=0.002). Males are more likely to get a recurrence (p=0.013), and fixation of the vaginal vault (in patients with previous hysterectomy) protect against recurrence (p=0.009). Patients under the age of 40 were more likely to undergo conventional laparoscopic procedures (six out of ten). From the age of 40 OR is significantly more present (44% in the age 40-60 years and 73% above 60).
Logistic regression analysis was performed with backward elimination procedure using - next to operation type - age, previous abdominal surgery, and previous uterus surgery as possible risk factors for recurrence. Multivariate analysis was repeated for all patients (n=82), using-next to operation type and follow-up time, gender, age, and previous abdominal surgery as risk factors. The final model now includes – next to operation type and follow-up time - only age. Results of this model are presented in Table 2.

Functional results

The mean Wexner score decreased from 13.4±7.5 to 10.3±7.1 post-operatively (p < 0.001). The mean IDL score decreased from 8.3±1.5 to 4.8±2.7 post-operatively (p = 0.041). Repeated measures ANOVA was performed to test for differences in IDL- and Wexner trends for the three operation types. To test for homogeneity of the decrease in Wexner score over the

Table 1 Univariate relationships between having a recurrence and relevant (clinical) parameters ($n=82$)

Parameter	Category	N	%rec	X_L^2	p value	Odds ratio	95% CI
Operation type	OR	47	2.1	9.652	0.008*	–	–
	LR	15	26.7			16.73	1.68–164.88
	RR	20	20.0			11.50	1.195–110.641
Operation type dichotomy	Open	47	2.1	9.438	0.002*		
	Minimally invasive	35	22.9			13.63	1.62–114.98
Follow-up time (years)	–	–	–	0.116	0.734	1.07	0.73–1.56
Procedure	Well's	40	12.5	0.186	0.666	0.737	0.183–2.966
	D'Hoore	42	9.5				
Gender	Female	71	7	6.152	0.013*	7.543	1.636–34.774
	Male	11	36.4				
Age (years)				8.948	0.003*	0.928	0.881–0.978
Age (categorized)*	≤40	10	50.0			15.500	2.336–102.848
	40–60	39	5.1			0.838	0.111–6.298
	>60	33	6.1	12.015	0.002*	–	–
ASA	1	29	13.8	0.646	0.724	–	–
	2	37	10.8			0.758	0.172–3.328
	3	16	6.3			0.417	0.042–4.085
Abdominal surgery in history	No	28	21.4	4.476	0.034*	0.216	0.049–0.941
	Yes	54	5.6				
Constipation in history	No	53	11.3	0.018	0.892	0.904	0.209–3.917
	Yes	29	10.3				

%rec percentage of recurrence
*$p<0.05$ Statistically significant
[a] Reference group is age >60 years of age

different operation types the F ratio is 0.001 by 2 and 69 degrees of freedom (p=0.999). The F ratio for decrease in IDL differences between the three operation types is 1.183 by 2 and 69 degrees of freedom (p= 0.313). Therefore, no differences were found for either decrease in Wexner score or IDL score between the three operation types (table 3).
Urinary incontinence increased after rectopexy (22 patients suffered from stress, urge, or mixed incontinence before versus 27 patients after the operation). Fecal incontinence was still present in

Table 2. Final model logistic analysis results for recurrence (n=82)

	Odds ratio	p value	95% CI
Follow-up time	1.54	0.103	0.92 - 2.59
Operation		0.081	
LR vs. OR	13.94	0.059	0.90 – 215.58
RR vs. OR	24.41	0.027	1.45 – 410.65
Age	0.93	0.024	0.87 – 0.99

27 patients (33%). In 15 of the 42 (36%) patients the fecal incontinence improved after rectopexy. Fifty percent of the patients needed laxatives during admission. Twenty-nine percent of the patients were still using laxatives at time of the questionnaire. The use of the rectal irrigation pump for intractable constipation and/or fecal incontinence increased from 4% during hospital stay to 21% at time of the questionnaire.

Table 3 Means and standard deviations (SD) of both pre- and post-operative Wexner- and IDL scores for the three types of surgery examined ($n=72$)

	pre-wex		post-wex		pre-IDL		post-IDL		
Operation type	Mean	SD	Mean	SD	Mean	SD	Mean	SD	N
OR	14.30	6.603	11.15	6.762	8.25	1.581	5.10	2.468	40
LR	13.08	8.939	10.00	9.205	8.42	1.379	3.92	3.343	12
RR	11.90	8.309	8.30	6.375	8.35	1.309	4.75	2.552	20
Total	13.43	7.477	10.28	7.089	8.31	1.460	4.81	2.646	72

DISCUSSION

In this study we compared conventional laparoscopic, robot-assisted laparoscopic, and open rectopexy. However, it remains difficult to really determine the influence of either technique on the outcome in a limited population. Open surgery seems to lead to less recurrences. Several reasons may explain the disappointing results after minimal invasive rectopexy. A possible explanation might be the use of different fixation instruments or techniques.
Besides the differences in results due to technical failure, there is a possibility that OR leads to more adhesions, resulting in a more firm fixation of the rectum to the promontory and subsequently less recurrences. However, if recurrence rates are statistically corrected for age, the differences in recurrence rate for the various operative techniques become statistically non-significant. One explanation of this difference in outcome between females in childbearing age and older patients might be the fact that there was no combined rectovaginopexy with fixation of the top of the vagina in the younger group. LR and RR result in a significant increased operating time compared to OR, respectively 42 and 77 min more.
Increased time consumption in robot-assisted advanced laparoscopy was described before[13,22,23] in contrast to the beneficial effect of robotic assistance on time consumption in the performance of laparoscopic training drills[15,24,25]. Probably, part of this increase in time consumption is due to the relative extensive effort exchanging robotic instruments and due to still relative limited experience with robotic surgery at this moment.
The use of laparoscopic techniques leads to similar functional results when comparing the different parameters measured as described before, such as the constipation, incontinence, and IDL scores pre- and post-operatively.

CONCLUSION

Minimal invasive techniques (conventional laparoscopic and robotic assisted) for rectopexy can be performed safely with similar functional results but possibly at the expense of higher recurrence rates. Fixation of the top of the vagina or uterus results in better fixation and therefore less recurrences. Rectovaginopexy was performed mainly on older patients. Well-powered randomized controlled trials are needed to eliminate selection bias and assess the definite role of (robotic assistance in) laparoscopic surgery in rectopexy.

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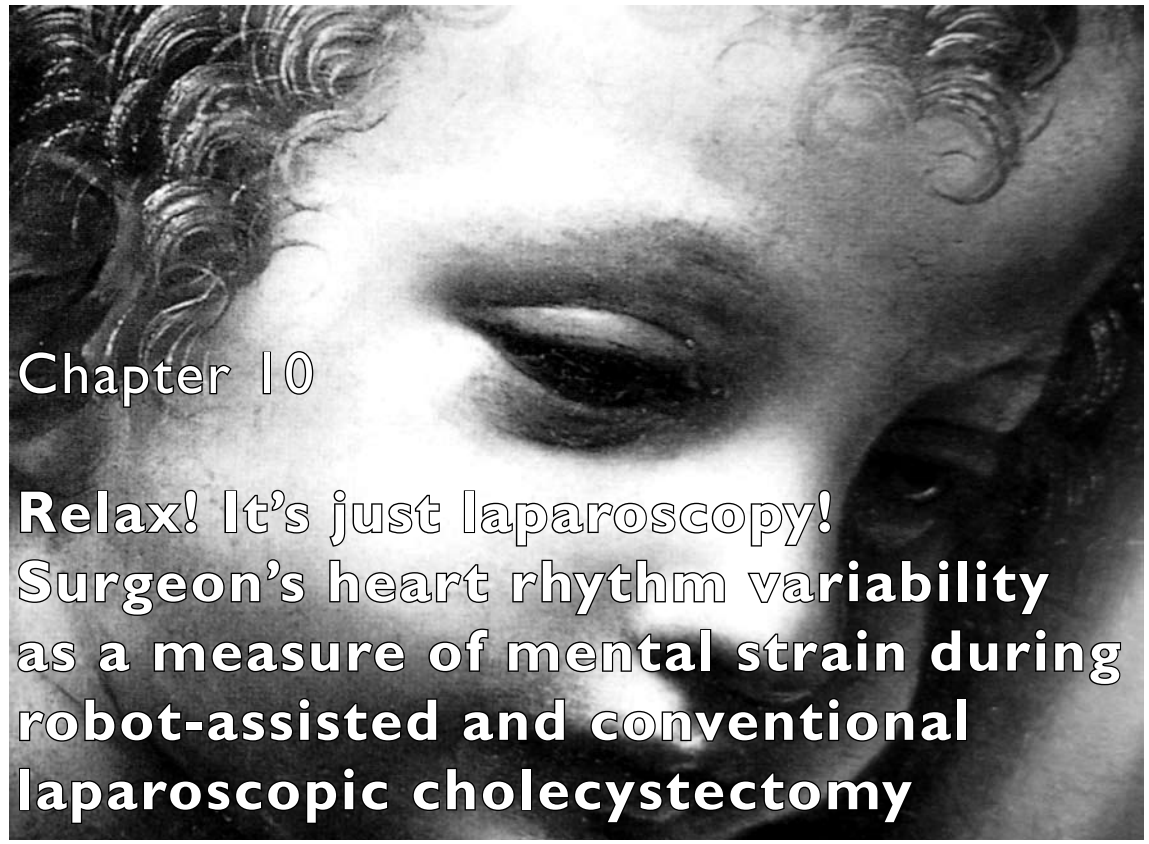

Chapter 10

Relax! It's just laparoscopy! Surgeon's heart rhythm variability as a measure of mental strain during robot-assisted and conventional laparoscopic cholecystectomy

Submitted as:

Relax, it's just laparoscopy!
A prospective randomized trial on Heart Rate Variability of the Surgeon in Robot-assisted versus Conventional Laparoscopic Cholecystectomy.
Heemskerk J, Zandbergen HR, Keet S, Martijnse I, van Montfort G, Peters RJA, Bouwman RA, Baeten CGMI, Bouvy ND

DETAIL FROM: VIRGIN OF THE ROCKS
OIL ON WOODEN PANEL, 1483-1486

John the Baptist kneels, gazing towards the Christ child with his hands together in an attitude of prayer.

ABSTRACT

Background: Laparoscopic surgery might be beneficial for the patient, but it imposes increased physical and mental strain on the surgeon. Robot-assisted laparoscopic surgery addresses some of the laparoscopic drawbacks and may potentially reduce mental strain. This could reduce the risk of surgeon's fatigue, mishaps and stress-induced illnesses, which may eventually improve the safety of laparoscopic surgical procedures.

Methods: To test this hypothesis, a randomized study was performed, comparing both heart rate and heart rate variability (HRV) of the surgeon as a measure of total and mental strain respectively, during conventional- and robot-assisted laparoscopic cholecystectomy.

Results: Both heart rate and the low frequency band/high frequency band ratio (LF/HF ratio) were significantly decreased using robotic assistance.

Conclusions: These data suggest the use of the daVinci®Surgical System leads to less physical and less mental strain of the surgeon during surgery. However, assessing significant mental strain by means of heart rate variability is cumbersome since there is no clear cut-off point or scale for critical mental strain during surgery.

INTRODUCTION

The demanding nature of surgery poses significant physical and mental strain on surgeons. Increased sympathetic activity increases mean heart rate over 120/min during surgery. Peak heart rates well over 150/min secondary to catecholamine release have been reported[1]. Although laparoscopic surgery is beneficial for patients in terms of post-operative pain, convalescence and duration of hospital admission, various drawbacks may contribute to increased mental and physical strain for the surgeon. Drawbacks include impaired visual perception of depth, use of long inflexible instruments and the fulcrum effect (movement of the tips of the instruments in the opposite direction of the movement of the handles of the instrument). In particular, advanced laparoscopic procedures compared to conventional open surgery are more time consuming and exhausting, and may thus contribute to an increase in mental strain[2]. Mental strain has been identified as a risk factor for the development of myocardial infarction, hypertension, atherosclerosis, arrhythmia, heart failure and sudden death. This might account for the impaired health of physicians and other professionals suffering from high work-related mental strain[3-6].

Robotic assistance in laparoscopic surgery addresses some of these drawbacks potentially leading to faster, more accurate and less exhausting surgery. However, despite numerous comparative studies these expected clinical benefits of robot-assisted laparoscopy over conventional laparoscopy in terms of time consumption, complication rate or cost-effectivity have not been demonstrated. Improved ergonomics from robotic assistance may reduce operative mental strain of the surgeon, leading to reduced fatigue, less complications and perhaps to a better outcome. In addition, it might reduce stress-induced illness of the surgeon.

While stress comprises all objective environmental factors influencing an individual, strain is defined as the physical and psychological effects of this stress on the individual[2]. A variety of conditions or stressors (even under defined stress conditions) may give rise to different physical responses and different perceived levels of strain. This depends on coping mechanisms, previous experience, level of training and the emotional status of the surgeon at a specific time. Therefore, perceived mental strain seems to be more relevant than stress. Although total strain is probably best assessed by measuring heart rate and physical strain is best measured by physical activity, mental strain can be best assessed by measuring heart rate variability (HRV) of the surgeon[7]. HRV is the quantitative assessment of beat-to-beat variation in heart rate reflecting parasympathetic and sympathetic control of the sino-atrial node. The autonomic nervous system is a major determinant of the functional properties of the heart in that it alters spontaneous sinus node depolarization and cardiac rhythm. Increased mental strain leads to a more regular heart rhythm and thus decreased HRV[8-10]. In particular, the low-frequency component (LF) increases whilst the high-frequency component (HF) decreases. Previously, intra-operative HRV-measurements in surgeons performing general[11] or thoracic surgery[12] showed significant increased heart rate and a decreased HRV in surgeons.

In this study, we investigated the level of experienced mental strain of the surgeon performing robot-assisted laparoscopic surgery compared to conventional laparoscopic surgery. In particular, we decided to differentiate between stress and strain. We hypothesized that the use of robotic-assisted laparoscopy might improve ergonomics and therefore might decrease mental strain compared to conventional laparoscopy, bringing heart rate variability levels back to similar levels as in open surgery while still offering the benefits of laparoscopic surgery to the patient.

MATERIAL AND METHODS

Participants

In order to minimize inter-individual variations, only two surgeons (one female and one male) participated in this study (IM and GvM). In order to reduce external influences as much as possible, pre-operative activities were standardized[13,14]. The procedures were performed after at least 7 hours of sleep the night before. Participants refrained from smoking, alcohol and caffeine-containing beverages from 24 hours before the surgical procedure. The participants were cardiovascular healthy and used no cardiac modifying medication.

ECG recording

R-R intervals were obtained from standard bipolar ECG leads connected to a recorder. The electrocardiogram recorded continuously with a sample rate of 400/s. All digital data were transferred to a personal computer after surgery for off-line analysis. Using one baseline and six well-defined stages in the surgical procedure as explained in table 1, seven interval tachograms of five minutes were selected and analysed.

