The British Society of Interventional Radiology

First Biliary Drainage & Stent Audit Report 2009

Prepared by

Raman Uberoi BMSCPath MBBChir MRCP FRCR
Iain Robertson MBChB MRCP FRCR
on behalf of the British Society of Interventional Radiology

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Preface

In collecting data on the largest series of percutaneous biliary intervention the British Society of Interventional Radiology should be justly proud.

And like all good data this document will both stimulate and challenge. The procedural data reveal a group of Interventional Radiologists who are highly skilled. There is a high technical success rate with few passes through the liver capsule. The clinical outcomes should cause us all to stop and reflect. Over 21% of patients with malignant disease either died in hospital or had a major complication. Furthermore, half the patients had died by 80 days. Whilst this surely reflects how sick the patients are, those outcomes are poor. The authors should look to identify groups who do well and badly, for that latter group may be better served with an alternative therapeutic strategy. Perhaps more alarming is the fact that nearly 19% of patients with a *benign* stricture either died in hospital or had a major complication. 37% of these patients had died by one year. Whilst the aetiology of the stricture may be benign, the treatment isn't. This surely needs further review, perhaps collaboration with other workers to verify the result, and more research into why the outcomes are worse than expected.

And what of this registry? Clearly the data are so striking that it should continue. The authors should look to rationalise the data set so that outcomes are clear and important, and participation is easy and worthwhile. A dictionary of terms will ensure that we are all talking the same language and the quality of data is enhanced.

The Society is indebted to the authors for their hard work, and the collaborating centres for making the effort to participate in what has been an excellent venture.

Peter Gaines

President of the British Society of Interventional Radiology

Foreword

This is the first BSIR Biliary Drainage and Stenting Report. The aim is to provide important outcome data to guide current practice and this will form an important element of operator revalidation in the future. The BSIR is committed to continually improving standards for interventional procedures and setting outcome benchmarks that will help to deliver better outcomes for patients.

This initial report focuses on key outcomes in biliary drainage and stenting: mortality, complications, procedural success and relief of symptoms. We have initially chosen to concentrate on elements that will make the greatest contribution to improving outcomes for patients. Information from this registry will help inform patient decision-making during the consent process for a procedure that clearly has a high morbidity and mortality.

There are very limited data on patient outcomes and current United Kingdom practice in this field and this report represents the largest collection of data on percutaneous biliary drainage and stenting in the world literature.

This report represents the start of a journey to improve outcomes in biliary intervention. Access to high-quality individual operator data and working collaboratively with clinical colleagues involved in the care of these complex patients will be essential future steps. It is hoped that the registry will provide a valuable resource for all practitioners in the United Kingdom and the wider international community.

Raman Uberoi & Iain Robertson

on behalf of the British Society of Interventional Radiology

Introduction

Biliary obstruction requiring drainage is a common clinical scenario that will present to most hospitals across the United Kingdom. Many patients will be treated endoscopically, but a significant number require percutaneous intervention. Percutaneous treatment is usually performed under conscious sedation using specialised equipment with fluoroscopic and ultrasound guidance, performed by skilled Radiologists within the Radiology Department. The majority of patients undergoing these procedures will have malignant disease and will have a metal stent placed to provide palliation of jaundice.

This report is based upon data collected prospectively between 1st November 2006 to 18th August 2009. It includes analyses based on the largest published database of collated procedure records on percutaneous biliary intervention worldwide: data on 833 patients submitted by 62 operators from 44 centres across the United Kingdom . Data entry was on-line and open to operators irrespective of whether or not they were members of the BSIR . Data completeness, particularly for long-term follow up data, is limited This initial report focuses on key outcomes in biliary drainage and stenting: procedural success, mortality, complications, and relief of symptoms.

Executive summary

Outcomes: procedure

- 93% of procedures were directly performed by a consultant.
- Immediate technical success for biliary drainage and stenting is high (>95%).
- The majority of interventions were for distal common bile duct (CBD) disease.

Outcomes: mortality and complications

- In-hospital mortality for biliary drainage and stenting is significant (19.8%).
- There is a high in-hospital mortality rate for patients with benign disease (15.6%); this rate is lower than that reported for patients with malignant disease.
- Major complications occurred in 7.9% of patients; haemorrhage (3.5%), renal failure (1.8%), sepsis (1.6%) were the most common events.
- Minor complications occurred in 26.0% of patients; pain (14.3%), sepsis (7.7%), haemorrhage (4.5%) were the most common events.
- There are significant associations between the rate of bleeding complications and the presence of gross ascites, elevated international normalized ratio (INR) & a mild association with low platelet levels (p=0.276, 0.012 & 0.087 respectively for the minor haemorrhage / haematoma outcome).
- For patients with malignant disease, the 1-year survival rate post-procedure is less than 20%.
- Risk of death or major complication was 21.2% overall, 18.3% for patients with benign disease and 21.7% for patients with malignant disease.

Outcomes: relief of symptoms

- Bilirubin levels are reduced and the symptoms relieved in the vast majority of patients.
- Symptom relief is significantly greater in patients with the greatest (>50%) post-procedural reduction in bilirubin.
- Drainage is more effective at reducing the bilirubin levels if a stent is placed across the sphincter of Oddi (p<0.001%).

Recommendations

Further audit of this cohort is required to determine cause of death and to demonstrate whether or not there are any significantly associated risk factors. Work is underway to permit risk-modelling for this group of patients.

Given the high mortality in this group of patients further data collection will be required. Significant improvements in data completeness are required. Data submission remains voluntary, but NHS services should consider how they can make resources available to support data collection for individual operators.

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Contents

Basic principles of biliary drainage and stenting

Bile ducts are the special tubes inside the liver, that deliver bile to the bowel. They contain special salts that are helpful in digestion. If these ducts become blocked (figure 1) the bile backs up into the blood, causing jaundice and severe itching of the skin.

Figure 1.

Magnetic resonance cholangio-pancreatography (MRCP) showing distal obstruction of the common bile duct

Percutaneous biliary drainage and stenting has become a widely-accepted method for non-operative relief of biliary obstruction. This is often performed where endoscopic techniques have failed (telescope through the mouth; figure 2), are not available or are contra-indicated (*e.g.*, after stomach surgery). These drainage and stenting procedures are usually performed by interventional radiologists.

Once initial catheter (plastic tube) access has been obtained, a variety of secondary interventional procedures can be performed. These include insertion of plastic or metal stents, stricture dilatation, basket extraction of stones or chemical stone dissolution and tumor brushings or biopsy.

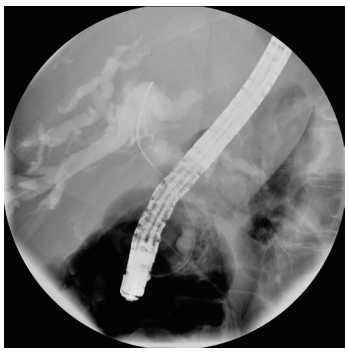

Figure 2.

Endoscopic Retrograde Cholangio-Pancreatography (ERCP) showing opacification and successful crossing with a guidewire of a biliary obstruction.

What is biliary drainage?

Biliary drainage is where access is gained to bile ducts in the liver to relieve the patient's symptoms (usually itching and jaundice) as well as providing access for subsequent stenting where necessary. The benefit provided by this process alone is usually temporary, but it can allow for a more long-term solution to the patient's symptoms *i.e.*, metal or plastic stenting, stricture dilatation or stone removal. For safety this procedure is performed in the radiology department using ultrasound and / or fluoroscopy (x-rays) to guide the operator. Using fine needles the smaller ducts are punctured within the liver through the skin (figure 3), through which guidewires can then be introduced. This allows for a tract to the bile ducts to be opened and plastic tubes placed to help drain off the excess bile into a plastic bag situated externally (figure 4).

Biliary stenting

Depending on the cause of the obstruction, the patient may need a more long-term solution to the blockage of their bile ducts. For example, if the blockage is due to cancer that cannot be treated an internal tube can be placed through the previously created tract to cross the obstruction. This tube can be manufactured from plastic or metal and is called a stent (figure 5). Metal stents are more expensive, but longer-lasting. Plastic stents are used when a more intermediate-term solution is required *i.e.*, if the patient is due to have an operation in the following few weeks. Once these stents are in place and shown to be working, the drainage tube can be removed, a situation that is more comfortable and convenient for the patient (figure 6a).

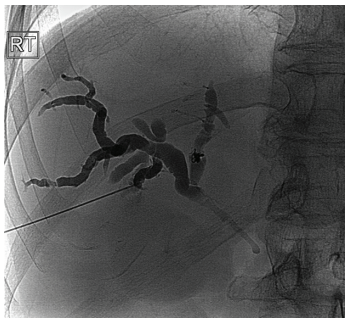

Figure 3.

Percutaneous transhepatic cholangiogram, with puncture of a peripheral duct prior to insertion of a guidewire and placement of a drain.

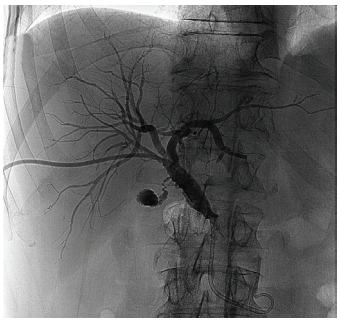

Figure 4.

Successful placement of a plastic internal / external drain (Ring Lunderquist), which allows drainage of bile externally and / or internally and preserves access for subsequent stent placement.

Often the blockage is very tough and this needs to be opened up either before or after placement of the stent. This is performed with a balloon (figure 6b).

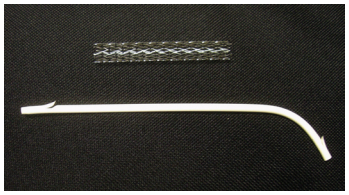

Figure 5.

Plastic and metal biliary stents side by side

Figure 6a.

Cholangiogram to confirm drainage through a metal stent placed across the biliary obstruction. There is still some residual narrowing.

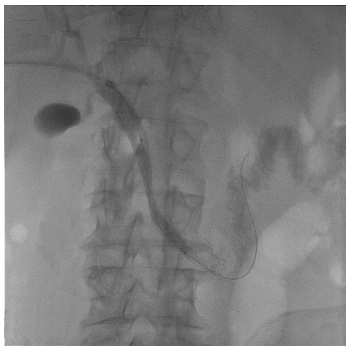

Figure 6b.

Balloon dilatation of the distal part of the stent to optimize the channel for bile drainage.

Problems that may arise with biliary drainage or stenting

Complications can occur after any clinical procedure and are of particular concern in these patients, who are often very fragile and may have been ill for some time. Many of the complications are minor such as puncture site bleeding or localised infection. However, there can be much more severe consequences such as massive internal bleeding or generalised blood infection, leading to shock. In some cases patients may die.

The Biliary Drainage and Stenting Registry

Although this technique is widely-accepted and increasingly employed, there are little data on current practice and outcomes, particularly in the United Kingdom. To address the paucity of data and ultimately to improve outcomes for patients, the British Society of Interventional Radiology set up the Biliary Drainage and Stenting Registry (BDSR) in November 2006. The BDSR is an internet-based registry and data are submitted on-line.

This is the first report on this registry and it will help us to understand how well these procedures are being performed in the United Kingdom. In particular, how effective they are at improving patients' symptoms, how commonly patients experience complications and, more importantly, what can be learnt to enable improvements in practice. To this end the Society will examine results for individual operators and centres to determine where the best results are achieved and seek to propagate best practice from these high-performing centres to colleagues elsewhere in order to raise standards across the board.

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Conventions used in the report

There are a number of conventions used in the report in an attempt to ensure that the data are presented in a simple and consistent way. These conventions relate largely to the tables and graphs, and some of these conventions are outlined below.

Conventions used in tables

On the whole, unless otherwise stated, the tables in this report record numbers of patient-entries (see the example below reproduced from page 32).

Approach and passes through the liver capsule

		Approach				
		Left	Right	Bilateral	Unspecified	**All**
Passes through the liver capsule	<2	33	252	3	0	**288**
	2-3	17	193	30	0	**240**
	>3	8	31	20	0	**59**
	Unspecified	31	156	14	45	**246**
	All	**89**	**632**	**67**	**45**	**833**

The numbers in each table are colour-coded so that patient-entries with complete data for all of the components under consideration (in this example both the operative approach and the number of passes through the liver capsule) are shown in regular black text. If one or more of the database questions under analysis is blank, the data are reported as unspecified in purple text. The totals for both rows and columns are highlighted as bold text.

