Percutaneous transhepatic drainage in obstructive jaundice

Citation for published version (APA):

Gouma, D. J. (1984). *Percutaneous transhepatic drainage in obstructive jaundice*. [Doctoral Thesis, Maastricht University]. Rijksuniversiteit Limburg. <https://doi.org/10.26481/dis.19840210dg>

Document status and date:

Published: 01/01/1984

DOI:

[10.26481/dis.19840210dg](https://doi.org/10.26481/dis.19840210dg)

Document Version:

Publisher's PDF, also known as Version of record

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
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PERCUTANEOUS TRANSHEPATIC DRAINAGE
IN OBSTRUCTIVE JAUNDICE

PERCUTANEOUS TRANSHEPATIC DRAINAGE IN OBSTRUCTIVE JAUNDICE

PROEFSCHRIFT

Ter verkrijging van de graad van doctor in de geneeskunde
aan de Rijksuniversiteit te Maastricht,
op gezag van de Rector Magnificus Prof. Dr. H. C. Hemker,
volgens besluit van het College van Dekanen,
in het openbaar te verdedigen in de aula van de universiteit
op vrijdag 10 februari 1984 des namiddags te vier uur

door

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Zet- en drukwerk: Krips Repro Meppel

Financial support for the publication of this thesis was received from:
Beecham Farma B. V., Amstelveen, The Netherlands

To my parents
To Ineke

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Chapter 1

Introduction

The approach to the jaundiced patient has been radically changed by application of new diagnostic and therapeutic procedures.

New techniques such as Ultrasound (US) and Computed Tomography (CT) and the invasive techniques of Percutaneous Transhepatic Cholangiography (PTC) or Endoscopic Retrograde Cholangio-Pancreaticography (ERCP) are available in most general hospitals.

The PTC and ERCP are not only important in the diagnostic approach to the jaundiced patient, but have both their therapeutic possibilities, as in Percutaneous Transhepatic Drainage (PTD) and nasobiliary drainage or insertion of an endoprosthesis.

In St. Annadal Hospital, Maastricht, PTC has been routinely performed since 1977 in patients with obstructive jaundice. The results of this 'diagnostic' PTC have been studied retrospectively after a period of two years and form the first part of the present study. In consequence of these results a standard diagnostic approach to patients with jaundice (the so-called decision tree) has been developed in 1979.

The Percutaneous Transhepatic Drainage, a logical extension of the PTC procedure has been introduced at the same time (1979) and included in the decision tree.

The PTD is used as a preoperative, temporary drainage to improve the general condition of the patient before laparotomy or as a palliative continuous drainage procedure in patients with unresectable obstruction of the bile ducts.

In the second part of the thesis the technique of PTD and insertion of an Endoprosthesis (PTE) is described and are studied prospectively.

The aim of this thesis is:

To give an assessment of the value of PTC as a diagnostic procedure in obstructive jaundice.

To discuss different aspects of the percutaneous drainage procedure:

- Is there any benefit of preoperative drainage in patients with a benign obstruction?
- Should preoperative drainage be performed in patients with a malignant obstruction? Does it improve the general condition?
- Is continuous drainage a good alternative for the surgical bypass procedures as palliative treatment or should it be reserved for high risk patients or patients in whom bypass surgery is technically difficult?

Recommendations will be made for the use of percutaneous drainage and a new diagnostic approach to patients with obstructive jaundice is introduced.

Chapter 2

Review of the literature

2.1 History of Percutaneous Transhepatic Cholangiography (PTC)

The first radiological visualisation of the bile ducts was carried out by Burckhardt and Müller in 1921, by percutaneous introduction of a needle into the gallbladder (33). This method never became accepted because of the high incidence of bile leakage with subsequent bile peritonitis (213).

A modification, puncturing the gallbladder through the liver, was developed to avoid this complication, but the incidence of complications was still considerable (124, 224). Another disadvantage of these techniques was that they were useless when there was no communication between the gallbladder and the bile ducts.

2.1.1 PTC with a 'sheathed' needle

Percutaneous transhepatic cholangiography with a sheathed needle was first reported by the French physician Huard and his Vietnamese colleague, Do Xuan Hop in 1937 (114, 185, 249). This was the first time that a contrast medium (Lipiodol) was directly introduced into the bile ducts.

It was not until 1952 that the first publications appeared in the Western world. The rediscovery was reported almost at the same time by Carter and Saypol in New York and Leger *et al* in France (40, 141). It is interesting to note that these investigators not only performed PTC but also introduced the percutaneous drainage.

During the following years (1952 to 1968), many series of PTC were published (7, 58, 74, 81, 105, 119, 163, 221, 254). In all these series, the stiff sheathed needle was used (7, 221). The techniques described by Seldinger and Wiechel were the most commonly used (221, 254).

The anterior approach was described by Seldinger (221). Puncture of the bile ducts was performed under local anaesthesia anteriorly in the right upper quadrant of the abdomen. Wiechel preferred the lateral approach in the mid axillary line to avoid accidental puncture of the gallbladder (254). General anaesthesia was recommended sometimes because the apnoea was more controlled, reducing the risk of puncture of the lung (254). In The Netherlands, the PTC procedure was first described by Daniëls and Schmidt in 1960 (58).

Three reviews of PTC with a sheathed needle, partly collecting the same series, are summarised in Table I (94, 105, 254). The success rate of the puncture was not reported by Wiechel. The others reported 74% in all patients and 86.5% in patients with dilated bile ducts respectively (94, 105).

Table 1 PTC with the large sheathed needle; success and complications of the procedure.

Author	Year	Total procedures	Success rate	Complications	Death
Wiechel ¹	1964	713	?	57 (8%)	4 (0.56%)
Hines ¹	1972	1629	74% ²	82 (5%)	4 (0.26%)
Harbin ¹	1980	2464	86.5% ³	128 (5.2%)	9 (0.37%)

¹ Collected series; ² Overall success rate; ³ Success rate in dilated bile ducts.

Death due to the PTC procedure was reported between 0.26-0.56% while complications after puncture with a large sheathed needle were described in 5-8% (94).

Bile leakage was the most common complication (3.45%) and intraperitoneal haemorrhage was reported in 1.7% (94). Due to the substantial amount of complications and especially the incidence of serious complications as bile leakage and haemorrhage, PTC with the large sheathed needle was never generally accepted as a safe diagnostic procedure.

The method was only believed to be safe when laparotomy could be undertaken immediately after the procedure (58, 81, 254).

2.1.2 PTC with the Chiba needle

In 1968, a long thin and flexible needle was developed by Japanese investigators. Okuda's name is mostly connected with the Chiba needle but the first reports were from Tsuchiga and Ohto (181, 240). They reported a high success rate with minimal complications. The marked flexibility and the smaller diameter of the needle contributed to the safety of the puncture technique. Bending of the needle, which was commonly observed at the entrance of the liver capsule, produced less liver damage than with the use of a sheathed needle after which liver damage with tearing and bleeding has been described (254).

The most commonly used puncture technique is the lateral approach in the midaxillary line and usually in the ninth intercostal space as reported previously (254). The needle is inserted during apnoea not further than 3 cm to the right of the vertebral column. Some Japanese investigators were drawing a vertical line between the air filled apex of the duodenal bulb and the right cupula of the diaphragm and aimed the needle at this mid-point (5). Others reported that in view of the variable relationship between the liver, lung and vertebrae (especially in patients with pulmonary pathology) reference had not to be made to vertebral body levels but to the left of the dome of the right diaphragm (121). Wiechel never injected contrast medium before the bile duct was punctured and bile passed through the catheter (254). Most authors, however, used the so-called injection withdrawal manoeuvre (9, 28, 65, 70, 183, 196, 262). Using the Chiba needle, it appeared

Table 2 PTC with the Chiba needle; success and complications of the procedure.

Author	Year	Number of patients	Visualisation dilated ducts		Visualisation non-dilated ducts		Overall success rate	Complications	
			N	%	N	%		%	%
Okuda	1974	314	234	91.2	80	67.5	85.3	8	
Redeker	1975	40	20	100	20	60	80	5	
Shirakabe	1975	687	230	96.2	457	85.3	89.9	0.19	
Elias	1976	44	20	95	24	25	56	2.5	
Ferrucci	1976	50	33	100	14	82	92	10	
Burcharth	1977	160	115	98	45	58	87	4	
Jain	1977	80	54	94.4	26	50	80	5	
Pereiras	1977	131	86	100	45	95.6	98.5	3	
Yap	1977	32	78	100	4	50	94	12	
Ariyama	1978	885	290	99	594	85	90	3.21	
Benjamin	1978	46	20	100	26	71	85	6	
Zilly	1978	88	48	95	40	62	78	5	
Harbin [†]	1980	3596	1813	98				3.28	
Kreek [†]	1980	322	252	89	70	52	81	10.2	

[†] Multi-institutional survey.

difficult to remove bile and for that reason, the contrast medium was injected directly under fluoroscopic control while the Chiba needle was slowly withdrawn.

Some of the reported series of fine needle PTC are summarised in Table 2. The success rate of visualisation of dilated bile ducts varied between 95 and 100% and was 98% in the multi-institutional survey of Harbin *et al* (94).

Visualisation of non dilated bile ducts was reported between 50 and 95%. The success rate of the PTC was correlated with the number of passes through the liver (94). Complications were reported in between 0.2 and 12%. Major complications of bile leakage, intraperitoneal haemorrhage and septicaemia were reported in 1, 0.28 and 1.8% respectively by Harbin *et al* (94). Death was reported in 0.1%.

Kreek and Barlint reported on the basis of data from a number of centres an overall complication rate of 31.7% (136). Their data included every reportable complication such as pain during the procedure, slight fever, relative hypotension and slight bleeding. If these minor complications were excluded, this survey still showed a complication rate of 10%. The discrepancy between the surveys of Harbin *et al* and Kreek and Barlint was explained by increasing experience with the procedure (94, 136, 170, 172).

It was reported that there was no difference in the incidence of serious complications when related to the number of punctures performed (5).

When the results of the literature of sheathed needle PTC (Table 1) and Chiba needle PTC (Table 2) are compared it is shown that there is a higher success rate and a lower complication rate (especially major complications) when the fine needle is used.

With the introduction of the Chiba needle, PTC has become accepted as a safe and reliable diagnostic procedure.

2.1.3 Ultrasonically guided PTC

Recently, Makuuchi *et al* have reported the first series of ultrasonically guided PTC (146).

This method has the advantage of puncturing a selected dilated bile duct. Due to the possibility of exact localisation of these ducts, the complication rate of this approach should be less than the radiologically guided PTC (146, 182, 257).

This method is especially useful for puncture of the left hepatic duct by the anterior approach because the depth of the duct below the skin can be measured and the preferred point of entry can be marked. Radiation exposure to the operator's hands which is normally a matter of greater concern with the radiologically guided approach is reduced by this method (173). This ultrasonically guided puncture technique has been introduced in The Netherlands by Laméris and Seyen (137).

2.1.4 PTC and/or ERCP

For visualisation of the bile ducts the percutaneous or the duodenal route can be used (251). Both transhepatic- and endoscopic cholangiography have advantages and disadvantages which should be weighed against each other. In the prospective randomised trial of Elias *et al* results of PTC with the Chiba needle and ERCP in patients with jaundice are compared (66). When analysed separately for extrahepatic or intrahepatic cholestasis, PTC was the procedure of choice in patients with extrahepatic jaundice (95% success rate) and ERCP was superior in intrahepatic cholestasis (76% success rate). The morbidity of both procedures was almost the same.

Other studies have compared the two techniques retrospectively concluding that PTC was superior, simpler, with a higher success rate and lower costs (77, 262).

The complication rate of PTC was slightly higher than ERCP while the mortality was the same (0.2%) with both methods.

A more recently published series by Zilly *et al* reported 5% bile leakage after PTC and they concluded that bile leakage is an important risk factor in an obstructed biliary tree and warned against excessively optimistic reports regarding PTC (261). On the other hand, experience has little influence on the success rate of PTC whereas the reverse is true for ERCP (120). In a collected review of 10,435 ERCP's, Bilbao *et al* reported that the results were directly related to the experience of the examiner (14). In their series, the investigators had a mean success rate of 38% in the first 23 ERCP's while the investigator with 200 or more ERCP's had a success rate of 85%.

The accuracy of direct cholangiography by ERCP or PTC in jaundice is discussed by Matzen *et al* (152). These authors concluded in a prospective study (in which cholangiography was compared with operative findings) that a direct cholangiography obtained by ERCP or PTC was a safe basis for the appropriate non-operative or operative management of patients with clinically suspected obstructive jaundice.

Some authors preferred ERCP and only used PTC when ERCP had failed (250, 263). The advantage of ERCP is, of course, visualisation of the pancreatic duct in associated pancreatic disease and the possibility of direct biopsy of an ampullary lesion (12, 21, 263).

It is difficult to decide which of these two techniques should be preferred. Both techniques are complementary and perhaps one of the important questions before making a choice which technique should be preferred, is the experience of the investigator with both techniques obtained in any particular hospital.

2.2 History of Percutaneous Transhepatic Drainage (PTD)

Percutaneous drainage of bile ducts was introduced at the same time in the USA and in France and was developed as a logical extension of the PTC procedure (40, 141). In 1952 Carter and Saypol performed bile drainage through the needle used for the PTC which was strapped firmly to the skin surface (40). This technique was dangerous because of the respiratory movements of the diaphragm which could easily introduce liver damage

in this way. Although the patient died 7 days after the procedure this was not due to complications of the drainage but to bleeding of oesophageal varices.

Leger *et al* reported in 1952 drainage of bile ducts in two patients and introduced a 2.5 mm polyethylene tube in the bile ducts to improve the general condition of the patient preoperatively by drainage of the bile (141). He warned about complications such as cholangitis and bile leakage.

Due to these complications PTD did not become widely accepted. In the PTC series of Glenn *et al* most patients were operated on within a few hours of the procedure but in one of the 30 patients a temporary drainage procedure was carried out for five days (81). He used a polyethylene catheter and the anterior approach for puncture of the bile ducts. Glenn *et al* advised that the bile should be fed back to the patients orally or by nasogastric tube (81). In spite of using the polyethylene catheter biliary peritonitis was reported (81, 222). This complication was probably related to multiple punctures of the liver with the large sheathed needle because no bile leakage was encountered in patients in whom the bile duct was punctured at the first attempt.

In the Netherlands, PTD was described for the first time by Miranda in 1967 in 7 patients (163). He was not enthusiastic about the quality of drainage and reported that all patients with an external drainage for a long period had at least one attack of cholangitis. He concluded that the percutaneous drainage was only indicated in patients with obstructive jaundice combined with severe itching not responding to medical treatment. According to Miranda this method should be reserved for patients in whom surgical drainage was impossible and whose disease would lead to death within a short period of time.

Marions and Wiechel (1974) and Molnar and Stockum were the first authors who reported a combined external/internal drainage procedure in the same year (149, 165). After a few days of external drainage the stenotic lesion was passed with a rigid polyurethane catheter with a tapered tip.

With the introduction of the thin Chiba needle these procedures became more and more generally accepted. New technical possibilities with thinner catheters and more flexible wire guides made percutaneous drainage an increasingly safe procedure.

The 'rediscovery' of the drainage procedure took place at the same time in Europe, especially in the Scandinavian countries (29, 30, 106, 107, 149, 241), in the USA (71, 197, 201, 208), and in Japan (6, 168, 175, 230, 231, 242, 243).

2.2.1 Technical aspects of puncture

Most investigators perform the procedure under local anaesthesia and mention this as an advantage over surgical drainage. Only a few authors prefer general anaesthesia (102, 149). The puncture is mostly performed by the lateral approach as described by Wiechel and the Japanese investigators (5, 6, 175, 183), although others prefer the anterior approach for drainage (41, 168, 230).

The ultrasonically guided percutaneous transhepatic bile drainage is also mostly performed by the anterior approach (137, 147, 182).

There are two different techniques for the lateral approach in use:

1. A two stage procedure mostly used in Japan and in the USA. The first puncture is performed with the thin needle with a 0.7 mm diameter (the normal PTC procedure) and after visualisation of the bile ducts a second 'selective' puncture is performed with a 1.4 mm diameter drainage needle.

This second puncture is performed in the dorsocaudal branch of the right hepatic duct (149, 175). Some other workers recommend the main right hepatic duct immediately at the confluence for introduction of the drainage catheter (71).

2. The one stage procedure described in the Scandinavian literature (29, 30, 149, 241). The first puncture is already performed with the thin Wiechel-Stille drainage needle (1.4 mm diameter).

Both techniques have their advantages and disadvantages. If more punctures are needed, the thin needle technique is obviously less traumatising to the liver with less chance of bile leakage. On the other hand, if the first puncture visualises the biliary tree and drainage is already possible through this tract, the chance of bile leakage is even smaller when the one stage procedure is used because there is only one puncture tract in the liver.