HRV analysis

Since mental strain is difficult to measure, HRV was chosen as the primary end point. HRV analysis was performed according to the recommendations of the Task Force of the European

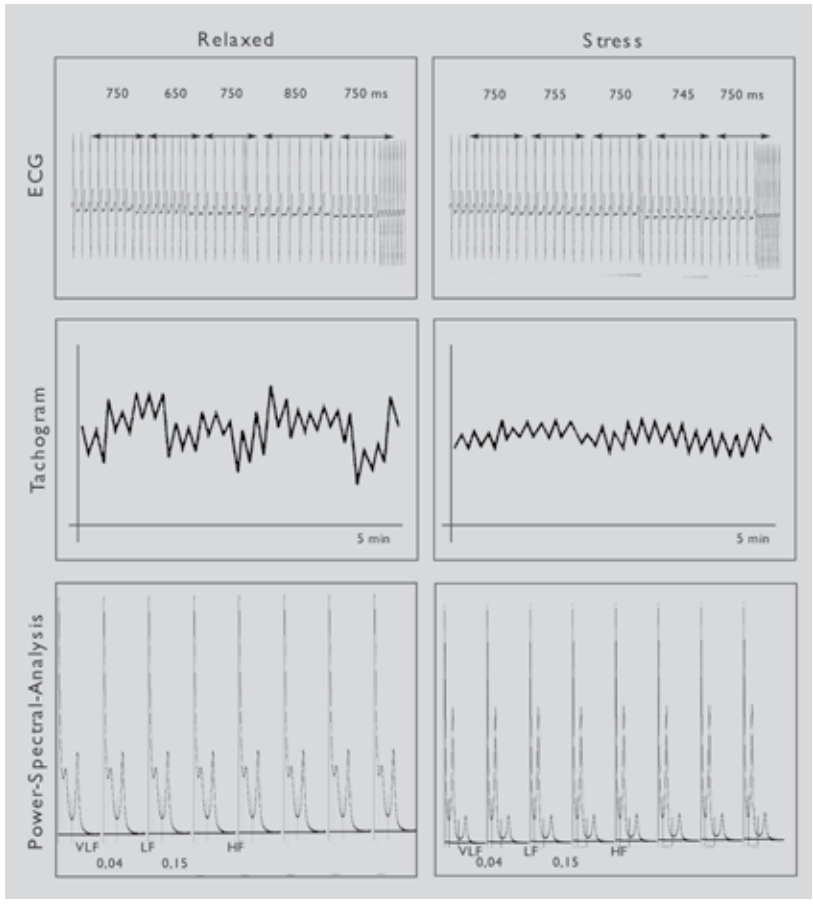

Figure 1. Heart rate variability in a relaxed state and under severe mental strain. ECG indicates electrocardiogram; VLF, very-low-frequency component; LF, low-frequency component; and HF, high-frequency component.

Society of Cardiology and the North American Society of Pacing and Electrophysiology[15]. Signals were visually inspected for premature beats, arrhythmias and movement artifacts and further analysed using free available software (Kubios HRV version 2.0, University of Kuopio, Finland)[16]. Mean heart rate and R-R intervals were analysed. From the recorded R-R intervals, this software performs spectral analysis using fast Fourier transformation, and translates the overall variability into its composing frequencies. This provides insight into what extent a frequency contributes to the overall variability of the signal. The power spectrum of HRV has been shown to consist of three peaks: the very low frequency (VLF) band (<0.04Hz), the low-frequency (LF) band (0.04 – 0.12 Hz) and the high-frequency (HF) band (0.12 – 0.40 Hz)[14,17]. Increased mental strain is closely associated with increased sympathetic and decreased parasympathetic (vagal) activity, leading to an increased LF component, a decreased HF component and an increased LF/HF Ratio[18] as explained in Figure 1.

Study protocol

In order to obtain reliable, well-comparable data, selection of a well-standardized procedure with limited variation in operation-induced mental strain to the surgeon was necessary. Therefore, only elective laparoscopic cholecystectomy procedures were studied. Procedures in patients with (a history of) acute cholecystitis were excluded. The type of procedure (conventional vs. robot-assisted laparoscopic cholecystectomy) was randomized on the day of the operation. Laparoscopic cholecystectomy was performed using a 4-trocar technique. In case of robot-assisted cholecystectomy, the daVinci®four-armed telemanipulator was used as described by Heemskerk et al[19]. Before surgery, the surgeon was connected to the Holter portable recording unit and a 5-minute baseline ECG was obtained during rest and continuously throughout the surgical procedure. One observer continuously documented any environmental factors that could influence the surgeon. Laparoscopic cholecystectomy was divided in seven well-defined stages in order to evaluate the most demanding stages of the procedure, and to allow for a proper comparison between procedures, as has been shown in table 1.

Table 1. The seven stages of laparoscopic cholecystectomy

1	Baseline
2	First incision and insertion of the trocars
3	Dissection of Calot's Triangle
4	Clip and Cut of the cystic duct and artery
5	Dissection of the gallbladder from the liverbed
6	Removal of the gallbladder
7	Closure of the incisions

Statistical Analysis

Sample size was derived by power analysis, assuming a mean LF/HF ratio of 11 in laparoscopy surgery and a mean LF/HF ratio of 7 in robot-assisted surgery. If we assume that robotic assistance leads to a HRV comparable to open surgery in surgeons with comparable expertise[2] and we accept a type I error alpha of 0.05 and a type II error beta of 0,80, a sample size n of 11 per group was calculated.

Statistical analysis was done using SPSS 19 (SPSS Inc., Chicago, IL, USA). Univariate differences between two groups were analyzed using the Student T-test for the parametric and the Mann-

table 2

	Heart Rate mean (St Dev)			VLF median (range)			LF median (range)			HF median (range)			LF/HF Ratio median (range)		
	RC	CC	p	RC	CC	p	RC	CC	p	RC	CC	p	RC	CC	p
1. Baseline	84.6 (10.4)	84.9 (5.6)	0.93	1,987 (605-39,739)	1354 (633-3737)	0.28	741 (204-2,344)	941 (370-2,755)	0.34	266 (45-2,868)	277 (145-1,102)	0.77	2.67 (0.38-8.82)	2.70 (1.54-7.51)	0.62
2. Trocar placement	82.7 (5.9)	89,2 (7,3)	0.01	609 (271-6,006)	1268 (166-4117)	0.87	965 (572-1,916)	730 (285-2,630)	0.31	447 (168-3,073)	176 (83-1,381)	0.01	2.23 (0.31-5.75)	3.30 (1.48-9.45)	0.18
3. Dissection calot	78.7 (7.9)	92,8 (6,9)	<0.001	1,746 (501-3,546)	526 (159-930)	0.01	956 (309-3,682)	436 (233-832)	0.01	308 (153-1,623)	218 (75-404)	0.05	2.26 (0.65-4.67)	2.26 (1.08-6.08)	0.67
4. Clip and cut	75.7 (9.4)	97,2 (6,7)	<0.001	1,180 (792-11,631)	581 (209-934)	<0.001	506 (255-4,846)	592 (198-1,057)	0.47	418 (184-6,037)	170 (51-374)	0.01	1.21 (0.31-2.21)	2.98 (1.66-5.60)	<0.001
5. Dissection gallbladder	75.3 (8.9)	96,2 (6,7)	<0.001	1,486 (394-11,177)	704 (107-1370)	0.03	513 (321-3,861)	436 (194-1,136)	0.16	569 (157-3,062)	171 (53-491)	0.01	1.60 (0.25-3.28)	3.12 (0.77-4.16)	0.01
6. Start removal	76.6 (11.1)	95,6 (7,4)	<0.001	1,303 (769-2,560)	864 (372-1938)	0.02	902 (270-2,220)	487 (148-1,076)	0.05	600 (164-5,000)	158 (59-444)	0.01	1.48 (0.39-2.62)	2.71 (1.34-8.50)	0.01
7. Closure	79.3 (5.6)	91.3 (4.9)	<0.001	2,350 (1,268-18,422)	845 (351-1194)	<0.001	1,829 (821-5,494)	522 (227-1,218)	<0.001	500 (179-3,399)	152 (76-248)	<0.001	2.99 (1.41-5.93)	3.48 (1.55-7.43)	0.38

Whitney U test for the non-parametric data. Primary outcome of interest was defined as LF/HF ratio of the surgeon. We tested the null hypothesis that robot-assisted laparoscopic cholecystectomy (RC) does not lead to an altered HRV with the surgeon, compared to conventional laparoscopic cholecystectomy (CC). The alternative hypotheses was that RC does change HRV compared to CC. Secondary outcome parameters were Heart Rate and VLF, LF and HF components during the surgical procedure, and duration of the operative procedure.

RESULTS

Operating time was measured, starting from first skin incision until the final suture. Robot-assisted laparoscopic cholecystectomy (RC) did take significantly longer to perform than conventional laparoscopic cholecystectomy (CC) (86 vs. 48 minutes, p=0.003). Intra-operative complications did not occur and there were no conversions in either group. The postoperative course of all patients was uneventful.

Heart rate registration and heart rate variability analysis were performed, comparing the RC and the CC group. Results are shown in table 2.

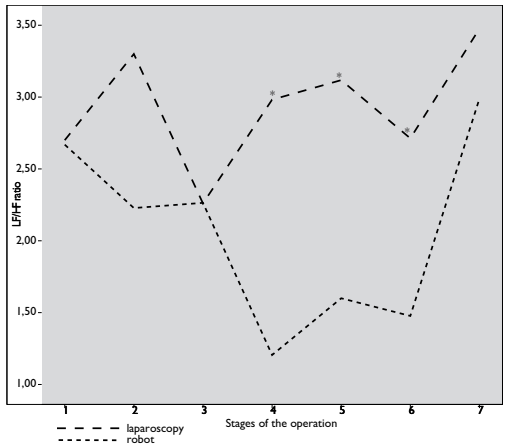

Figure 2. Heart rate during the seven stages of the operation.

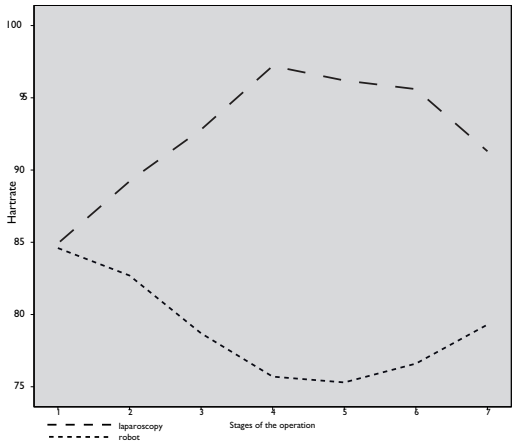

Figure 3. LF/HF ratio during the seven stages of the operation.
Interestingly, the LF/HF ratios performing RC are significantly lower then those performing CC during stage four, five and six of the operation, even despite the rather small numbers of operations.

Table 2. Mean heart Rate and VLF, LF, HF and LF/HF ratio during the seven stages of the operation. VLF, very-low frequency component; LF, low-frequency component; HF, high-frequency component; and LF/HF ratio, ratio between low-frequency and high-frequency components. RC means robot-assisted laparoscopic cholecystectomy and CC means conventional laparoscopic cholecystectomy.

Figure 2 shows the mean heart rate for both groups during the seven stages of the operation. Baseline is equal for both groups, but in the course of the operation, CC leads to a significant higher mean heart rate compared to baseline level, whereas RC leads to a lower HR compared to baseline level. As an example, during stage four (clipping and cutting of cystic artery and duct), mean heart rate increases from 84.9 at baseline to 97.2 when performing CC. However, when using robotic assistance, mean heart rate decreases from 84.9 at baseline to 75.7.

Figure 3 shows the LF/HF ratio for both groups over the seven stages of the surgical procedure. Again, baseline is similar for both groups, but during the operation, CC leads to a significant higher LF/HF ratio than RC. Figure 3 exemplifies the significant differences in LF/HF ratio during the different stages.

DISCUSSION

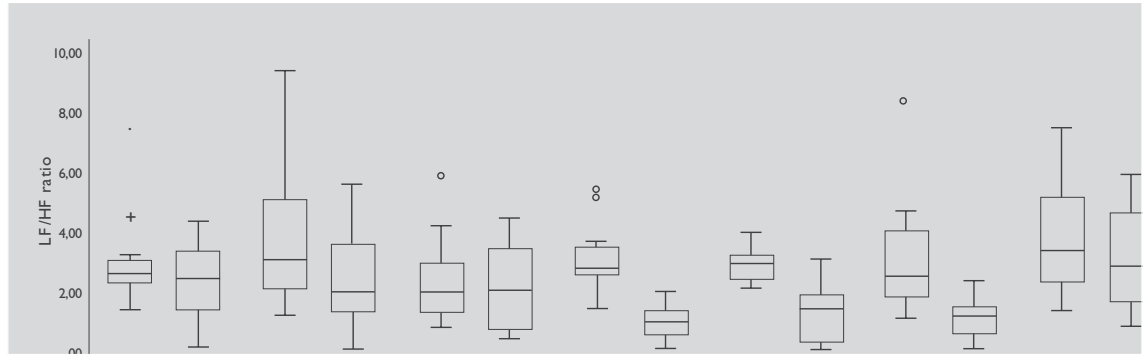

Figure 4. Boxplot diagram of the LF/HF ratio during the seven stages of the operation. RC means robot-assisted laparoscopic cholecystectomy and CC means conventional laparoscopic cholecystectomy.

robot-assisted laparoscopic cholecystectomy. Our results show that the mean heart rate during robotic assisted laparoscopic cholecystectomy is lower compared to conventional laparoscopic cholecystectomy. This suggests that the use of robotic assistance for this procedure reduces total strain, which is the combined physical and mental strain. However, mean heart rate differences alone cannot differentiate between physical and mental strain. We therefore performed HRV analysis and were able to show a significant lower LF/HF ratio in the robot-assisted procedure. This suggests that even in a common and generally considered hardly stressful laparoscopic procedure, performing a CC leads to significant mental strain and the use of robotic assistance significantly reduces this mental strain.

Surgeons generally evaluate a procedure based on the advantages and disadvantages for their patients. It is rather unconventional to assess the drawbacks imposed on the surgeon, such as increased physical or mental strain and fatigue. Our present results were quite comparable with previous publications[1,20,21], that demonstrate that increased mental and physical strain during surgery can significantly increase the surgeons heart rate till well up to 150 beats/min. Importantly, these excessive tachycardic rhythms were not limited to generally considered "high risk operations", but they also included generally considered "low risk and low strain" operations such as cholecystectomy and hernia surgery. Whether experienced surgeons really are as well adapted to this kind of stress as stated before[22] remains under debate. The fact that the vast majority of surgeons reaches these extreme fast heart rhythms during their daily occupational activities, and the fact that surgeons are at a significantly increased risk of death from ischemic heart disease compared to general practitioners[23] might suggest that even experienced surgeons might overestimate their own capability of coping with occupational strain.

Interestingly, the LF/HF ratio was lower when the surgeon used robot-assistance for the cholecystectomy. This suggests that a common and hardly stressful laparoscopic procedure leads to significant mental strain and that the use of robotic assistance seems to be able to significantly reduce this mental strain. The more ergonomic position of the surgeon and the motorized manipulation offered by robotic-assistance may reduce physical strain on the surgeon, and may explain our findings. This line of reasoning is supported by evidence of Klein et al[11], who suggest that optimal ergonomics in the operating room are able to reduce mental strain in the operating surgeon. They clearly show a decrease in postoperative physical strain and pain measurements in the surgeon working in a modern, ergonomically optimized operating room compared to the surgeon working in a standard operating room. However, other parameters substantiated their conclusions as differences in HRV parameters were not detected because of high inter- and intra-individual variation. In our study, we therefore limited our surgeons to two individuals performing well-standardized operations, leading to a lower inter- and intra-individual variation.

Looking at the different stages of the operation, it is interesting to notice that the significant difference in LF/HF ratio between CC and RC is present in stage four (clip and cut of the cystic artery and duct), stage five (dissection of the gallbladder from the liver bed) and stage six (removal of the gallbladder). During stage three (dissection of Calot's triangle) there was no significant difference. This is quite remarkable, since stage three could generally be considered one of the most stressful stages of the operation. An explanation could be, that the measurable physical effects of decreased heart rate variability due to increased sympathetic activity caused by increased mental strain, do occur only after a delay of a few minutes. In that case, the interval tachograms should probably have been selected only after a delay of three to five minutes.
Previous studies comparing HRV in conventional open surgery versus laparoscopic surgery have been published before. However, to our knowledge there have been no previous publications comparing conventional laparoscopic surgery versus robot-assisted surgery. Therefore, we are

the first to show that the use of high-tech surgical solutions such as the daVinci®Surgical System seems to be able to reduce the increased mental strain that is being put on the surgeon during the performance of minimal invasive surgical procedure. This suggests the use of robotics in minimal invasive surgery might well lead to improved ergonomics, less fatigue, and a better health of the surgeon.

LIMITATIONS

Several limitations need to be taken into account with the interpretation of the present results. Assessing mental strain by means of heart rate variability is cumbersome. This is partly due to the fact that interpretation of HRV is challenging and subject to bias. As we measured only a limited amount of participants and focused on HRV changes in time, we circumvented several of the potential sources of bias of HRV analysis. Second, previous studies have shown before that laparoscopic surgery is more demanding than conventional open surgery and puts a higher mental strain on surgeons[2]. Our study suggests that the use of robotic assistance in laparoscopic surgery might (partially) compensate for this increase in mental strain being put on the surgeon. Although reference values for short-term heart rate variability in healthy adults have been determined[24], there is no clear cut-off point or scale for critical mental strain during surgery. Furthermore, as the effects of daily recurrent increased mental strain and the potentially associated health risk for the surgeon are unclear, the exact relevance of the observation on the difference in LF/HF ratio for clinical practice remains speculative. Third, from our present results we cannot exactly discriminate the relative contribution of mental strain versus physical activity on our findings regarding HRV. However previous studies comparing laparoscopic versus open procedures have been using the HRV parameter similarly[2].