Some tables record percentage values; in such cases this is made clear by the use of an appropriate title within the table and a % symbol after the numeric value. Yet other tables report average numbers (the patient's age at operation for example) and, again, this is made clear by the use of an appropriate title within the table.

Rows and columns within tables have been ordered so that they are either in ascending order (calendar years; post-operative stay; Low, Medium, High) or with negative response options first (No; No re-operation; None) followed by positive response options (Yes; Re-operation; One or more).

Row and column titles are as detailed as possible within the confines of the space available on the page. Where a title in either a row or a column is not as detailed as the authors would have liked, then footnotes have been added to provide clarification.

There are some charts in the report that are not accompanied by data in a tabular format. In such cases the tables are omitted for one of a number of reasons:

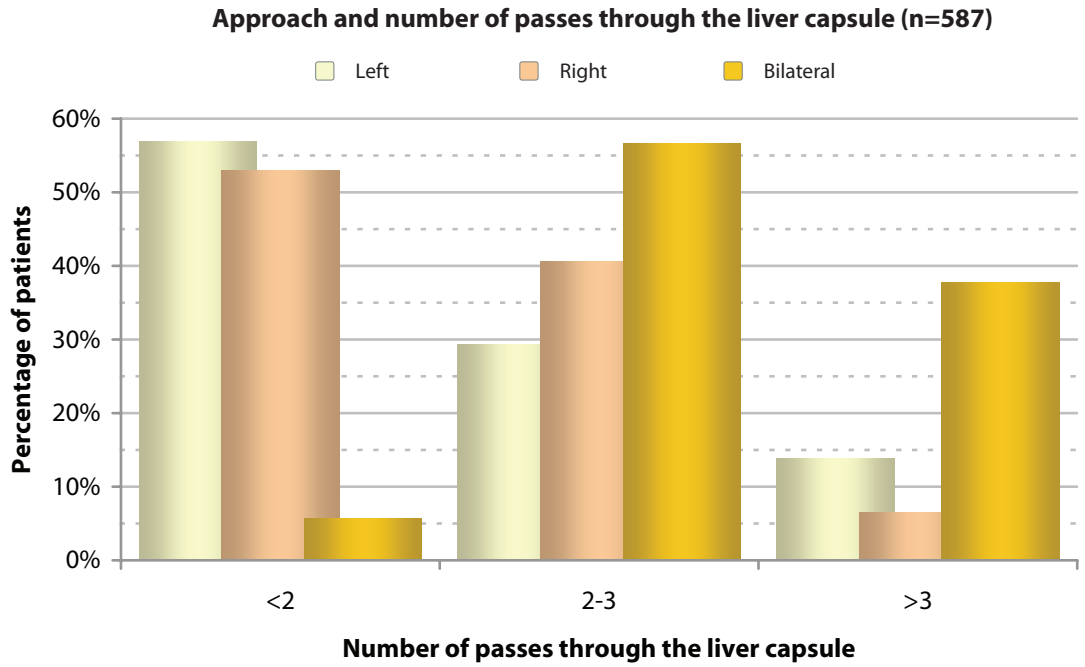
- insufficient space on the page to accommodate both the table and graph.
- there would be more rows / columns of data than could reasonably be accommodated on the page (post-operative stay data).
- the tabular data had already been presented elsewhere in the report.
- analyses were prepared separately from the preparation of the report by other workers.

Conventions used in graphs

The basic principles applied when preparing graphs for the Biliary Stent & Drainage Audit Report were based, as far as possible, upon William S. Cleveland's book *The elements of graphing data* [i]. This book details both best practice and the theoretical bases that underlie these practices, demonstrating that there are sound, scientific reasons for plotting charts in particular ways.

Counts: The counts (shown as n= in each graph's title) associated with graphs are affected by a number of independent factors and will therefore vary from chapter to chapter and from page to page. Most obviously, many of the charts in the Biliary Stent & Drainage Audit Report are graphic representations of results for a particular group (or sub-set) extracted from the database, such as patients with malignant disease, patients undergoing drainage only, and so on. This clearly restricts the total number of database-entries available for any such analysis. In addition to this, some entries within the group under consideration have data missing in one or more of the database questions being examined (reported as unspecified in tables); entries with missing data are excluded from the analysis used to generate the graph because they do not add any useful information.

For example, in the graph below, only the patient-entries with both operative approach and the number of passes through the liver capsule recorded are included in the analysis; this comes to 587 patient-entries (33 + 17 + 8 + 252 + 193 + 31 + 3 + 30 + 20 from examining the table; the 246 patient-entries with one or more unspecified data-items are excluded from the chart).



Confidence interval: In the charts prepared for this report, most of the bars plotted around rates (percentage values) represent 95% confidence intervals. The width of the confidence interval gives us some idea of how certain we can be about the calculated rate of an event or occurrence. If the confidence intervals around two rates do not overlap, then we can say, with a specified level of confidence, that the rates in these two populations are different; if the bars do overlap, we cannot make such an assertion.

i. Cleveland WS. The elements of graphing data. 1,985, 1994. Hobart Press, Summit, New Jersey, USA.

Demographics and disease profile

Demographics and pre-procedure data

General overview of the data

Data for this report were extracted from the database on 19th August 2009. There were 833 procedures recorded in the period since 1st November 2006. The data were provided by 62 members from 44 hospitals.

Demographics and disease profile

Age at procedure and gender

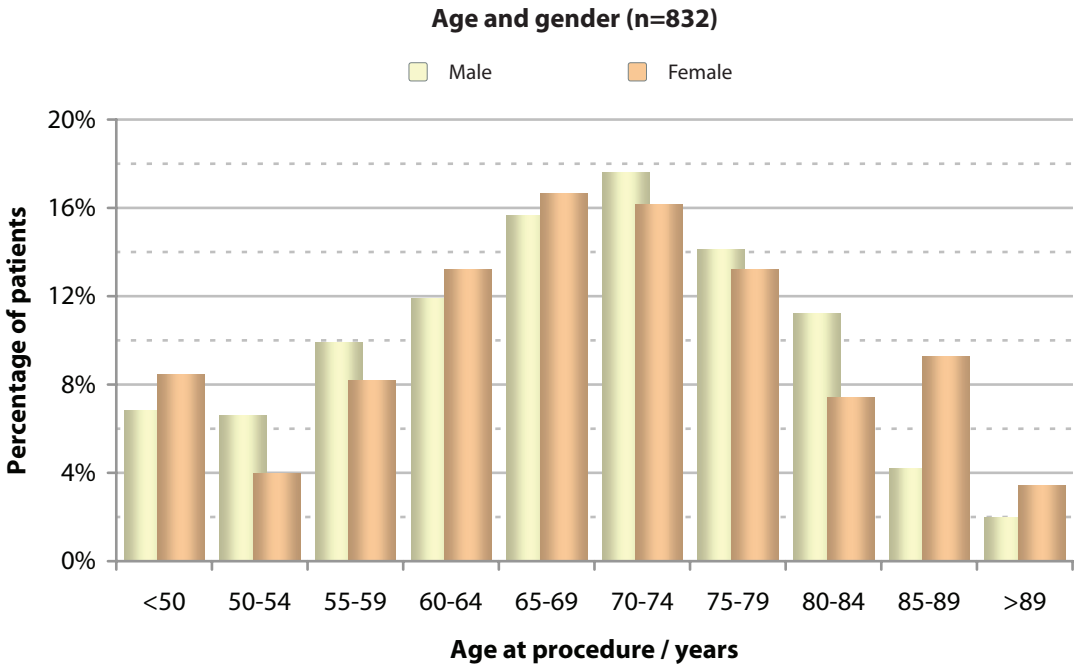
There was slight predominance of male patients undergoing biliary interventions reflecting the higher incidence of pancreatic cancer in men, which was the commonest malignancy treated. This is generally a disease of later life; patients have a median age of 69 years, irrespective of gender. The data also suggest that there were more younger patients in the group reported as having benign disease, although this apparent difference has not yet attained statistical significance.

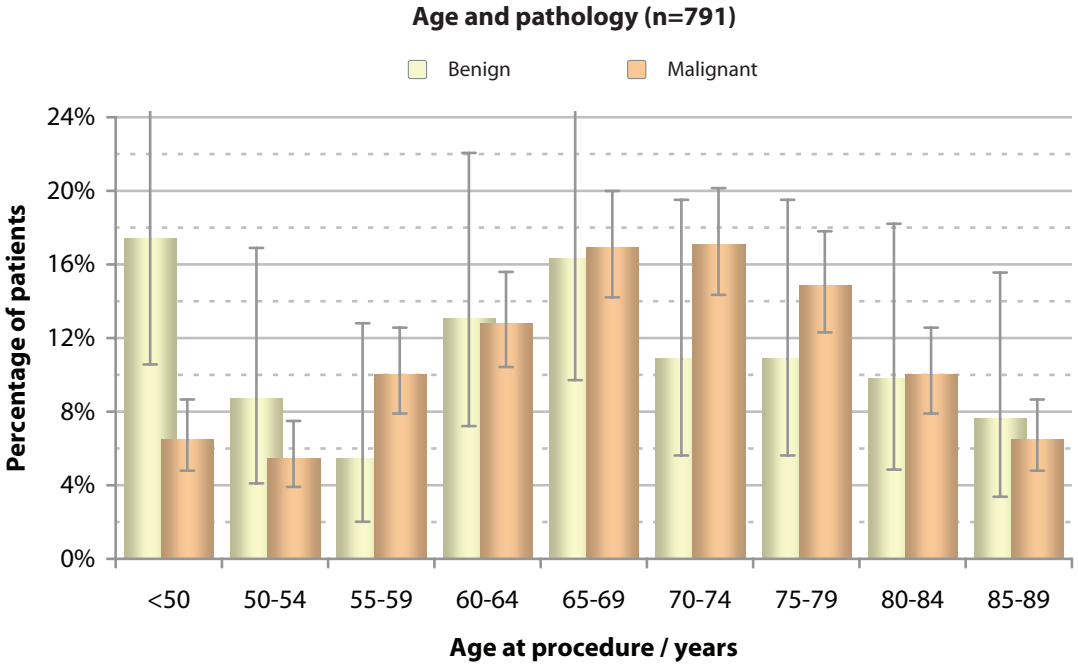
Basic statistics on patients' age at the time of procedure / years

Gender	Count	Average	Standard deviation	Lower quartile	Median	Upper quartile
Male	454	68.0	12.2	60.5	69	77
Female	378	68.7	13.4	61	69	77
All with known age data	**832**	**68.3**	**12.7**	**61**	**69**	**77**

Age and gender

		Gender			
		Male	Female	Unspecified	All
Age at procedure / years	<50	31	32	0	**63**
	50-54	30	15	0	**45**
	55-59	45	31	0	**76**
	60-64	54	50	0	**104**
	65-69	71	63	0	**134**
	70-74	80	61	0	**141**
	75-79	64	50	0	**114**
	80-84	51	28	0	**79**
	85-89	19	35	0	**54**
	>89	9	13	0	**22**
	Unspecified	1	0	0	**1**
	All	**455**	**378**	**0**	**833**


Age and gender (n=832)
Male
Female
20%
16%
12%
8%
4%
0%
Percentage of patients
<50
50-54
55-59
60-64
65-69
70-74
75-79
80-84
85-89
>89
Age at procedure / years


Age and pathology (n=791)
Benign
Malignant
24%
20%
16%
12%
8%
4%
0%
Percentage of patients
<50
50-54
55-59
60-64
65-69
70-74
75-79
80-84
85-89
Age at procedure / years