2.2.2 The different types of percutaneous drainage

Percutaneous Transhepatic Drainage can be performed as an external drainage, a combined external/internal drainage or as an internal drainage, depending on the position of the catheter in the biliary tract.

A. External drainage

The catheter for external drainage (fig. 1) is inserted in the bile duct with the tip just above the site of obstruction and only external decompression is possible. External drainage has some disadvantages.

Catheters can be dislodged more easily due to the short length of the catheter within the bile ducts and relative mobility of the liver. Patients with external drainage have to live with a drainage bag and due to the daily bile output of 500-1000 ml hyponatremia and bile salt depletion can occur. Complications of exogenous infections are frequently seen during external drainage. Because of these disadvantages external drainage is only used temporarily as preoperative drainage in patients with a very bad general condition or if passage through the stricture is impossible.

Fig. 1. External drainage of the bile ducts.

Fig. 2. Combined external and internal drainage of the bile ducts.

B. Combined external/internal drainage

The catheter is passed through the obstruction and a combined external/internal drainage is made possible by multiple side holes in the catheter proximal and distal to the obstruction (fig. 2). The tip of the catheter is located in the distal common bile duct or duodenum. The advantage of combined external/internal drainage to external drainage is that the catheter is less easily dislodged.

Manipulations such as implantation of iridium wires or changing of the catheters can be performed through the external part of the catheter. A disadvantage of the external/internal drainage to internal drainage is the infection of the external tract.

The combined external/internal drainage is most commonly used in the USA (13, 72, 165, 201, 226, 252).

C. Internal Drainage (Endoprosthesis)

After insertion of an endoprosthesis through the obstruction and removal of the external drainage catheter only internal drainage is achieved (fig. 3). The endoprosthesis has side holes proximal and distal from the obstruction. The advantage of an internal drainage is that dislodgement is seldom seen, that there are no problems of bile loss or external infective complications.

Fig. 3. Internal drainage of the bile ducts (Endoprosthesis).

The disadvantage of an endoprosthesis is that manipulations of the endoprosthesis, flushing or insertion of irradiation wires are impossible. The internal drainage is most commonly used in Europe (30, 32, 63, 83, 84, 93, 107, 108, 149).

According to the literature, the three types of drainage (A, B and C) have been used with varying success. There are up to now no prospective investigations comparing these different types of drainage and in most series on biliary drainage they are not even mentioned separately.

Despite the fact which type of drainage is ultimately performed, PTD is used as a preoperative (temporary) decompression of the bile ducts or as a continuous palliative procedure and they will be discussed separately.

2.2.3 Preoperative drainage in malignant obstruction

It has been accepted for many years that morbidity and mortality of a laparotomy in obstructive jaundice correlate with the degree of jaundice (23, 242).

The so-called two-stage operation was based on this principle, advised and performed by Whipple in 1935 (253). The first stage was surgical decompression of the biliary tract to reduce the serum bilirubin level and to improve the liver function and the second stage was the surgical resection. However, this two-stage approach has never been compared with single-stage surgery in a prospective trial.

Two retrospective studies showed an increased morbidity and mortality in severely jaundiced patients (23, 242). In a series of 99 operated patients, reported by Ukai *et al*, 42 'severely' jaundiced patients had a postoperative mortality of 35.7%, while in the group of 57 patients with 'less severe' jaundice the mortality was 17.5% (242).

Braasch and Gray showed an increase of mortality from 12.5% to 22% in patients with serum bilirubin levels greater than 170 $\mu\text{mol/l}$ (23). Clinical studies that have investigated which factors are responsible for the higher morbidity and mortality in the jaundiced patients are not available. Only acute renal failure after surgery in patients with obstructive jaundice is a well-known complication with a poor prognosis (59). Experimental studies have shown a reduction of renal function and an impaired wound healing (3, 4, 232). Although these data are very suggestive, they cannot be extrapolated to patients directly.

Based on clinical experience and animal studies many investigators advised the use of preoperative drainage in patients with high surgical risk because it should confer beneficial effects on postoperative morbidity and mortality (31, 43, 60, 61, 71, 93, 107, 171, 198, 201, 230, 241). After a drainage period of 2-4 weeks the serum bilirubin level could return to normal levels (60, 93, 165). Temporary drainage should improve the general condition due to increased food intake (107, 149, 175).

A number of reports of preoperative drainage are summarised in appendix I. However, in most series, patients with preoperative and continuous drainage are mixed

Table 3 Preoperative drainage; indication, length and complications of drainage related to postoperative mortality and morbidity.

Author	Year	Number of patients with preoperative drainage	Serum bilirubin level as indication for drainage $\mu\text{mol/l}$	Period of drainage (days)	Complications of PTD procedure	Mortality of surgical procedure		Morbidity of surgical procedure	
						preop. drainage	without drainage	preop. drainage	without drainage
Takada	1976	38		27	few	4 %	41 %		
Nakayama	1978	69		8.7	few	8.2%	28.3%		
Dooley	1979	21		—	5%	24 %			
Denning	1981	25	> 85	13	20%	16 %	25 %	28%	56%
Norlander	1982	58		18	$\pm 10\%$	14 %	21 %		
McPherson	1982	33	>300	18	many	24 %			
Hatfield	1982	22	>150	12	many	14 %	15 %	16%	18%

and details of both groups are not reported. Therefore the series in which important details of preoperative drainage, such as criteria for drainage, period of drainage, morbidity and mortality with or without drainage are presented, are summarised in Table 3 and discussed. Other series without any of these details are excluded (6, 31, 44, 93, 107, 201).

The selection of patients was in most series obstructive jaundice at least established by Ultrasound. Only in a few studies the minimum serum bilirubin level was mentioned. It was reported between 85 $\mu\text{mol/l}$ and 300 $\mu\text{mol/l}$ (60, 159).

McPherson *et al* made the selection of patients according to more criteria such as the serum bilirubin $> 300 \mu\text{mol/l}$ and a creatinine clearance $< 50 \mu\text{mol/min}$ as absolute criteria, and albumin $< 30 \text{ g/l}$, weight loss $> 10\%$ and age > 60 years as relative criteria (159).

The period of preoperative drainage varied widely between 8 and 27 days in reports from Japan (175, 230) but was about two weeks in most series (60, 62, 99, 158, 179).

Mortality of the surgical procedure with or without preoperative drainage was described in most series. A significant difference was found in two series but no criteria of selection of patients or type of operation were published and a historical group was used to compare the results of drainage with a non drainage group (175, 230).

Morbidity figures after the surgical procedure with or without preoperative drainage are only presented in two series and in one of these Denning *et al* reported a significant difference in morbidity between the two groups: 28% in the patients with preoperative drainage and 56% in patients without drainage (60, 99).

The complications of the PTD procedure (mostly preoperative and continuous drainage mixed up together) will be discussed in chapter 2.2.6.

The first prospective controlled investigation of the effect of preoperative external biliary drainage in obstructive jaundice was published in 1982 by Hatfield *et al* (99). In this series of 57 patients 22 patients underwent preoperative drainage (mean drainage period 11.7 days) and 25 patients were operated without drainage. Ten patients were excluded from the study. The postoperative complication rate was low and similar in both groups while complications associated with the drainage procedure were considerable ($\pm 50\%$). No difference in operative mortality was found between the two groups, 14% dying in the preoperative drainage group and 15% in the non-drainage group.

Differences in results between external and internal drainage can be expected because of closing of the enterohepatic cycle. This aspect has not yet been studied, however, refeeding of bile has been reported by Norlander *et al* and the serum bilirubin level fell to lower levels in patients who had bile refeeding (179).

Burcharth (32) is the only author who performed temporary internal drainage with an endoprosthesis. Theoretically this technique should reduce the incidence of exogenous infections but he did not study this aspect.

The effects of temporary decompression by laparotomy and drainage (T tube drainage or bypass surgery) have been compared with percutaneous drainage and it was apparent that jaundice was cleared at the same rate by these procedures (175, 230). Looking at the reported data concerning preoperative drainage it is too early to draw any conclusion and it is obvious that more controlled trials will be necessary to show the risks and benefits of this procedure (11, 64). Furthermore, it is evident that temporary (internal) drainage should especially be evaluated further in high risk patients.

2.2.4 Preoperative drainage in non-malignant obstruction

Preoperative drainage to improve the general condition has not been used frequently in patients with a benign obstruction. However, the use of temporary drainage has been reported successfully in patients with suppurative cholangitis, recurrent benign strictures and for percutaneous stone removal.

Suppurative cholangitis: Patients with acute suppurative cholangitis can be treated successfully with temporary decompression by a drainage catheter (45, 62, 72, 123, 175). From the largest series (18 patients) with suppurative cholangitis in which percutaneous drainage was performed as a life saving procedure 3 patients died (123). Despite the good results with percutaneous drainage, it was surprising that the possibility of an endoscopic sphincterotomy, which has been reported as the treatment of choice (53, 214, 263) was not mentioned in these reports (123, 175).

Benign stricture: PTD is usually restricted to malignant biliary obstruction but an exception can be made for recurrent benign strictures. The recurrent high strictures after biliary-enteric anastomosis which are difficult to treat surgically (16, 219, 227) can be treated successfully by balloon dilatation (150, 166, 233, 198). This technique was first described in 1973 and will be discussed later (34).

Stone extraction: Temporary drainage catheters can be used for percutaneous stone extraction. A discrepancy between the stone size and the transparenchymal tract calibre is the limiting factor and indications are rare, particularly when other methods such as endoscopic sphincterotomy are available (50, 51, 214, 220).

2.2.5 Continuous drainage

Most authors agree that drainage is only a palliative treatment and that the decision to perform continuous drainage should not be made until the lesion is found to be inoperable (31, 43, 63, 71, 95, 161, 163, 187, 209, 226).

Dealing with patients with an unresectable tumour, biliary drainage is directed solely toward the relief of symptoms and should therefore not be employed until pallia-

tion becomes necessary (187). Others describe the continuous drainage as a good alternative to bypass surgery and claim that the mortality of the drainage procedure is less and the survival is the same as for bypass surgery (31, 71).

Many series of continuous drainage have been published during the last 10 years. The reports of a total of 647 patients have been collected in appendix 1.

The series in which the type of drainage, survival time and mortality are mentioned have been summarised in Table 4.

The mortality directly related to the PTD procedure is low and is difficult to correlate with mortality of bypass surgery. In most papers in which surgical bypass procedures have been performed, death in hospital (or within 30 days) has been reported and this generally high mortality rate is partly due to the operative procedure or due to the general condition of the patient and the extent of the malignancy.

The death in hospital (or within 30 days) in the PTD series has only been reported precisely and for all patients in a few well documented papers and was around 30% in most of these series (63, 71, 93, 102, 108, 207). In other reports, however, all patients were discharged from hospital with a drainage catheter (43, 97, 161, 201, 226). It is still difficult to compare these data.

The survival time after continuous drainage varied between 4 and 36 weeks but in most series it was between 8 and 12 weeks. A mean survival time of 36 weeks was only described by Smale *et al* (226). However, patients who did not survive 3 months, were excluded from this report and the long survival time is therefore of 'limited' value and at least misleading. A correlation between survival time and type of drainage could not be found. Death was mainly due to underlying malignancy and not due to the type of drainage.

The continuous drainage was most commonly performed either with a combined external/internal drainage system (in the USA, 13, 71, 171, 201) or with an endoprosthesis (in Europe, 31, 63, 102, 108, 207). External drainage was only used if the catheter did not pass the tumour (71, 171).

Dislodgement of the endoprosthesis was less frequent than dislodgement of the external/internal catheter and external contamination was eliminated after introduction of an endoprosthesis (161).

Furthermore, it has become clear that the psychological burden of patients with an outside catheter should not be underestimated (161, 187).

Some authors have also described migration of an endoprosthesis, therefore the endoprosthesis with a flared tip and the pigtail catheter were introduced to prevent inadvertent withdrawal (108, 187, 209, 210).

Routine prophylactic catheter exchanges for external/internal drainage catheters have been carried out by Ring *et al* (209), although others have preferred to wait with this manoeuvre until the catheter was occluded or dislodged (71, 175).

Table 4 Continuous drainage, type of drainage, survival time of patients with malignant obstruction and mortality within 30 days.

Author	Year	Number of patients with continuous drainage	Type of drainage ¹	Patients with malignant obstruction		Mortality within 30 days	
				Number	Survival time (weeks)	Number	Percentage
Molnar	1974	7	I	5	4	4/5	80
Takada	1976	61	I	30	>12		
Nakayama	1978	22	I	15	>12		
Pereiras	1978	12	P	6	4-30	2/12	17
Hoevens	1978	7	I	7	>27	1/7	15
Hansson	1979	32	I/P	32	8	8/32	25
Hoevens	1979	13	I/P	13	8	5/13	38
Burcharth	1979	34	I/P	32	8.5		
Koster	1979	8	I	8	6	5/8	62
Pollock	1979	15	I	10	14	0/15	0
Mendez	1980	15	P	15	<26	0/15	0
Ferrucci	1980	58	E/I	38	17	12/38	31.5
Hellekant	1980	8	P	8	8	2/8	25
Berquist	1981	37	I	34	18		
Dooley	1981	37	I/P			12/37	32
Riemann	1981	33	I			16/33	48
Smale	1981	35	I	25	36		

¹ Type of drainage: E = external; I = external/internal; P = endoprosthesis.

2.2.6 Complications of PTD

Temporary drainage and insertion of an endoprosthesis have their specific complications. These complications are not reported separately in most papers. The number of PTD related complications is variable in the reported series. Major complications are reported in approximately 10-15% of the patients, which is acceptable considering the fact that most patients are in a terminal stage of their malignancy.

The most common complications after PTD are discussed separately. The number or percentages of patients with complications are summarised from the series collected from the literature (appendix II).

Pain was experienced by every patient during the catheter insertion and especially in the first 48 hours after insertion and pain was located at the catheter entry site. Most investigators are satisfied with local anaesthesia although others prefer general anaesthesia during the insertion of an endoprosthesis (102, 149).

Pneumothorax was reported in the collected series in 8 patients (0.5%) (13, 43, 98, 99, 171, 175, 197). Three patients were reported with a bile-stained pleural effusion due to this complication. The pneumothorax and pleural effusion had to be managed with thoracostomy drainage in these patients. The other five patients were treated conservatively. This complication led to death in one patient who also suffered from severe emphysema.

Haemobilia was mostly caused by bleeding through the catheter from side holes placed within the hepatic parenchyma and was described by many authors (13, 71, 99, 159, 165, 168, 171, 175, 201). Among the 34 reported cases (2%) in the summarised literature, no problems in the management of this complication were reported. The bleeding was easily controlled by replacing the catheter. Due to this complication, clotting could lead to occlusion of the catheter.

Intra-abdominal haemorrhage was reported in 16 patients (1%) and leading to death in 3 patients (0.2%) (171, 179). Bleeding was believed to be the result of multiple punctures with a sheathed needle (71, 171, 179).

Bile leakage was reported in 19 patients (1.1%). Leakage was found around the catheter even after a successful drainage procedure. Localised pockets of bile were reported in the right upper abdomen which could be treated conservatively in most patients. Three patients were treated with emergency laparotomy and two patients (0.1%) died due to bile leakage and septicaemia (179). However, in some patients bile leakage was only discovered at autopsy (31).

Dislodgement of the catheter was reported in 71 patients (4%). It was less frequently seen after insertion of an endoprosthesis (31, 161). In the patients who underwent

internal/external drainage dislodgement was a major problem according to some authors (60, 107). In contrast to this, others reported only a few patients with dislodgement of a drainage catheter (175, 179). Direct reintroduction of the catheter along the transhepatic tract using fluoroscopic guidance was advised by Ferrucci *et al* in order to avoid cholangitis or bile leakage (71).

Fever, cholangitis and septicæmia were reported with a wide variation in frequency. Some authors (5, 149, 175) did not report any infection at all, while others reported an incidence of cholangitis between 10-50% (45, 71, 93, 159).

McPherson *et al* reported that infection was the major hazard of catheter drainage (158, 159). In this study, most patients were operated on while the bile was infected and at least two postoperative deaths (6%) were associated with this infection. Liver abscesses were also reported during the drainage period (45, 135, 159, 195).

Despite the different data of infection most authors agree that antibiotic prophylaxis should be used during every catheter manipulation and during cholangiography. However, Burcharth *et al* and Wiechel reported cholangitis in only a few patients without using antibiotic prophylaxis (30, 255). The chance of septicæmia is much higher after catheter dislodgement or occlusion, because bile duct pressure can rise again. The PTD procedure sometimes creates small biliary venous fistulae in the liver permitting direct flow of infected bile into the blood stream (43).

Recently Clouse *et al* reported that the presence of bacteria in the bile of well drained patients did not lead to septicæmia and he clearly showed that multiple duct obstruction was the main factor in determining which patients would develop clinical infection (45).