During both procedures we found remarkable high heart rates at baseline. It could be questioned whether this is a normal physiologic phenomenon, or whether the measurements were biased by the extra mental strain caused by the study-circumstances. Surgeons may not recognize this anticipative strain in themselves, but we may be underestimating the effects of surgery on the surgeon's body and mind. This is nicely illustrated by the previous publication by Foster et al[1]. In this study it was demonstrated that all surgeons that participated in their study did have significant tachycardia during surgery, even while performing quite routinely low-stress operations such as hernia repair and cholecystectomy. Interestingly, a significant rise in heart rate well over 100/min began as soon as scrubbing for an operation was commenced. The mean heart rate for the whole group in their study was over 120/min with peak heart rates over 150/min. These data suggest that significant preoperative anticipative mental strain and intraoperative mental strain do occur on a regular basis in general surgery. Considering these observations, the surgeons in our present study were not more stressed compared to the other surgeons studied before[11].

Future studies

Our study was limited to surgeons performing laparoscopic cholecystectomy, generally considered a relative low-stress well-standardized operation. It would be very interesting to see if the differences in HRV would increase if a more stressful operation would be selected such as laparoscopic total mesorectal resection or surgery for aortic aneurysm.
At this moment, the exact impact of decreased HRV on the health status of the surgeon is difficult to measure, although previous studies have shown a significant increase in potentially lethal health issues after prolonged exposure to decreased HRV[25]. More research should be performed in order to clarify whether a decrease in HRV does impose an unacceptable health risk on the surgeon and therefore should warrant stress-reducing measures such as the acquaintance of high-tech, costly, ergonomy improving tools such as the daVinci®Surgical System.

CONCLUSION

We conclude that the use of robotic assistance in laparoscopic surgery leads to significant decrease in mean heart rate and an increase in heart rate variability of the surgeon during surgery, strongly suggesting a reduction in intra-operative mental strain.

A decrease in mental strain of the surgeon could potentially lead to less fatigue, less surgical mistakes and less stress-induced illnesses to the surgeon. The continuous drive to introduce new, less invasive techniques for our patients leads to an ongoing exposure of more stress-inducing techniques to our surgeons. In an era where mean life expectancy increases and the length of the medical carrier elongates accordingly with it, prevention of work-related stress-induced illnesses might gain importance. The use of robotics could therefore potentially prove to be beneficial for the health of both patients and surgeons. Preventing work-related illnesses and associated work incapacity, the acquisition and use of a robotic surgical system might prove to be a cost-effective strategy to enable surgeons to perform minimal-invasive surgery until their retirement at old age.

The associated disadvantages such as increased operative time and increased costs have to be taken into account before a decision can be made to use or abandon robotic surgery. Until then, surgeons should be aware that if they try to accomplish multiple, prolonged and demanding procedures per day, they will probably risk the health of their patients resulting from exhaustion-induced surgical mishaps, as well as risk their own health.

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Section 4
Summary and general discussion

Chapter 11
Summary

DETAIL FROM: BENOIS MADONNA
OIL ON CANVAS, 1478

Probably the first work painted by Leonardo independently from his master Verrocchio. The painting suggests the artists was concentrating on the idea of sight. It was thought that human eyes exhibited rays to cause vision, with a central beam being the most important. The child is thought to be guiding his mother's hands into his central vision.

SUMMARY

The initial introduction of laparoscopy into general surgical practise has met major scepticism. Three decades later, laparoscopic surgery has become the standard technique in some fields of surgery such as cholecystectomy. In many other surgical fields it has become an attractive alternative to traditional open surgery, still gaining popularity. Patients benefit from reduced postoperative pain, fewer pulmonary complications, less incisional hernias and faster recovery after surgery. However, surgeons do suffer from a longer learning curve, decreased ergonomics and increased intra-operative mental strain.

Robotic surgical systems address some of these drawbacks and might facilitate endoscopic surgery. Using a master-slave concept, the surgeon still performs the operation but downscaling of movement and tremor filtration allow for increased dexterity beyond the possibilities of the human hand. The objectives of this thesis were to clarify the role of robotic assistance in laparoscopic surgery and to determine if and where the use of robotics offers significant advantages. We performed a variety of studies, both in a dry lab environment and in clinical practise.

In chapter four we focused on the advantages (and disadvantages) of the separate parts of the daVinci®telemanipulator in the performance of laparoscopic tasks in a dry lab environment. We concluded that the most significant drawbacks in conventional laparoscopy compared to robot-assisted laparoscopy were:

a) the lack of stereoscopic vision adequate restoration of the eye-hand-target axis
b) (possibly to a lesser extent) the use of rigid instruments with limited degrees of freedom

Major advances in laparoscopic surgery might only be expected if these drawbacks are adequately addressed. This seems possible using console-based telemanipulator systems such as the daVinci®Surgical System, or using a combination of a high-definition stereoscopic visual system with adequate restoration of the eye-hand-target axis such as the Viking®System in a combination with a handheld instrument offering six degrees of freedom such as the Radius®System.

The difference in learning curve between conventional and robot-assisted laparoscopic surgery in a dry lab environment was studied in chapter five. Since it is rather impossible to find experienced surgeons with equal experience in conventional laparoscopy and in robot-assisted laparoscopy, we selected inexperienced users. The presence of a relatively long learning curve in conventional laparoscopy is relevant for daily clinical practise, since learning curves are associated with prolonged operating time, increased patient morbidity and higher costs. We found that the use of robotic assistance in laparoscopic surgery leads to faster and more accurate performance of laparoscopic tasks. However, conventional laparoscopy showed a steeper learning curve and therefore faster skill acquisition. This might suggest that the advantages offered by the use of robotic assistance might be significant in inexperienced users. However, whether this leads to a faster acquisition of an adequate level of proficiency in surgeons acquiring new surgical skills in actual surgery remains under debate.

Laparoscopic cholecystectomy is one of the most common laparoscopic procedures, if not the most common laparoscopic procedure performed worldwide. In cholecystectomy, laparoscopy is generally considered the gold standard. In chapter six, we asked ourselves the question whether fully robotic laparoscopic cholecystectomy would be feasible in daily clinical practise. The use of the fourth arm of the telemanipulator enabled us to perform surgery with one assistant less. Fully-robotic cholecystectomy proved to be safe and feasible. However, operating time was 31 minutes more and costs were increased with € 1,180.62. Therefore, no significant benefits from the use of robotic surgery could be determined for the patient, the surgeon or the hospital.
Laparoscopy is considered the standard of care for anti-reflux surgery. One of the most common performed anti-reflux procedures at this time is laparoscopic Nissen fundoplication. However, this procedure is generally considered technically more demanding than laparoscopic cholecystectomy. The use of robotic assistance in such an advanced procedure might be more beneficial than in a relatively less advanced procedure such as cholecystectomy. In chapter seven we studied patients undergoing either conventional laparoscopic or robot-assisted laparoscopic Nissen fundoplication. Robot-assisted laparoscopic Nissen fundoplication proved to be safe and feasible in this study, but resulted in an increase of the operating time of 47 minutes. Costs were increased by € 987.47. Therefore, no significant benefits from the use of robotic surgery could be determined for the patient, the surgeon or the hospital.

We focused on laparoscopic d'Hoore's rectopexy for full thickness rectal prolapse in chapter eight. This procedure might be considered even more technically demanding because of the restricted working space in the narrow pelvis, and the increased need for suturing and for subtle manipulation of the tissues. Again, robot-assisted laparoscopy proved to be safe and feasible, but resulted in an increased operating time of 39 minutes and increased costs of € 557.28. No significant benefits from the use of robotic surgery could be determined for the patient, the surgeon or the hospital. Peri-operative results after robot-assisted and conventional laparoscopic d'Hoore's rectopexy might be similar, but this study was not focused on long term functional results.

In order to study late results after rectopexy, We conducted a study described in chapter nine. We focused on the long-term results and recurrence rates after conventional open, conventional laparoscopic and robot-assisted laparoscopic surgery.
In our study, recurrence rate after open surgery was a mere 2% compared to 27% in conventional laparoscopic surgery and 20% in robot-assisted rectopexy. The difference between open surgery and minimal invasive techniques was significant. There was no significant difference between conventional laparoscopy and robot-assisted laparoscopy. Functional results, defined as a post-operative decrease in Wexner Incontinence Score or a decrease in IDL score compared to pre-operative scores, were similar in all three groups. Therefore, no significant benefit of the use of robotic surgery could be determined

In chapter ten, we shifted our focus from the effects on the patient (in terms on safety and complications) and society (in terms of costs) to the potential detrimental effects of laparoscopic surgery on the surgeon. This is a quite uncommon focus for medical research. The effects of newly developed surgical techniques are generally measured mainly (if not exclusively) by their direct effects on the patient (in terms of post-operative pain and complications, tissue damage, time-to-recovery, functional and aesthetic results, Quality Of Life and chance of recurrence) or they are focused on the impact on the health system (in terms of costs, operative time and duration of admission). However, we know that newly developed, minimal invasive techniques might be advantageous for our patients but may be quite demanding, exhausting and harmful to the surgeon. Increased mental strain to the minimal invasive surgeon is closely associated with decreased heart rate variability (HRV), impaired health and limited life expectancy. Although adverse health effects to the surgeon are difficult to measure, the physical effects of mental strain can be measured as a precursor for stress-induced health risk.
In this clinical study, we measured heart rate variability of the surgeon performing actual conventional laparoscopic or robot-assisted laparoscopic cholecystectomy in general daily

practise. Previous studies have shown that conventional laparoscopic surgery leads to significant increase in heart rate and LF/HF ratio, suggestive of increased mental strain. The use of robotic assistance during laparoscopic cholecystectomy resulted in an significant decrease in heart rate and an increase of heart rate variability during various stages of surgery. This strongly suggests a significant reduction of intra-operative physical and mental strain. At this moment, interpretation of these results is challenging since the exact impact of decreased heart rate variability on the health status of the surgeon is difficult to measure. However, previous studies have shown a significant increase in potentially lethal health issues after prolonged exposure to decreased heart rate variability. These results suggest that surgeons should be aware that if they try to accomplish multiple prolonged demanding laparoscopic procedures per day without the use of robotic assistance, they will probably risk the health of their patients resulting from exhaustion-induced surgical mishaps, as well as risk their own health.

CONCLUSION

The studies described above suggest that the use of robotic assistance in a dry lab environment leads to faster and more accurate performance of laparoscopic tasks. However, in daily clinical practise, the advantages of the use of robotics are disappointing. Robotic surgery takes longer to perform and is more expensive. The most significant advantage of the use of robotics, might be the increased ergonomics and subsequent reduction in mental strain of the surgeon. This might potentially lead to a reduction in operative complications for the patient and a decrease in potentially lethal health issues for the surgeon.

Chapter 12

The end of robot-assisted laparoscopy?

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The end of robot-assisted laparoscopy? A critical appraisal of scientific evidence on the use of robot-assisted laparoscopic surgery.
Heemskerk J, BouvyND, Baeten CGMI. Surg Endosc. (epub ahead of print)

DETAIL FROM: VIRGIN OF THE ROCKS
OIL ON WOODEN PANEL, 1483-1486

The Virgin of the Rocks (or Madonna of the Rocks) is the name used for two similar paintings by Leonardo da Vinci. The version belonging to the National Gallery in London, shows the eyes of the angel turned down in a contemplative manner. The other version of the painting, belonging to the Louvre Museum, Paris, shows the eyes of the angel staring at the direction of the viewer.

ABSTRACT

Robot-assisted laparoscopy has been used in a wide variety of surgical fields. However, the financial costs involved are high and convincing proof of superiority in terms of Quality of life, cost-effectiveness and survival is often lacking. However, there might be small benefits for the patient or for the surgeon's health that might warrant the use of robotics in limited fields of surgery. In an era of world-wide economic crisis, it is about time to start a critical discussion whether we should drastically limit, or even abandon, the use of robot-assisted laparoscopic surgery and focus on more cost-effective strategies of health care improvement.

INTRODUCTION

The era of telemanipulator systems in minimal invasive surgery started with the introduction of the Automated Endoscopic System for Optimal Positioning (AESOP). In 1994 this system was approved by the US FDA as the first surgical "robot" ever. Since the introduction, many prototype advanced manipulator systems have been developed. However, introduction to the field of surgery and delivering solid proof of its added value remains cumbersome.

In 2000 the daVinci®Surgical System was approved by the US FDA for general laparoscopic surgery, and at this moment it is the only commercially available "robotic" system offering an integrated stereoscopic visual system with a motorized telemanipulator. The term "robot" might, semantically speaking, be outplaced here, since this suggests the presence of an automated process instead of a technically advanced distance-controlled integrated visual and manipulator system. However, over the last decade, this term has been (mis)used at such an extend in the field of advanced minimal invasive surgery in order to address the daVinci®Surgical System, that the two terms have become synonymous. Therefore, we will use both terms interchangeable in this manuscript.

Almost 2000 daVinci systems have been installed worldwide and the number of indications seems to grow rapidly in a wide variety of field, including urology, gynaecology and general, cardiothoracic, paediatric and gastrointestinal surgery. The use of the system has been proven safe and feasible, but costs are high and clear medical benefits are difficult to prove. In the Netherlands alone, eighteen hospitals have already invested significant sums to acquire twenty robotic systems. After more than 10 years of extensive use and living in an era where an economic crisis forces us to optimize resource utilization and critically reconsider every penny we spend on health care, the role of robotic assistance in laparoscopic surgery merits robust evaluation.

Introducing new technology in medicine is intended to improve disease management either by leading to an increased survival, an enhanced Quality of Life (QOL) or reduced costs. In considering the cost-effectiveness of robotics, one must first consider what the potential benefits are and then determine whether these additional benefits justify the additional costs. Looking at the extensive field of indications, it is practically impossible to evaluate every operation in every field of surgery. Therefore we will try to limit ourselves to some of the most used and best evaluated operations.

CURRENT STATUS OF THE STANDARD DAVINCI®SURGICAL SYSTEM

General Surgery

Thyroidectomy has been used for benign and malign lesions of the thyroid gland. Minimal invasive thyroidectomy has been introduced in order to minimize visible scar formation in the neck. The main advantage compared to conventional thyroidectomy seems to be the improved cosmesis and patient satisfaction, while leading to a safe and radical excision of the thyroid. Minimal invasive thyroidectomy (either via the axillary, the anterior neck or a combined approach) leads to a longer operative time and more postoperative pain[1]. The open operation is generally considered the gold standard.
Robotic assistance has been used but there is no sound proof whether this leads to a faster[2] or slower[3-5] operative procedure compared to minimal invasive surgery. No significant medical advantages have been identified resulting from the use of robotics in minimal invasive thyroidectomy. Compared to open thyroidectomy, there is little evidence of superiority except for possibly improved cosmesis[6,7].

Gastro-intestinal Surgery

Colon resections are performed frequently for the treatment of colon carcinoma. Laparoscopic Colon resection has been performed and studied extensively following the introduction and success of laparoscopic cholecystectomy. Numerous well-developed Randomised Clinical Trials have shown that conventional laparoscopic colectomy is safe and feasible if performed by a well-trained surgeon, offering short term benefits and a faster recovery after surgery without compromising oncologic outcome[8-12]. There is no consensus whether laparoscopic or open colectomy should be considered the gold standard.
The use of robotics in laparoscopic colectomy is safe and feasible[13-16] but seems more time consuming and more expensive[14,16-18] without significant medical advantages over conventional laparoscopy.

Laparoscopic rectum resection is generally considered to be technically more demanding than laparoscopic colon resection. Working in a small confined space where nerves could risk inadverted damage, the potential benefits of the daVinci®Surgical System could possibly be higher. However, laparoscopic rectum resections have been performed safe and feasible without robotic assistance and with results at least equal to open surgery[15,19-21]. The use of Robotic assistance leads to a comparable or longer[22-25] operative time and to similar oncologic outcome and post-operative complications compared to conventional laparoscopic surgery[26-29]. Recovery and return of sexual function might be equal or possibly slightly faster after robotic surgery[30].