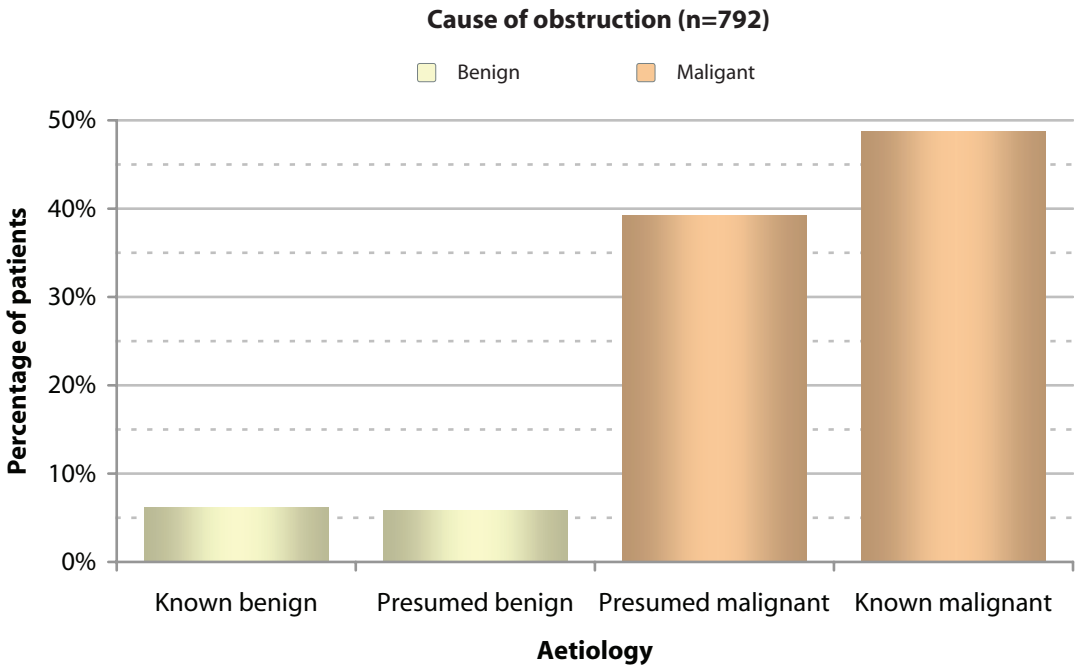
Aetiology

Gross aetiology

The vast majority of patients will have had an attempt at ERCP (Endoscopic Retrograde Cholangio-Pancreatography). Where ERCP fails (54.7%) this leaves a highly-selected cohort of patients with potentially more complex and difficult lesions, who usually then proceed to a percutaneous approach. However, the majority of obstructing lesions in these patients are still in the distal common bile duct (CBD; 51.4%) caused by malignant or presumed malignant disease (88.0%).

Cause of obstruction

		Data	
		Count	Percentage
Cause of obstruction	Known benign	49	**6.2%**
	Presumed benign	46	**5.8%**
	Presumed malignant	311	**39.3%**
	Known malignant	386	**48.7%**
	Unspecified	41	
	All	**833**	

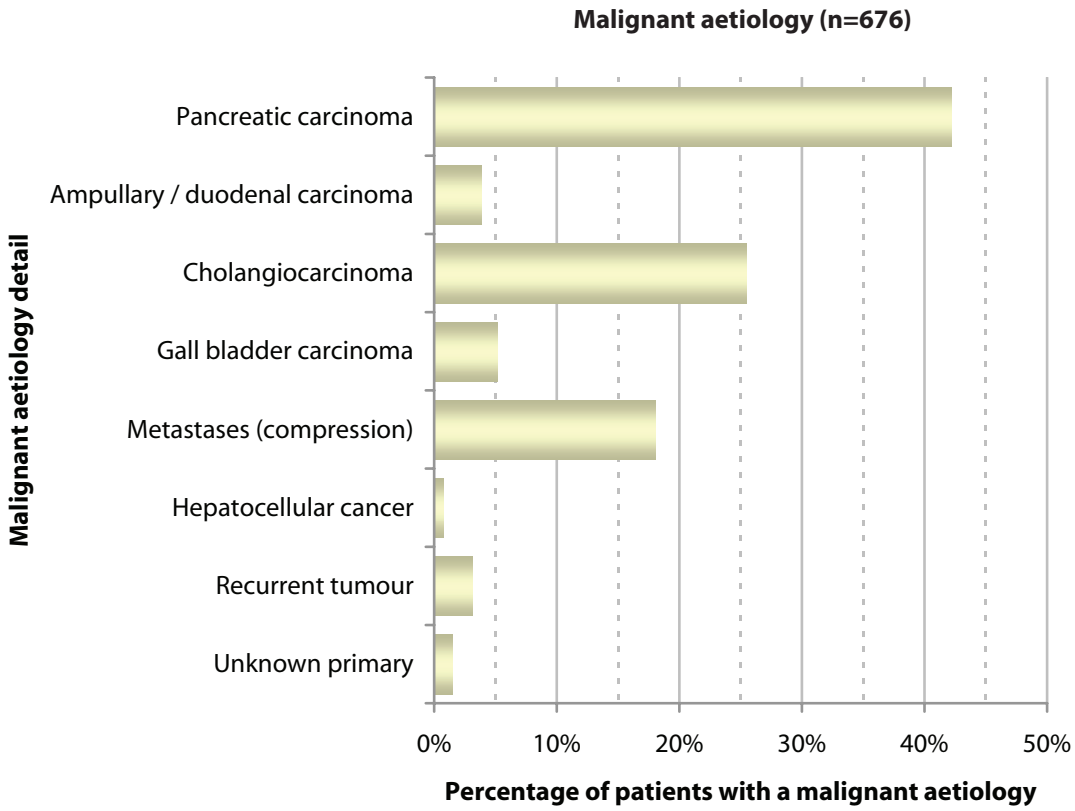


Malignant aetiology detail

The commonest malignancy was pancreatic carcinoma (42.2%), despite many patients with pancreatic cancer being successfully treated by ERCP. This reflects the dominance of pancreatic cancer as the leading tumour type causing biliary obstruction in these patients. Cholangiocarcinoma (25.4%) and metastases (18.0%) come second and third, usually causing more proximal obstructions.

Malignant aetiology

		Data	
		Count	Percentage
Malignant aetiology	Pancreatic carcinoma	285	**42.2%**
	Ampullary / duodenal carcinoma	26	**3.8%**
	Cholangiocarcinoma	172	**25.4%**
	Gall bladder carcinoma	35	**5.2%**
	Metastases (compression)	122	**18.0%**
	Hepatocellular cancer	5	**0.7%**
	Recurrent tumour	21	**3.1%**
	Unknown primary	10	**1.5%**
	Unspecified	21	
	All	**697**	

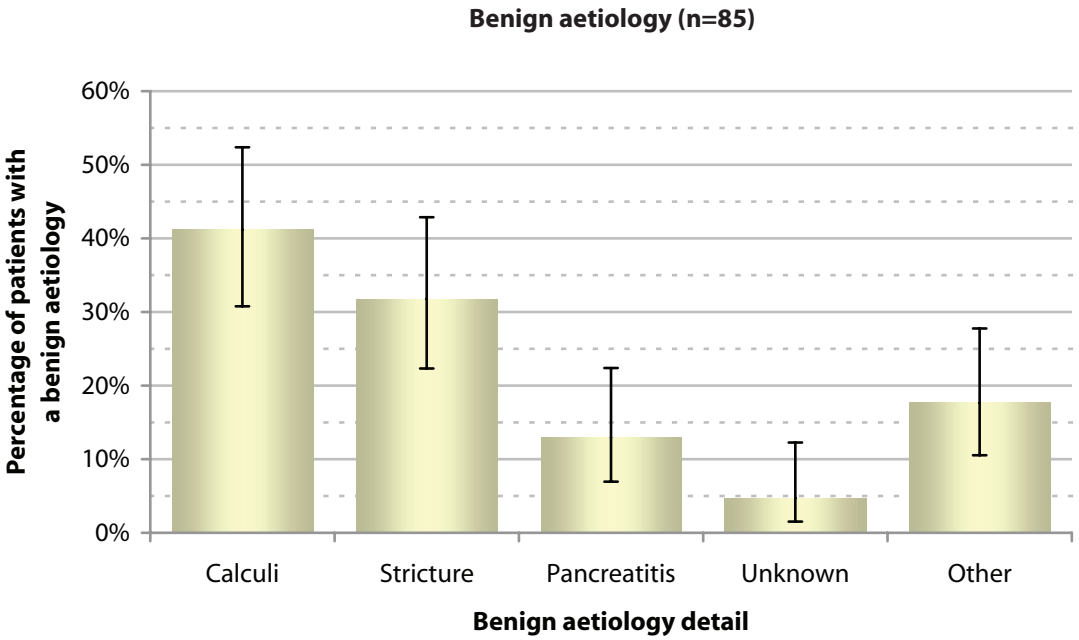


Benign aetiology detail

Overall, only 12% of patients had benign or presumed benign disease, with stone disease & strictures accounting for 73% of these. Even more so than for malignant disease, initial or repeat ERCP successfully treats the vast majority of these patients, and only a tiny fraction require percutaneous intervention. For many in this latter group of patients there are technical reasons as to why ERCP was not feasible, such as previous surgery.

Benign aetiology

		Data	
		Count	Percentage
Benign aetiology	Calculi	35	**41.2%**
	Stricture	27	**31.8%**
	Pancreatitis	11	**12.9%**
	Unknown	4	**4.7%**
	Other	15	**17.6%**
	Unspecified	10	
	All	**95**	

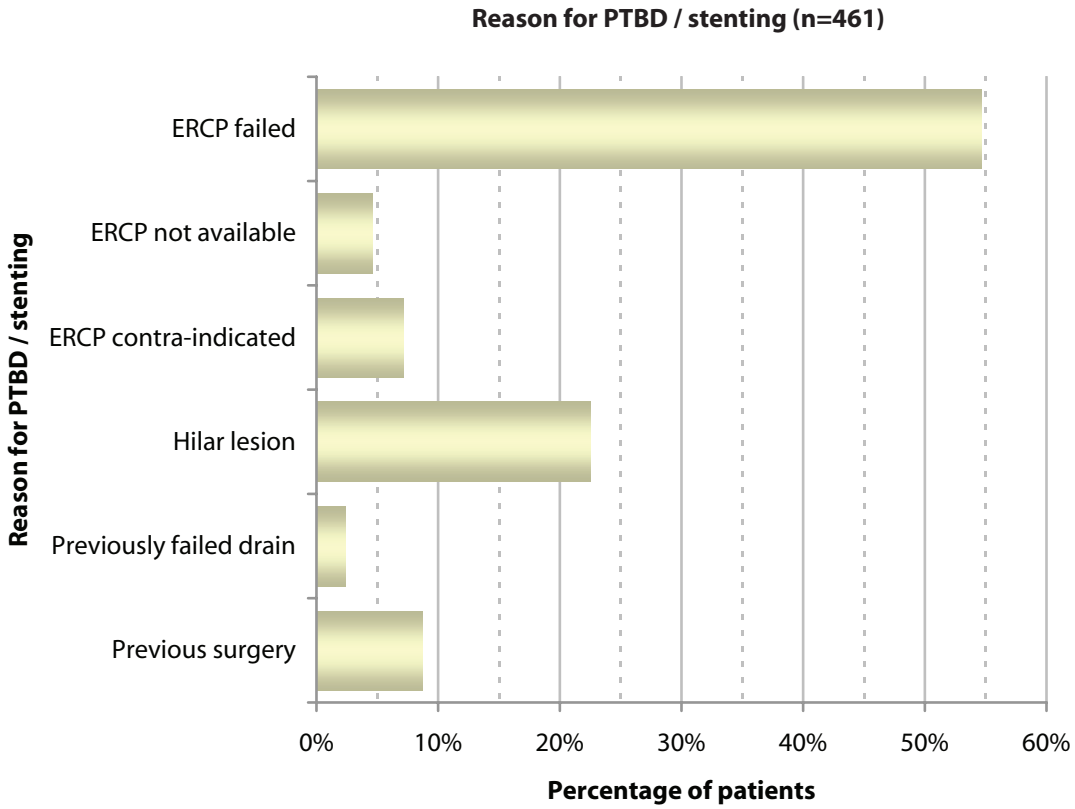


Reason for percutanous transhepatic billiary drainage (PTBD) / stenting

Where available, ERCP was employed as a first-line treatment modality in the majority of cases (54.7%). However, where there was a hilar lesion (22.6%) patients proceeded directly to percutaneous intervention and in only 15 such patients was a prior attempt made to treat with ERCP. This reflects the widespread recognition that hilar lesions are more difficult to treat and percutaneous techniques are usually much more successful for these patients. Where left and right duct origins are involved, biliary drainage and stenting is more likely to be an effective treatment.