Cholangitis after a drainage period of a few months was seldom seen in some reports (30, 226) although others suggested that every patient with a drainage period of more than 3 months had at least one attack of cholangitis (71, 93).

Arteriovenous shunts in the puncture tract were reported in a few patients. Angiography showed also arterioportal shunts in patients after PTC-procedure (101, 109). Okuda *et al* reported that arteriovenous fistulae were mostly arterioportal and occurred in almost 5% after liver biopsy, in 3.8% after PTC and in 26.2% after PTD-procedure (184). The calibre of the needle and the length of penetration in the liver parenchyma seemed responsible for the increasing numbers. Small fistulae seemed to close spontaneously and were mostly unaccompanied by symptoms. However, one patient of Hoevels and Nilsson with an intrahepatic aneurysm died of liver insufficiency following therapeutic embolisation of the arteriovenous shunt (109).

Metabolic effects were reported in the more recently published series (71, 99, 159). After several days of external drainage these patients showed clinical symptoms of lethargy and altered mental status caused by hyponatremia. Bile contains large quantities of sodium and bile salts and bile or electrolyte replacement is sometimes required. Unfortunately most patients do not like to drink their bile, but the use of small bore nasogastric tubes can be helpful (179).

Metastases in the skin near the catheter entrance or in the catheter tract were reported in 3 patients (0.2%) (107, 130, 186). This complication was seen in one patient after two years of palliative drainage. Peritoneal seeding was once reported after bile leakage (162).

Mortality, directly related to the drainage procedure was reported in only 13 patients (0.8%) in the series collected in appendix II. These patients died due to complications which have already been summarised.

2.3 The percutaneous transhepatic approach and new diagnostic and therapeutic possibilities

Introduction

In recent years due to improved experience with PTD secondary diagnostic and therapeutic manipulations through the catheter have been developed. All types of equipment to perform a brush biopsy, balloon dilatation, transhepatic stone removal, percutaneous cholangioscopy and even insertion of radiation wires have been developed. Despite these acquired technical exercises, such techniques will have to prove their practical value in the near future.

It seems appropriate to summarise the current status of a few of these new techniques.

Percutaneous brush biopsy for cytological diagnosis of lesions affecting the bile ducts has recently been reported and a biopsy forceps can be introduced along a preplaced guide wire (67, 73, 161, 204). Although the results are limited, a confirmed diagnosis has been possible in 80% of the patients (67, 161, 204).

The direct fine needle aspiration biopsy is more commonly used and has been described by many authors (8, 68, 149, 182). The success rate of direct aspiration biopsy in the published series varies from 60-90%.

Balloon dilatation of benign biliary strictures was suggested by Burhenne in 1973 through the T tube tract (34). The use of the transhepatic approach to dilate stenoses at the site of the choledocho-enterostomy anastomosis was first described in 1978 by Molnar and Stockum (166). The progressive dilatation was obtained by indwelling catheters and later a caged balloon catheter was used. In their series the longest follow-up period after such a dilatation was 7 years without symptoms of recurrence. The use of a Grüntzig angioplasty balloon catheter has been described more recently (73, 150, 187, 233). The balloon is inflated 6 times per sitting and the inflation pressure is about 6 atm. Several dilatations have to be carried out and after the procedure a drain is left through the dilated area for at least 3 months.

Oleaga and Ring reported that the balloon-dilatation was less effective in dilatation of primary strictures of the common bile duct (187). The authors declared that in a circumferential stricture, like in an anastomosis, the pressure of the balloon was

transmitted directly to all areas of scarring while in eccentric lesions the balloon was only displacing the softer normal tissue (187).

Percutaneous dilatation has also been used in two patients with sclerosing cholangitis and both seem to have benefited from it (150, 151).

Despite the good results of balloon dilatation, the long-term success rate is still uncertain, however, in high risk patients it seems a reasonable alternative to surgical treatment.

Percutaneous transhepatic stone removal was developed analogous to the balloon dilatation. The stone removal through the T tube tract, the so-called Burhenne-technique, was described by the same authors (34, 35, 36, 154, 155).

The percutaneous tract as a new approach for basket extraction of retained stones was reported in 1979 (199). The discrepancy between stone size and liver parenchyma tract calibre is the limiting factor.

The removal of common bile duct stones is also performed by manoeuvring the stone into the duodenum with a Dormia basket (46, 149). Sometimes dilatation of the papilla of Vater or stone dissolution solvents were necessary to allow stone passage (42, 89, 145).

However, endoscopic sphincterotomy and stone removal is very successful ($\pm 85\%$) and is generally accepted as the method of choice (51, 79, 220). The percutaneous approach should be reserved for selected patients (46).

Percutaneous Transhepatic Cholangioscopy (PTCS) has recently been developed by Japanese investigators (Nimura *et al*, 177). The endoscope with a 3.8 mm diameter is brought in through the drainage catheter. With this endoscope, biopsies can be taken and retained bile duct stones can be crumbled under direct cholangio-fiberscopic control. The newest technique of crumbling common bile duct stones is the laser technique, which was also introduced by Nimura *et al* (178).

Transhepatic radiotherapy has been reported by Conroy *et al* (47). Radium is inserted through the drainage catheter in the area of a malignant stricture and applied for 24 hours.

A new technique of internal radiotherapy with a ^{192}Ir Iridium wire through a biliary tract catheter in patients with proximal bile duct carcinoma was introduced at the same time (2, 73, 75, 103). The radionuclide in the bile duct catheter can deliver a highly concentrated dose to the tumour and a limited dose to the surroundings. The ^{192}Ir Iridium wire can also be combined with external radiotherapy (169). Despite longer survival time after radiotherapy in some reports (20, 86, 140, 236, 237), the benefit of external and/or internal radiotherapy has never been shown in a randomised study.

Percutaneous manoeuvres in the catheter track: After improved experience with percutaneous drainage and manipulations through the drainage catheter and catheter track many manoeuvres have been described for preventing catheter dislodgement or for replacing dislodged catheters.

New biliary endoprostheses have been described (48, 210, 234) in order to prevent dislodgement and endoprostheses have been secured by subcutaneous buttons (164) or by stoma wafers (225).

Cannulation of the catheter track has been described for replacement of a dislodged catheter (82, 191, 238) and the balloon catheter has been used for repositioning of biliary endoprosthesis (90, 96, 113).

2.4 Palliative drainage procedures other than PTD

2.4.1 Bypass surgery

Bypass surgery in obstructive jaundice will only be briefly reviewed. The results of the palliative percutaneous drainage will be compared with the results of the surgical bypass procedure in chapter 5.

Bypass surgery for distal bile duct obstruction: Eight different types of biliary bypass procedures in patients with malignant obstruction in the area of the periampullary region were described by Buckwalter *et al* in 1965 (27). The results of these different bypass procedures have frequently been reported by others (25, 26, 39, 56, 57, 69, 174, 216, 223), with a survival time varying between 2 months (57) and 12 months (56) while the 30 day mortality of the procedures varies between 4% (223) and 33% (69). The series of Sarr and Cameron will be discussed separately (216). These authors reviewed 8571 patients, published in the English literature in the period 1965 to 1980, with an inoperable carcinoma of the pancreas. The mortality of bypass procedures was 19% with a mean survival time of 5.4 months. The mortality in patients in whom only a laparotomy was performed was even higher (26%). In the larger series in his review a bypass procedure could be carried out in approximately 70% of the patients (55, 76, 133, 203). The mortality of bypass surgery in these collected series was high but one has to realise that some of the patients collected, dated back as far as 1929 (55).

In more recent studies, mortality after a bypass procedure is reported between 4-10% (167, 180, 188, 247).

Bypass surgery for high bile duct obstruction: In most series, surgical drainage of a high stricture (mostly caused by bile duct or extensive gallbladder carcinoma) is achieved by an intrahepatic bilio-jejunal anastomosis as first described in the French literature by Soupault and Couinaud in 1957 (229).

Excellent results were reported by Bismuth and Corlette with a mortality of 4.5% and a mean survival of 13 months (15). In most other reports the mortality of this type of bypass procedure was much higher and varied from 10-40% (115, 138). Resection of the lateral part of the liver lobe with an extra-hepatic cholangio- or hepato-jejunostomy (38, 143, 144, 148) or other intrahepatic anastomoses have also been described (37, 227).

The results of these bilioenteric bypass procedures were summarised in the thesis of Boerma (20). The operative mortality in his collected data was 23.8% with mean postoperative survival of 11.2 months.

2.4.2 Transtumoural tube drainage

Several types of peroperative tube intubation after dilatation or perforation of the tumour have been described (104, 176). The U-tube drainage reported by Terblanche *et al* and modified by others appears to be the method of choice (19, 134, 235, 236, 239). It has the advantage that the tube can be easily changed after occlusion. The survival time of patients with a tube drainage varies widely in different reports (from a few months up to five years) especially when the tube drainage is combined with radiation therapy (20, 24, 236).

In the collected series the operative mortality has been 15.3% and 17% and mean survival times were 11.4 and 9.9 months respectively (20, 24).

2.4.3 Transpapillary biliary drainage and endoprosthesis

The transpapillary introduction of an endoprosthesis was first described in 1980 by Soehendra and Reynders-Frederix (228). The nasobiliary tube had already been introduced earlier and was in regular use after endoscopic sphincterotomy for common bile duct stones (49, 258, 259) and even as a preoperative decompression in patients with malignant obstruction (118, 189).

Today, the endoscopic method for placing an endoprosthesis is adopted in many centres but not very many patients results have been reported (44, 52, 91, 92, 117, 139, 215).

In the series of Cotton duodenoscopic placement of a biliary prosthesis was attempted in 23 patients (52). In 5 patients, the endoscopic approach failed, 3 patients were submitted to laparotomy and of the remaining 15 patients with a functioning prosthesis, 5 died due to septic complications.

At the same time, Huibregtse and Tytgat reported a series of 54 patients of whom in 45 (85%) an endoprosthesis was introduced successfully. Eighteen died with a median survival time of 6 weeks, one patient was operated on, and 26 were alive with a median follow-up of 4 weeks. A thirty day mortality rate was not mentioned but 4 patients died during the first week after insertion of the endoprosthesis (117). Similar results were also reported by Safrany *et al* (215).

Septic complications were described as the most common problem (52, 117, 215). However, longer calibre endoprostheses diminished these complications (78, 116, 126).

Recently, Hagenmüller and Soehendra reported on 58 patients with an endoprosthesis. The mean survival time was 17 weeks and the median survival time 9 weeks. The hospital mortality was 31% (18/58) while complications were reported in approximately 14% (92).

The same authors studied collected data of endoscopic transpapillary drainage and percutaneous drainage. The placement of an endoprosthesis could be achieved in 82.5% endoscopically and by a percutaneous transhepatic approach in 95%. The frequency of complications was roughly identical 14.8% and 15.9% respectively (91, 92). The endoscopic and percutaneous technique are currently being compared in a prospective trial (54).

Investigations concerning PTC and PTD

Chapter 3

Retrospective study on percutaneous transhepatic cholangiography

3.1. Introduction

The PTC was introduced in St. Annadal Hospital in 1977 as a diagnostic procedure in patients with jaundice. Ultrasound, CT-scan and ERCP were not available at that time.

Therefore PTC was sometimes performed to differentiate between intrahepatic and extrahepatic disease. However, in most patients PTC was performed to confirm the diagnosis of obstructive jaundice, to visualise the biliary tree and localise the level and origin of the obstruction.

This retrospective study was performed to examine whether the more liberal use of PTC and the extension of this procedure with percutaneous drainage was justified. After the results were studied a standard diagnostic approach to patients with jaundice (the so-called 'decision-tree') was developed in 1979.

3.2 Patients and methods

During the period from February 1977 to February 1979, PTC was performed in 45 patients (25 female and 20 male) with jaundice with a mean age of 68 ± 14.1 years. The mean duration of jaundice was 2.8 ± 4.4 weeks. The mean plasma bilirubin level before PTC was $185 \pm 169 \mu\text{mol/l}$ (normal $< 14.5 \mu\text{mol/l}$). The mean alkaline phosphatase was $644 \pm 406 \text{ U/l}$ (normal $< 120 \text{ U/l}$) Coagulation disorders had to be corrected in 7 patients before the procedure.

After clinical and laboratory examination, 38 patients (84%) seemed to have obstructive jaundice and PTC was performed to confirm the diagnosis (extrahepatic jaundice), to visualise the biliary tree and to localise the level and the origin of the obstruction. In the remaining 7 patients PTC was performed to differentiate between intrahepatic (parenchymal) and extrahepatic disease.

Technique After correction of coagulation disorders by parenteral administration of vitamin K the patient was premedicated with 5 mg diazepam. The examination was carried out in the radiology department under fluoroscopic control.

The Chiba needle (a 17 cm long thin flexible needle, 0.7 mm in diameter, with a stylet) was used in all patients.

Under local anaesthesia with 1% lidocaine the needle and stylet were introduced in the midaxillary line at the eighth or ninth intercostal space. The needle was inserted

during apnoea, parallel to the plane of the table in the direction and not further than about 3 cm to the right of the 12th thoracic vertebra.

After the stylet had been removed, contrast medium was injected while the needle was withdrawn very slowly. When the bile duct was entered and identified, approximately 50 ml contrast medium was injected for visualisation of the biliary tree.

The contrast medium in the biliary tree flowed slowly in a hepatofugal direction while contrast medium in the blood vessels was recognised easily by rapid disappearance. Parenchymal injection was identified by a persistent collection of contrast medium. After visualisation of the bile ducts, the needle was withdrawn and radiographs were taken in two directions and in an upright position for visualisation of the lower biliary tree.

One radiograph was made 15 minutes after the procedure for the same reason. If no bile duct was punctured a maximum of six attempts were made.

3.3 Results

In 43 of the 45 patients (95.5%) visualisation of the bile ducts was obtained. The success rate was 97.5% in patients with dilated ducts and 86% in the non-dilated bile duct group (6 out of 7 patients).

Four patients had no bile duct dilatation and no abnormality in the intrahepatic or extrahepatic biliary tree and in 3 patients common bile duct stones were found

Table 5 PTC (chiba needle) St. Annadal Hospital, February 1977 – February 1979: success of the procedure and diagnosis of the patients (n = 45).

	Number of patients	Visualisation N	%	Extrahepatic disease	Intrahepatic disease
Dilated bile ducts	38	37	97.5	37 + 1 ¹	–
Non-dilated bile ducts	7	6	86	2 + 1 ¹	4
Total	45	43	95.5	41	4

Diagnosis extrahepatic disease (n = 41)

<i>Benign</i>		<i>Malignant</i>	
Common bile duct stones	15	Pancreatic carcinoma	11
Benign stricture	4	Bile duct carcinoma	6
		Gallbladder carcinoma	4
		Peri-ampullary carcinoma	1
	19		22

¹ Bile ducts visualised during laparotomy.

without bile duct dilatation. The remaining 38 patients proved to have obstructive jaundice with bile duct dilatation.

The diagnosis of the 41 patients with extrahepatic disease are summarised in Table 5. All these patients except two who refused treatment were operated on within 72 hours of the PTC procedure.

The PTC diagnosis could not be confirmed at laparotomy in two patients. In both, the PTC was reported as a high common bile duct stricture probably due to bile duct carcinoma. At laparotomy, one patient had a pancreatic carcinoma and a choledochojejunostomy could easily be performed. The other patient had a papillary stenosis without any sign of malignancy. The PTC diagnosis was confirmed at laparotomy in the remaining patients.

The complications of the procedure were all minor except in one patient with bile leakage. This patient was operated on 12 hours before schedule because of fever and upper abdominal tenderness. In one patient, the gallbladder was inadvertently punctured without any complaints or signs of bile leakage. Two patients developed temperature after the procedure without further septic complications.

The operations which were performed are summarised in Table 6. The patients with pancreatic carcinoma in which a choledochojejunostomy was performed are discussed in chapter 5 in an attempt to compare the results of bypass surgery with endoprosthesis as a palliative procedure.

3.4 Discussion

The overall success rate in visualising the bile ducts was 97.5% in patients with dilated ducts. The same percentages have been described in the recent literature (chapter 2.1.2)

Complications were reported in 4 patients in this study and except one, were minor. In

Table 6 Treatment of patients (PTC study) with extrahepatic obstruction (n = 41).

A Benign disease (n = 19)

- Common bile duct stones	choledochotomy (T drain)	9
	choledochojejunostomy	5
	no treatment (refused)	1
- Benign stricture	choledochojejunostomy	4

B Malignant disease (n = 22)

choledochojejunostomy	10
hepaticojejunostomy	7
Whipple procedure	1
laparotomy and biopsy	3
no treatment (refused)	1

the summarised series and the review of Harbin *et al* the complication rate was reported about 5% (94). No deaths were reported in the present study.

Looking at these results it can be concluded that PTC can be used effectively in the work-up of the patient with jaundice.

The lateral approach was successfully used in these patients and will also be used in the PTD study.