Abdominal rectopexy has been performed as a treatment for full-thickness rectum prolapse. In western Europe, the laparoscopic anterior mesh technique as described by d'Hoore[31] is one of the most frequently used, resulting in excellent long term results with minimal complications[32-34]. Generally, laparoscopic rectopexy is considered the gold standard.
Robotic assistance has proven safe and feasible[35] with a comparable recurrence rate, complication rate and functional results compared to laparoscopic surgery[36]. However, the operative time seems to be longer and costs are higher in robot-assisted laparoscopic rectopexy[35].

Nissen fundoplication has been performed as an anti-reflux procedure extensively. The laparoscopic Nissen fundoplication is generally considered the gold standard for anti-reflux surgery over the last few years, offering a successful treatment for adults and children[37],

potentially performed in day care. Both short-term results [38] and in long-term follow-up[39-41], results are excellent while recovery after laparoscopic surgery is faster[42,43] than after open surgery. Incisional hernia appeared significantly more frequent after open surgery as compared to laparoscopic surgery [44,45]. Introduction of the daVinci®Surgical System leads to similar results [46], but is more expensive [47-51].

Roux-en-y Gastric Bypass has been performed as a bariatric procedure. The laparoscopic procedure has taken an impressive flight in the last few years as one of the most effective and frequently performed bariatric operations. In expert centres, hundreds or even thousands of these operations are performed annually with limited morbidity and mortality. Laparoscopic RYGB results in a faster recovery, shorter length of stay, lower morbidity, lower mortality and lower costs compared to its open counterpart and should be considered the gold standard at this time[52-54].
The use of robotic assistance results in similar postoperative functional results and complications[55]. There is no agreement whether the use of the daVinci®Surgical System leads to a shorter[56] or longer[57-59] operation time. The costs associated with the use of robotics are generally considered higher[58-60], although some studies suggest lower costs[61]. This difference might be due to a difference in operative techniques, use of staplers and other surgical devices, and a difference in complication risk and length of stay.

Thoracic surgery

Thymectomy for Myasthenia Gravis is an invasive operation, traditionally performed by transsternal approach. Using Video-Assisted Thorascopic Surgery (VATS), the procedure can be performed equally effective with a decreased need for post-operative ventilation and decreased length of stay in both adults[62-64] and children[65,66]. The use of the daVinci®system is safe and feasible, offering enhanced post-operative recovery compared to transsternal approach[67-71]. Unfortunately, no randomized trials have been published, comparing the results of traditional VATS thymectomy with robot-assisted thymectomy.

Lobectomy for early stage non-small cell lung cancer is a frequently performed procedure. The traditional open approach using a thoracotomy is considered painful, potentially attributing to frequent pulmonary complications and a relatively long length of stay. VATS-lobectomy is safe and feasible[72], leading to similar[73-76] or even better[77-79] oncologic results as the open approach, in combination with faster recovery.
The use of robotic assistance is feasible[80-83] and does arguably lead to similar[84], better or worse[85] results. Adequately powered well-balanced studies comparing VATS with robot-assisted lobectomy are lacking[86].

Gynaecology

Hysterectomy has been used for benign indications and for the treatment of early stage cervical cancer. In general, operative times for laparoscopic resection seem longer than for open surgery, but recovery after surgery is faster and oncologic outcome is similar[87,88]. The use of the daVinci®Surgical System has been used and evaluated repeatedly. The robotic procedure is safe and feasible[89] and blood loss might possibly be marginally less[90], but operative time seems longer[90-94] without significant advantages in postoperative outcome compared to conventional laparoscopic surgery. In general, robotic assistance seems significantly more expensive[91,92,94].

Sacrocolpopexy has been developed as a treatment for management of apical prolapse. Abdominal suspension of the vaginal apex results in superior results compared to transvaginal procedures.

Laparoscopic sacrocolpopexy results in significantly less blood loss and less postoperative pain compared to abdominal surgery, leading to faster convalescence[95]. Therefore, laparoscopic sacrocolpopexy should be considered the gold standard. It is not clear whether the use of robotic assistance leads to a faster[96] or slower[97] operative procedure compared to conventional laparoscopy. Including the set-up time of the daVinci®Surgical System, time consumption seems more. Costs are significantly higher when using robotics[97]. In a comparison of robot-assisted sacrocolpopexy vs open sacrocolpopexy, the latter technique seems more expensive due to a longer admission[98,99].

Urology

Laparoscopic nephrectomy has been used as a less invasive alternative to open (and often painful) nephrectomy in renal cancer[100], leading to similar oncologic results[101-103]. The use of a daVinci®telemanipulator has been studied in mainly small and underpowered trials[104,105] but seems to result in a more time-consuming operation compared to open[106] or laparoscopic[107] surgery. The results and complications seem comparable[106-110], but costs seem significantly higher[104,108-110].

Laparoscopic radical prostatectomy (LRP) for prostate cancer has been introduced as a technically demanding but less invasive operation compared to the open retropubic radical prostatectomy (RRP), leading to less blood loss and similar oncologic results compared to retropubic surgery[111]. However, conventional LRP is considered an extremely demanding operation and only few urologists are capable of performing this kind of surgery safe without robotic assistance. Comparing LRP to Robot-Assisted Radical prostatectomy (RARP), oncologic results seem similar[112-114] but long term results of RARP concerning urinary continence and erectile function 1 year after surgery might possibly be slightly better[114-116].
An adequate comparison between RARP and LRP is difficult to perform, as many urologists do not perform LRP. Compared to RRP, the use of a robot seems to lead to equivalent oncologic results[112,116-118]. Recovery of potency and urinary continence might be marginally better after robotic surgery[119] although scientific evidence is weak. Generally, RARP is considered more expensive than both open and conventional laparoscopic prostatectomy[120-123].

New developments in robot-assisted laparoscopy

The daVinci®S Surgical System: The next generation has arrived!
Intuitive Surgical has developed a new generation robotic systems, offering improved manoeuvrability and increased working space. There are several advantages of the newly developed daVinci®S and daVinci®Si Surgical Systems over the current standard daVinci®system. The new generation robotic systems has undergone significant structural and functional modifications, affecting their respective applications. Some of the major differences are:
• An increased range of motion. The arms of the standard daVinci®system allow for a rotational-axis-range-of-motion (yaw) of 180 degrees. The newly designed and optimized instrument arm design of the daVinci®S and Si yields a yaw of 336 degrees, increasing manoeuvrability and instrument workspace. Workspace refers to the total physical area that can be reached by an Endowrist®instrument once it has been attached to one arm of the patient side cart.
• An increased instrument length. The newly developed instruments are five centimetres longer than the standard daVinci®instruments. In combination with the increased range of motion, the use of these longer instruments leads to an impressively increased instrument working space by over a factor three. To reach the same anatomy as the standard daVinci®system, the new systems require less patient cart and arm adjustments.
• Improved third arm access. The new generation patient-side cart contains the third instrument

arm on the top, allowing for better manoeuvrability and less instrument collisions.
• Slim telescopic arms. The new generation patient-side cart has been equipped with instrument arms with a slim profile and telescopic design, minimizing intra-operative interference and collisions.

The daVinci®Si Surgical System: Single incision laparoscopy made easy

One of the recent developments in laparoscopic surgery, is the trend to minimize the number of trocars used during surgery. Theoretically, the use of less trocars might reduce postoperative pain and trocar-related complications. Ultimately, this leads to a form of surgery using only one trocar, generally referred to as Single-port, Single-access or Single-incision laparoscopic surgery. At this moment, single access surgery using conventional laparoscopic (or slightly adjusted) instruments is considered technically demanding due to frequent collisions of instruments and limited workspace. Although there are no convincing studies showing significant clinical benefit from single access surgery over conventional laparoscopy, development of this technique is booming. The use of robotics might prove to be indispensable in the performance of technically demanding single access procedures.

The daVinci®Si system has specially been developed in order to be used in single-access minimal invasive surgery. The use of robotics might lead to easier adaptation of this technically demanding technique, potentially minimizing tissue damage and leading to faster convalescence.

The Firefly®Fluorescence Imaging System: enhanced visualization of crucial structures
The image offered by the standard daVinci®Surgical System consists of high-definition stereoscopic vision. A further increase in the number of pixels (in order to increase sharpness of the image) of image refresh rate (in order to decrease flickering and reduce eye strain) is generally considered not significantly useful in improving surgical performance. One development that could contribute to increased safety and better surgery, is the application of image enhancement. Using fluorescence, vital structures can be made visible that could not be seen with the human eye using plain white light.
Intuitive Surgical has developed a new tool named the Firefly®fluorescence imaging system. By switching from conventional white light to fluorescency, crucial anatomical structures such as hepato-biliary structures can be made easily visible, potentially leading to safer surgery and preventing inadverted common bile duct lesions. This optional tool could for example be used for assistance in single access cholecystectomy using the daVinci®Si system.

DISCUSSION

Since the introduction of the daVinci®Surgical System, the number of robotic systems has risen dramatically in countries across the world. Despite the extensive experience in the past years in various fields of surgery, gynaecology and urology, there is little evidence of superiority of the robot-assisted procedures over conventional laparoscopy. Well-designed and adequately powered, blinded, randomised controlled trials are scarce and the risk for publication bias is significant[124,125].
Historically, the implementation of new technology in medicine has always outpaced the available sound data to support its rapid adoption. However, in the contemporary situation of an economic crisis disturbing the economies in Europe and (probably to a lesser extend) the rest of the world, it will be considered absolutely inacceptable to introduce these new and highly expensive techniques in any field of medicine as the new standard of care, without offering or at least

searching for robust evidence of significant improved survival, cost-effectivity or Quality of Life. The use of robotics adds approximately between 600 and 3000 Euro per procedure compared to conventional laparoscopy. This is an impressive cost without evidence of improved outcome. Our patients and the society in general, would be better off if only a fraction of that sum would be spend on additional training and further differentiation of surgeons and residents who could perform laparoscopic procedures without robots more cost-effectively. Comparative-effectiveness studies are indispensable before standard widespread adoption of robot-assisted surgery can be considered.

Besides considering the added financial costs associated with robotic surgery, a second concern is safety and the generally prolonged duration of the operation. Although the daVinci®system has been FDA approved as a surgical tool for minimal invasive surgery, the lack of tactile feedback associated with this system does potentially cause a serious threat to our patients. Besides this, there is no general agreement on the exact mean time added to the operative procedure when robotic assistance is used, but most publications show a longer duration of the operation in robotic surgery and therefore an increased exposure to anaesthesiology-associated risks and side-effects without significant benefit of robotic assistance.

Various arguments have been used to advocate the contemporary trend to increase the use of robotic devices. Patient demand has often been used as one of the most common mentioned arguments, or as an excuse, to the growing use of robotics. Even in professional literature, it has recently been stated that “well developed randomized controlled trials comparing conventional laparoscopy with robot-assisted laparoscopy have not been performed yet. Unfortunately, that ship has sailed. At this moment, such trials seem infeasible to conduct since our patients will choose robot-assisted laparoscopy based on the information available”[126].
However, in an era of evidence-based medicine, such a patient demand cannot be granted if not supported by sound evidence. The source of this patient demand is more likely to be industry-driven and hospital-driven marketing, than the limited evidence of clinical superiority that is now available. Prof. dr IA Broeders has stated that “in countries where the health care system is more commercial than in The Netherlands, the daVinci robot is being used as a marketing tool”[126].
It does not seem unthinkable that exact the same marketing potential is being used (or abused) in our country, although possibly to a slightly lesser extent. Only in the field of minimal invasive radical prostatectomy for prostatic cancer, scientific evidence suggest a slight potential advantage in improved sexual function and possible better urinary continence postoperative after the use of robotic assistance. Whether a potential marginal improvement of sexual function in an individual 70-year old patient should justify a mayor increase in health care costs to the society should be subject to an honest and open debate.

A second argument that seems to play a significant role in the contemporary Dutch medical society, is the “Fear Of Missing Out”, also known as FOMO. Medical professionals feel a continuous drive to improve the care and cure they deliver. They are constantly looking for new techniques and methods. Failure to become and stay a trendsetter or early adjuster does result in the fear of being left behind in important new developments. This might initially sound somewhat overdone, but it certainly is not an unrealistic fear. Contemporary developments in the Dutch healthcare system, stimulating competition between different health care providers, do actively stimulate such behaviour.
Various organisations including the Dutch Health Care Inspectorate, Health insurance companies and patient support groups have developed an attitude of “Quantity equals Quality”, requiring certain minimal numbers of specific operations per hospital and per surgeon in order to improve

quality. Despite scientific lack of proof supporting such regulations, various hospitals perceive difficulty in reaching the required minimum numbers of these operations, potentially leading to an interdiction to deliver such care irrespective of the real quality of the delivered care. Hospitals are directly threatened in their existence, and so are the jobs of medical professionals working in these institutions. A failure to attract sufficient numbers of patients with a strong marketing tool such as an operating robot, can make the difference between a thriving referral medical centre and a marginalized insignificant clinic balancing on the edge of bankruptcy. This is not a theoretical doom scenario for small hospitals, it is every day practise. Only a health care system that would refuse to reimburse the increased costs associated with robotic surgery in all surgical fields where its value has not been sufficiently scientifically proven, would stimulate the realistic use of the daVinci®Surgical System where it is medically useful. It would be used as a research tool and (probably in limited cases) as an advanced surgical tool, not as a marketing tool. The contemporary system leads to a situation where relative small hospitals cease to deliver specific forms of care, leading to an increased scale of the larger institutions. Only a few relative large Medical Centres, assured of sufficient numbers of patients, can easily afford to withstand the pressure to comply to the demand of such "False innovation" or "Pseudo-innovation", as it is named by oncologist Ezekiel Emanuel in the New York Times[127]. In the Academic Medical Centre Amsterdam, the deliberate decision has been made not to invest in robotic surgery. The managing director has stated "Such false innovations, or probably better named exnovations, should not be implemented in an effective and efficient health care system"[128].

The third argument to advocate the use of robotics is its magnificent potential benefits of stereoscopic magnification, increased precision, miniaturization, tremor filtration and articulation beyond human manipulation, potentially leading to improved outcome in the future. In a truly open-minded scientific atmosphere, leading forms of technology should be offered the possibility to be pursued within a critical context. Yes, we do believe new technologies should be developed and carefully introduced to medical practice. It is definitely not our intention to thwart technical and scientific progress in the field of surgery. On the contrary. It is our goal to aim for a scientific atmosphere where our limited financial resources are spend thoughtfully, leading to optimal efficacy of every penny spend on health care and on research. Therefore, as long as evidence of superiority is lacking, introduction of these tremendous costly technologies should be limited to research facilities within well-designed research projects and should not be extended to normal daily practise. There is no good argument why new surgical technologies should not be subject to the same strict rules as applied to newly developed medication. Well powered studies are mandatory before the widespread adoption of robot-assisted laparoscopy over conventional laparoscopy or even open surgery can be justified.

A fourth argument often used, is that the costs involved in robotic surgery will decrease with increased use. During the introduction of conventional laparoscopic surgery in the late 1980s, the initially increased costs of surgical treatment were considered a potential drawback. Thirty years later, conventional laparoscopy has proved to be cost-effective in various fields of surgery. We should not make the same erroneous assumptions used back then, by focussing mainly on the capital costs while overlooking the greater cost savings to the health system due to decreased length of hospital stay, decreased wound related costs, decreased use of analgesics and decreased cost to the society. We definitely do not argue that the costs for the use of robotic surgery will probably decrease in time and with increased experience. However, whether this will lead to cost-effective treatment should be subject to debate. Introducing conventional laparoscopy in the '80s of the 20th century, the operative procedure changed significantly from open to minimal access surgery, thereby potentially leading to smaller wounds, less pain, less wound infections,

less incisional hernia, decreased pulmonary impairment, less postoperative infections, faster convalescence and a shorter length of hospital stay. Therefore, the initial capital costs might have been high, but the potential savings were considerable. Introducing robotic surgery, a new and expensive minimal invasive approach is offered for many indications as an alternative for conventional laparoscopy. In that case, the operative procedure might change, but the potential benefits in terms of smaller wounds, less pain, faster convalescence and shorter hospital admission seem absent. This makes it rather unlikely that the costs for robotic surgery will become lower than those for conventional laparoscopy.