Reason for PTBD / stenting

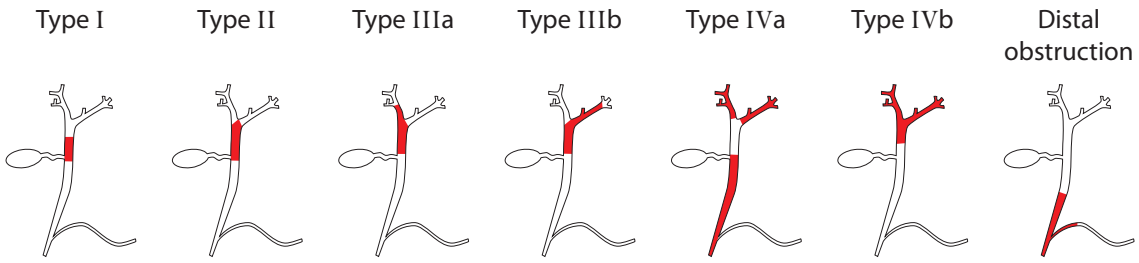
		Data	
		Count	Percentage
Reason for PTBD / stenting	ERCP failed	252	**54.7%**
	ERCP not available	21	**4.6%**
	ERCP contra-indicated	33	**7.2%**
	Hilar lesion	104	**22.6%**
	Previously failed drain	11	**2.4%**
	Previously failed access	40	**8.7%**
	Unspecified	372	
	All	**833**	



Level of obstruction

As malignant disease was the commonest cause of obstruction, and the most common cancer was pancreatic carcinoma, the level of obstruction in the majority of patients was distal (51.4%) with a significant minority involving the hilum (36.1%) caused by cholangiocarcinom and metastases. So, although many distal obstructions will have been treated with ERCP, most patients undergoing percutaneous intervention still have distal lesions that are relatively easier to treat.

The Bismuth classification



Level of obstruction (Bismuth classification)

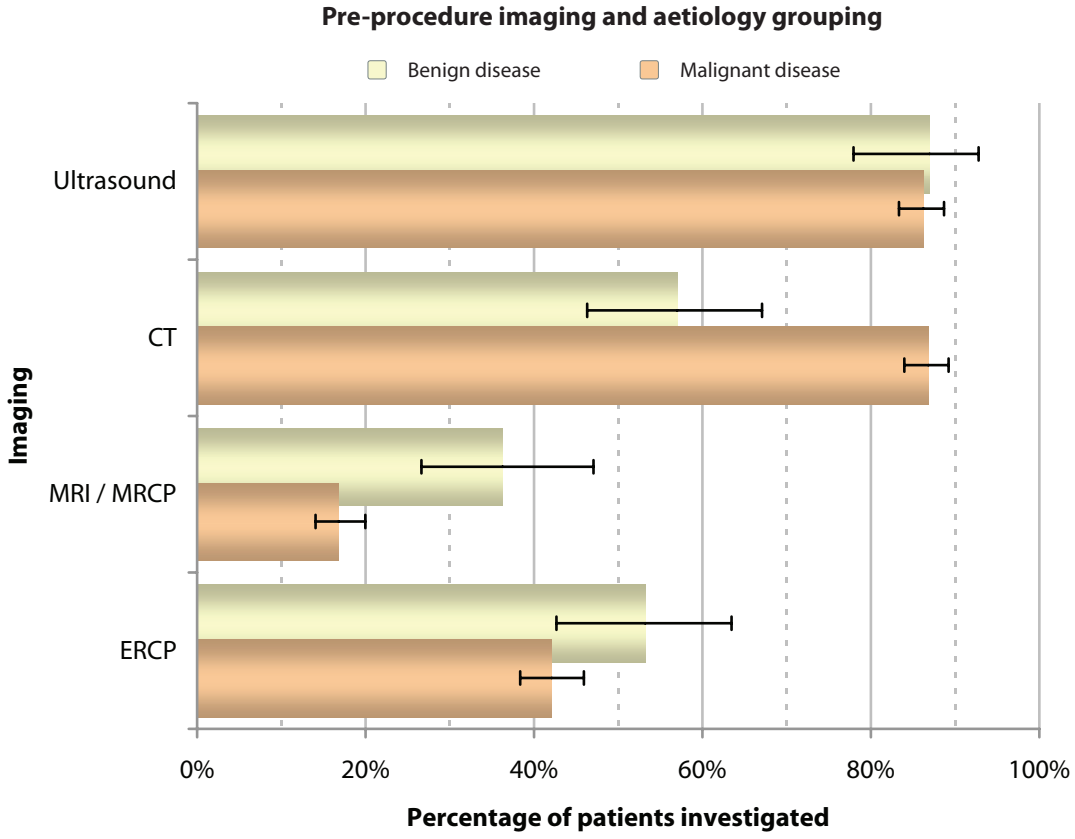
		Data	
		Count	**Percentage**
Level of obstruction	Type I	58	**8.2%**
	Type II	83	**11.7%**
	Type IIIa	48	**6.8%**
	Type IIIb	28	**4.0%**
	Type IVa	31	**4.4%**
	Type IVb	96	**13.6%**
	Distal obstruction	364	**51.4%**
	Unspecified	78	
	All	**786**	

Pre-procedure imaging

The vast majority of patients with malignant disease had pre-procedural computed tomography (CT; 86.8%), which reflects the disease staging process. In benign disease CT is performed much less frequently (57.0%) and magnetic resonance cholangiopancreatography (MRCP) is more frequently used.

Pre-procedure imaging and aetiology grouping

		Imaging performed							
		Benign disease				Malignant disease			
		No	Yes	Unspecified	Percentage performed	No	Yes	Unspecified	Percentage performed
Imaging	Ultrasound	12	80	3	**87.0%**	93	582	22	**86.2%**
	CT	40	53	2	**57.0%**	89	586	22	**86.8%**
	MRI / MRCP	58	33	4	**36.3%**	539	109	49	**16.8%**
	ERCP	44	50	1	**53.2%**	392	285	20	**42.1%**
	Unspecified	0	0	6	**NA**	0	0	57	**NA**
	All	**2**	**87**	6	**97.8%**	**5**	**635**	57	**99.2%**



Procedure

Procedure data

Basic procedure data

Primary operator

Interventional Radiology is very much a consultant-led specialty. This is confirmed by the data in the BDSR, which demonstrates that the vast majority of these complex procedures in high-risk patients were performed by consultants (93.0%). This needs to be taken into account for manpower planning in radiology .

Primary operator

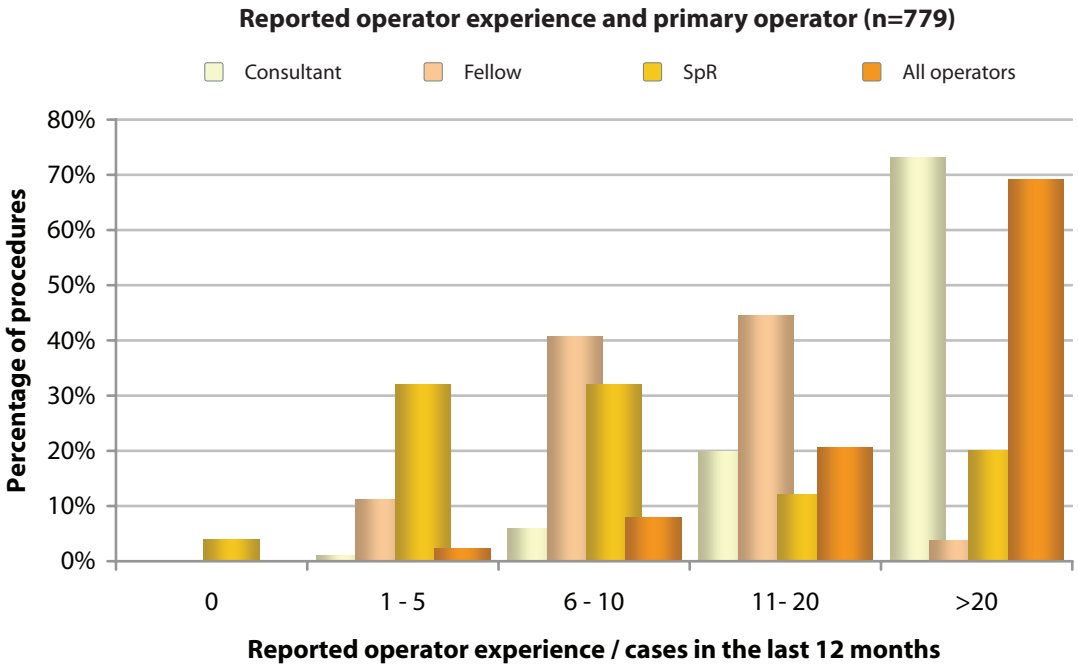
		Data	
		Count	**Percentage**
Primary operator	Consultant	740	**93.0%**
	Fellow	31	**3.9%**
	SpR	25	**3.1%**
	Unspecified	37	
	All	**833**	

Operator experience

To gauge the expertise of operators, they were asked to record their activity / experience of biliary procedures in the previous 12 months. Most operators reported that they performed more than 10 cases *per annum* (89.6%). However, on analysis of the data, it became clear that the vast majority of operators were entering data on many fewer cases than their reported estimate. This may be for two possible reasons: operators may not be entering data on all the cases that they are performing (which has major implications for data quality); alternatively, the anomaly may simply be due to an unrealistic estimate of clinical activity.

Reported operator experience in the last 12 months and primary operator

		Primary operator				
		Consultant	Fellow	SpR	Unspecified	**All**
Reported operator experience	0 cases	0	0	1	0	**1**
	1-5 cases	7	3	8	0	**18**
	6-10 cases	43	11	8	0	**62**
	11-20 cases	145	12	3	0	**160**
	>20 cases	532	1	5	0	**538**
	Unspecified	13	4	0	37	**54**
	All	**740**	**31**	**25**	**37**	**833**

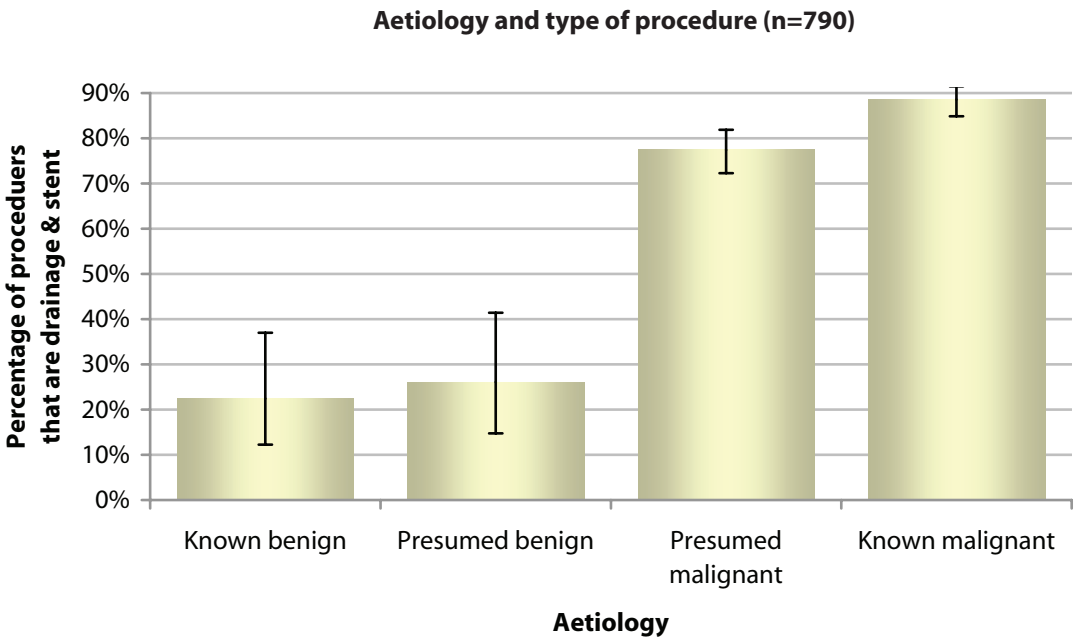


Procedure performed

Unlike patients with cancer, few patients with benign disease went on to have a metal stent placed and were treated by biliary drainage only. In part, this may be driven by the limited experience of the long-term outcomes associated with the placement of a metal stent in patients with benign disease. A small proportion (16.4%) of patients with malignant disease had drainage-only procedures, and presumably either went on to have curative surgery or died as they had very advanced disease. For the very ill patient with malignant disease, drainage was probably attempted to see if their liver function and symptoms might be improved.