The question: is the level of obstruction visualised accurately after PTC is important, because in the following study endoprotheses were inserted in the inoperable patients and the length of the endoprosthesis and the location of side holes in it had to be measured during the cholangiography studies.

In spite of upright and prone X-rays made during the PTC procedure, the exact level of obstruction could not be confirmed in 2 patients (5%) at laparotomy. A pseudo-obstruction at hilar level has also been reported in the literature (70, 132, 142, 170). These various authors have reported the failure of the contrast material to enter the stagnant pool of bile proximal to the obstruction. Some authors advise aspiration of as much bile as possible before injection of the contrast medium to avoid this problem (70, 142). However, this is difficult through the Chiba needle and directly related to the thinness of the needle used (9, 65, 119). In the future this problem will probably be solved by advancing a catheter in the bile ducts up to the proximal border of the stricture (chapter 5).

Chapter 4

Diagnostic approach to the jaundiced patient in St. Annadal Hospital in the period 1979-1983

During the past 10 years a diagnostic revolution has occurred and diagnostic laparotomy in the jaundiced patient has been abandoned. After new and safe techniques such as Ultrasound and Computed Tomography became available and the relatively safe but invasive PTC technique was established, it seemed reasonable to look for a more programmed diagnostic approach to the jaundiced patient.

A standard diagnostic work-up of the patient with jaundice has been described recently by many investigators (18, 110, 190). These so-called 'decision-trees' were all more or less the same and had the advantage of establishing the diagnosis in most patients within a short period of time.

The first results from percutaneous drainage were then starting to appear and it seemed justified to include the PTD procedure in the decision-tree (175, 230).

The PTD could either be used as a preoperative temporary drainage for improving the general condition of the patient before laparotomy or as a palliative continuous drainage procedure in patients with unresectable obstructions of the bile ducts.

The decision-tree which has been used from 1979 is given in fig. 4.

After medical history, physical and laboratory examination, Ultrasound is used to differentiate between dilated and non-dilated bile ducts. If the Ultrasound demonstrates dilated bile ducts, PTC is performed. Every PTC is followed by PTD. During the PTD procedure an aspiration biopsy is performed for cytological diagnosis. In most cases, the diagnosis is established and adequate information is obtained for a definitive choice of treatment (laparotomy or non-surgical treatment).

The non-surgical treatment, palliative continuous drainage preferably with an endoprosthesis, is performed in patients with inoperable extensive disease or in patients with a bad general condition.

In the other patients further investigations such as CT scan, selective angiography and percutaneous portography are performed in order to investigate the operability of the obstruction. When patients appear to be inoperable during these investigations palliative treatment can also be performed by insertion of an endoprosthesis. At that time ERCP was only seldom used and was therefore not included in this decision-tree.

Fig. 4. Diagnostic approach to the jaundiced patient in St. Annadal Hospital in the period 1979 – 1983.

Chapter 5

Prospective study on percutaneous transhepatic drainage

5.1 Introduction

From February 1979 up to August 1983 Percutaneous Transhepatic Drainage was performed in a group of 82 consecutive patients. All patients had obstructive jaundice and the procedure was performed after demonstration of dilated bile ducts by Ultrasound as described in the decision-tree based on the PTC study (fig. 4).

First of all the technique of PTD, the equipment for PTD and the post-procedural care are described extensively because it will be clearly shown that these are the factors of determining the results of the drainage procedure.

The diagnostic value of the PTD procedure and the results and quality of the drainage are studied. The different aspects of the drainage procedure: preoperative drainage in patients with benign and malignant obstruction and continuous palliative drainage as an alternative to surgical bypass procedures will be discussed.

5.2 Technique of PTD

5.2.1 Preparation

Careful preparation of the patient and review of all previous diagnostic studies are necessary, as they are critical steps in the reduction of complications from PTD. Both corrections of possible coagulation disorders by parenteral administration of vitamin K and antibiotic prophylaxis (gentamicin and amoxycillin) started one hour before PTD are mandatory. Complications such as bleeding and (immediate) post procedural septicaemia caused by the passage of infected bile directly into the bloodstream (due to the trauma) can so be avoided.

Ultrasound and/or CT examination can provide information on the presence and the location of intrahepatic (metastatic) lesions or degree of dilatation of the different intrahepatic ducts.

Puncture through metastatic lesions in the right lobe of the liver makes movements of the needle and correction of direction of the puncture more difficult and if possible the puncture tract should be selected elsewhere.

The PTD procedure is performed directly following the PTC. Depending on the patient's condition, local anaesthesia can be used, but analgetics are necessary in order to avoid liver damage caused by movement during the actual procedure.

5.2.2 The PTD procedure

The PTD procedure is performed in the radiology department under fluoroscopic control with facilities for lateral screening. In most patients, a catheter with 1.0 mm inner diameter and 1.4 mm outer diameter is used for puncture of the bile ducts.

Prior to the puncture, the lateral costophrenic angle is localised in deep inspiration and the intercostal space is marked at this point. The border of the liver has already been distinguished in most patients during the initial fluoroscopic monitoring. Puncture of the bile ducts is performed during apnoea in the 8th or 9th intercostal space at least one below the marked level, in the midaxillary line and pointed towards the 12th thoracic vertebra.

The needle is inserted horizontally and pointed not further than about 2 cm to the right of the vertebral bodies. The stylet is removed and while the patient may breathe again the catheter is slowly withdrawn until bile passes through it. The injection withdrawal manoeuvre is not used. After puncture of the bile ducts, a bile culture is taken, bile pressure can be measured and the bile ducts are visualised. When (unexpectedly) non-dilated bile ducts are found without abnormality the procedure is terminated. When dilated bile ducts are found, a J wire guide is passed through the catheter into the bile ducts and the catheter is advanced over the wire guide into the

Fig. 5. Puncture of the bile ducts.

Fig. 6. The wire guide is passed through the catheter into the bile ducts.

Fig. 7. The catheter is advanced over the wire guide into the bile ducts.

duct system (fig. 5-7). Sometimes, the wire guide and catheter are inserted without difficulty up to the level of obstruction. Otherwise, the catheter is advanced in one of the bile ducts. After as much bile as possible is drained off, the proximal margin of the obstruction can be visualised and one can get an impression of the cause of obstruction. When common bile duct stones are found, the catheter is left behind as a temporary drainage and surgery is performed within a few days (fig. 8).

If the obstruction is not caused by bile duct stones, a longer drainage period and further investigations are necessary. A second catheter is inserted, preferably in the dorsocaudal branch of the right hepatic duct, so as to make the length of catheter in

Fig 8. Percutaneous drainage catheter (arrow) in patient with a common bile duct stone.

Fig. 9. Puncture with a second needle into the dorso caudal branch of the right hepatic duct.

the bile ducts longer and in the liver parenchyma shorter (fig. 9). The first catheter is left behind in the bile duct during the whole procedure and can be used to inject more contrast medium during the manipulation of the second catheter. This second catheter is inserted at least 2 cm posteriorly and 2 cm caudally from the first one. The wall of the already visualised bile duct indents slightly when this second needle enters the duct and after this, the needle is pushed 1-2 mm further forward.

The wire guide and later the catheter are inserted and manoeuvred to the proximal margin of the constricted area until the flexible tip of the wire guide is in front of the beginning of the stricture (fig. 10-11). In most patients, the wire guide and catheter are most easily manipulated through the dorsocaudal branch of the right hepatic duct because this branch follows a semicircular route and pressure on the catheter from the outside is uniformly transferred to the tip of the catheter.

The wire guide and afterwards the catheter are then manoeuvred through the stricture (fig. 12-13). A straight wire guide with a flexible tip is most useful. When the stricture cannot be passed in the first attempt, the bile ducts are decompressed externally for a few days after which a second attempt is usually successful. This is probably due to decreasing of oedema around the stricture. After passing the constricted area, the wire guide is pushed into the duodenum to diminish movements of the wire and prevent

Fig. 10/11. The wire guide and later the catheter are inserted and manoeuvred to the proximal margin of the constricted area.

Fig. 12/13. The wire guide and afterwards the catheter are manoeuvred through the constricted area into the duodenum.

Fig. 14. Fine-needle aspiration biopsy at the proximal border of the obstruction (arrow).

Fig. 15. Multiple side holes in the catheter proximal and distal to the obstruction for external and internal drainage.

pull-back proximal to the obstruction. The exact extension of the obstruction can be visualised and percutaneous fine needle aspiration biopsy with the Cameco aspiration pistol can be performed for cytological diagnosis. Aspiration biopsies are taken anteriorly and at the proximal border of the obstruction (fig. 14).

Temporary drainage is allowed externally and internally through multiple side holes in the catheter proximal and distal to the obstruction (fig. 15). For temporary drainage, the catheter is changed over the wire guide for a stiffer and thicker catheter (2 mm). The Wiechel-Stillé catheter is too thin and flexible so that dislodgement occurs frequently. Further investigations concerning the operability of the stricture are necessary (chapter 4). If the patient and/or the obstruction proves to be inoperable, the temporary drainage can be changed for continuous drainage by an endoprosthesis but before this can be inserted, the catheter tract has to be dilated to 3.4 mm with two dilators (fig. 16). At this stage, a rather stiff wire guide is sometimes helpful. A rotary or screw-like motion often helps to penetrate the liver capsule and to enter the bile duct. The larger dilator is reversed and used to advance the endoprosthesis (which has the same diameter) over the smaller dilator into the correct position (fig. 17). The dilatation and insertion of the endoprosthesis is most of the time painful

Fig. 16. The catheter tract is dilated to 3.4 mm with two dilators over a stiff wire guide.

Fig. 17. The larger dilator is used to advance the endoprosthesis over the smaller dilator into the correct position.

Fig. 18. The endoprosthesis is in the correct position. A thin catheter is left in the bile ducts to perform a control cholangiography.

and adequate analgesia should be used. The dilator is removed and a thin catheter is inserted over the wire guide and left in the bile ducts just proximal to the endoprosthesis for external drainage and for performing a control cholangiography one day later (fig. 18). If drainage via the endoprosthesis is adequate, this catheter is subsequently removed (fig. 19). The insertion of an endoprosthesis is summarised in Appendix III.

In patients with a high obstruction of the bile ducts palliative drainage is performed in an identical way by insertion of an endoprosthesis when free communication between the left and right hepatic ducts should result. Even in some patients with the right and left hepatic ducts both blocked, palliation is sufficient when only one liver lobe is decompressed (fig. 20 ab).

However, in most patients with obstruction of the confluence the undrained lobe is not completely obstructed and unfortunately ascending cholangitis of the undrained lobe is a common problem. For these patients, it is advisable to use a combined left-right internal drainage system:

The first part of the drainage procedure is equal and in most patients the procedure is started with internal drainage of the right liver lobe (fig. 21).

Selective puncture of the left hepatic duct is performed from the right side (lateral approach) or via a left subcostal approach. The right side approach is more conve-

Fig. 19. Continuous drainage after insertion of an endoprosthesis in a patient with pancreatic carcinoma.

Fig. 20. a, b. Combined external/internal drainage (a. arrow) and drainage after insertion of an endoprosthesis (b) in a patient with proximal bile duct carcinoma. The left hepatic duct is not completely obstructed (b. arrow).

nient because fluoroscopic monitoring is easier and allows a lower radiation dose to the operator's hands. The puncture site at the right side approach is 1 cm anterior and 1 cm superior to the first needle entry. After puncture of the left hepatic duct, the wire guide and drainage catheter are always easily manipulated because of the straight course of the left hepatic duct (fig. 22). The left external drainage catheter can be connected externally to the right drainage catheter which passes through the obstruction so that bile from the left lobe can be drained internally to the duodenum via the right side catheter in a closed system (fig. 23 ab).

When the constricted area extends into the liver obstructing more intrahepatic ductal systems, a third drain can be placed selectively and also connected to the closed system (fig. 24). Up to 3 percutaneous catheters were necessary in some patients. Sometimes, drainage of the right liver lobe is only external and the left hepatic duct has to be punctured from the left side because this is the best approach for internal drainage of the left lobe of the liver (fig. 25).

Fig. 21. Internal drainage of the right liver lobe in a patient with proximal bile duct carcinoma. A broken catheter is left behind in the liver (arrow).

Fig. 22. External drainage of the left liver lobe (same patient as fig. 21). Straight course of the left hepatic duct (arrow).

Fig. 23. a, b. A.P. and side view of a patient with proximal bile duct carcinoma. The left liver lobe is drained externally (nr. 2). This catheter is connected outside the patient to the internal drainage of the right liver lobe (nr. 1). Thus bile from both liver lobes is drained into the common bile duct.

Fig. 24. The right liver lobe is drained internally (nr. 1) and the left liver lobe is drained selectively by one catheter in the Segment II duct (nr. 2) and one in the Segment III duct (nr. 3). Both external catheters of the left hepatic duct are connected to the internal drainage catheter of the right liver lobe.

Fig. 25. The right hepatic duct is drained externally (nr. 1) and connected to the internal drainage of the left hepatic duct (nr. 2) in a patient with proximal bile duct carcinoma.

Fig. 26. Equipment for the PTD procedure:

1. drainage catheter 1.8 mm; 2. puncture and drainage catheter 1.4 mm; 3. Chiba needle; 4. dilators 2.0 and 3.4 mm; 5. endoprosthesis 3.4 mm; 6. endoprosthesis 2.0 mm; 7. J-wire guide.

5.2.3 Equipment

In all patients, a thin catheter is used for puncture of the bile ducts (fig. 26). Straight-and J-wire guides are used to advance the catheter in the bile ducts towards the obstruction. The stiff Lunderquist wire guide is mostly used for changing the catheters. The temporary external or combined external/internal drainage is performed with a 6-8 French polyethylene catheter with selfmade side holes. Softer silastic and less traumatic catheters are used for the long-term combined left/right internal drainage. The soft silastic catheter is stored at -20°C to facilitate its introduction. In the first part of the study, the polyethylene catheter (2.0 mm) was used as an endoprosthesis, but during recent years, the Lunderquist-Owman endoprosthesis (3.4 mm) has been used and introduced with the help of a dilator set.

5.2.4 Post-procedural care

The post-procedural care is performed on a surgical ward. The patient remains in bed and is not allowed to turn on his left side for the first 24 hours. Early mobilisation,

Fig. 27. Dislodgement of a thin drainage catheter in a patient with pancreatic carcinoma. Mobilisation created a space between liver (arrow) and abdominal wall.

particularly when the patient turns to his left side, creates a space between liver and abdominal wall and can cause dislodgement of the catheter (fig. 27). Pulse rate, blood pressure and ventilation are checked hourly for 12 hours.

The daily care of the catheter is simple. Irrigation of the catheter is performed once a day with 10 ml saline. The catheter entrance is sealed off with betadine iodine. The drainage bag is emptied every 24 hours and the bile production is measured. Bile cultures are taken if the patient develops fever and always during catheter changes and cholangiography.

Liver function tests and electrolytes are repeated twice weekly. In patients with external drainage, electrolytes have to be measured more frequently. If a patient has external drainage for a long period, bile is returned orally or by nasogastric tube. Control cholangiography is performed after 2 days or earlier if bile drainage is decreased or if signs of septicaemia are present.

In patients with a combined internal and external drainage system the daily care is the same. The daily external bile production is not representative for catheter function because bile is mostly drained internally. If the patient is discharged with an external drainage catheter, daily saline irrigations are continued.

Out-patient visits are in the beginning monthly and thereafter every three months; patients are instructed to return immediately should signs of fever (cholangitis) develop or if bile drainage decreases. Cholangiography or catheter changes are only performed if necessary. Liver function tests are performed at every visit.

5.3 Patients and materials

The mean age of the 82 patients was 71.1 ± 11 years. There was no difference in age between the patients with benign ($n = 21$) or malignant ($n = 61$) disease (fig. 28).

The male to female ratio was almost 1:1 (40 male and 42 female).

All patients had obstructive jaundice for a mean period of 3.1 ± 4 weeks. There was no difference in duration of jaundice between patients with benign or malignant disease. Forty-four of the jaundiced patients (54%) had complaints of itching and most of these patients (36/44) had malignant disease.

Fig. 28. Distribution in age of patients with malignant ($n = 61$) and benign ($n = 21$) obstruction.

Table 7 Medical history of patients with obstructive jaundice (n = 82).

	Number of patients	Period of jaundice weeks mean $\pm$ SD	Number and (percentages) of patients with:			
			Itching	Pain	Fever	Cholecystectomy
Benign	21	3.2 $\pm$ 2.8	8 (38)	14 (66)	7 (33)	5 (24)
Malignant	61	3.1 $\pm$ 4.4	36 (59)	26 (43)	6 (10)	8 (13)
Total	82	3.1 $\pm$ 4.0	44 (54)	40 (49)	13 (16)	13 (16)

Pain was reported in 40 patients (49%) of which 26 patients had malignant disease and 14 had benign disease. A history of typical colic pain was reported in 33% of the patients with common bile duct stones but also in 11% of the patients with malignant disease.