A last (and hardly ever mentioned) argument could be that the benefits for the patients might be limited, but benefits for the surgeon are significant. Surgeons performing conventional laparoscopy do not only suffer from high perceived mental strain levels[129], they also seem to suffer from an increased stress-induced health risk compared to other health professionals[130]. Therefore, it seems that the minimal invasive surgeon, who is fighting for the health of his patient, might well be risking his own health. In robotic surgery, the excellent view and increased ergonomics lead to an experience to the surgeon of decreased physical and mental strain[131]. This might lead to less lower back, neck and shoulder pain[132-134], decreased fatigue and decreased stress-related health risks to the surgeon. Training-box based studies trying to objectivate this decrease in mental strain in robot-assisted laparoscopy as compared to conventional laparoscopy, has indeed shown a significant increase in beat-to-beat variability of the heart rate during performance of robot-assisted laparoscopic tasks, suggesting a decreased mental strain in the robot-assisted group[131]. We performed a clinical study showing an impressive increase in heart rate variability, suggesting decrease in mental strain, using robotic assistance during laparoscopic surgery. This occurred even during surgery performing laparoscopic cholecystectomy, an operative procedure generally considered hardly stressful to the surgeon[135]. In technically more demanding procedures such as laparoscopic rectum resection and laparoscopic radical prostatectomy, the positive effect of the use of robotic assistance on mental strain, could well be expected more profound. Unfortunately, it is quite difficult to measure the exact effect of a certain amount of job-related mental strain on multifactorial caused (but partially stress-induced) impaired health status such as hypertension, myocardial infarction, acute cardiac death and diabetes mellitus.

At this moment in time, it is considered rather unconventional or even unprecedented to spend significant funds on development of new surgical techniques, improving the health of our surgeons instead of the health of our patients. However, if we stop seeing robotic assistance as a brand new technique, and we address it as merely a protective tool against job related health issues, the use of robotics might in the future be seen as just as normal as the use of the operation gloves and gown, surgeons have been using for ages in order to protect themselves from various transmittable diseases. Such protective measures do not need to lead to superior survival or quality of life to our patients, and might be disputably cost-effective. However, they do offer health professionals protection against job-related illnesses. Unfortunately, as long as strong evidence is lacking, supporting the health claims made by advocators of the use of robotics, the significantly associated increased costs cannot be accepted.

CONCLUSION

At this moment, proof of superior outcome after robot-assisted surgery for both the patient and the surgeon is less than convincing. The Dutch National Health Care Insurance Board has stated that "All scientific evidence available is consistent. Robot-assisted laparoscopic prostatectomy is equally effective as conventional laparoscopic and open prostatectomy. Therefore, such intervention should be reimbursed". The insurance board does unfortunately not state whether the extra, and probably unnecessary costs associated with the use of robotics should be reimbursed too. Individual health insurance companies follow different reimbursement policies. Some of the largest companies, such as Achmea and Menzis, have decided to pay for the regular open of conventional laparoscopic procedure, but they refuse to pay extra for the use of robotics. Other companies such as CZ do continue to offer financial support to hospitals for acquisition, maintenance and use of operative robots. This disparity leads to an inequality in the treatment of patients suffering from the same disease, which seems not recommendable. However, it seems difficult or virtually impossible to approve to consensus in a national guideline. Every debate on health issues suggesting certain new expensive techniques should not be afforded because of financial arguments, leads to extreme sensitive reactions of the public out of a fear of getting a " second-best" or even insufficient treatment[124,125,136-138]. A true open and honest public discussion on whether robotic surgery should be reimbursed, and under what conditions, is needed urgently in the Netherlands. At this moment, such debate is still in its infancy[139-141]. Invalid arguments as stated above are frequently used by authorities in this field of surgery, in order to serve other goals such as the protection of their intellectual, time and financial investments in robotics.

If we are really serious in our efforts to constrain the rapidly increasing costs in the Dutch health system in an era of financial crisis, and we really want to offer the best medical care we are able to afford, there is only one conclusion that can be drawn here. The extremely increased costs do not warrant the implementation of robotic laparoscopy as standard care at this moment. The use of robotic-assisted surgery should be restricted to well-designed and adequately powered randomized controlled trials. The areas where robotic surgery seems most likely to show any benefit, are limited. Research projects should probably best be aimed at the following targets:

1) The use of the currently available standard daVinci®Surgical System in improving Quality of Life, nerve preservation, sexual function, urologic continence and oncologic outcome after technically demanding procedures such as minimal invasive radical prostatectomy or rectum resection.

2) The use of the standard daVinci®system in decreasing mental and physical strain of the surgeon performing technically demanding laparoscopic procedures. Measurement of strain and of its effects on the physical health status of the surgeon would be very interesting in order to decide whether a robot-induced decrease in such strain does prevent potentially lethal profession-related health issues.

3) The advantages of improved manoeuvrability and increased working space using the new generation daVinci®S and Si Surgical Systems.

4) Implementation of daVinci®Si in single-access minimal invasive surgery.

5) Implementation of the Firefly®fluorescence imaging system, potentially improving visualization of crucial anatomical structures and decreasing the risk of inadverted bile duct lesions performing

(single access) laparoscopic cholecystectomy using the daVinci®Si system.
Besides these randomized controlled trials, it would be very interesting and probably enlightening to organize a nation-wide registration for advanced laparoscopic surgery, organized by the Dutch Institute for Clinical Auditing (DICA). Such a registration should include radical prostatectomy, rectum resection and cystectomy, and should include registration of the technique used (open surgery, conventional laparoscopy or robot-assisted laparoscopy). A registration could be used for monitoring and evaluating the role of robotic assistance in laparoscopic surgery. Until such research and registration has been performed and looking at the tremendous recent technical developments in robot assisted laparoscopic surgery, it becomes clear that the speed of technical progress dramatically exceeds the speed of scientific proof of efficacy. Historically, the implementation of new technology in medicine has always outpaced the available sound data to support its rapid adoption. This gap between newly developed surgical possibilities on one side, and scientifically proven effective standard surgical care on the other side, seems bigger than ever. If we want to keep good medical care affordable for our patients, we will have to make choices. Comparative-effectiveness studies are indispensable before standard adoption of robot-assisted surgery can be considered. Until than, we strongly believe that the use of robotic surgery should be restricted to well-designed trials and nation-wide registrations aimed at the targets mentioned above.
Does this mean we suggest or even promote the end of this promising technical development, mainly based on pragmatic financial reasons? We certainly do not. Is this the end for robot-assisted laparoscopic surgery? We certainly hope not. We do sincerely believe that the contemporary technical developments offer potential interesting advantages that might lead to successful cost-effective robot-assisted surgery in the near future, or to the development of lateral spin-off of such as stereoscopic conventional laparoscopy and the development of advanced handheld instruments. If we may quote Sir Winston Churchill :"Now, this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning"

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Chapter 13

Samenvatting

Nederlandse vertaling van hoofdstuk 11

DETAIL FROM: VIRGIN OF THE ROCKS
OIL ON WOODEN PANEL, 1483-1486

Virgin Mary raises her left hand above the head of the Christ child in a blessing.

SAMENVATTING

De aanvankelijke introductie van laparoscopie in de algemene chirurgische praktijk werd ontvangen met forse scepsis. Drie decennia later is laparoscopie de standaard techniek geworden op meerdere chirurgische gebieden zoals de cholecystectomie. In veel andere chirurgische gebieden is het een aantrekkelijk alternatief geworden voor traditionele open chirurgie die nog steeds aan populariteit wint. Patiënten profiteren van minder postoperatieve pijn, minder pulmonale complicaties, minder littekenbreuken en sneller postoperatief herstel. Echter, chirurgen lijden onder een langere leercurve, verminderde ergonomie en verhoogde intraoperatieve mentale stress.

Robot chirurgische systemen zijn erop gericht om sommige van deze nadelen aan te pakken en mogelijk endoscopische chirurgie te vergemakkelijken. Gebruikmakend van een meester-slaaf concept, verricht de chirurg nog steeds de operatie maar downscaling van bewegingen en tremor filtratie leiden tot een verbeterde handigheid voorbij de mogelijkheden van de menselijke hand. De doelstellingen van dit boekje waren om de rol van robotassistentie in laparoscopische chirurgie te verduidelijken en om te bepalen of en waar het gebruik van robots significante voordelen oplevert. We hebben hiervoor een scala aan studies verricht, zowel in een laboratoriumomgeving als in de klinische praktijk.

In hoofdstuk vier hebben we ons gericht op de voordelen (en nadelen) van de verschillende onderdelen van de daVinci®telemanipulator tijdens het verrichten van laparoscopische taken in een laboratoriumomgeving. We concludeerden dat de meest significante nadelen van conventionele laparoscopie in vergelijking met robot geassisteerde laparoscopie de volgende zijn:

a) Het gebrek aan stereoscopisch zicht
b) Adequaat herstel van de oog-hand-doel-as
c) Het gebruik van rechte, rigide instrumenten met een beperkt aantal vrijheidsgraden (hoewel dit minder significant lijkt)

Grote vooruitgang in laparoscopische chirurgie kan mogelijkerwijs slechts worden verwacht indien deze nadelen adequaat worden aangepakt. Dit lijkt goed mogelijk met gebruikmaking van consolegebaseerde telemanipulator systemen zoals het daVinci®chirurgisch system, danwel door gebruik te maken van een combinatie van een High Definition stereoscopisch visueel systeem samen met een adequaat herstel van de oog-hand-doel-as. Een mogelijke combinatie zou het Viking®visueel systeem kunnen vormen samen met een handinstrument met zes vrijheidsgraden zoals het Radius®chirurgisch systeem.

Het verschil in leercurve tussen conventionele en robotgeassisteerde laparoscopische chirurgie in een laboratoriumomgeving werd bestudeerd in hoofdstuk vijf. Aangezien het praktisch onmogelijk is om voldoende ervaren chirurgen te vinden met exact evenveel expertise in conventionele laparoscopie als in robotgeassisteerde laparoscopische chirurgie, hebben we onervaren gebruikers geselecteerd. De aanwezigheid van een relatief lange leercurve in conventionele laparoscopie is zeker significant voor de dagelijkse klinische praktijk, aangezien leercurves geassocieerd worden met verlengde operatietijd, verhoogde patiëntmorbiditeit en hogere kosten. Wij zagen dat het gebruik van robotassistentie in laparoscopische chirurgie leidde tot sneller en meer accurate uitvoering van laparoscopische taken. Echter, conventionele laparoscopie vertoonde een steilere leercurve en dus een snellere beheersing van nieuwe vaardigheden. Dit zou kunnen suggereren dat de voordelen van het gebruik van robotassistentie met name aanwezig zijn bij onervaren gebruikers. Of het gebruik van robotassistentie ook daadwerkelijk leidt tot een sneller bereiken van een voldoende beheersingsniveau van nieuw aan te leren chirurgische vaardigheden bij een chirurg, blijft discutabel.

Laparoscopische cholecystectomie (galblaasverwijdering) is één van de meest voorkomende laparoscopische, zoniet de meest verrichtte laparoscopische procedure wereldwijd. Voor cholecystectomie wordt laparoscopie in het algemeen beschouwd als de goudstandaard. In hoofdstuk zes stelden we onszelf de vraag of volledige robot laparoscopische cholecystectomie wel haalbaar zou zijn in de dagelijkse klinische praktijk. Gebruikmaking van de vierde arm van de telemanipulator stelde ons in staat om de operatie te verrichten met een operatieassistent minder. Volledige robot cholecystectomie bleek veilig en haalbaar. Echter, de operatietijd was 31 minuten langer en de kosten waren toegenomen met € 1,180.62. Er konden geen significante voordelen worden aangetoond van het gebruik van robotchirurgie voor de patiënt, de chirurg of het ziekenhuis.

Laparoscopie wordt in het algemeen beschouwd als de standaardbehandeling voor anti-reflux chirurgie. Eén van de meest verrichtte anti-reflux procedures op dit moment is de laparoscopische Nissen fundoplicatie. Echter, deze operatie wordt beschouwd als technisch meer uitdagend dan laparoscopische cholecystectomie. Het gebruik van robotassistentie in een dergelijke complexere procedure zou voordeliger kunnen zijn dan het gebruik bij minder complexe procedures als cholecystectomie. In hoofdstuk zeven hebben we patiënten bestudeerd die conventionele laparoscopische of robotgeassisteerde laparoscopische Nissen fundoplicatie ondergingen. Robotgeassisteerde laparoscopische Nissen fundoplicatie bleek veilig en haalbaar in deze studie, maar resulteerde in een toename van de operatietijd van 47 minuten. Costen namen toe met € 987.47 per patiënt. Er kon geen significant voordeel worden aangetoond van het gebruik van robotchirurgie voor de patiënt, de chirurg of het ziekenhuis.

We richtten ons op laparoscopische d'Hoore's rectopexie (endeldarmophanging) voor volledige rectumprolaps in hoofdstuk acht. Deze procedure zou nog meer technisch uitdagend kunnen worden beschouwd vanwege de beperkte werkruimte in het nauwe kleine bekken en de toegenomen noodzaak voor hechten en subtiele weefselmanipulatie. Ook hier bleek robotchirurgie veilig en haalbaar, maar leidde het tot een toename van operatietijd van 39 minuten en een verhoging van de kosten met 557.28. Geen significant voordeel van het gebruik van robotassistentie kon worden aangetoond voor de patiënt, de chirurg of het ziekenhuis.

Om de functionele resultaten op langere termijn na rectopexie te bestuderen, verrichtten we een studie beschreven in hoofdstuk negen. We richtten ons op de lange termijn resultaten en recidiefkans na conventionele open, conventioneel laparoscopische en robotgeassisteerde laparoscopische chirurgie. In onze studie bleek het recidiefpercentage na open chirurgie 2% vergeleken met 27% in de conventioneel laparoscopische groep en 20% in de robotgeassisteerde laparoscopische groep. Het verschil tussen open chirurgie en de minimaal invasieve technieken was significant. Er was geen significant verschil tussen conventionele laparoscopie en robotgeassisteerde laparoscopie. Functionele resultaten, gedefinieerd als een postoperatieve daling van de Wexner Incontinentie score of een afname in IDL score vergeleken met de preoperatieve scores, waren vergelijkbaar in alle drie groepen. Er kon geen significant voordeel worden aangetoond van het gebruik van robotchirurgie.

In hoofdstuk tien hebben we ons focus verlegd van het effect op de patiënt (in termen van veiligheid en complicaties) en samenleving (in termen van kosten) naar de potentiele schadelijke

effecten van laparoscopie op de chirurg. Dit is een vrij ongebruikelijk onderwerp voor medisch onderzoek. De effecten van nieuw ontwikkelde technieken worden in het algemeen gemeten (zoniet exclusief) gemeten aan de hand van het effect op de patient (in termen van post-operatieve pijnbeleving, complicaties, weefselschade, hersteltijd, functioneel en esthetisch resultaat, kwaliteit van leven en recidiefkans) of ze zij gericht op het gevolg voor de samenleving en het zorgstelsel (in de zin van kosten, operatieduur en opnameduur). We weten echter, dat nieuw ontwikkelde minimaal invasieve technieken mogelijk een voordeel voor de patient opleveren, maar dat ze erg veeleisend, uitputtend en schadelijk voor de chirurg kunnen zijn. Verhoogde geestelijke stress bij de minimaal invasief chirurg is vrij nauw gelieerd aan een verminderde hart ritme variabiliteit (HRV), verminderde gezondheidstoestand en een beperkte levensverwachting. Hoewel negatieve effecten op de gezondheid van de chirurg moeilijk te meten zijn, zijn de lichamelijke effecten van mentale stress goed te meten als een voorloper van stressgeïnduceerde gezondheidsrisico's. In deze klinische studie hebben we de hart ritme variabiliteit van de chirurg gemeten terwijl deze conventionele laparoscopische danwel robotgeassisteerde laparoscopische cholecystectomie aan het verrichten was binnen de omgeving van de dagelijkse chirurgische praktijk. Eerdere studies hadden al laten zien, dat conventionele laparoscopische chirurgie tot een significante verhoging van hart ritme en LF/HF ratio leidt, wat een verhoogde mentale stress suggereert. Het gebruik van robot assistentie tijdens laparoscopische cholecystectomie resulteerde in een significante afname van hart ritme en een stijging van hart ritme variabiliteit tijdens meerdere fasen van de operatie. Dit suggereert een sterke vermindering van intra-operatieve lichamelijke en mentale stress.
Op dit moment is interpretatie van dergelijke gegevens nog moeizaam, aangezien de exacte impact van verminderde hart ritme variabiliteit op de gezondheidstoestand van de chirurg moeilijk te meten is. Eerdere studies hebben echter een significante stijging laten zien van potentieel dodelijke gezondheidsproblemen na langdurige blootstelling aan verminderde hart ritme variabiliteit. Deze resultaten suggereren dat chirurgen zich er van bewust moeten zijn dat ze, indien ze proberen meerdere langdurige, uitdagende laparoscopische procedures per dag te verrichten zonder gebruikmaking van robot assistentie, ze waarschijnlijk een verhoogd gezondheidsrisico voor hun patiënten veroorzaken ten gevolge van vermoeidheidsgeïndiceerde chirurgische misstappen, alsmede dat ze zelf een verhoogd gezondheidsrisico lopen.