Aetiology and type of procedure

		Procedure			
		Drainage only	Drainage & stent	Unspecified	**All**
Aetiology	Known benign	38	11	0	**49**
	Presumed benign	34	12	0	**46**
	Presumed malignant	70	240	1	**311**
	Known malignant	44	341	1	**386**
	Unspecified	10	11	20	**41**
	All	**196**	**615**	**22**	**833**

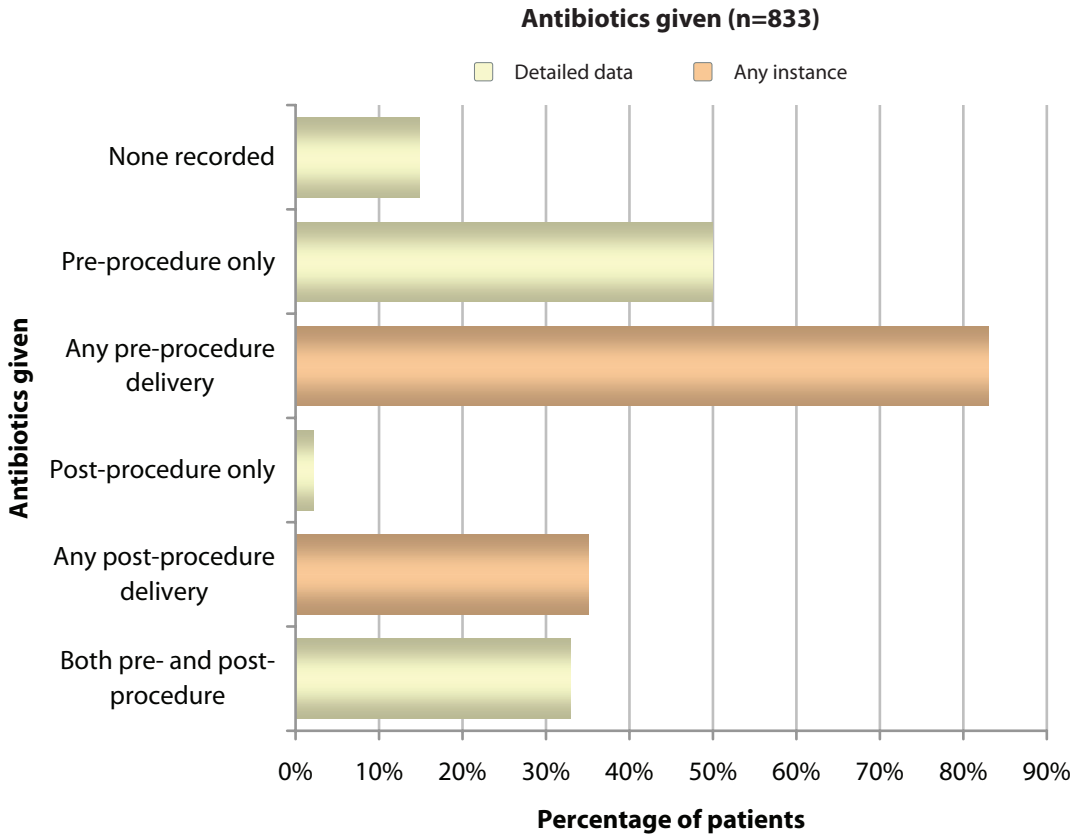


Anitbiotics

The vast majority of patients were given either pre- or pre- & or post-procedural antibiotics. The recorded data suggest that 14.9% of patients were given neither pre- or post-procedural antibiotics. This may be because many of these patients were being given antibiotics on the ward and operators therefore (correctly) did not record any additional antibiotics as being given. However, this question did not have a specific option for no antibiotics given and so the potential anomaly in the data may reflect the inadequacy in the format of the question and / or poor data entry.

Antibiotics given

		Data	
		Count	**Percentage**
Timing of antibiotics	None recorded	124	**14.9%**
	Pre-procedure only	416	**49.9%**
	Post-procedure only	18	**2.2%**
	Both pre- and post-procedure	275	**33.0%**
	Unspecified [i]	0	
	All	**833**	



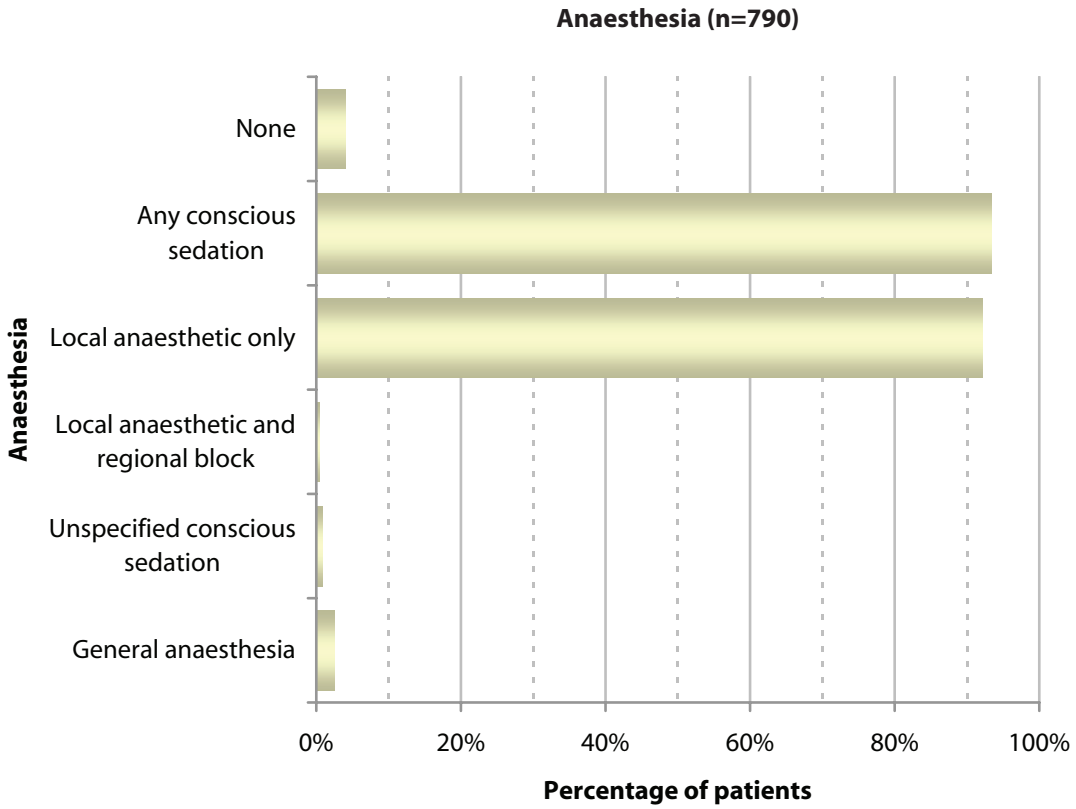
i. In this analysis the absence of any data are reported as *None recorded* as there is no facility in the database to formally record the fact that no antibiotics were delivered.

Anaesthesia

The vast majority of procedures were performed under conscious sedation (93.4%) with a small group, (2.5%) having a general anaesthetic. 4.1% of the patients recorded in the registry have apparently had neither sedation nor any analgesia. This would be very surprising in view of the severe peri-procedural pain and discomfort likely to be experienced by the large majority of patients who undergo these procedures in the absence of adequate pain management. It is more likely that there was confusion with this question, which will be modified in a future release of the registry to make it clearer.

Anaesthesia

			Data	
			Count	Percentage
Anaesthesia	None		32	**4.1%**
	Conscious sedation	Any conscious sedation	738	**93.4%**
		Local anaesthetic only	728	**92.2%**
		Local anaesthetic and regional block	3	**0.4%**
		Unspecified	7	**0.9%**
	General anaesthesia		20	**2.5%**
	Unspecified		43	
	All		**833**	



Monitoring

Monitoring was carried out during virtually all procedures (99.9%) with a minimum of blood pressure monitoring and pulse oximetry as recommended by the Royal College of Radiologists (RCR). Only one entry recorded no monitoring during this high-risk procedure. It is heartening that this important message from the RCR that all patients undergoing these potentially hazardous procedures should be routinely monitored has been adopted by virtually all operators.

Passes through the liver capsule

Only 10% of procedures required more than three passes through the liver capsule to access the bile ducts with almost half getting access into the ducts on the first pass. This is quite impressive, particularly as the vast majority of operators did not use ultrasound guidance during the procedure, and shows that good technique with simple fluoroscopy is adequate for most patients who have dilated biliary ducts.

Number of passes through the liver capsule

		Data	
		Count	**Percentage**
Passes through the liver capsule	0	2	**0.3%**
	1	286	**48.7%**
	2	159	**27.1%**
	3	81	**13.8%**
	4	31	**5.3%**
	5	17	**2.9%**
	6	2	**0.3%**
	7	2	**0.3%**
	8	5	**0.9%**
	>8	2	**0.3%**
	Unspecified	246	
	All	**833**	

Approach and level of obstruction

Approach and level of obstruction

A right-sided approach was utilised in the majority (79.5%) of cases. A bilateral or left-sided approach was utilised for the more complex or proximal bile duct obstructions (19.5%). It is not surprising, therefore, that a greater number of punctures were required when using a bilateral approach. Although there was an association between increased numbers of punctures and a left-sided approach; the link was not statistically significant.

Patients with an obstruction: approach and level of obstruction

		Approach				
		Left	Right	Bilateral	Unspecified	**All**
Level of obstructions	Type I	3	53	2	0	**58**
	Type II	18	56	7	2	**83**
	Type IIIa	17	17	14	0	**48**
	Type IIIb	11	15	1	1	**28**
	Type IVa	3	23	5	0	**31**
	Type IVb	22	37	35	2	**96**
	Distal obstruction	7	351	2	4	**364**
	Unspecified	5	67	1	5	**78**
	All	**86**	**619**	**67**	**14**	**786**

Approach and passes through the liver capsule

Approach and passes through the liver capsule

		Approach				
		Left	Right	Bilateral	Unspecified	**All**
Passes through the liver capsule	<2	33	252	3	0	**288**
	2-3	17	193	30	0	**240**
	>3	8	31	20	0	**59**
	Unspecified	31	156	14	45	**246**
	All	**89**	**632**	**67**	**45**	**833**

Drainage

Successful drainage

Successful placement of a stent across a bile duct obstruction was high (98.7%) with primary stenting performed by most operators (62.8%).

Successful drainage and approach

		Successful drainage			
		No	Yes	Unspecified	Rate
Approach	Left	2	75	12	**97.4%**
	Right	2	527	103	**99.6%**
	Bilateral	3	58	6	**95.1%**
	Unspecified	1	3	41	**75.0%**
	All	**8**	**663**	**162**	**98.8%**

Drain outcome

Only a small number of drains were inadvertently displaced (3.3%), with the vast majority available for subsequent internalisation. There seem to be a high number of drains intentionally removed (41.6%). This probably reflects some confusion in the way that this database question was interpreted as many more patients went on to have stenting than this would suggest, and the database may require a little redesigning to remove any potential confusion.

Drain outcome

		Data	
		Count	Percentage
Drain outcome	Access for subsequent internalisation	331	**55.1%**
	Displaced prior to internalisation	20	**3.3%**
	Intentionally removed	250	**41.6%**
	Unspecified	232	
	All	**833**	

Stenting

Biliary stenting procedure

Technical success for stenting was high at 98.7%; most operators performed primary stenting (62.8%). A single-stage procedure has the advantage of reducing in-hospital stay and minimising the morbidity usually associated with having a drain in place for several days. The stents deployed were overwhelmingly bare metal stents (96.6%) placed unilaterally (82.6%), with a tiny minority of operators placing plastic stents (3.4%).