Fever was more commonly noted in patients with benign disease: it was observed in 33% of the patients with benign obstruction and in 10% of the patients with malignant disease.

Cholecystectomy had been performed in 13 patients (16%): in 5 patients with benign obstruction and 8 patients with malignant obstruction.

Weight loss was more commonly seen in the malignant disease group but was not well documented in all patients.

The preoperative findings are summarised in Table 7.

Physical examination

A palpable mass in the right upper abdomen was found in 36 patients; in 29 patients with malignant disease (48%) and in 7 with benign disease (33%).

The presence of a palpable mass and painless jaundice suggesting a distal malignant obstruction of the common bile duct, well-known as the Courvoisier sign, was reported only in 28% of the patients with malignant disease when the patients with a previously performed cholecystectomy were excluded and was not seen in patients with benign obstruction. The liver was palpable under the costal arch in 58 patients (71%).

5.3.1 Diagnostic investigations

Laboratory tests

Haematological, biochemical and serological investigations are helpful in the diagnosis of the jaundiced patient. The liver function tests are summarised in Table 8.

Plasma bilirubin level of the benign patients had a mean value of $127 \pm 97 \mu\text{mol/l}$ while the mean plasma bilirubin level in the malignant group was significantly higher: $249 \pm 146 \mu\text{mol/l}$. The difference between the mean alkaline phosphatase level in both groups of patients was also significant $433 \pm 146 \text{ U/l}$ and $573 \pm 97 \text{ U/l}$ respectively.

Table 8 Patients with obstructive jaundice (n = 82) and liver function tests (mean $\pm$ SD) before PTD.

	Normal value	Benign n = 21	Malignant n = 61	P value ¹
Bilirubin	< 17 μ mol/l	127 $\pm$ 97	249 $\pm$ 146	< 0.001
Alk. phosphatase	< 120 U/l	433 $\pm$ 146	573 $\pm$ 351	< 0.05
SGOT	< 40 U/l	85 $\pm$ 70	135 $\pm$ 97	< 0.05
SGPT	< 40 U/l	137 $\pm$ 161	194 $\pm$ 165	n.s.

¹ Students unpaired T-test.

The mean SGOT and SGPT in the benign group was 85 $\pm$ 70 U/l and 137 $\pm$ 161 U/l, while the mean SGOT and SGPT in the malignant group was 137 $\pm$ 161 U/l and 194 $\pm$ 165 U/l.

Some laboratory tests are thought to be associated with a differentiation between high and low risk patients. The haematocrit, white blood cell count, serum albumin, serum creatinine and liver function tests are most commonly used (200). A critical level for these laboratory tests has been adapted from Pitt *et al* and the number of patients with increased risk for each factor are summarised in Table 9.

Ultrasound

Ultrasound was used in 77 of the 82 patients (94%) and in all patients dilated intrahepatic bile ducts could be demonstrated.

In most patients with calculous disease stones in the gallbladder could be shown; only in a few cases 4/21 common bile duct stones could be indentified. The level of obstruction could be demonstrated correctly in 47 patients (61%) and could not be reported exactly in 23. It was false reported in 7 patients. In 12 patients liver metastases were detected.

Table 9 Patients with obstructive jaundice (n = 82). Laboratory results assigned to the critical levels to Pitt (200).

	Critical levels according to Pitt	Benign (n = 21)		Malignant (n = 61)	
		N	%	N	%
Haematocrit	< 30%	0	0	0	0
White blood cell count	> 10.10 ⁹ /l	7	33	12	20
Serum albumin	< 30 g/l	8	38	33	54
Serum creatinine	> 115 μ mol/l	3	14	6	10
Bilirubin	> 170 μ mol/l	5	24	42	62
Alkaline phosphatase	> 360 U/l	13	69	44	72

Computed Tomography

Computed Tomography was performed in 22 patients. The cause of obstruction could be reported in 18 patients (88%) of which in 10 patients liver metastases were also detected. In 4 patients all with a proximal bile duct obstruction the level of constricted area was reported correctly, however, the cause of obstruction (gall-bladder carcinoma 2, proximal bile duct carcinoma 1, metastatic lymphadenopathy 1) could not be identified.

Angiography/Portography

Selective angiography and percutaneous portography were performed in 7 and 5 patients respectively during the drainage procedure to investigate the operability and to demonstrate any anatomical variations before laparotomy.

Angiography suggested unresectability in 4 patients. One patient had evidence of liver metastases and in 3 patients the arteriograms showed vascular encasement. Anatomical variations were not reported.

The percutaneous portogram showed encasement of the main portal vein in one patient.

Endoscopic Retrograde Cholangio-Pancreaticography

Endoscopic Retrograde Cholangiography was only performed in the last part of the study. In 10 patients, it was performed before the PTD procedure in an attempt to visualise the biliary tree and in 7 patients after the PTD. In 6 of these 7 patients it was carried out to biopsy the papilla area for histological examination and in one high risk patient with common bile duct stones to perform a sphincterotomy.

5.4 Results

5.4.1 Diagnostic aspects of PTD

PTD was performed in 82 patients. In all patients visualisation of the bile ducts could be obtained. The number of punctures ranged from one to fourteen, but were not recorded in all procedures. In 17 patients, the exact visualisation of the extent of obstruction was obtained after two days of drainage. In this way, the level of obstruction could be clearly visualised in all patients. The diagnosis was verified either by aspiration biopsy, laparotomy or post mortem examination in 72 patients. In 10 patients (12%), the diagnosis was made most likely after ultrasound combined with CT scan and PTD, because no histologically proven diagnosis could otherwise be obtained in these patients. The diagnoses are summarised in Table 10.

Twenty-one patients proved to have a benign obstruction and 61 had a malignancy. The diagnosis of bile duct stones was confirmed at laparotomy in all patients ($n = 18$). The other benign lesions ($n = 3$) were also confirmed at laparotomy by multiple negative biopsies.

Table 10 Diagnosis of the patients with obstructive jaundice (n = 82).

Benign obstruction		Malignant obstruction	
Common bile duct stones	16	Metastatic lymphadenopathy	16 (1) [†]
+ cholangitis	2	Bile duct carcinoma	13 (3) [†]
Papillary adenoma	1	Gallbladder carcinoma	4
Stricture	2	Pancreatic carcinoma	25 (5) [†]
		Periampullary carcinoma	3 (1) [†]
Total	21		61 (10) [†]

[†] Diagnosis on the basis of ultrasound and/or CT-scan and of PTD procedure, not histologically proven.

Table 11 The patients with obstructive jaundice who underwent PTD (n = 82) divided in subgroups according to the drainage procedure used.

Of the 61 patients with a malignancy there was an histological diagnosis in 46 (75%). In five other patients (9%), the diagnosis was confirmed elsewhere before referral to our institution for installation of an endoprosthesis.

A drainage procedure was performed in all patients except one in whom an adequate drainage catheter could not be inserted. This patient was operated on and a surgical bypass was performed (choledocho-jejunostomy).

Because of the different drainage procedures used the patients had to be divided into four groups. In each subgroup a different kind of drainage was employed (Table 11).

5.4.2 Percutaneous drainage in patients with benign obstruction

All patients (n = 21) with a benign obstruction were temporary drained and the diagnostic findings in this group of patients have already been summarised in table 10.

In 13 patients, with common bile duct stones, the drainage catheter was only left behind to prevent bile leakage and bleeding through the puncture tract, whereas the diagnosis of the obstruction was the main issue of the PTD procedure.

These patients were operated on a few days after the procedure and because of this planned short drainage period, only one relatively thin catheter proximal of the bile duct stones was used for drainage. At laparotomy, no bile leakage or blood was found in these patients.

In the remaining 8 patients the temporary drainage procedure was mainly used to improve the general condition of the patient but also to prevent bile leakage during further investigation.

Three of these 8 patients (85, 87 and 88 years) had a preoperative drainage because they were thought to be inoperable at time of the PTD. In one of these patients ERCP was twice performed unsuccessfully in an effort to remove the common bile duct stones but both this patient and the other two were operated on after improvement of their general condition.

Two other patients had severe cholangitis and PTD was performed as an emergency procedure for biliary drainage. After 4 and 6 days of drainage, a laparotomy and cholecystectomy with common bile duct exploration could be performed.

Two patients had benign distal common bile duct strictures and were drained. During that period, further investigations were performed and both patients were operated on successfully.

The remainder of these 8 patients had a stricture after a hepato-jejunostomy and drainage was performed during a period of cholangitis.

The mean drainage period for the 8 patients was 10.2 ± 6.2 days. The serum bilirubin and alkaline phosphatase levels were measured at the beginning and at the end of the drainage period. The mean serum bilirubin level was $140 \pm 101 \mu\text{mol/l}$ dropped to a mean of $64 \pm 87 \mu\text{mol/l}$ while the mean alkaline phosphatase was $405 \pm 171 \text{ U/l}$ decreasing to $234 \pm 70 \text{ U/l}$.

The indications for the drainage procedure in the patients with benign obstruction and the mean drainage period are summarised in Table 12.

Table 12 Indication for preoperative drainage in patients with a benign obstruction (n = 21).

Indication PTD	Number of patients	Mean drainage period (days) $\pm$ SD
To prevent leakage after PTC	13	1
Inoperable (general condition)	3	8
Inoperable severe cholangitis	2	5
Stricture (benign)	2	12
Stricture + cholangitis (postoperatively)	1	25
Total	8	10.2 ± 6.2

In spite of the preoperative drainage there were two deaths in the postoperative period. One of them, a 88 year old female died due to pericarditis probably caused by insertion of a pacemaker preoperatively induced for heart rhythm irregularities.

The second patient (85 years) with common bile duct stones died of pancreatitis. A laparotomy was performed on the fifth day after the drainage procedure, the common bile duct stones were removed and the pancreas area was drained but no improvement was seen after this procedure.

5.4.3 Percutaneous drainage in patients with malignant obstruction

The drainage procedure was performed in 61 patients with malignant obstruction and the diagnoses of these patients are summarised in Table 13. As outlined previously the total group of patients with malignant disease is subdivided in three groups. Fifteen patients had a temporary drainage, 14 patients had continuous drainage with an external drainage catheter and 32 patients had continuous drainage by means of an endoprosthesis. The number of patients with metastatic disease was much higher than the 16 patients with metastatic lymphadenopathy in which the primary reason for obstruction was caused by metastases around the hepatoduodenal ligament. In at least 11 of the other patients with pancreatic or bile duct carcinoma, liver metastases could also be demonstrated.

5.4.3.1 Preoperative drainage in patients with malignant obstruction

This subgroup (n = 15) was made to study the benefits and risks of preoperative drainage. Twelve patients had pancreatic carcinoma, while the other three patients had metastatic lymphadenopathy. A laparotomy was performed in an attempt to perform a curative resection in three patients but in only one a total pancreatectomy could be performed as planned. In all other patients a palliative choledocho-jejunostomy was performed.

Table 13 The diagnosis of patients with malignant obstruction (n = 61) divided into the subgroups.

Diagnosis	Preoperative drainage	Continuous drainage		Total
		External catheter	Endoprosthesis	
Metastatic lymphadenopathy	3	5	8	16
Bile duct carcinoma	-	4	9	13
Gallbladder carcinoma	-	3	1	4
Pancreatic carcinoma	12	2	11	25
Peri-ampullary carcinoma	-	-	3	3
Total	15	14	32	61

The mean age of the patients with preoperative drainage was 64.4 ± 11.2 years. The mean preoperative drainage period was 16.6 ± 16.9 days and the mean bilirubin and alkaline phosphatase levels during this period were those outlined in fig. 29. The number of patients from whom the bilirubin and alkaline phosphatase levels could be calculated were not equal. Despite this, there was a good response to the drainage as expressed by the decrease of bilirubin levels.

Fig. 29. Preoperative drainage in patients with malignant obstruction ($n = 15$). Bilirubin (interrupted line) and Alkaline phosphatase levels after PTD.

To evaluate the possible benefits of the preoperative drainage the postoperative course of the patients can be used as a parameter. Two patients had a wound infection and one patient died 17 days postoperatively from a bleeding of the hepatic artery due to metastatic growth in the artery. The bleeding could be controlled by embolisation but the patient died two days later.

The mean survival time of the patients after palliative bypass surgery for pancreatic carcinoma was 37 weeks (range 2-96 weeks) and one patient (histologically proven pancreatic carcinoma) was still alive 96 weeks later.

5.4.3.2 Continuous drainage in patients with malignant obstruction

Continuous drainage as a palliative treatment ($n = 46$) was performed in 14 patients with external drainage catheters and in 32 patients with endoprosthesis.

The reason for performing a palliative continuous drainage was a combination of:

- the level of obstruction;
- the cause of the obstruction (metastatic disease);
- the general condition of the patient.

Continuous drainage by external drainage catheter (n = 14)

Continuous drainage by an external catheter was performed in 7 patients in whom the drainage catheter could not pass the strictured area, so that external drainage was the only possibility of obtaining biliary drainage. Seven patients had a combined external-/internal drainage but were in such a bad condition that even the insertion of an endoprosthesis was not carried out because of the wish of the family or decision of the medical team.

In the beginning of the study, all jaundiced patients with severe itching were accepted for a drainage procedure and in that period, drainage was even performed in patients who were in the terminal stages of their malignancy. In the second part of this study, after a few years of experience, patients in a very poor condition with a very short life expectancy were refused for drainage.

The mean age of patients that underwent external drainage was 71.4 ± 8.5 years. The mean bilirubin and mean alkaline phosphatase levels of these patients are summarised in fig. 30. The quality of drainage in this group of patients was good in 5 patients (36%), whereas in 5 others, the drainage was moderate because the itching disappeared but the patient remained jaundiced. Four patients (26%) did not benefit at all from the drainage.

Only 4 patients could be sent home with an external drainage catheter. Ten patients died during the same hospital admission after a mean drainage period of 2 weeks. Most patients died from extensive malignant disease or related disorders. Three patients died due to the drainage procedure but they will be discussed in chapter 5.4.4.

Continuous drainage by endoprosthesis (n = 32)

In this group of patients, 33 endoprostheses were installed in 32 patients. In one patient, a second endoprosthesis was installed after the first one became occluded.

Fig. 30. Continuous external drainage in patients with malignant obstruction (n = 14). Bilirubin (interrupted line) and Alkaline phosphatase levels after PTD.

Fig. 31. Continuous drainage (Endoprosthesis) in patients with malignant obstruction (n = 32). Bilirubin (interrupted line) and Alkaline phosphatase levels after PTD.

The mean age of the patients with an endoprosthesis was 73.6 ± 9.7 years. The mean bilirubin and alkaline phosphatase levels of this group of patients are summarised in fig. 31. In 22 patients (69%), the drainage was excellent and bilirubin levels returned to normal. In 7 patients (22%), itching disappeared and jaundice diminished but the bilirubin level decreased only slightly although the drainage was reasonable. Three patients (9%) had a poor drainage: they remained jaundiced and the bilirubin levels did not decrease at all.

The mean survival of the total group of 32 patients was 21 weeks (range 2-99 weeks). When divided into the different malignancies the mean survival time of patients with pancreatic carcinoma, bile duct carcinoma and metastatic lymphadenopathy were 17, 27 and 16 weeks respectively. Three patients are still alive after 82, 16 and 8 weeks with histologically proven malignancies. Twenty-four patients (75%) could be sent home with the endoprosthesis.

In one patient, a 80 year old female with metastasis of a gastric carcinoma, the endoprosthesis became occluded after 20 weeks and a second endoprosthesis was inserted next to the first one. This patient survived 33 weeks.

5.4.4 Complications of PTD

The complications of the drainage procedure were significant during the first year of the study but after that period (with more experience) the number of complications diminished. The data from the total group of patients have been broken down in three groups, the first 27, the second 27 and the last 27 patients to see whether there were any differences in complication rate during the period of the study (Table 14).

Table 14 Complications of the drainage procedures during the study related to experience.

	Groups of patients			Total number of complications
	First (1-27)	Second (28-54)	Third (55-81)	
<i>Complications</i>				
<i>Major complications</i>				
Dislodgement	8	1 (late)	1 + 1 (late)	9 + 2
Occlusion			1 (late)	1
Liver abscess	1			1
Duodenal perforation (Fever/cholangitis ¹)	1 (10 ¹)	(3 ¹)	(2 ¹)	1 (15 ¹)
Percentages	37	11	7	18
<i>Minor complications</i>				
Bleeding through catheter	1			1
Pleural effusion			1	1
False route			1	1
Broken catheter		2		2
Electrolyte disturbance	1	5	1	7
Percentages	7	26	11	15

¹ Most patients with fever/cholangitis are the same patients already reported under major complications (dislodgement, occlusion and abscess).

Dislodgement

Dislodgement of the catheter occurred in 11 patients during the study. In most of these patients (8 out of the first group), the thin Wiechel-Stillé catheter was also used for drainage. After changing this type of catheter to a thicker and more stiff drainage catheter, this complication was seldom noted.