CONCLUSIE

De hierboven beschreven studies suggereren dat het gebruik van robot assistentie in een laboratoriumomgeving leidt tot snellere en meer accurate uitvoering van laparoscopische taken. In de dagelijkse klinische praktijk blijken de resultaten van het gebruik van robots echter teleurstellend. Robot chirurgie duurt langer en is duurder. Het meest significante voordeel van het gebruik van robots is mogelijk de verbeterde ergonomie voor de chirurg, en dientengevolge de verminderde mentale belasting van de chirurg. Dit zou potentieel kunnen leiden tot een vermindering van het aantal operatieve complicaties voor de patiënt en een vermindering van potentieel dodelijke gezondheidsproblemen bij de chirurg.

Chapter 14

Het einde van robot-geassisteerde laparoscopie?

Nederlandse vertaling van hoofdstuk 12

DETAIL FROM: MADONNA OF THE CARNATION
OIL ON WOODEN PANEL, 1478-1480

Virgin Mary is seated and wears precious clothes and jewelry. With her left hand she is holding a carnation, interpreted as a healing symbol.

ABSTRACT

Robotgeassisteerde laparoscopie wordt gebruikt in een breed spectrum van chirurgische deelgebieden. Echter, de financiële kosten die hiermee gepaard gaan zijn hoog en overtuigend bewijs van superieure resultaten op het gebied van Kwaliteit-van-Leven, kosteneffectiviteit en overleving is niet voorhanden. Mogelijk zijn er kleine voordelen voor de gezondheid van de patient of van de chirurg die het gebruik van robots zouden rechtvaardigen in geselecteerde deelgebieden van de chirurgie. In een tijdperk van wereldwijde economische crisis is de tijd gekomen om een kritische discussie te starten over de vraag of we het gebruik van robotgeassisteerde laparoscopische chirurgie zouden moeten beperken of zelfs zouden moeten verlaten, en ons meer zouden moeten toeleggen op kosteneffectievere methoden om de gezondheidszorg te verbeteren.

INTRODUCTIE

Het tijdperk van de telemanipulator systemen binnen de minimaal invasieve chirurgie startte met de introductie van het "Automated Endoscopic System for Optimal Positioning" (AESOP). In 1994 werd het systeem toegelaten door de Amerikaanse FDAS als de eerste chirurgische "robot" ooit. Sinds de introductie zijn diverse prototypes van geavanceerde manipulatorsystemen ontwikkeld. Echter, de introductie binnen de chirurgie en het leveren van solide bewijs van haar toegevoegde waarde, blijft moeizaam.

In 2000 werd het "daVinci®Surgical System" goedgekeurd door de Amerikaanse FDA voor gebruik binnen de algemene laparoscopische chirurgie. Op dit moment is het het enige commercieel verkrijgbare "robot"-systeem dat een geïntegreerd stereoscopisch visueel systeem combineert met een gemotoriseerde telemanipulator. De term "robot" lijkt, semantisch gesproken, hier niet op zijn plaats, aangezien dit de aanwezigheid van een geautomatiseerd proces suggereert in plaats van een technisch geavanceerd en op afstand bestuurd geïntegreerd visueel en manipulator systeem. Echter, over de laatste decade is de term zo veelvuldig gebruikt (of misbruikt) binnen het gebied van geavanceerde minimaal invasieve chirurgie om het daVinci®Surgical System te duiden, dat de twee termen in de praktijk de facto synoniem zijn geworden. We zullen in dit manuscript beide termen dan ook door elkaar gebruiken.

Bijna 2000 daVinci®systemen zijn inmiddels wereldwijd geïnstalleerd en het aantal indicaties lijkt snel te groeien in een breed werkgebied, waaronder algemene, cardio-thoracale, kinder- en gastrointestinale chirurgie, urologie en gynaecologie. Het gebruik van het systeem is bewezen veilig en technisch uitvoerbaar, maar de kosten zijn hoog en duidelijke medische voordelen zijn moeilijk te bewijzen. In Nederland alleen al zijn achttien ziekenhuizen over gegaan tot het investeren van grote bedragen voor de aanschaf van twintig robotsystemen. Na ruim tien jaar van uitgebreid gebruik en levend in een tijdperk waar een economische crisis ons dwingt om optimaal gebruik te maken van de ons ter beschikking gestelde fondsen, moeten we iedere cent die we uitgeven aan gezondheidszorg kunnen verantwoorden. De rol van robot assistentie in laparoscopische chirurgie vereist dan ook een kritische evaluatie.

Het introduceren van nieuwe technologieën in de geneeskunde wordt normaliter gedaan om een verbeterde overleving, een verbeterde Kwaliteit-van-Leven of verminderde kosten te bewerkstelligen. Als we de kosteneffectiviteit van robots willen overwegen, zullen we eerst moeten overwegen wat de potentiële voordelen zouden kunnen zijn, en daarna beslissen of deze toegevoegde voordelen wel de extra kosten rechtvaardigen. Als we kijken naar het uitgebreide veld van indicatiestellingen, is duidelijk dat het praktisch onmogelijk is om van iedere operatie in ieder chirurgisch aandachtsgebied te bepalen of de toegevoegde voordelen wel opwegen tegen

de toegevoegde kosten. We zullen onszelf in dit stuk dan ook beperken tot enkele van de mest gebruikte en best geëvalueerde operaties.

DE HUIDIGE STATUS VAN HET STANDAARD DAVINCI®SURGICAL SYSTEM

Algemene Chirurgie

Schildklierdissectie (thyroidectomie) wordt verricht voor goedaardige en kwaadaardige afwijkingen van de schildklier. Minimaal invasieve thyroidectomie werd geïntroduceerd om zichtbare littekens in de hals te minimaliseren. Het belangrijkste voordeel ten opzichte van klassieke open thyroidectomie lijkt de verbeterde cosmetiek en patiënttevredenheid, terwijl toch veilig en radicaal de schildklier wordt verwijderd. Minimaal invasieve thyroidectomie (of dit nu via de oksel, voorin de hals of een gecombineerde route wordt verricht) leidt tot een langere operatieduur en meer postoperatieve pijn[1]. De open operatie wordt in het algemeen beschouwd als de goud standaard..
Robot assistentie werd eerder gebruikt, maar er is geen overtuigend bewijs dat dit leidt tot een snellere[2] of juist een langzamere[3-5] operatieve procedure vergeleken met conventionele laparoscopische chirurgie. Er werden geen medische voordelen geïdentificeerd van het gebruik van robots tijdens minimaal invasieve thyroidectomie. Vergeleken met open thyroidectomie is er geen overtuigend bewijs van superioriteit vergeleken met open schildklierdissectie, behoudens mogelijk een iets verbeterde cosmetiek[6,7].

Gastro-intestinale Chirurgie

Dikke darmresecties (colectomieën) worden regelmatig verricht voor de behandeling van dikke darm kanker. Laparoscopische colonresecties worden al geruime tijd verricht en uitgebreid bestudeerd na de introductie en het succes van laparoscopische cholecystectomie. Talloze goed opgezette gerandomiseerde klinische onderzoeken hebben laten zien dat conventionele laparoscopische colectomie is veilig en technisch goed uitvoerbaar indien verricht door een goed getraind chirurg. Het biedt korte termijn voordelen voor de patiënt en een sneller herstel na de operatie, zonder dat het de oncologische resultaten negatief beinvloedt[8-12]. Op dit moment is er geen consensus of laparoscopische, danwel open colectomie zou moeten worden beschouwd als de goudstandaard. Het gebruik van robots in laparoscopische colectomie is veilig en uitvoerbaar[13-16] maar lijkt meer tijd te kosten en duurder te zijn[14,16-18] zonder dat er significante medische voordelen worden gezien ten opzichte van conventionele laparoscopie.

Laparoscopische endeldarmresecties worden in het algemeen beschouwd als technisch lastiger uitvoerbaar dan laparoscopische dikke darmresecties. Werkend in de beperkte ruimte van het kleine bekken waar zenuwen het risico van iatrogene beschadiging lopen, lijken de potentiële voordelen van het daVinci®systeem mogelijk groter. Dit neemt niet weg, dat laparoscopische rectumresecties regelmatig verricht worden op een veilige en technisch adequate wijze zonder robot assistentie en met resultaten die minstens zo goed zijn als van de open chirurgie[15,19-21]. Het gebruik van robots leidt tot een vergelijkbare of langere opeatieduur[22-25] en tot vergelijkbare oncologische resultaten en postoperatieve complicaties vergeleken met conventionele laparoscopische chirurgie[26-29]. Herstel en terugkeer van seksuele functie lijkt vergelijkbaar of mogelijk iets sneller na robot geassisteerde chirurgie[30].

Abdominale rectopexie wordt verricht als een behandeling van procidentia recti, ofwel volledige endeldarmverzakking. In West-Europa wordt de laparoscopische anterieure meshtechniek relatief

veelvuldig gebruikt, zoals beschreven door André d'Hoore[31]. Deze techniek kent uitstekende lange termijn resultaten en vrij weinig complicaties[32-34]. In het algemeen wordt laparoscopische rectopexie dan ook beschouwd als de goudstandaard.
Het gebruik van robots is bewezen veilig en uitvoerbaar[35] met een vergelijkbare recidiefkans, complicatiekans en functionele resultaten vergeleken met conventionele laparoscopische chirurgie[36]. De operatieduur lijkt echter langer en de kosten liggen hoger bij het gebruik van robot geassisteerde rectopexie[35].

Nissen fundoplicatie wordt veelvuldig verricht als een anti-reflux procedure. De laparoscopische Nissen fundoplicatie wordt de laatste jaren in het algemeen beschouwd als de goudstandaard voor anti-reflux procedure en biedt een succesvolle behandeling aan volwassenen en kinderen[37], potentieel zelfs te verrichten in dagbehandeling. Zowel korte termijn resultaten[38] als lange termijn resultaten[39-41] zijn uitstekend terwijl postoperatief herstel sneller is na laparoscopische chirurgie[42,43] dan na open chirurgie. Littekenbreuken traden significant vaker op na open chirurgie dan na laparoscopische chirurgie[44,45]. introductie van het daVinci®systeem leidt tot vergelijkbare resultaten[46], maar is duurder[47-51].

Roux-en-Y Gastric Bypass (RYGB) wordt verricht als een bariatrische procedure. De laparoscopische procedure heeft een enorme vlucht genomen in de afgelopen paar jaren als één van de meest effectieve en meest frequent verrichtte bariatrische ingrepen. In expert centra worden honderden of zelfs duizenden van dergelijke operaties jaarlijks verricht met een lage morbiditeit en mortaliteit. De laparoscopische RYGB resulteert in een sneller postoperatief herstel, kortere opname duur, lagere morbiditeit, lagere mortaliteit en lagere kosten vergeleken met de open procedure en zou dan ook moeten worden beschouwd als de standaard behandeling op dit moment[52-54.]
Het gebruik van robot assistentie leidt tot een vergelijkbaar postoperatief functioneel resultaat en complicaties[55]. Er is geen overtuigend bewijs of het gebruik van het daVinci®systeem leidt tot een kortere[56] of juist langere[57-59] operatie duur. De kosten die gepaard gaan met het gebruik van robots worden in het algemeen hoger ingeschat[58-60], hoewel enkele studies lagere kosten suggereren[61]. Dit verschil zou te verklaren kunnen zijn aan een verschil in operatietechniek, een ander gebruik van staplers en andere chirurgische apparatuur, en een verschil in complicatie risico en opname duur.

Thoracale Chirurgie

Thymectomie voor myasthenie (Myasthenia Gravis) is een invasieve operatie, traditioneel verricht via een transsternale benadering. Gebruikmakend van videogeassisteerde thoracoscopische chirurgie (VATS) kan de procedure net zo effectief worden verricht, maar met een verminderde postoperatieve beademingsbehoefte en een kortere opnameduur in zowel volwassenen[62-64] en kinderen[65,66]. Het gebruik van het daVinci®systeem is veilig en uitvoerbaar, en leidt tot een sneller postoperatief herstel vergeleken met de transsternale benadering[67-71]. Helaas zijn er geen gerandomiseerde onderzoeken gepubliceerd die de resultaten van traditionele VATS thymectomie vergelijken met die van robot geassisteerde thymectomie.

Lobectomie voor vroeg stadium niet-kleincellig longcarcinoom is een regelmatig verrichtte procedure. De traditionele open benadering met gebruikmaking van een thoracotomie wordt beschouwd als pijnlijk, wat mogelijk bijdraagt aan het frequent ontstaan van pulmonale complicaties en aan de relatief lange opnameduur. VATS-lobectomie is veilig en technisch goed uitvoerbaar[72], leidend tot vergelijkbare[73-76] of zelfs betere[77-79] oncologische resultaten dan na open chirurgie, in combinatie met een sneller herstel.

Het gebruik van robot assistentie is technisch goed te doen[80-83] en leidt mogelijk tot vergelijkbare[84], betere of juist slechtere[85] resultaten. Adequaat gepowerde en goed uitgevoerde studies die VATS lobectomie vergelijken met robot geassisteerde lobectomie, ontbreken helaas[86].

Gynaecologie

Hysterectomie wordt gebruikt voor de behandeling van benigne aandoeningen en voor de behandeling van vroeg stadium cervix carcinoom. In het algemeen lijkt de operatieduur voor laparoscopische behandeling langer dan voor open chirurgie, maar het herstel na laparoscopische chirurgie is sneller en het oncologisch resultaat is vergelijkbaar[87,88.] Het daVinci®systeem is hiervoor veelvuldig gebruikt en geëvalueerd. De robot procedure is veilig en uitvoerbaar[89] en bloedverlies zou mogelijk marginaal minder zijn[90], maar de operatieduur lijkt langer[90-94] zonder wezenlijke voordelen in postoperatieve uitkomst vergeleken met conventionele laparoscopische hysterectomie. In het algemeen lijkt robot assistentie significant duurder te zijn[91,92,94].

Sacrocolpopexie was ontwikkeld als een behandeling van vaginatop verzakking. De abdominale ophanging van de vaginatop resulteert in superieure resultaten vergeleken met transvaginale procedures. Laparoscopische sacrocolpopexie resulteert in significant minder bloedverlies en minder postoperatieve pijn vergeleken met open abdominale chirurgie, en leidt tot een sneller postoperatief herstel[95]. Daarom wordt laparoscopische sacrocolpopexie beschouwd als de standaard. Het is nog onduidelijk of het gebruik van robot assistentie leidt tot een snellere[96] of juist langzamere[97] operatieve procedure vergeleken met conventionele laparoscopie. Als de voorbereidingstijd van het daVinci®systeem wordt meegeteld, lijkt de benodigde operatietijd langer. De kosten zijn significant hoger bij het gebruik van robots[97]. In een vergelijking tussen robot geassisteerde sacrocolpopexie vs open sacrocolpopexie lijkt de laatste techniek uiteindelijk de duurste te zijn ten gevolge van een langere opnameduur[98,99].