Plastic stents have a much reduced long-term patency compared to metal stents, and are generally only used when medium-term drainage is required; for example, when a patient requires symptomatic relief prior to curative surgery.

Drainage and stent procedures: stent

		Data	
		Count	Percentage
Stent	Plastic	19	**3.4%**
	Metal	536	**96.6%**
	Unspecified	60	
	All	**615**	

Stent placed

Drainage and stent procedures: biliary stenting procedure

		Data	
		Count	Percentage
Stenting procedure	Primary	359	**62.8%**
	Staged	147	**25.7%**
	Combined	7	**1.2%**
	Repeat for blocked stent	59	**10.3%**
	Unspecified	43	
	All	**615**	

Drainage and stent procedures: successful stent placement

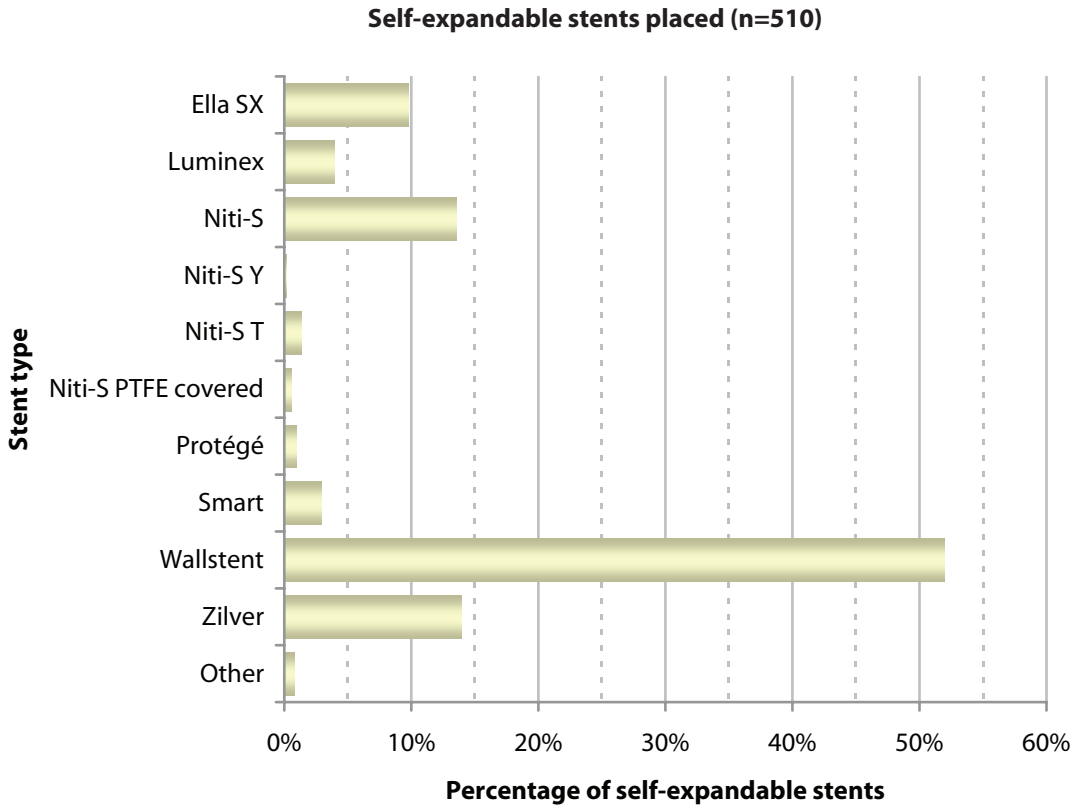
		Data	
		Count	Percentage
Successful placement	No	8	**1.3%**
	Yes	586	**98.7%**
	Unspecified	21	
	All	**615**	

Stent type

Interestingly, although several newer stents have become available in the market, the older wall stent design is still the most commonly used stent. This probably reflects device familiarity with the Wallstent.

Name of stents used in drainage and stent procedures: name of stent

		Data	
		Count	Percentage
Name of stent	Ella SX	50	**9.8%**
	Luminex	20	**3.9%**
	Niti-S	69	**13.5%**
	Niti-S Y	1	**0.2%**
	Niti-S T	7	**1.4%**
	Niti-S PTFE covered	3	**0.6%**
	Protégé	5	**1.0%**
	Smart	15	**2.9%**
	Wallstent	265	**52.0%**
	Zilver	71	**13.9%**
	Other	4	**0.8%**
	Unspecified	48	
	All	**558**	



Stent configuration

The majority of patients had a unilateral stent placed, from a right-sided approach. Bilateral and kissing stents were used for treating lesions involving the more proximal biliary tree, usually near the liver hilum (17.4%). In many cases of proximal obstructions at the junction of the right and left hepatic ducts, it is usually sufficient to drain the right-sided ducts for the purpose of palliation. In the literature, patency of single stents generally appears to be better. However, it is recognized that if both duct systems are seen during cholangiography and only one side is stented, there is a higher septic complication rate.

Drainage and stent procedures: stent configuration

		Data	
		Count	**Percentage**
Stent configuration	Unilateral	426	**82.6%**
	Bilateral	58	**11.2%**
	Kissing	32	**6.2%**
	Unspecified	99	
	All	**615**	

Outcomes

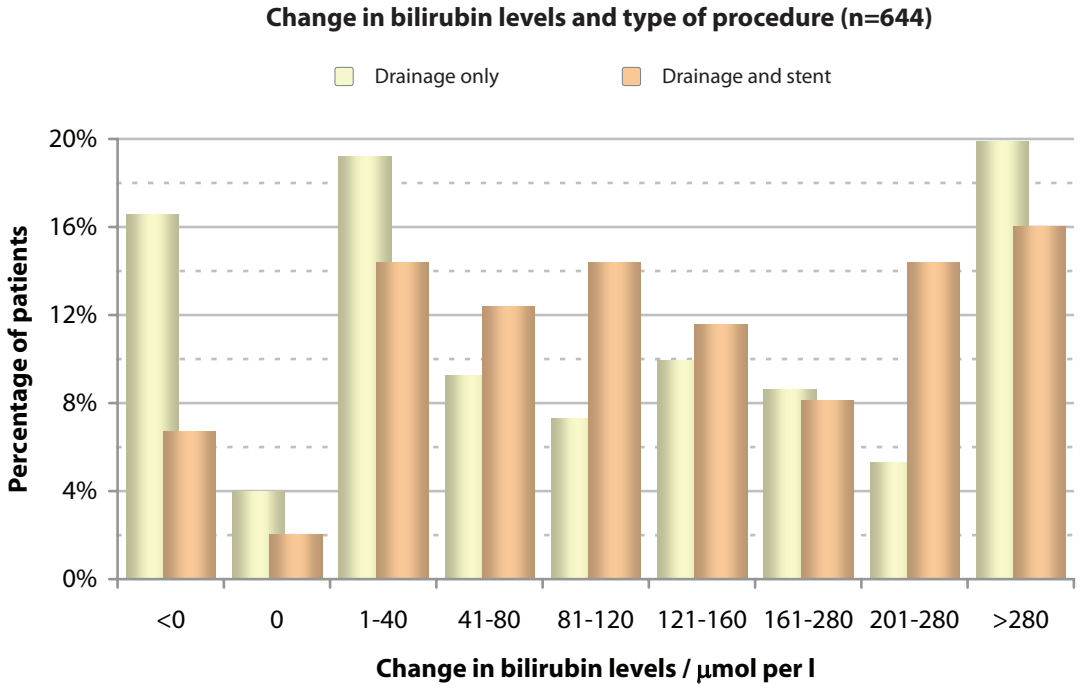
Outcomes

Changes in bilirubin levels

For the majority of patients there was a substantial reduction in bilirubin levels after biliary drainage or combined drainage & stent. Reduction in bilirubin levels was greater for distal obstructions compared to the more proximal obstructing lesions. However, some patients experienced minimal change or even an increase in pre-interventional bilirubin levels, suggesting inadequate drainage of the biliary tree. It is likely that these poor results were associated with the more complex hilar / proximal obstructions, where insufficient patent ducts were available for adequate drainage and multiple drains were felt to be inappropriate. There was no significant difference in post-procedural bilirubin levels between patients who had drainage only and those having combined drainage & stenting. Where there was a hilar lesion and patients had a bilateral drainage and / or stents, there was a significantly greater bilirubin reduction compared to right- or left-sided only drainage and / or stent procedures. There was a suggestion of a greater reduction in bilirubin levels for right-sided (as opposed to left-sided) drainage & stent procedures, but this difference did not attain significance.

Post-intervention changes in bilirubin levels and type of procedure

Change in bilirubin / μmol l^{-1}	Type of procedure			
	Drainage only	Drainage & stent	Unspecified	**All**
Any increase post procedure	25	33	0	**58**
No change	6	10	0	**16**
1-40	29	71	0	**100**
41-80	14	61	1	**76**
81-120	11	71	0	**82**
121-160	15	57	1	**73**
161-280	13	40	0	**53**
201-280	8	71	0	**79**
>280	30	79	0	**109**
Unspecified	45	122	20	**187**
All	**196**	**615**	**22**	**833**



Relief of symptoms

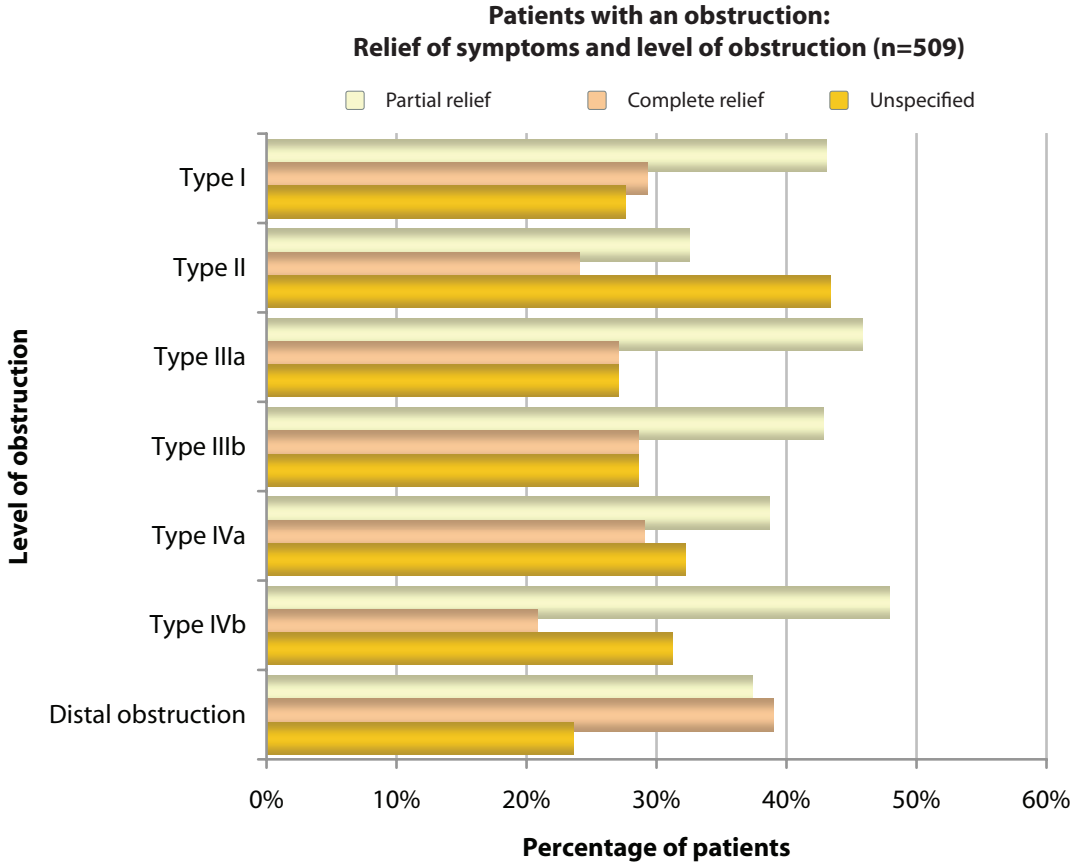
Relief of symptoms and level of obstruction

The degree of symptomatic relief was not dependent on the level of obstruction, despite more complex hilar lesions being technically more difficult to treat. This would support palliative treatment even in patients with complex proximal obstructive disease.