All patients with dislodgement of the catheter had an episode of fever and in 8 patients it was accompanied by septicaemia. A liver abscess was found at autopsy in one of these patients.

In two of these patients (both preoperative drainage group) a laparotomy had to be performed a few days earlier than planned.

Dislodgement of the endoprosthesis as a late complication was reported twice. One patient became jaundiced after she left the hospital. A second drainage procedure was refused and at autopsy the endoprosthesis was found in the small bowel.

In one patient, the endoprosthesis was displaced only a few cm distally (fig. 32) may be because of tumour growth. This patient had obstructive jaundice 16 weeks after installation of an endoprosthesis, refused further treatment and subsequently died.

Occlusion

Occlusion of the endoprosthesis during the follow-up period was seen in one patient and as mentioned a second endoprosthesis could be inserted alongside.

Fig. 32. Recurrent jaundice 16 weeks after insertion of an endoprosthesis in a patient with pancreatic carcinoma. The endoprosthesis is displaced a few cm distally.

Duodenal perforation

In one patient, a home-made teflon endoprosthesis with too sharp an edge perforated the duodenal wall after the patient was sent home for a few weeks without jaundice. Laparotomy was performed but this patient died due to septic complications.

Minor complications

Minor complications were reported in 15%. One patient had a haemorrhage through the catheter due to migration of the catheter into the liver parenchyma.

Pleural effusion was seen in one patient and a false route without clinical symptoms was reported once.

Two patients had broken catheters. In one patient the catheter was removed easily during the procedure and one broken catheter was left behind in the liver without any symptoms during more than 86 weeks of drainage (fig.20).

Electrolyte disturbances were seen in 7 patients during the period of external drainage. Hyponatremia was the most common disorder in these patients but was easily regulated.

Late complications

Late complications such as cholangitis were noted in 8 of 10 patients who survived more than 6 months. They were successfully treated with antibiotics.

The complications are summarised in Table 14. During the study, major complications were seen in 18%. Looking at the three groups of patients into which the total group was broken down the complication rate declined significantly (chi-square test $p < 0.01$) during the study. In the three groups of patients major complications were reported in 37%, 11% and 7% respectively.

Mortality

Three patients, all in the external drainage group, died probably from septic complications and in one of these patients a liver abscess was found at autopsy.

The patient with a duodenal perforation died after 6 weeks of drainage due to a technical failure.

The 30-day mortality for all patients with a malignant obstruction was 25%. Death was mainly reported in the external drainage group. In the group of patients with an endoprosthesis the 30-day mortality was 12%.

5.4.5 PTD and bile cultures

In the beginning of the study, fever, cholangitis and septicaemia were not expected to constitute common or serious complications and for this reason, antibiotic prophylaxis was not used at the start of this study. However, many patients in the first group (37%) developed fever and septicaemia and antibiotics were used routinely thereafter. In 75 of the 82 patients (91%) at least one bile culture was taken during the drainage period. The bile cultures will be reported separately for the patients with benign or malignant disease.

Patients with benign disease

In the group of patients with benign disease, bile cultures were taken at the time of PTD in 15 patients (71%). These cultures were positive in 10 patients (67%) and the following micro-organisms were isolated: *Escherichia coli* (5); *Enterobacter sp.* (2); *Proteus sp.* (1) and *Candida krusei* (2) (Table 15).

Table 15 Patients with benign disease (n = 21); results of bile cultures.

Bile culture	PTD	1 week drainage
<i>Gram positive</i>		
- <i>Streptococcus faecalis</i>		1
<i>Gram negative</i>		
- <i>E. coli</i>	5	5
- <i>Enterobacter sp</i>	2	
- <i>Proteus sp</i>	1	
<i>Candida</i>	2	1
<i>Positive culture</i>	10/15	7/9
	67%	78%

The bile culture could be repeated in 9 patients after approximately one week.

This culture was obtained from the external drainage catheter or from the common bile duct during laparotomy and was positive in 7 patients (77%). *Escherichia coli* was isolated from 5 patients (in one patient a mixed infection with *Pseudomonas aeruginosa* occurred) and from two other patients *Streptococcus faecalis* and *Candida sp.* respectively could be isolated.

Two patients had a wound infection and the cultures of bile and pus of the wound were identical. In all patients with previous biliary surgery, bile cultures were positive at the time of PTD.

Patients with malignant disease

In the group of patients with malignant obstruction, bile cultures were taken in 46 patients (75%) at PTD. Eight patients (17%) had positive cultures with *Escherichia coli* (5), *Enterobacter sp.* (1), *Klebsiella sp.* (1) or *Streptococcus viridans* (1). From these 8 patients, 5 underwent previous biliary surgery. Only 3 patients (5%) with malignant obstruction and without previous biliary surgery had a positive culture; 2 of these 3 patients had a perampullary tumour in which infected bile is more commonly seen.

Bile cultures were taken in 32 patients after approximately one week of drainage. Most cultures were taken routinely during a second drainage procedure (introduction of endoprosthesis) and were not just performed because of fever or other symptoms of infection.

At this time 21 patients (66%) had positive cultures. *Escherichia coli* was isolated from 7 patients; *Enterobacter sp.* from 3 patients; *Proteus sp.* from 3 patients; *Klebsiella sp.* from 2 patients; *Streptococcus faecalis* from 2 patients; *Staphylococcus aureus* from 3 patients and *Staphylococcus epidermidis* from 1 patient.

After 2 weeks of drainage, a bile culture was performed in 15 patients of whom 14 (93%) had a positive culture. *Escherichia coli* was isolated from 4 patients; *Enterobacter sp.* from 1 patient; *Klebsiella sp.* from 3 patients; *Streptococcus faecalis* from 3

Table 16 Patients with malignant disease (n = 61); results of bile cultures.

Bile culture	PTD	1 week drainage	2 weeks drainage
<i>Gram positive</i>			
- Streptococcus faecalis		2	3
- Streptococcus viridans	1		
- Staphylococcus aureus		3	2
- Staphylococcus epidermidis		1	1
<i>Gram negative</i>			
- E. coli	5	7	4
- Enterobacter sp	1	3	1
- Proteus sp		3	
- Klebsiella sp	1	2	3
<i>Positive culture</i>	8/46	21/32	14/15
	17%	66%	93%

patients; *Staphylococcus aureus* from 2 patients and *Staphylococcus epidermidis* from 1 patient.

So after two weeks of drainage, only 1 patient had a negative culture. The bile cultures are summarised in Table 16 and the percentage of positive cultures are outlined in fig. 33.

The numbers of bile cultures after one or two weeks of drainage were less because in some patients a surgical bypass procedure had been performed or an endoprosthesis had already been installed.

Fig. 33. Patients with malignant disease and positive bile culture (percentage) during PTD.

In all patients in the malignant group in which Gram negative bacteria or *Streptococcus faecalis* were found, the drainage was an internal or combined internal/external drainage system and in these patients the drainage tube reached into the duodenum.

No differences in infection rates or in species of isolated micro-organisms were observed between patients with tubes into the distal common bile duct or into the duodenum.

All patients from whom a *Staphylococcus aureus*, *Streptococcus viridans* or *Staphylococcus epidermidis* was isolated, had at least one external drainage catheter.

Quality of drainage related to bile cultures

Some authors have reported that the bile culture should remain or become negative during drainage (30, 225). In this study the quality of drainage and the bile cultures could be correlated after one week of drainage in 32 patients. The decrease of serum bilirubin was taken as a indication for the quality of drainage.

After one week of drainage, 11 patients in the malignant group still had a negative bile culture. In all these patients, the bilirubin level decreased during the drainage procedure. The mean fall of bilirubin was $96 \pm 78 \mu\text{mol/l}$. Among the 21 patients with positive bile cultures the bilirubin was decreased in 16 and the mean fall of the bilirubin was $89 \pm 49 \mu\text{mol/l}$ for these patients. Despite an adequate drainage in these patients the bile cultures remained positive and no correlation between bile culture and decrease of serum bilirubin could be shown.

Long-term drainage, bile cultures and cholangitis

From the 46 patients in whom a palliative continuous drainage was performed, 10 patients survived for more than 6 months. Eight of these 10 patients had at least one period of cholangitis and 7 of them had a positive bile culture at the time of insertion of the endoprosthesis. *Escherichia coli* was isolated from 2 patients; *Enterobacter sp.* from 1 patient; *Klebsiella sp.* from 1 patient; *Streptococcus faecalis* from 3 patients and *Staphylococcus aureus* from 1 patient. These results suggest that after introduction of a foreign body into the biliary tract, the chance of septic complications is in all circumstances much higher, even without an external drainage catheter.

5.5 Discussion

5.5.1 Diagnostic aspects of PTD

The main issue of diagnostic aspects of the percutaneous approach has already been discussed in chapter 4 (retrospective PTC study). Visualisation of the bile ducts was obtained in all patients in the PTD study and in the literature the same percentages concerning success rate of PTD have been reported (73, 171). However, when the quality of visualisation of the level of obstruction and delineation of the margin of the obstruction after a routine 'Chiba procedure' and during PTD are compared, it

became clear that the exact extent of the obstruction was much more precisely visualised during PTD.

A pseudo-obstruction due to a stagnant pool of bile was not observed in this series and the level of obstruction was visualised correctly in all patients whereas in the PTC study the exact level of obstruction could not be ascertained in two patients. As mentioned previously, after insertion of the catheter as much bile as possible was drained off and the catheter was inserted close to the proximal margin of the constricted area in order to obtain a sharp delineation of the obstruction. Sometimes the bile ducts were drained for a few days and were then visualised again to obtain a sharper delineation.

Another advantage of the PTD was that in 90% of the patients, in whom the constricted area could be passed, the distal border of the obstruction could also be visualised which facilitated assessment of the extent of the obstruction.

Despite the advantages of more accurate visualisation of the bile ducts after insertion of a catheter, it is not suggested that the routine diagnostic Chiba needle should be replaced by this procedure.

When, however, any doubt of the level of obstruction still exists after PTC, insertion of a drainage catheter can be justified in order to visualise the exact level and dimensions of the obstruction and to facilitate further investigations.

5.5.2 Percutaneous drainage in patients with benign obstruction

Different indications for this procedure have to be evaluated. It should be realised that endoscopic sphincterotomy was not performed at the beginning of this study.

A short preoperative drainage can be performed to prevent bile leakage, one of the complications after PTC, which has been reported in between 1-2% (94, 136).

The pressure in the biliary tree is higher than normal in patients with obstructive jaundice and therefore the chance of bile leakage through the puncture tract is much higher (254). The drainage procedure can prevent this complication.

Bile leakage has not been observed at laparotomy after PTD in this study. So, when there is a delay of more than 24-48 hours between PTC and a planned laparotomy a drainage procedure is then advisable.

It has been suggested that preoperative drainage can also be performed to improve the general condition before laparotomy. Although operative mortality is less than 0.5% after cholecystectomy and 1-2% after common bile duct exploration, morbidity and mortality after complicated biliary tract procedures are considerably higher especially in high risk patients (131, 200, 219, 227).

In this study patients with severe cholangitis seemed to benefit from preoperative drainage. The same results have been reported in the literature and therefore temporary drainage can be suggested for these patients (46, 72, 123, 175). However, since ERCP is available endoscopic sphincterotomy should be the treatment of choice in high risk patients and PTD is only performed if ERCP fails (46, 263).

Temporary drainage can also be performed in patients with strictures after previous biliary surgery, even during a period of cholangitis. Surgical treatment of recurrent (high) strictures is a technical problem (14, 219, 227). On the other hand drainage of biliary strictures combined with balloon dilatation is said to be successful (73, 150, 166, 187, 233). It seems therefore to be a reasonable alternative to surgical treatment in high risk patients.

Sometimes patients with a benign stricture have preoperative drainage because the stricture is considered to be a malignant lesion and these patients are drained during further investigations.

Regarding the different motives for preoperative drainage in patients with a benign obstruction combined with results from this study and literature it is recommended that patients with obstructive jaundice due to common bile duct stones who are operable should be operated on shortly after PTC.

Regarding the experience with ERCP, endoscopic sphincterotomy should be performed in high risk patients and percutaneous drainage should only be performed after ERCP has failed (46, 51, 214, 220).

It needs to be emphasised that the drainage procedure is less time-consuming in patients with benign obstruction than in patients with malignant obstruction. In most patients, the constricted area is located in the common bile duct into which the catheter is easily advanced.

5.5.3 Preoperative drainage in patients with malignant obstruction

It has already been reported in 1935 that a two-stage procedure should be preferred in patients with obstructive jaundice who are in a bad general condition (253). The percutaneous approach is probably a better alternative for the surgical drainage procedure. Before the start of this study, the first published results of preoperative drainage were encouraging and it was thought at that time that temporary drainage would improve the general condition (175, 230). Therefore decompression was recommended in all jaundiced patients.

During this study, however, more critical reports with respect to preoperative drainage have been published and complications associated with the drainage procedure have been substantial (62, 99, 158, 159, 179).

In the present study, 15 patients were operated on after preoperative drainage. Eleven patients had inoperable pancreatic carcinoma and were treated with choledochojunostomy.

During the preoperative drainage the jaundice disappeared in most patients, while the bilirubin levels decreased markedly and the general condition seemed to improve. On the other hand, three patients had a septic period during the drainage procedure and two of these patients had to be operated on a few days earlier than planned.

When the postoperative morbidity of these patients ($n = 11$) is compared with mor-

bidity of patients with pancreatic carcinoma from the PTC study ($n = 11$) who were operated on without preoperative drainage, no difference could be found.

The postoperative complications, wound infection (both 18%), and hospital stay of these groups were equal while in both groups one patient (9%) died during the first 30 days after operation.

Also the mean survival time in both groups was the same, 37 and 34 weeks respectively. Although these two groups are not really comparable as in a prospective study it may be concluded that no benefits of preoperative drainage could be demonstrated. In consequence of these results and recent reports from the literature, preoperative decompression is not performed routinely at this moment anymore (99, 159, 179). However, when a PTC is performed the bile ducts are drained during further investigations concerning the operability.

5.5.4 Continuous drainage in patients with malignant obstruction

Biliary drainage is generally accepted as a palliative treatment for patients with unresectable tumours which lead to obstruction of the biliary tract.

The main point of discussion is whether continuous drainage should be performed by endoprosthesis or by a surgical bypass. Is the endoprosthesis really a good alternative for the surgical bypass procedure or should it only be used in patients in whom bypass surgery is technically impossible or in high risk patients?

Therefore the mortality associated with the different drainage procedures has to be discussed.

As mentioned before in chapter 2, the mortality directly related to PTD is remarkably low and reported between 1 and 2% (appendix II). In the present study an incidence of 5% was found. These results are difficult to compare with the mortality after bypass surgery and therefore the 30-day mortality after PTD has been included which varies widely in the literature from 0 to 62% (Table 4). In the present study it was 25% because initially all patients were accepted for the drainage procedure. It diminished after exclusion of patients with very restricted life expectancy.

The mortality of the bypass surgery also varies widely (4-40%) but this is partly related to the level of obstruction.

The quality of drainage and even more important the quality of life after insertion of an endoprosthesis is the key issue of this procedure.

In the present study itching disappeared in almost all patients within 48 hours of the procedure and jaundice disappeared in about 80%.

Furthermore, the quality of life is also affected by the length of hospital stay as well as late complications.

The length of hospital stay has not been reported in the literature but in the present study it was 7 days after insertion of an endoprosthesis although due, in most patients, to general condition or social circumstances.

Late complications (especially ascending cholangitis) have frequently been observed in this series and have also been reported in the literature (71).

The drainage procedure itself does not bother the patient and there are no limitations in daily activities after insertion of an endoprosthesis.

It should be mentioned that external drainage through an outside catheter is a psychological burden for the patient and that these catheters have to be flushed routinely (161, 187).

The survival time in the summarised series varies between 4 and 36 weeks for continuous drainage.

The survival time varies widely because in most series, the patient-group is very heterogenous and results of the studies are difficult to compare.

In the present series the mean survival time of patients with an endoprosthesis was 21 weeks (range 2 to 99 weeks) and for patients with external drainage only 2 weeks.

The mean survival time of only 2 weeks in this latter group was caused by the negative selection of patients. Therefore later in this study drainage procedures were not performed anymore in patients who were in the terminal stages of their malignancy. These circumstances do not allow any conclusion to be reached over external drainage. The results of the different malignancies in this study will be discussed in comparison with data published by others.

Pancreatic carcinoma

Results of bypass surgery and percutaneous drainage for unresectable pancreatic carcinoma are difficult to compare because in most series bypass surgery was only possible in 70% of the patients and the other jaundiced patients in whom no treatment could be performed were not evaluated (216).