Urologie

Laparoscopische nefrectomie wordt gebruikt als een minder invasief alternatief voor open (en vaak pijnlijke) nierverwijdering bij patiënten met renaalcelcarcinoom[100], en leidt tot vergelijkbare oncologische resultaten[101-103]. het gebruik van het daVinci®telemanipulator systeem is bestudeerd in voornamelijk kleine en onvoldoende gepowerde studies[104,105] maar lijkt te resulteren in een langer durende operatie vergeleken met open[106] of laparoscopische[107] chirurgie. De resultaten en complicaties lijken vergelijkbaar[106-110], maar de kosten lijken beduidend hoger[104,108-110].

Laparoscopische radicale prostatectomie (LRP) voor prostaat kanker is geïntroduceerd als een technisch lastige maar minder invasieve procedure vergeleken met open retropubische radicale prostatectomie (RRP). Het leidt tot minder bloedverlies en vergelijkbare oncologische uitkomsten vergeleken met retropubische chirurgie[111]. Conventionele LRP wordt echter beschouwd als een extreem uitdagende operatie en relatief weinig urologen zijn in staat om dergelijke chirurgie veilig te verrichten zonder robot assistentie. In een vergelijking van LRP met robot geassisteerde radicale prostatectomie (RARP) zijn de oncologische resultaten vergelijkbaar[112-114] maar lange termijn effecten van RARP laten mogelijk iets betere resultaten zien als het gaat om urine continentie en erectiele functie 1 jaar postoperatief[114-116].
Een adequate vergelijking tussen RARP en LRP is moeizaam te verrichten, aangezien veel urologen geen conventionele LRP verrichten. Vergeleken met RRP lijkt het gebruik van de robot te leiden tot vergelijkbare oncologische resultaten[112,116-118]. Postoperatief herstel van potentie en urine continentie zou mogelijk marginaal beter zijn na robot chirurgie[119] hoewel de wetenschappelijk onderbouwing erg zwak is. In het algemeen wordt RARP beschouwd als duurder dan zowel open als conventionele laparoscopische prostatectomie[120-123].

NIEUWE ONTWIKKELINGEN IN ROBOT GEASSISTEERDE LAPAROSCOPIE

Het daVinci®S en Si systeem: de volgende generatie is gearriveerd!
Intuitive Surgical heeft een nieuwe generatie robot systemen ontwikkeld, die een verbeterde manoeuvreerbaarheid en een vergrote werkruimte bieden. Er zijn meerdere voordelen aan het nieuw ontwikkelde daVinci®S en daVinci®Si systeem ten opzichten van het huidige standaard daVinci®system. De nieuwe generatie robot systemen hebben een significante structurele en functionele verandering ondergaan die hun toepasbaarheid beïnvloeden. Enkele van de grootste veranderingen zijn:
• Een vergrote manoeuvreerbaarheid. De armen van het standaard daVinci®systeem bieden een rotatie rond de verticale as (yaw) van 180 graden. Het nieuw ontwikkelde en geoptimaliseerde ontwerp van de instrument arm van het daVinci®S en Si systeem biedt een yaw van 336 graden, waardoor de manoeuvreerbaarheid en instrument werkruimte aanzienlijk worden vergroot. Onder de term "Werkruimte" wordt hier verstaan de totale fysieke ruimte die kan worden bereikt door een Endowrist®instrument indien dit gekoppeld is aan een arm van de "patient side cart".
• Langere instrumenten. De nieuw ontworpen instrumenten zijn vijf centimeter langer dan de standaard daVinci®instrumenten. In combinatie met de vergrote manoeuvreerbaarheid leidt het gebruik van deze verlengde instrumenten tot een fors vergrote werkruimte van ruim een factor drie. Om dezelfde anatomie te bereiken als het standaard daVinci®systeem, zijn tegenwoordig minder aanpassingen nodig van de "patient side cart" en van de armen van de robot.
• Verbeterde toegankelijkheid van de derde arm. De nieuwe generatie "patient side cart" bevat een derde instrument arm bovenop de kar, waardoor de manoeuvreerbaarheid verbetert en het aantal instrumentbotsingen afneemt.
• Dunnere uitschuifbare armen. De nieuwe generatie "patient side cart" is voorzien van instrument armen met een slanker profiel en telescopisch ontwerp, zodat het aantal intraoperatieve interferenties en botsingen geminimaliseerd wordt.

Het daVinci®Si Surgical System: Single Incision Laparoscopy wordt eenvoudig
Eén van de recente ontwikkelingen op het gebied van laparoscopische chirurgie is de trend om het aantal trocars te minimaliseren tijdens de operatie. Theoretisch zou het gebruik van minder trocars kunnen leiden tot minder postoperatieve pijn en trocar gerelateerde complicaties. In het uiterste geval leidt dit tot een vorm van chirurgie waarbij slechts één trocar wordt gebruikt, in het algemeen aangeduid als "Single-port, Single-access of Single-incision" laparoscopische chirurgie (SILS). Op dit moment wordt SILS met gebruik van conventionele laparoscopische instrumenten beschouwd als technisch erg lastig, met name tengevolgenvan de frequente botsingen van de instrumenten en de beperkte werkruimte. Hoewel er geen overtuigende studies zijn die een significant voordeel van SILS boven conventionele laparoscopie aantonen, neemt de ontwikkeling van deze techniek hand over hand toe. Het gebruik van robots zou nog wel eens onmisbaar kunnen blijken bij het goed uitvoeren van deze technisch lastige SILS procedures.
Het daVinci®Si systeem is speciaal ontworpen om ingezet te worden bij SILS procedures. Het gebruik van deze robot zou kunnen leiden tot een eenvoudigere introductie van deze technisch lastige techniek, waardoor iatrogene weefselschade zou kunnen worden geminimaliseerd en een sneller herstel mogelijk zou kunnen zijn.

Het Firefly®Fluorescence Imaging System: verbeterde visualisatie van cruciale structuren
Het standaard daVinci®systeem biedt een scherp High Definition stereoscopisch beeld. Een toename van het aantal pixels (om de scherpte van het beeld te verbeteren) of van de scherm ververs snelheid (om flikkering en vermoeide ogen te voorkomen) wordt in het algemeen

beschouwd als niet significant bijdragend om de chirurgische kwaliteit te verbeteren. Een ontwikkeling die wel zou kunnen bijdragen aan het verhogen van veiligheid en verbeteren van chirurgie, is de toevoeging van beeldbewerking. Indien gebruik wordt gemaakt van fluorescentie, kunnen vitale structuren zichtbaar worden gemaakt die eerder niet te zien waren voor het menselijk oog bij het gebruik van eenvoudig wit licht.
Intuitive Surgical heeft een nieuw hulpmiddel ontwikkeld, met de naam Firefly®fluorescence imaging System. Door over te schakelen van conventioneel wit licht naar fluorescentie, kunnen cruciale anatomische structuren zoals galwegen beter zichtbaar worden gemaakt. Dit zou mogelijk kunnen leiden tot veiligere chirurgie en zou onbedoeld iatrogeen galweg letsel kunnen voorkomen. Dit optioneel extra instrument zou bijvoorbeeld gebruikt kunnen worden als hulpmiddel bij SILS cholecystectomie tijdens het gebruik van het daVinci®Si system.

DISCUSSIE

Sinds de introductie van het daVinci®Surgical System is het aantal robot systemen dramatisch toegenomen over de gehele wereld. Ondanks de uitgebreide expertise in de afgelopen jaren in meerdere deelgebieden van chirurgie, gynaecologie en urologie, is er nog weinig ondersteunend bewijs met betrekking tot de superioriteit van de robot geassisteerde procedures ten opzichte van conventioneel laparoscopische procedures. Goed ontworpen en adequaat gepowerde, geblindeerde en gerandomiseerde onderzoeken zijn schaars en het risico van selectieve publicatie (publication bias) lijkt significant[124,125].
Historisch gezien is de implementatie van nieuwe medische technieken altijd vooraf gegaan aan de beschikbaarheid van deugdelijke wetenschappelijke bewijsvoering die een dergelijke snelle introductie ondersteunt. Echter, in de huidige situatie met een economische crisis die de economieën verstoort in Europa en (in mindere mate) in de rest van de wereld, zal het niet meer worden geaccepteerd dat dergelijke nieuwe en extreem dure technieken worden geïntroduceerd als standaard behandeling zonder dat er bewijs is geleverd of op z/n minst wordt verzameld dat een significante verbetering in overleving, kosteneffectiviteit of Kwaliteit-van-Leven ondersteunt. Het gebruik van robots voegt ongeveer tussen de € 600 en € 3000 euro aan extra kosten toe ten opzichte van een conventionele laparoscopische ingreep. Dit is een forse toename zonder bewijs voor verbeterd resultaat. Onze patiënten en de gemeenschap in het algemeen zouden beter af zijn als we slechts een fractie van dat geld zouden uitgeven aan extra training en verdere differentiatie van chirurgen en chirurgen-in-opleiding, zodat zij veiliger en kosteneffectief laparoscopische procedures kunnen verrichten zonder robot. Kosteneffectiviteit studies zijn onmisbaar voordat wijdverbreid robot geassisteerde chirurgie kan worden geïntroduceerd als standaard behandeling.

Buiten de toegevoegde financiële kosten van robot geassisteerde chirurgie, speelt er een tweede punt van zorg mee, namelijk veiligheid en de verlengde operatieduur. Ondanks het feit, dat het daVinci®systeem is goedgekeurd door de FDA als chirurgisch instrument voor minimaal invasieve chirurgie, mist het de tactiele terugkoppeling aan de chirurg, hetgeen potentieel een serieus gevaar kan opleveren voor patiënten. Bovendien is er geen overeenstemming over de exacte hoeveelheid extra tijd die een robot geassisteerde operatie duurt ten opzichte van een conventionele laparoscopische operatie. De meeste publicaties laten een langere operatieduur zien bij robot chirurgie en daardoor een verlengde blootstelling aan anesthesiologie-geassocieerde risico's en bijwerken zonder dat er sprake is van een significant voordeel.
Allerlei argumenten worden gebruikt om de huidige trend van toenemend gebruik van robots te verklaren. Het specifieke verzoek van de patient wordt vaak gebruikt als een argument, of als een excuus, voor het toenemend gebruik van robot systemen. Zelfs in professionele literatuur werd recent geponeerd:" Goed ontworpen, gerandomiseerde gecontroleerde onderzoeken die

conventionele laparoscopie vergelijken met robot geassisteerde laparoscopie bestaan (nog) niet. Dat is helaas een gepasseerd station. Op dit moment zijn dergelijke onderzoeken onuitvoerbaar aangezien onze patiënten robot geassisteerde laparoscopie zullen kiezen op basis van de informatie die momenteel voorhanden is"[126].
Echter, in een tijdperk van "Evidence-based medicine" kan een dergelijk verzoek van een patient niet gehonoreerd worden als het niet ondersteund wordt door adequaat bewijs. De bron van een dergelijk verzoek van een patient is waarschijnlijk gelegen in industrieondersteunde of ziekenhuisondersteunde marketing en is niet gelegen in het beperkte bewijs van klinische superioriteit zoals nu beschikbaar. Prof. dr IA Broeders stelt:" In landen waar het gezondheidszorg systeem commerciëler is dan in Nederland, wordt de daVinci®robot gebruikt als een hulpmiddel voor marketing"[126.] Het lijkt echter niet onaannemelijk dat exact datzelfde marketing potentieel wordt gebruikt (of misbruikt) in ons land, hoewel mogelijk op een iets kleinere schaal. Alleen op het gebied van minimaal invasieve radicale prostatectomie voor prostaatkanker, lijkt wetenschappelijk onderzoek een heel klein potentieel voordeel te suggereren op het gebied van betere seksuele functie en mogelijk betere urine continentie na het gebruik van robot chirurgie. Of een dergelijk marginale potentiële verbetering in seksuele functie van een individuele 70-jarige patient een dergelijke grote toename van kosten in de gezondheidszorg rechtvaardigt, zou onderwerp moeten zijn van een open debat.
Een tweede argument dat een significante rol lijkt te spelen in de hedendaagse Nederlandse medische gemeenschap, is de angst om achter te blijven. Medische professionals voelen een continue drang om de zorg die zij leveren te verbeteren/ ze zijn constant op zoek naar nieuwe technieken en methodes. Ieder risico om trendsetter of "early adjuster" te worden en te blijven resulteert in de angst om aansluiting te missen en achter te blijven in belangrijke ontwikkelingen. Dit klinkt wellicht iets overtrokken, maar het is zeker geen onrealistische angst. De huidige ontwikkelingen in het Nederlands gezondheidssysteem stimuleren competitie tussen verschillende zorgaanbieders en dragen bij aan een dergelijke angst.
Allerlei organisaties waaronder de Nederlandse Inspectie voor de gezondheidszorg, Zorgverzekeraars en patiëntenorganisaties hebben een houding ontwikkeld waarin grote kwantiteit gelijk wordt gesteld aan hoge kwaliteit. Er worden minimale aantallen van specifieke soorten operaties per ziekenhuis en per chirurg vereist in de hoop hiermee zorg te differentiëren en verbeteren. Ondanks een wetenschappelijk gebrek aan ondersteunend bewijs voor dergelijke regels ondervinden veel ziekenhuizen moeilijkheden in het behalen van de minimaal vereiste aantallen van dergelijke operaties, met als risico dat deze ziekenhuizen specifieke zorg niet meer mogen gaan leveren, onafhankelijk van de daadwerkelijke kwaliteit van de geleverde zorg. Ziekenhuizen worden direct bedreigd in hun voortbestaan, en hetzelfde geldt voor de banen van medisch personeel dat in deze instellingen werkt. Een onvermogen om voldoende aantallen patiënten aan te trekken (desnoods gebruikmakend van een sterk marketing instrument zoals een robot) kan het verschil maken tussen een bloeiend tertiair verwijzingscentrum en een gemarginaliseerde kliniek balancerend op de rand van bankroet. Dit is geen theoretisch doemscenario voor kleine ziekenhuizen, maar de dagelijkse praktijk. Alleen een gezondheidssysteem dat weigert om de extra kosten van robot chirurgie te vergoeden voor alle indicaties waar de toegevoegde waarde niet voldoende wetenschappelijk onderbouwd is, zou het realistisch gebruik van het daVinci®systeem stimuleren waar het medisch zinvol is.
Het robot systeem zou gebruikt worden als en onderzoeksinstrument en (waarschijnlijk voor een beperkt aantal indicaties) als een geavanceerd chirurgisch instrument, niet meer hoofdzakelijk als een marketinginstrument. Het huidige vergoedingensysteem leidt tot een situatie waarbij relatief kleine ziekenhuizen ophouden met het aanbieden van allerlei soorten specifieke zorg, leidend tot een vergroting van de grotere ziekenhuizen en dus een tweedeling van soorten ziekenhuizen. Alleen een paar zeer grote medische centra, verzekerd van voldoende aantallen patiënten, kunnen

eenvoudig de drang weerstaan om deel te nemen aan een wedloop van 'valse innovatie' of 'pseudo-innovatie', zoals dit genoemd werd door de internist-oncoloog Ezekiel Emanuel in de New York Times[127]. In het Academisch Medisch Centrum Amsterdam werd de bewuste keuze genomen om niet te investeren in robot chirurgie. De directeur stelde:" Dergelijke valse innovaties, of beter genaamd exnovaties, zouden niet geïmplementeerd moeten worden in een effectief en efficiënt gezondheidssysteem".[128].

Een derde argument om het gebruik van robots te verdedigen, is de aanwezigheid van grote potentiële voordelen van stereoscopische vergroting, vergrote precisie, mogelijke schaalverkleining van handbewegingen, tremorfiltratie en bewegingen van de tip van het instrument die de mogelijkheden van de menselijke hand overtreffen. Dit zou potentieel kunnen leiden tot betere operatie resultaten in de toekomst. In een echte open wetenschappelijke omgeving zou aan nieuwe en veelbelovende technologieën de mogelijkheid moeten worden geboden om ontwikkeld ruimte te krijgen voor ontwikkeling binnen een gezonde kritische context. En ja, wij geloven zeker dat nieuwe technologieën ontwikkeld moeten worden en zorgvuldig moeten worden geïntroduceerd in de medische praktijk. Het is zeker niet onze intentie om technische en wetenschappelijke vooruitgang binnen de medische wereld tegen te gaan. In tegendeel. Het is ons streven om een wetenschappelijk kader te creëren waar de ons ter beschikking staande beperkte financiële middelen zorgvuldig worden gespendeerd, leidend tot een optimale effectiviteit van iedere cent die uitgegeven wordt aan gezondheidszorg en aan onderzoek. Juist daarom is het zo belangrijk dat, zolang als er geen bewijs is van superioriteit van het gebruik van robots, de introductie van deze zeer dure technologieën beperkt blijft tot onderzoeksfaciliteiten binnen goed ontworpen onderzoeksprojecten en niet uitgebreid wordt naar de normale dagelijkse praktijk. Er is geen enkel goed argument om te verdedigen waarom nieuwe chirurgische technologieën niet onderworpen zouden moeten worden aan dezelfde strikte regels als die ook gelden voor nieuw ontwikkelde medicatie. Goed gepowerde studies zijn en blijven onmisbaar voordat het wijdverbreid gebruik van robot geassisteerde laparoscopie kan worden gerechtvaardigd.