For patients with hilar lesions, although there was an association between better relief of symptoms with a bilateral approach (as opposed to either right- or left-sided drains and stents), the apparent difference did not attain statistical significance.

Patients with obstructions: relief of symptoms and level of obstruction

		Relief of symptoms			
		Partial	Complete	Unspecified	**All**
Level of obstruction	Type I	25	17	16	**58**
	Type II	27	20	36	**83**
	Type IIIa	22	13	13	**48**
	Type IIIb	12	8	8	**28**
	Type IVa	12	9	10	**31**
	Type IVb	46	20	30	**96**
	Distal obstruction	136	142	86	**364**
	Unspecified	15	13	20	**78**
	All	**295**	**242**	**249**	**786**

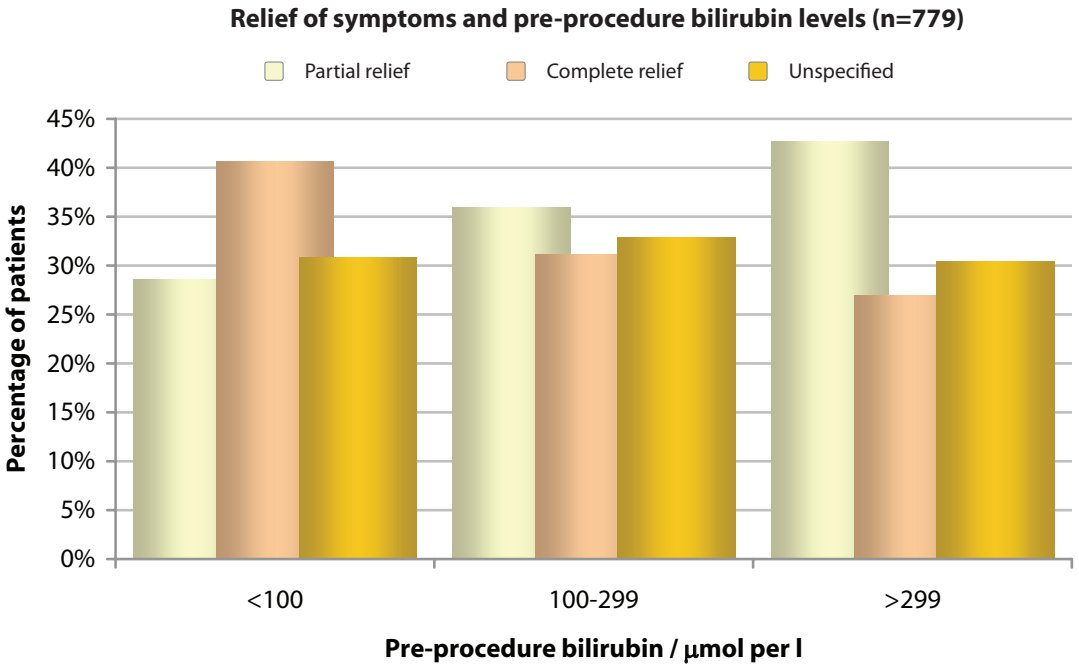


Relief of symptoms and pre-procedure bilirubin

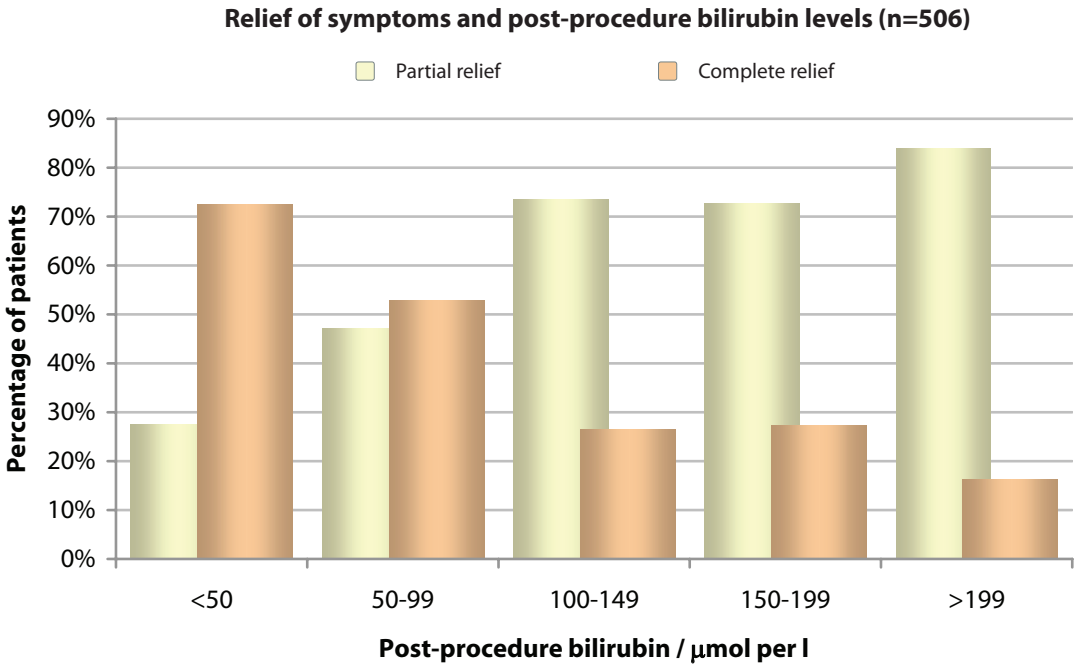
There was no statistically significant association between the rate of symptomatic relief and pre-procedure bilirubin levels for either complete or partial symptomatic relief.

Relief of symptoms and pre-procedure bilirubin levels

		Relief of symptoms			
		Partial	Complete	Unspecified	**All**
Pre-procedure bilirubin	<100 µmol l^{-1}	38	54	41	**133**
	100-299 µmol l^{-1}	127	110	116	**353**
	>299 µmol l^{-1}	125	79	89	**293**
	Unspecified	8	6	40	**54**
	All	**298**	**249**	**286**	**833**



However, not surprisingly, complete relief of symptoms did seem to be associated with lower post-procedure bilirubin levels and, concomitantly, only partial relief with higher levels of post-procedure bilirubin ($p<0.001$).



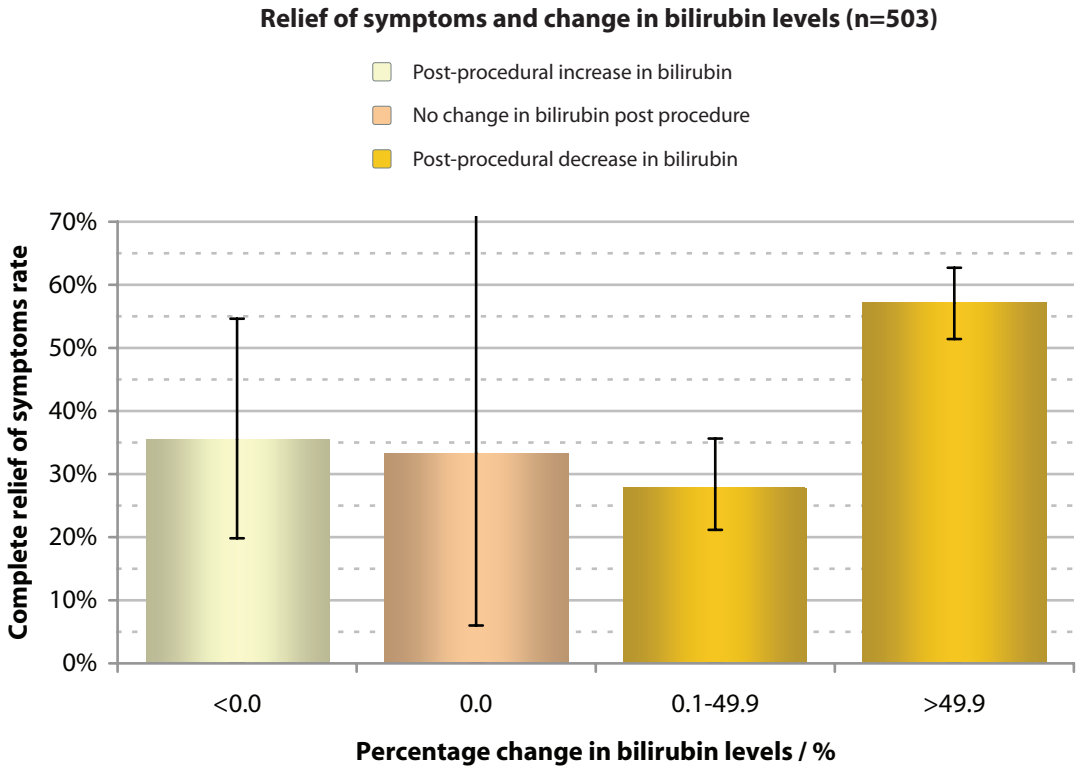
Relief of symptoms and changes in bilirubin level

To assess whether or not there was a direct link between post-procedure reduction in bilirubin levels and symptomatic relief, analysis was performed based changes in bilirubin levels stratified into two groups (<50.0% and ≥50.0% decrease). Chi-squared analysis shows a statistically significant result (χ^2 $p<0.001$). Complete symptom relief was seen in 29.2% of patients who had <50% reductions in bilirubin levels (95% CI: 23.1-36.2%) and 57.1% for patients who had ≥50.0% reductions in bilirubin levels (95% CI: 51.4-62.7%).

However, it was surprising to see improvement in symptoms in patients with minimal or no reduction in bilirubin levels. It is even more surprising to see improvement in patients where bilirubin levels actually increased post-procedure. The improvement for this group of patients may well reflect a combination of better post-procedural drug management and a possible placebo-effect component.

Relief of symptoms and changes in bilirubin levels

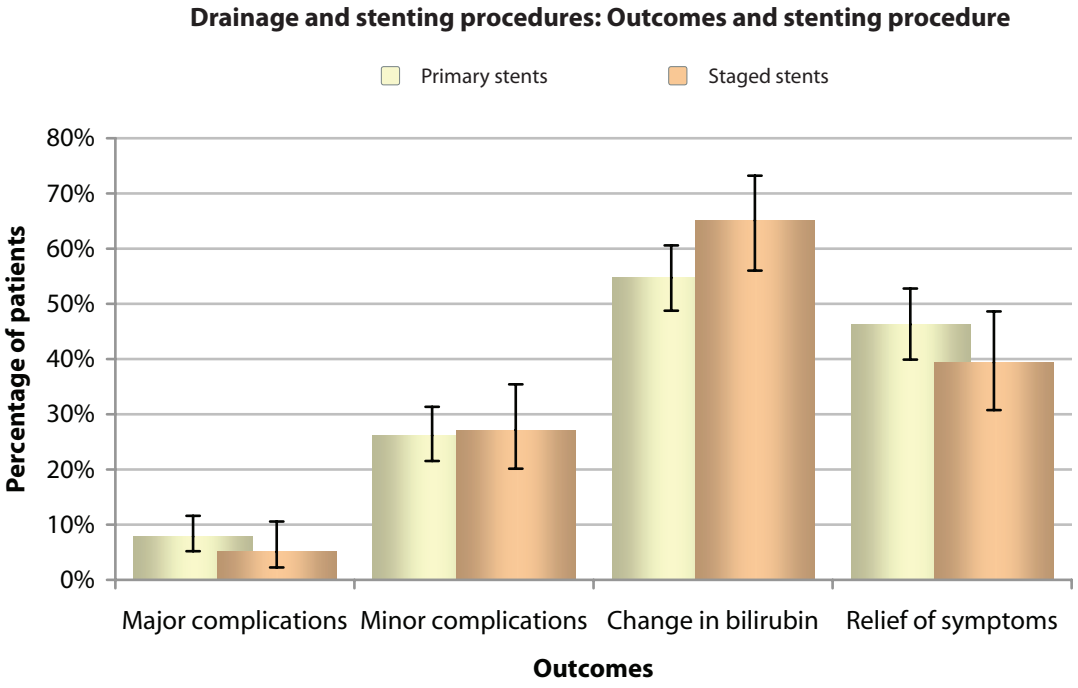
		Relief of symptoms			
		Partial	Complete	Unspecified	**All**
Percentage change in bilirubin	Any increase post procedure	20	11	22	**53**
	No change	4	2	10	**16**
	0.1-49.9% decrease	114	44	66	**224**
	>49.9% decrease	132	176	40	**348**
	Unspecified	28	16	148	**192**
	All	**298**	**249**	**286**	**833**