On the other hand, in most series of percutaneous drainage all patients were accepted for a palliative drainage procedure and in some series especially the 'untreatable' patients were referred for percutaneous drainage (13, 71, 108). When you still want to compare data it has been found that the mean survival time of patients with a pancreatic carcinoma treated with endoprostheses in the present study was 17 weeks whereas the mean survival time of patients after bypass surgery was 37 weeks.

Mortality within 30 days after PTD was 12% while mortality after bypass surgery during this study was 9%.

The quality of life after insertion of an endoprosthesis can be rated less because of the change of an ascending cholangitis which has only occasionally been reported in patients after choledcho-jejunostomy. Furthermore, this procedure is relatively easily performed and bypass surgery is now preferred to endoprosthesis in patients with obstructive jaundice due to unresectable pancreatic carcinoma. The insertion of an endoprosthesis is only indicated in high risk patients.

Peri-ampullary carcinoma

The endoprosthesis was used successfully in 3 patients. However, a bypass procedure for unresectable carcinoma, and since the introduction of ERCP, drainage by endoscopic sphincterotomy for high risk patients, is the treatment of choice (1, 211).

Bile duct carcinoma

The same difficulties in comparing results of bypass surgery and percutaneous drainage also apply to patients with bile duct carcinoma.

Broe and Cameron showed that only in a minority of patients, 14%, a bypass procedure could be performed so that most patients were treated with transtumoural tube drainage (24).

The survival time after bypass surgery was 50 weeks in the collected series of Boerma (20).

In the present study the mean survival time of patients with a bile duct carcinoma was 27 weeks but when the extremely old patients (84, 87 and 93 years) were excluded because of short life expectancy the mean survival time was 48 weeks and these results were comparable with results of bypass surgery.

Especially, the closed combined left/right drainage procedure in patients with a high stricture has been shown a very good palliative treatment (85).

The technically difficult intrahepatic bypass procedures with or without resection should only be performed in selected patients and the percutaneous approach seems to be an attractive palliative treatment for high risk patients and patients with unresectable tumours.

Metastatic lymphadenopathy

In patients with obstructive jaundice due to metastatic lymphadenopathy in the hepatoduodenal ligament, bypass surgery is impossible in most instances and these patients are not treated except with drugs to reduce the severe itching. There are no series of patients treated with surgical drainage procedures and very little literature on this (202).

The mean survival time of patients with metastatic lymphadenopathy in the present study was 16 weeks. Patients with metastases of colon and gastric carcinoma survived longer (21 weeks).

The quality of life was good in most patients and 75% left hospital after the drainage procedure. These results justify the drainage procedure in these patients especially since the drainage procedure was relative easily performed because the bile ducts were compressed from outside by metastatic growth, without being involved.

5.5.5 Complications of PTD

The complication rate after PTD varies widely between different studies. Some authors have differentiated between minor and major complications (71, 207). When the same classification is used major- and minor complications were found in 18% and 15% respectively in the present study. The number of major complications during the first year of the study was considerable (37%) but decreased significantly ($p < 0.01$) in the second and third groups of patients (11% and 7% respectively) due to increased experience with the procedure and better equipment.

Minor complications were reported during the whole study period but were easily managed.

Fig. 34. *a, b.* Combined right and left drainage in a patient with metastasis at the hilus of the liver. Internal drainage of the right hepatic duct (nr. 1) and external drainage of the left hepatic duct (nr. 2). A side hole of the left drainage catheter is situated within the liver parenchyma. Communication between vascular system (arrow) and the drainage catheter.

The management of post-procedural problems.

Pleural effusion can be caused by puncture of the pleural cavity with the catheter. Treatment is not always necessary but if biliary effusion persists, pleural puncture and drainage should be performed (171, 175).

Blood loss through the catheter during the first few hours after the procedure is not exceptional. Persistent bleeding through the catheter is mostly caused by a side hole that is situated within the liver parenchyma and this can create an open communication between the vascular system with the catheter (71, 165, 171). This complication is easily demonstrated on cholangiography (fig. 34) and replacement or even re-insertion of the catheter is necessary (71).

Catheter occlusion, especially the first days is mostly due to inspissated bile, debris or clots. Irrigation with saline and if necessary, with dilute heparin solutions is generally adequate (171). If not, a wire guide can be passed through the catheter and when this does not solve the problem, a new catheter has to be inserted.

Catheter dislodgement occurs sometimes after inadequate fixation of the catheter to the skin or when the catheter is not properly packed (71, 164, 225). As mentioned before early mobilisation can cause dislodgement of the catheter. Immediate re-insertion of the catheter should be undertaken. Contrast medium is injected through the displaced catheter to visualise the biliary tree if the catheter has completely fallen out, contrast medium is pressed into the small cutaneous hole (fig. 35). When the drainage

Fig. 35. Dislodgement of the catheter.

Contrast medium is pressed into the small cutaneous hole and the catheter tract (arrow) and bile ducts are visualised.

has been performed for a few weeks, a catheter tract is well established and it is relatively easy to reinsert a wire guide and a new catheter through this track (82, 191, 238). Otherwise, a new PTD procedure has to be carried out immediately.

Septicaemia is mostly a result of cholangitis usually due to inadequate drainage because of catheter occlusion or dislodgement (71, 107). Blood and bile cultures are taken and after antibiotic therapy has been started cholangiography should be helpful in the diagnosis (71). If necessary a new catheter is inserted.

As already mentioned, septicaemia can be caused by cholangitis arising from a

non-drained part of the liver (45). A second or third catheter sometimes have to be inserted to drain these parts of the liver (85).

Hyponatremia may occur during external drainage after a few days because bile contains a high concentration of sodium.

Electrolytes have to be controlled frequently in the beginning and if necessary, replacements have to be given or as mentioned bile has to be fed back (71, 179).

5.5.6 PTD and bile cultures

The reported incidence of positive bile cultures is variable and it is well known that the incidence is much higher in patients with obstructive jaundice, particularly in the presence of common bile duct stones (87, 88, 111, 112, 118, 119, 127).

In this study bile cultures taken during PTD were positive in 67% of the patients with benign obstruction and in 17% of the patients with malignant obstruction. These findings are in accordance with the literature (128, 129).

The predominant organisms in bile were *Escherichia coli*, *Klebsiella sp.* and *Streptococcus faecalis*.

The bile cultures became positive during PTD and the incidence increased from 17% to 66% and 93% after 1 and 2 weeks of drainage respectively.

The same incidence has been reported by McPherson *et al* who suggested that these positive bile cultures were caused by the external drainage catheter (17, 159).

Therefore these authors introduced a new closed system with added povidone iodine to diminish septic complications (159).

Most positive cultures yielded enteric micro-organisms and it was not clear whether these positive cultures were caused by the external catheter or were due to internal drainage tubes in the duodenum. It has been suggested that the presence of bacteria in the bile does not lead to septicaemia in patients with adequate drainage (45). It is well known that patients after a choledocho-jejunostomy have a high incidence of bacteria in the bile but most, however, do not have episodes of septicaemia (129).

Although both the use of the closed drainage system and careful manipulation of catheters may be helpful, adequate drainage of the biliary system does seem to be the most important single factor in preventing septicaemia.

Most patients have a positive bile culture after insertion of a foreign body into the biliary tract and therefore after a prolonged period of drainage (especially during a period of moderate drainage due to debris around the catheter) have a great chance of developing septicaemia.

Chapter 6

Conclusions and recommendations

In the retrospective PTC study it has been shown that percutaneous transhepatic cholangiography is a relatively safe diagnostic procedure in the jaundiced patient with a high success rate particularly when bile ducts are dilated. It has a low complication rate especially when laparotomy is performed within 24-48 hours of the procedure. The technique has obtained a central place in the approach to the jaundiced patient.

Based on the experience with PTC the drainage procedure (PTD) was introduced in 1979 and evaluated prospectively.

Regarding this study some conclusions can be drawn.

- The diagnostic value of PTD is high since it gives an additional information of the bile ducts as the proximal and distal margins of the obstruction can accurately be visualised.
- In patients with a benign obstruction the value of percutaneous drainage is very limited. Patients with stones in the common bile duct should be operated on soon after the diagnosis is made by PTC or an endoscopic sphincterotomy can be performed in high risk patients.

Percutaneous drainage can be used in patients with recurrent postoperative strictures.

- In patients with malignant obstruction preoperative drainage perhaps improves the general condition of the patient. However, it does not seem to reduce operative morbidity and mortality. Because of the septic complications of the drainage procedure routine preoperative decompression should not be recommended at this moment.
- When the results of continuous drainage as a palliative procedure are compared with the results of bypass surgery it can be concluded that morbidity and mortality after any type of drainage procedure (as well as the survival time) are more dependent on the general condition and stage of malignancy of the patient than to the type of drainage procedure used. However, late complications of bypass surgery are fewer than those of endoprostheses.

The endoprosthesis should therefore only be used in high risk patients and in patients in whom bypass surgery is technically impossible.

Patients with a distal common bile duct obstruction due to unresectable tumours should be treated with a choledocho-jejunostomy. However, in patients with a malignant obstruction of the proximal bile duct or the left and right intrahepatic ducts, as in patients due to bile duct carcinoma, extensive gallbladder carcinoma and metastatic lymphadenopathy in the hepatoduodenal ligament, Percutaneous Transhepatic Drainage and the insertion of an endoprosthesis is a good alternative to bypass surgery.

Chapter 7

Diagnostic approach to the jaundiced patient (1984)

After the present study and acceptance of conclusions as summarised in chapter 6, it has now become obvious that the diagnostic approach as established in 1979 has to be modified.

A new decision tree is represented in fig. 36.

Non-invasive techniques such as Ultrasound and Computed Tomography together with invasive techniques such as Percutaneous Transhepatic Cholangiography, Endoscopic Retrograde Cholangio-Pancreaticography and Angiography are used in the decision tree and the therapeutic possibilities of PTC and ERCP are also employed. However, not all these techniques will be available in every hospital and it is clear that the usefulness of each technique depends upon the experience in any particular institution.

Furthermore, although these techniques are a step forward, some authors mention the costs and risks associated with them (22, 218). The costs of these techniques in St. Annadal hospital are shown in table 17. The risks of the invasive procedures have already been mentioned and therefore non-invasive techniques will normally be used first.

The importance of the medical history and the physical and laboratory examinations has been stressed by many authors (21, 22, 218).

As mentioned before, in patients with common bile duct stones no further investigations should be performed and in these patients laparotomy or endoscopic sphincterotomy is the next step depending on the patients general condition (even when cholecystectomy has not been performed previously) (53, 160, 263).

Despite the good results of Ultrasound in detecting dilated bile ducts (100, 156, 244) it is less accurate for determining the site and the cause of obstruction (73, 80, 153, 206, 256) and therefore Computed Tomography has to be performed if Ultrasound examination is doubtful.

The results of CT are much better and an accuracy of 97% in determining the level of obstruction and 94% in determining the cause of obstruction are reported (193, 194). However, in high risk patients with proven malignancy or patients with extensive metastatic disease probably already diagnosed by Ultrasound, these further investigations should not be performed.

After accepting non surgical drainage as an alternative treatment for these patients the technique with the best opportunity for palliative treatment in that particular hospital should be used.

Fig. 36. Diagnostic approach to the jaundiced patient (1984).

Table 17 Costs of diagnostic tests employed in the evaluation of patients with jaundice.¹

Diagnostic test	Total cost (Dutch guilders)
Liver function tests ²	65
Plain abdominal radiograph	56
Ultrasound (liver, biliary tract)	148
CT scan (liver, biliary tract)	467
Percutaneous cholangiography	182
ERCP	357

¹ Costs at St. Annadal Hospital, October 1983, including professional and technical fees.

² Costs of liver function tests including AP, SGOT, SGPT, LDH, Bilirubin.

The terms 'operable' and 'high risk' which are used in the decision tree are somewhat vague.

Some authors have tried to define the factors associated with a poor prognosis (18, 159, 200). Between 5 and 8 factors have been studied by these authors and a correlation has been shown between mortality and the number of risk factors present. The most important factors (disease: benign – malignant; age > 60 years; white blood cell count > 10.10⁹/l; creatinine > 115 µmol/l; albumin > 30 g/l; bilirubin > 170 µmol/l and alkaline phosphatase > 360 U/l) perhaps will facilitate the classification of these patients. However, judgement of the state of the patient is still physician dependent.

In 'operable' patients CT scan can be used as complement to Ultrasound to determine distal and proximal obstructions and possible metastases.

If resection cannot be performed bypass surgery is preferred for patients with a distal obstruction. PTC is not indicated in these patients because cholangiography can be performed during laparotomy. However, further investigations such as angiography should be carried out before laparotomy in order to investigate the operability and to justify a radical surgical approach. When tumours of the ampullary region are suspected ERCP has to be performed.

In patients with a proximal obstruction PTC/PTD has to be performed. First of all, unresectability can be shown by the cholangiographic findings in many patients (246). Secondly, visualisation of all intrahepatic segmental bile ducts is required before laparotomy (21).

When unresectability has been demonstrated a combined left/right palliative drainage procedure can be recommended (85, 122, 157, 173) but other workers prefer the intrahepatic hepato-jejunostomy (15).

Angiography should be performed in patients with high bile duct tumours before laparotomy is done (246).

When the proximal obstruction is caused by gallbladder carcinoma or metastatic

lymphadenopathy in the hepatoduodenal ligament palliative treatment with an endoprosthesis is the treatment of choice. The drainage procedure can easily be performed because the bile ducts are compressed from outside by metastatic growth without being involved.

Summary

The approach of the jaundiced patient has changed radically during the last 10 years. New diagnostic techniques such as Ultrasound (US), Computed Tomography (CT), Percutaneous Transhepatic Cholangiography (PTC) and Endoscopic Retrograde Cholangio-Pancreaticography (ERCP) are now available in many hospitals.

The Percutaneous Transhepatic Drainage (PTD), Endoscopic Sphincterotomy and nasobiliary drainage have become possible since the introduction of these techniques. The percutaneous approach has been used during the last 6 years and the aim of this study was:

- To give an assessment of the value of PTC as a diagnostic procedure in obstructive jaundice.
- To discuss the (therapeutic) value of the drainage procedure in patients with obstructive jaundice.

In chapter 2 the literature of PTC/PTD and other palliative drainage procedures is reviewed.

The history of PTC is briefly reported and results of puncture with the sheathed needle and the Chiba needle are compared. The recently introduced ultrasonically guided PTC is also mentioned.

The question which technique PTC or ERCP should be used, for visualisation of the biliary tract, is discussed. It is concluded that the techniques are complementary and the choice of the one to be used is related to the experience and the therapeutic possibilities with the two techniques in any particular hospital.

The history of PTD is reviewed more extensively. Some technical aspects are reported and the different types of percutaneous drainage are outlined.

The indications for PTD, preoperative drainage and continuous drainage are discussed. The first results of preoperative drainage in patients with malignant obstruction in improving general condition and reducing postoperative morbidity and mortality are promising. However, some recent published series have shown substantial infective complications of the drainage procedure.

Temporary drainage in non malignant obstruction is not used frequently and is only briefly summarised.

Many series of patients with continuous drainage as a palliative treatment are reported and results are shown to vary widely.

The complications of PTD are discussed separately.

New possibilities of the percutaneous approach (brush biopsy, balloon dilatation, transhepatic stone removal, percutaneous cholangioscopy and insertion of radiation

wires) are mentioned but these new techniques have to prove their practical value in the near future.

Literature concerning other palliative procedures such as bypass surgery, trans-tumoural tube drainage and transpapillary biliary drainage is also reviewed in brief because results of PTD will be compared with other palliative bypass procedures in chapter 5.

In chapter 3 to 5 investigations concerning PTC and PTD in St. Annadal Hospital are described.

Chapter 3 gives details of a retrospective PTC study. The technique is described and results of 45 patients in whom a PTC was performed are discussed. Visualisation of the bile ducts has been obtained in 97.5% of patients with dilated bile ducts and 86% of patients with non dilated bile ducts.

Problems related to the visualisation of a pseudo-obstruction at hilar level are mentioned. It has been concluded that PTC can be used effectively in the work-up of the patient with jaundice.

In chapter 4 the diagnostic approach to the jaundiced patient (as used during the PTD study) is outlined. PTC/PTD was used as the main diagnostic technique in the patient with obstructive jaundice.

In chapter 5 which is the main chapter of this thesis, the prospective PTD study, is reported.

The technique of PTD is described extensively and the combined left and right internal drainage is introduced for high bile duct strictures. The preparation of the patient and post-procedural care are described, as these are the main factors determining the results of the drainage procedure.

The results of 82 consecutive patients in whom a PTD was performed are described in different sections and each section is discussed separately.

Visualisation of the extent of the obstruction is much more precise after PTD than after PTC because the proximal and distal borders of the obstruction can be outlined exactly and a stagnant pool of bile can be drained off before visualisation.

The benefit of preoperative drainage in patients with benign disease cannot be demonstrated and therefore patients with common bile duct stones should be operated on immediately after PTC. In high risk patients endoscopic sphincterotomy should be performed.