Een vierde veelgehoord argument is dat de kosten van robot chirurgie zullen dalen bij toegenomen gebruik. Tijdens de introductie van conventionele laparoscopische chirurgie in de late 1980's werden de initieel verhoogde kosten voor laparoscopie beschouwd als een potentiële hindernis. Dertig jaar later heeft conventionele laparoscopie uitgebreid bewezen om kosteneffectief te zijn in allerlei deelgebieden binnen de chirurgie. We zouden nu niet dezelfde foutieve aannames moeten maken als toen, door teveel te focussen op de kosten van aanschaf van initieel dure apparatuur, terwijl de grote kostenbesparingen voor het maatschappij ten gevolge van een verkorte opnameduur, verminderde wond gerelateerde kosten, verminderde kosten voor pijnstilling en verkort ziekteverlof over het hoofd worden gezien. We willen zeker niet ontkennen dat de kosten voor robot chirurgie waarschijnlijk zullen verminderen in de loop der tijd en met toegenomen ervaring. Of een dergelijke kostenreductie echter op termijn zal leiden tot kosteneffectieve behandeling, blijft discutabel. Tijdens de introductie van conventionele laparoscopie in de 80-er jaren van de twintigste eeuw veranderde de ingreep significant van een open procedure naar minimaal invasieve chirurgie, potentieel leidend tot kleinere wonden, minder pijn, minder wondinfecties, minder littekenbreuken, minder pulmonale complicaties en longontstekingen, een sneller herstel en een kortere opnameduur. De initieel hoge kosten van de laparoscopische ingreep konden dan ook potentieel worden terugverdiend met grote te verwachten besparingen. Bij de introductie van de robot wordt een nieuwe en dure minimaal invasieve benadering aangeboden voor veel indicaties als een alternatief voor reeds bestaande conventionele minimaal invasieve chirurgie. In dat geval verandert de operatieve procedure wel, maar de potentiële voordelen in termen van kleinere wonden, minder pijn, sneller herstel en kortere opnameduur

lijken afwezig. Dit maakt het vrij onwaarschijnlijk dat de kosten voor robot chirurgie lager zullen uitvallen dan de kosten voor conventionele laparoscopie. Alleen bij de radicale prostatectomie, waar de conventionele laparoscopie technisch erg lastig blijkt en zelden wordt gezien als een viabele optie, lijkt de robot geassisteerde minimaal invasieve operatie het alternatief voor open chirurgie en kunnen er dus wel dergelijke potentiële voordelen verwacht worden.

Een laatste (en zelden vernoemd) argument zou kunnen zijn, dat de voordelen voor de patiënt misschien beperkt zijn, maar dat de voordelen voor de chirurg groot zijn. Laparoscopisch opererende chirurgen lijden niet slechts aan een hoge belasting van mentale stress[129], ze lijken ook te lijden aan een verhoogd risico op stress gerelateerde gezondheidsproblemen vergeleken met andere zorgprofessionals[130.] Het lijkt er dan ook op, dat de minimaal invasief chirurg vecht voor de gezondheid van zijn patiënt, maar hierbij zijn eigen gezondheid riskeert. Tijdens robot chirurgie leidt het uitstekende zicht en de verbeterde ergonomie tot een ervaring bij de chirurg van verminderde fysieke en mentale stress[131]. Dit zou kunnen leiden tot minder lage rugpijn, nek en schouderpijn[132-134], verminderde vermoeidheid en verminderde stress gerelateerde gezondheidsrisico's voor de chirurg. Studies in een trainingsomgeving hebben een significante stijging in hartritme variabiliteit tijdens robot chirurgie laten zien in vergelijking met conventionele chirurgie, wat een lager niveau van mentale stress suggereert in de robotgroep[131]. Wij verrichtten een klinische studie die een indrukwekkende stijging in hart ritme variabiliteit liet zien tijdens het gebruik van robot chirurgie, wat suggereert dat er minder mentale stress is vergeleken met conventionele laparoscopie. Dit was zelfs meetbaar tijdens laparoscopische cholecystectomie, een operatieve procedure die in het algemeen als weinig mentaal belastend wordt beschouwd voor de chirurg[135]. Tijdens technisch meer uitdagende procedures zoals laparoscopische rectumresectie en laparoscopische radicale prostatectomie zou het positieve effect van het gebruik van robots op de aanwezigheid van mentale stress, indrukwekkender kunnen worden verwacht. Helaas blijft het lastig om het exacte effect te meten van een bepaalde hoeveelheid werk gerelateerde mentale stress op het ontstaan van multifactoriëel veroorzaakte (maar deels stress geïnduceerde) negatieve gezondheidseffecten zoals hoge bloeddruk, hartinfarct, acute hartdood en suikerziekte.

Tot op heden wordt het nog als onconventioneel of zelf vernieuwend beschouwd, om veel geld te investeren in de ontwikkeling van nieuwe chirurgische technieken die de gezondheid van de chirurg verbeteren in plaats van de gezondheid van onze patiënten. Als we het gebruik van robots echter niet meer blijven zien als een totaal nieuwe operatietechniek, en er mee omgaan zoals met ieder voorzorgmaatregel ter bescherming van werkgerelateerde ziekte, dan zou het gebruik van robots voor sommige ingrepen in de toekomst net zo normaal kunnen worden als het gebruik van operatie handschoenen en jas. Chirurgen gebruiken die voorzorgsmaatregelen al tijden om zichzelf te beschermen tegen overdraagbare aandoeningen. Dergelijke beschermingsmaatregelen hoeven niet te leiden tot een betere overleving of Kwaliteit-van-Leven van onze patiënten en zijn hoogstwaarschijnlijk niet kosteneffectief. Ze beschermen de werknemers in de gezondheidszorg echter tegen werkgerelateerde ziekten. Zo lang overtuigend bewijs (nog) niet geleverd is, dat de gezondheidsclaims van verdedigers van het gebruik van robots ondersteunt, zullen de hiermee gepaard gaande forse kostenstijgingen helaas niet geaccepteerd kunnen worden

CONCLUSIE

Op dit moment is het bewijs van een beter resultaat na robot geassisteerde chirurgie voor zowel de patient als de chirurg niet overtuigend. De Nederlandse Zorgautoriteit (NZa) heeft gesteld:" Al het wetenschappelijk bewijs is consistent. Robot geassisteerde laparoscopische prostatectomie is net zo effectief als conventionele laparoscopische en open prostatectomie,

en moet dus vergoed worden". De NZa geeft echter niet aan of de extra (en waarschijnlijk onnodige) kosten die gepaard gaan met het gebruik van robots, ook vergoed moeten worden. De individuele verzekeringsmaatschappijen volgen hierin een divers beleid. Sommige van de grootste verzekeraars, zoals Achmea en Menzis, hebben besloten om de standaard open en conventioneel laparoscopische prostatectomie volledig te vergoeden, maar ze weigeren om extra vergoedingen uit te keren voor het gebruik van robots. Andere verzekeraars zoals Centrale Zorgverzekeraar (CZ) blijven doorgaan met het financieel ondersteunen van ziekenhuizen bij de aanschaf, onderhoud en gebruik van robots. Dit verschil leidt tot een ongelijkheid in de behandeling van patiënten met dezelfde ziekte, wat niet aan te bevelen lijkt. Het blijkt echter moeizaam of vrijwel onmogelijk om tot consensus te komen in een nationale richtlijn. Ieder debat over gezondheidszorg waarin gesuggereerd wordt dat een bepaalde nieuwe dure techniek niet zou moeten worden vergoed vanwege financiële argumenten, leidt tot extreem gevoelige reacties bij het publiek uit angst om een tweederangs of zelfs insufficiënte behandeling te krijgen[124,125,136-138]. Een open en eerlijke publieke discussie over of robot chirurgie zou moeten worden vergoed, en onder welke omstandigheden, is hoogst naadzakelijk in Nederland. Op dit moment staat een dergelijk debat nog in de kinderschoenen[139-141]. Ongeldige argumenten zoals eerder vermeld worden veelvuldig gebruikt door autoriteiten op het gebied van chirurgie om andere doelen na te streven, zoals het beschermen van hun persoonlijke intellectuele, tijd- en financiële investeringen in robot chirurgie.

Als we eindelijk serieus worden in onze pogingen om de snel groeiende kosten in de Nederlandse gezondheidszorg te beperken tijdens een tijdperk van financiële crisis, en als we echt de beste medische zorg willen leveren die we ons kunnen veroorloven, dan kunne we slechts één conclusie trekken hier. De extreem toegenomen kosten staan implementatie van robot chirurgie als standaardbehandeling nu niet toe. Het gebruik van robot geassisteerde chirurgie moet beperkt worden tot goed ontworpen en adequaat gepowerde gecontroleerde onderzoeken. De gebieden waar robot chirurgie de beste kans heeft om voordeel te laten zien, zijn beperkt. Onderzoeksprojecten zouden dan ook het best beperkt moeten blijven tot de volgende onderwerpen:

1) Het gebruik van het standaard daVinci®systeem in het verbeteren van de Kwaliteit-van-Leven, zenuwsparend opereren, seksuele functie, urine continentie en oncologisch resultaat bij technisch lastige procedures zoals minimaal invasieve radicale prostatectomie en rectumresectie.

2) Het gebruik van het standaard daVinci®systeem in het verminderen van mentale en fysieke stress bij de chirurg tijdens het verrichten van dergelijke technisch uitdagende laparoscopische procedures. Het meten van mentale belasting en van haar effecten op de lichamelijke gezondheid van de chirurg zou erg interessant zijn om te beoordelen of een robotgeïnduceerde vermindering van mentale stress ook daadwerkelijk leidt tot een bescherming tegen potentieel dodelijke werkgerelateerde gezondheidsrisico's.

3) De voordelen van verbeterde manoeuvreerbaarheid en vergrote werkruimte bij het gebruik van de nieuwe generatie daVinci®S and Si chirurgische systemen.

4) De implementatie van het daVinci®Si systeem tijdens het verrichten van "SILS".

5) De implementatie van het Firefly®fluorescentie systeem, om visualisatie van cruciale anatomische structuren mogelijk te verbeteren en zo het risico op iatrogeen galweg letsel tijdens (SILS of conventionele) laparoscopische chirurgie te voorkomen met gebruikmaking van het daVinci®Si systeem.

Buiten deze gerandomiseerde gecontroleerde onderzoeken, zou het erg interessant en mogelijk verhelderend kunnen zijn als er een nationale registratie zou worden opgezet voor dergelijke geavanceerde laparoscopische chirurgie, analoog aan of zelfs georganiseerd door het Dutch Institute for Clinical Auditing (DICA). Een dergelijke registratie zou in ieder geval de radicale prostatectomie, rectumresectie en cystectomie moeten bevatten met registratie van zowel open, conventioneel laparoscopische als robot geassisteerde laparoscopische ingrepen. Een dergelijke registratie zou kunnen worden gebruikt voor het vervolgen en evalueren van de rol van robots binnen de laparoscopische chirurgie. Tot dergelijk onderzoek is uitgevoerd en registratie is verricht, en kijkend naar de ongelofelijke recente chirurgische ontwikkelingen in robot geassisteerde chirurgie, wordt het duidelijk dat de snelheid van technische ontwikkeling dramatisch veel sneller gaat dan de snelheid van de wetenschappelijke onderbouwing van haar (kosten)effectiviteit.
Historisch gezien is de implementatie van nieuwe technieken in de geneeskunde altijd sneller gegaan dan het beschikbaar worden van data om deze implementatie te verantwoorden. Deze kloof tussen nieuw ontwikkelde chirurgische mogelijkheden enerzijds en wetenschappelijk onderbouwde effectieve standaard chirurgische zorg anderzijds, lijkt vandaag de dag echter groter dan ooit. Als we goede medische zorg betaalbaar willen houden voor onze patiënten, zullen we keuzes moeten (durven) maken. Goede vergelijkende studies over kosteneffectiviteit zijn onmisbaar voordat robot chirurgie kan worden aangeboden als standaard behandeling. Tot die tijd geloven wij sterk dat het gebruik van robots zou moeten worden beperkt wot goed ontworpen onderzoeken en nationale registraties gericht op eerder genoemde onderwerpen.
Betekent dit, dat we het einde suggereren of promoten van deze veelbelovende techniek, hoofdzakelijk gebaseerd op financiële gronden? Dat doen we zeker niet. Is dit het eind van robot geassisteerde laparoscopische chirurgie? Dat hopen wij zeker niet. Wij geloven oprecht dat de huidige technische ontwikkelingen grote potentiële voordelen zouden kunnen bieden en zouden kunnen leiden naar succesvolle en kosteneffectieve robot geassisteerde chirurgie in de nabije toekomst, of tot de ontwikkeling van laterale spin-off zoals stereoscopische conventionele laparoscopie en de verdere ontwikkeling van geavanceerdere handinstrumenten. Als we Sir Winston Churchill mogen aanhalen:" Dit is niet het einde. Het is nog niet eens het begin van het einde. Misschien, is dit slechts het einde van het begin."

REFERENTIES zie bladzijde 114

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CURRICULUM VITAE AUCTORIS

Jeroen Heemskerk werd geboren op 25 oktober 1972 in Alphen aan den Rijn. Hij bracht het grootste deel van zijn jeugd door in Veldhoven en volgde middelbare school aan het Van Maerlantlyceum in Eindhoven. In 1991 startte hij aan zijn studie Geneeskunde aan de RijksUniversiteit Leiden. Datzelfde jaar werd hij ook lid van studentenvereniging Quintus en van het Leidsch Heerendispuut Houphnyx.

In 1996 begon hij aan zijn coschappen in Nederland, Suriname en Ghana. Hij behaalde het artsexamen in 1998. Na anderhalf jaar gewerkt te hebben als arts-assistent thoraxchirurgie in het VU Medisch Centrum Amsterdam, begon hij als arts-assistent algemene chirurgie in het St Elisabeth Ziekenhuis te Willemstad, Curaçao. In het jaar 200 kwam hij terug naar Nederland en begon als arts-assistent in het Maastrichts Universitair Medisch centrum, alwaar hij aan zijn opleiding begon in 2002. Hij vervolgde zijn chirurgische training in 2004 in het Catharina Ziekenhuis Eindhoven. Gedurende deze jaren ontwikkelde hij een grote liefde voor de minimaal invasieve chirurgie, resulterend in meerdere onderzoeksprojecten op het gebied van geavanceerde laparoscopie. In dezelfde tijd ontwikkelde hij een nog grotere liefde voor zijn Martien (buiten werktijd aangeduid als "dushi"), resulterend in een huwelijk en twee schatten van kinderen, Thijs en Laura.

Sinds 2008 is hij werkzaam als gastro-intestinaal chirurg en chirurg-oncoloog in het Laurentius Ziekenhuis te Roermond. Buiten deze klinische werkzaamheden en enkele nieuwe onderzoeksprojecten, wordt hij door verpleging en kinderen geschoold in de beheersing van de midden-Limburgse taal, met opvallend weinig succes.

foto boven: de auteur tijdens laparoscopische totaal extraperitoneale plastiek. zelfs (of misschien wel juist) zonder de aanwezigheid van een chirurgische robot lijkt deze minimaal invasieve ingreep relatief snel, eenvoudig en veilig te verrichten.

foto rechts: de auteur en zijn publiek verdiept in andermans werk. Ondanks de matige wetenschappelijke onderbouwing en onrustige lay-out lijken de oplage, impact factor en de publiekswaardering wellicht hoger dan van het boekje dat voor u ligt.

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