Preoperative drainage in patients with malignant obstruction seems to improve the general condition, however, does not reduce operative morbidity and mortality. Because septic complications are frequently reported routine preoperative drainage is still not advised.

Continuous drainage with an endoprosthesis was successfully used in 32 patients. Itching disappeared in almost all patients within 48 hours of the procedure and jaundice disappeared in about 80% while liver function tests returned to normal in 69%.

However, in the total group of patients, major complications after PTD occurred in 18%. Therefore the surgical bypass procedure is preferred in patients with a distal obstruction of the bile ducts and the endoprosthesis is only used in high risk patients and in patients with a proximal bile duct obstruction in whom a bypass procedure is technically difficult. The drainage procedure was relative easily performed in patients with obstructive jaundice due to metastatic lymphadenopathy in the hepatoduodenal ligament because the bile ducts are compressed from outside by metastatic growth without being involved.

Bile cultures after the drainage procedure were studied. Despite adequate drainage most patients have positive bile cultures after 2 weeks of drainage. The micro-organisms present do not lead to clinical infections in most patients with adequate drainage.

In chapter 6 the results of the PTC and PTD studies are summarised and the conclusions presented. With regard to the main points of the PTD study, a new diagnostic approach to the jaundiced patient is suggested in chapter 7.

Samenvatting

De diagnostiek van de icterische patiënt is de afgelopen 10 jaar aan veel veranderingen onderhevig geweest. Nieuwe technieken zoals echografie, computer tomografie, percutane transhepatische cholangiografie (PTC) en endoscopische retrograde cholangio- en pancreaticografie (ERCP) worden momenteel in vele ziekenhuizen toegepast. De percutane transhepatische drainage (PTD), de endoscopische sfincterotomie en de nasobiliaire drainage zijn nieuwe therapeutische mogelijkheden voortgekomen uit deze technieken.

De percutane transhepatische cholangiografie en drainage zijn de afgelopen 6 jaar veelvuldig toegepast in Ziekenhuis St. Annadal, Maastricht en onderwerp van deze studie.

Het doel van dit proefschrift is:

- de waarde van PTC als diagnostisch onderzoek bij obstructie icterus te beschouwen;
- de therapeutische mogelijkheden van de drainageprocedure bij patiënten met een obstructie icterus te evalueren.

In hoofdstuk 2 wordt een literatuuroverzicht gegeven van de PTC/PTD en andere palliatieve drainageprocedures. De geschiedenis van de PTC wordt kort besproken en de resultaten van PTC met de initieel gebruikte stugge dikke naald en PTC met de dunne Chibanaald worden vergeleken.

De galwegen kunnen worden afgebeeld middels PTC en ERCP. Welke van deze twee methoden de voorkeur verdient bij gedilateerde galwegen hangt voornamelijk af van de ervaring van de onderzoeker en de therapeutische mogelijkheden van deze methoden.

De huidige literatuurbevindingen van de percutane transhepatische drainage worden in een overzicht samengevat.

De verschillende soorten en technische aspecten van drainageprocedures worden beschreven.

De in de literatuur beschreven indicaties voor PTD, preoperatieve drainage en continue (palliatieve) drainage worden besproken. Preoperatieve drainage wordt toegepast om de algemene conditie van de patiënt te verbeteren teneinde de mortaliteit en morbiditeit van de te volgen operatie te verlagen.

In de literatuur waren de eerste resultaten van de preoperatieve drainage bemoedigend. In meer recente publicaties werd nadruk gelegd op complicaties van de drainageprocedure, met name cholangitis werd frequent gezien.

Bij benigne afwijkingen wordt tijdelijke preoperatieve drainage nauwelijks toegepast. Publicaties over continue drainage met behulp van een endoprothese als palliatieve behandeling vermelden uiteenlopende resultaten.

Complicaties van de in de literatuur beschreven PTD-studies zijn separaat besproken en samengevat in appendix II.

Andere mogelijkheden via de percutane transhepatische weg zoals biopsiën, ballon-dilatatie, verwijdering van stenen, cholangioscopie en inwendige radiotherapie worden gememoreerd doch de betekenis van deze technische hoogstanden moet nog worden afgewacht.

De literatuur betreffende andere palliatieve drainagemogelijkheden zoals bypass chirurgie, drainage middels een 'drain' die door de tumor wordt gebracht tijdens operatie en endoscopische transpapillaire drainage worden kort samengevat.

In hoofdstuk 3 t/m 5 worden de patiëntenstudies betreffende de PTC en PTD zoals verricht in Ziekenhuis St. Annadal beschreven.

Hoofdstuk 3 bevat een retrospectieve PTC-studie. De techniek wordt beschreven en de resultaten van 45 patiënten die dit PTC-onderzoek hebben ondergaan worden besproken.

De galwegen werden afgebeeld bij 97.5% van de patiënten met gedilateerde galwegen en bij 86% van de patiënten met niet-gedilateerde galwegen. De waarneming van een 'pseudo-obstructie', door ingedikte gal, wordt beschreven.

In hoofdstuk 4 wordt het diagnostisch protocol van de icterische patiënt beschreven. De PTC neemt in dit protocol een centrale plaats in. Tegelijkertijd wordt de PTD geïntroduceerd en gekoppeld aan het PTC-onderzoek.

In hoofdstuk 5 wordt een prospectieve studie betreffende de percutane drainage beschreven. De toegepaste techniek van de PTD-procedure wordt uitgelegd en de gecombineerde drainage van het linker- en rechter-galwegsysteem wordt geïntroduceerd.

Na een PTD zijn het niveau en de uitgebreidheid van de obstructie beter vast te stellen dan na de PTC omdat zowel de proximale als distale begrenzing van de obstructie kan worden afgebeeld.

Wat de resultaten betreft:

Voordelen van preoperatieve drainage bij patiënten met een benigne afwijking zijn niet aangetoond. Het is daarom aan te bevelen patiënten met stenen in de galwegen na PTC snel te opereren; uiteraard dient bij high risk patiënten en bij post-cholecystectomy patiënten een endoscopische sfincterotomie te worden overwogen.

Tijdelijke drainage kan mogelijk op beperkte schaal worden toegepast bij recidiverende stricturen na operaties en bij inoperabele patiënten met een cholangitis waarbij endoscopische sfincterotomie mislukt is.

Preoperatieve drainage bij patiënten met een maligne aandoening lijkt de algemene conditie van de patiënt te verbeteren doch de morbiditeit en mortaliteit van de operatie zijn niet verminderd.

Sepsis werd tijdens PTD regelmatig gediagnostiseerd en mede daardoor lijkt algemene toepassing van preoperatieve drainage niet gewenst.

De continue drainage middels een endoprothese werd bij 80% van de patiënten met succes toegepast. De jeuk verdwijnt over het algemeen binnen 48 uur en bij 69% van de patiënten normaliseerden de leverfuncties.

Helaas komt vooral bij langdurige drainage regelmatig cholangitis voor. De chirurgische bypass verdient daarom de voorkeur bij patiënten met een distale obstructie. De endoprothese blijft een goed alternatief voor de high risk patiënt. Goede resultaten werden gezien bij de technisch moeilijk te opereren centrale galwegobstructies.

De percutane drainage wordt dan ook bij voorkeur gebruikt bij uitgebreide galblaascarcinomen, hilus-carcinomen en metastasen in het ligamentum hepatoduodenale.

De galkweken werden geanalyseerd en ongeacht de goede resultaten van de drainage blijkt 93% van de patiënten een positieve galkweek te hebben na twee weken drainage.

In hoofdstuk 6, conclusies, worden de resultaten van de PTC en PTD studie aan een analyse onderworpen. Naar aanleiding van deze resultaten wordt mede op basis van de literatuur een nieuw behandelingsprotocol voor de patiënt met obstructe icterus uitgewerkt (hoofdstuk 7).

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Appendix I

Series of Percutaneous Transhepatic Drainage collected from literature

Author	Year	Number of patients	Success rate PTD	Benign obstruction	Malignant obstruction
Kaude	1969	2	2	1	1
Ukai	1971	5	5	0	5
Molnar	1974	11	11	6	5
Urchida	1975	46	46	14	32
Takada	1976	99	99	16	83
Mori	1977	13	11	0	13
Tylen/ Hoevels ¹	1977	83	83		
Ariyama ¹	1978	23	18		
Burcharth ¹	1978	19			
Hansson/ Hoevels	1978	105	105	20	85
Hoevels ¹	1978	15	15	2	13
Nakayama	1978	105	104	21	84
Pereiras	1978	12	12	0	12
Ring ¹	1978	23	21		
Ariyama	1979	71	65	14	57
Burcharth	1979	58	48	7	51
Dooley	1979	41	40	10	30
Harrington	1979	10	10	0	10
Hoevels	1979	13	13	1	12
Koster	1979	14	13	4	10
Pollock ¹	1979	43	41	17	26
Ring ¹	1979	43	41		
Ferrucci ¹	1980	62	58	24	38
Harbin ¹	1980	12	12		
Hellekant	1980	8	8	0	8
Mendez	1980	15	15	1	14
Makuuchi	1980	16	16	4	12
Berquist	1981	50	45	8	42
Burcharth	1981	5	5	5	
Castaneda	1981	21	21		
Clark	1981	42	42	8	34
Denning	1981	57	25	3	22
Dooley	1981	44	41	5	39
Hatfield	1981	12	12	2	10
Mueller	1981	200	188	17	183
Riemann	1981	76	67	13	54
Smale/ Ring	1981	35	35	10	25
Hatfield	1982	57	29	13	25
McPherson	1982	37	37	2	35
Norlander	1982	109	109	19	90

¹ Partly same patients reported in other studies.

Preoperative drainage	Period of drainage (days)	Continuous drainage	Patients with malignant obstruction		Mortality 30 days	
			Number	Survival time (weeks)	N	%
1	6	1	1	8	0	0
4	40	1	1	12		
4	12	7	5	4	4/5	80
38	27	61	30	>12		
8		5				
66	7-14	17				
73	15	32	32	8	8/32	25
8		7	7	>27	1/7	15
69	8.7	22	15	>12		
0		12	6	4-30	2/12	17
14		34	32	8.5		
21		19				
0		10				
0		13	13	8	5/13	38
6	1-60	8	8	6	5/8	62
26	22	15	10	14	0/0	0
0		58	38	17	12/38	31.5
0		8	8	8	2/8	25
0		15	15	<26	0/15	0
8		37	34	18		
5	3-5 mth					
23		19			4/19	21
25	13	0				
4		37			12/37	
10	10	2	1	3	1/2	50
80	3-7	108				
30	18	37			16/33	50
0		35	25	36		
22	12	3				
33	18	4				
58	18	51				

Appendix II

Series of Percutaneous Transhepatic Drainage collected from literature
complications after PTD procedure and mortality of PTD

Author	Year	Number of patients	Fever	Cholan- gitits	Septi- caemia	Haemor- rhage	Haemo- bilias	Haema- toma	Pneumo- thorax
Kaude	1969	2							
Ukai	1971	5			1				
Molnar	1974	11	most				2		
Urchida	1975	46							
Takada	1976	99	some						
Mori	1977	11					2		
Tylen/ Hoevels ¹	1977	83		1				2	
Ariyama ¹	1978	18							
Burcharth ¹	1978	19							
Hansson/ Hoevels	1978	105	most	9				3	
Hoevels ¹	1978	15		2					
Nakayama	1978	104				1	4		2
Pereiras	1978	12	6		2				1
Ring ¹	1978	21							
Ariyama	1979	65							
Burcharth	1979	48		2	2	1			
Dooley	1979	40			1				
Harrington	1979	10							
Hoevels	1979	13		10					
Koster	1979	13							
Pollock ¹	1979	41	3	2	2		2	2	
Ring ¹	1979	41							
Ferrucci ¹	1980	58	most	9	1	2			
Harbin ¹	1980	12							
Hellekant	1980	8							
Mendez	1980	15		2					
Makuuchi	1980	16							
Berquist	1981	45	13		4	4	4		1
Burcharth	1981	5							
Castaneda	1981	21							
Clark	1981	42			8			1	1
Denning	1981	25							
Dooley	1981	41		1					
Hatfield	1981	12			2		2		1
Mueller	1981	188	21	21	7	6	18		1
Riemann	1981	67			3				
Smale/ Ring	1981	35			4		1		
Hatfield	1982	28		1			4		1
McPherson	1982	37	10		2		2		1
Norlander	1982	109		4		1			

¹ Partly same patients reported in other studies.

Dislodgement	Occlusion of catheter	Bile leakage	Liver abscess	Metabolic disturbance	Complications		Emergency laparotomy	Death
					Total number	Percentage		
					0		0	0
2		1			2	40	0	0
2					4	25	0	0
		1			1	2	0	0
2					2	2		
					2	18	0	1
		2			5	6	2	0
12	4	3			31	30	3	1
10					10	66	0	0
9		2			18	17	2	1
					3	55	0	0
1					6	12	1	0
		1			2	5	0	0
3					3	30	0	0
5					10	77	1	1
3					3	25	0	0
					8	20	0	0
				3	15	26	1	0
		1	1		1	12	0	0
			1		3	20	0	0
		1			1	6	0	0
2	6				21	46	1	1
					10	24	0	1
5					5	20	0	0
1		1			6	15	1	1
1				2	6	50	0	0
11 (late)					53	28	4	3
		2			5	8	5	0
					5	15	0	0
2	3				15	54	3	?
4		3	2	2	16	43	2	0
7		2			14	13	7	3

Appendix III

The PTD procedure and insertion of an endoprosthesis

A 87 year old female was admitted with obstructive jaundice (bilirubin: 326 $\mu\text{mol/l}$) and severe itching. The bile duct obstruction was caused by local recurrent disease or metastases after hemicolectomy for an adenocarcinoma of the colon.

The patient insisted on palliative treatment and an endoprosthesis was inserted. She left hospital after 7 days and survived 24 weeks.

Fig. 1 Puncture of the bile ducts and visualisation of an obstruction in the common hepatic duct.

Fig. 11 A wire guide and afterwards a thin catheter is inserted in the dorsocaudal branch of the right hepatic duct (arrow) and manoeuvred through the constricted area. The distal common bile duct is visualised.

Fig. III Drainage is allowed externally and internally through side holes in the catheter proximal and distal to the obstruction (arrow). (Air bubbles in the distal common bile duct.)

Fig. IV A stiff wire guide (arrow) is inserted before dilatation of the catheter tract.

Fig. V The larger dilator (arrow) is used to advance the endoprosthesis (p) over the smaller dilator into the correct position.

Fig. VI The endoprosthesis (p) is in the correct position; the dilator is removed and a catheter (c) is left in the bile ducts for performing a control cholangiography.

Fig. VII Side view after insertion of the endoprosthesis (p) and external drainage catheter (c).

Fig. VIII The endoprosthesis (p) and external drainage catheter (c) inserted in the bile ducts.

Acknowledgements

Many people have been involved in realising this thesis. It is impossible to thank everyone in person for their great help. I would like to take the opportunity, however, to express my gratitude towards those without whom this thesis would never have been finished.

Professor J. M. Greep who introduced, with stimulating enthusiasm, the Percutaneous Transhepatic Drainage in St. Annadal Hospital and created the opportunity to learn the technique from Professor Wiechel in Stockholm, Sweden.

Professor L. H. Blumgart, your radical surgical approach did me realise some disadvantages of the new PTD technique. I greatly appreciated the stay in the Hepatobiliary Surgical Unit of the Hammersmith Hospital, London.

Professor J. A. Flendrig and Professor A. C. Klinkhamer, I greatly appreciated your critical contributions to this work.

Dr. Huug Obertop, your critical reading of the manuscript and stimulating discussions concerning the biliary drainage during the last years were of great value to me.

Dr. Rob Wesdorp, your help proved essential in coaching the difficult start of PTD and during the whole study.

Cees van der Linden, I thank you for your corrections.

I like to thank the colleagues of the Radiology Department, especially Dr. Jos van Engelshoven, and the radiology nursing staff for their pleasant collaboration during the study.

Mrs. Panis-Rousie and Mrs. Muijtjens-Janssen, I am grateful for organising the PTD equipment.

Dr. Davies, I feel much obliged for your assistance in correcting 'my English'.

L. Volovics, I owe a great deal for your statistical advises.

Chris Voskamp, I thank you for your high quality illustrations and preparation of the cover design.

Members of the medical photography department, I am grateful for the quality and accuracy of the photographs in this thesis.

Maartje Duyzings and Gerda Moers-Haemers, I thank you very much for your patience and intelligence in (re)typing the manuscript. Marcia Steegmans-Van Puyenbroek and Henk Jas, I am thankful for your help in processing the manuscript to the computerised typesetter in the printing office.

Finally, I thank my colleagues of the surgical department for taking over my duty during my involvements in this thesis.

Last but not least, special thanks to Ineke.

Curriculum Vitae

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