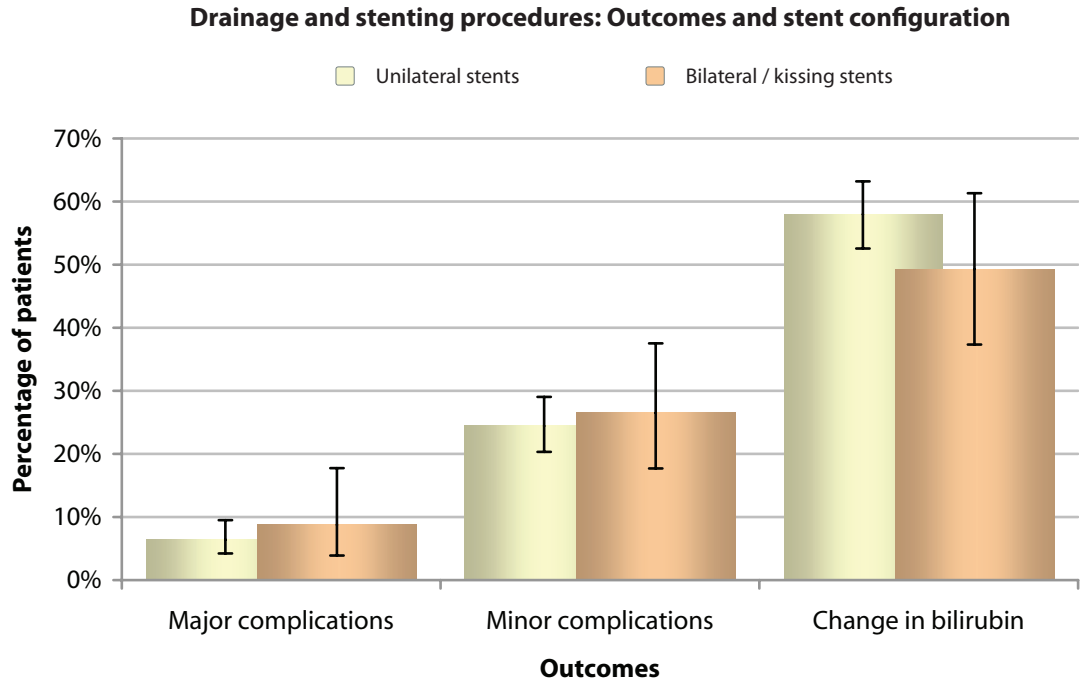


Stenting outcome

Comparing staged *versus* primary stents, there are no statistically significant differences in major complication rates (χ^2 p=0.390), minor complication rates (χ^2 p=0.915), bilirubin reduction (χ^2 p=0.064; comparing <50.0% *versus* ≥50.0% reduction) or relief of symptoms (χ^2 p=0.251 comparing partial relief *versus* complete relief).

When comparing unilateral *versus* bilateral / kissing stenting, there was no significant difference in bilirubin reduction (χ^2 p=0.226), minor complications (χ^2 p=0.796) or major complications (χ^2 p=0.608).





Stenting across the sphincter of Oddi

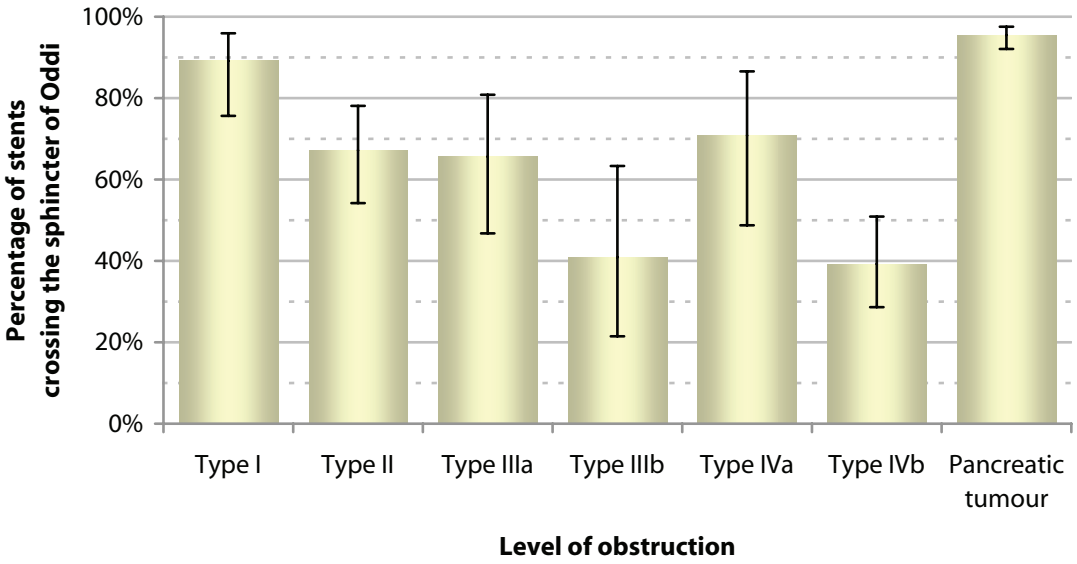
Traditional training for operators has been to ensure that biliary stents extended beyond the sphincter of Oddi to ensure better drainage. Comparison between stents that did and did not cross the sphincter of Oddi into the duodenum showed a significant difference in reduction of bilirubin post-stenting; the reduction in bilirubin levels (<50.0% *versus* ≥50.0%) are significantly different on chi-squared analysis (χ^2 p<0.001). 40% of patients have ≥50.0% reduction when the stent does not cross and 63% have the same result when it does cross.

However, there was no difference in relief of symptoms (χ^2 p=0.145), minor complications (χ^2 p=0.970), or major complications (χ^2 p=0.116).

Patients undergoing drainage and stenting procedures for an obstruction: level of obstruction and stent crosses the sphincter of Oddi

		Stent crosses the sphincter of Oddi			
		No	Yes	Unspecified	**All**
Level of obstruction	Type I	5	41	3	**49**
	Type II	21	43	4	**68**
	Type IIIa	11	21	3	**35**
	Type IIIb	13	9	1	**23**
	Type IVa	7	17	1	**25**
	Type IVb	48	31	6	**85**
	Pancreatic tumour	12	255	12	**279**
	Unspecified	5	11	26	**42**
	All	**122**	**428**	**56**	**606**

Drainage and stenting procedures for obstructions:
Stent crosses the sphincter of Oddi and level of obstruction (n=534)



Minor complications

Minor complications overview

The data entry screens for the complications section of the web-based database were presented as a series of complications that the operator can classify as either minor or major. At the time of data entry there were no on-screen prompts to ensure that a uniform definition of minor / major classification was applied. This has led to some minor data anomalies *e.g.*, pleural fistulae classified as minor complications.

The majority of patients did not experience any minor complications (74.0%). Dilation of the tract through the liver capsule is painful and biliary drainage catheters can cause significant discomfort, and this was reflected in the 14.3% rate of post-procedural pain reported. Minor sepsis and haemorrhage occurred in 7.7% and 4.5% of patients respectively.

Minor complications

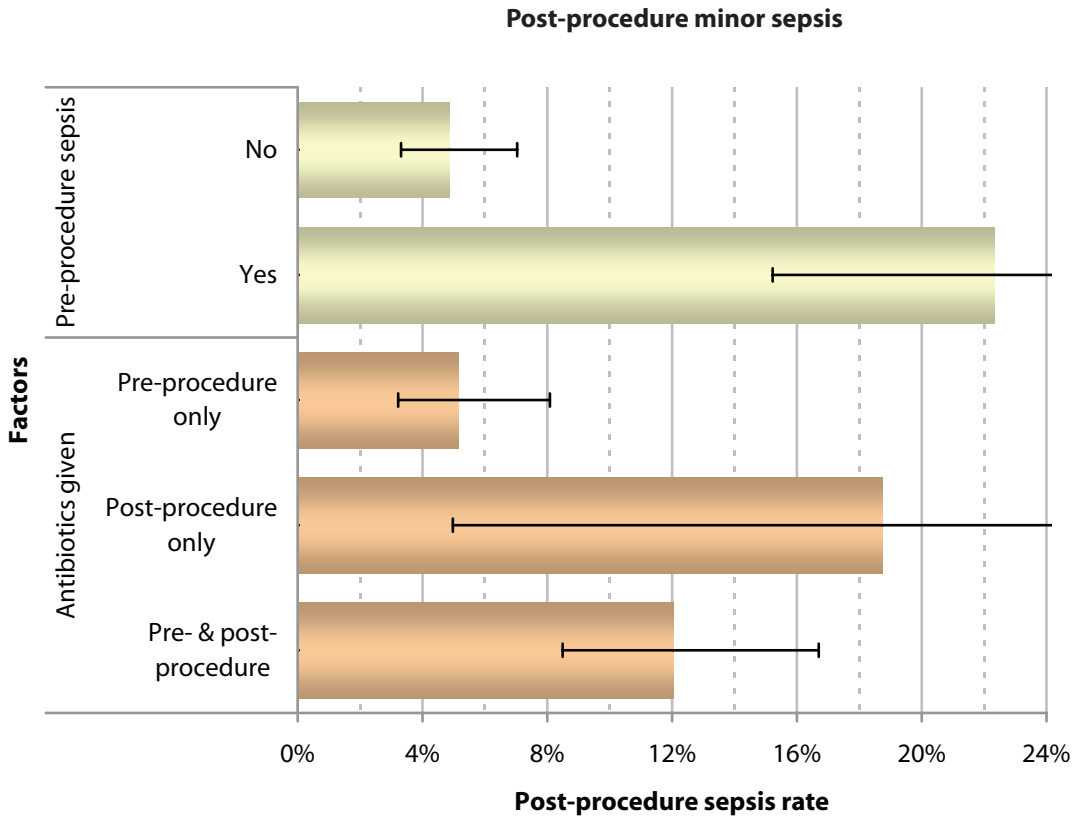
		Data	
		Count	**Percentage**
Minor complications	None	531	**74.0%**
	Abscess	1	**0.1%**
	Pancreatitis	4	**0.6%**
	Renal failure	4	**0.6%**
	Sepsis	55	**7.7%**
	Peritonitis	3	**0.4%**
	Pneumothorax	2	**0.3%**
	Haemorrhage / haematoma	32	**4.5%**
	Colecystitis	0	**0.0%**
	Pleural fistula	2	**0.3%**
	Pain	103	**14.3%**
	Unspecified	115	
	All	**833**	

Minor complication: sepsis

The overall sepsis rate was 7.7% post-procedure and even with pre-procedural antibiotics the sepsis rate was 5.2%. Surprisingly, the group recorded as not having been given any antibiotics appears to have the lowest incidence of post-procedure sepsis (1.5%). However, as previously discussed, these patients may have been given antibiotics on the ward and longer-term antibiotics may improve sterilisation of the biliary tree. There was no significant difference in the sepsis rate for drainage *versus* combined drainage & stent procedures.

Minor sepsis complication: post-procedure sepsis and selected factors

			Post-procedure sepsis			
			No	Yes	Unspecified	Rate
Selected factors	Pre-procedure sepsis	No	548	28	64	**4.9%**
		Yes	87	25	9	**22.3%**
		Unspecified	28	2	42	**6.7%**
		All	**663**	**55**	**115**	**7.7%**
	Antibiotics	Pre-procedre antibiotics only	349	19	48	**5.2%**
		Post-procedre antibiotics only	13	3	2	**18.8%**
		Pre- & post-procedre antibiotics	234	32	9	**12.0%**
		Unspecified	67	1	56	**1.5%**
		All	**663**	**55**	**115**	**7.7%**



Minor complication: haematoma / haemorrhage

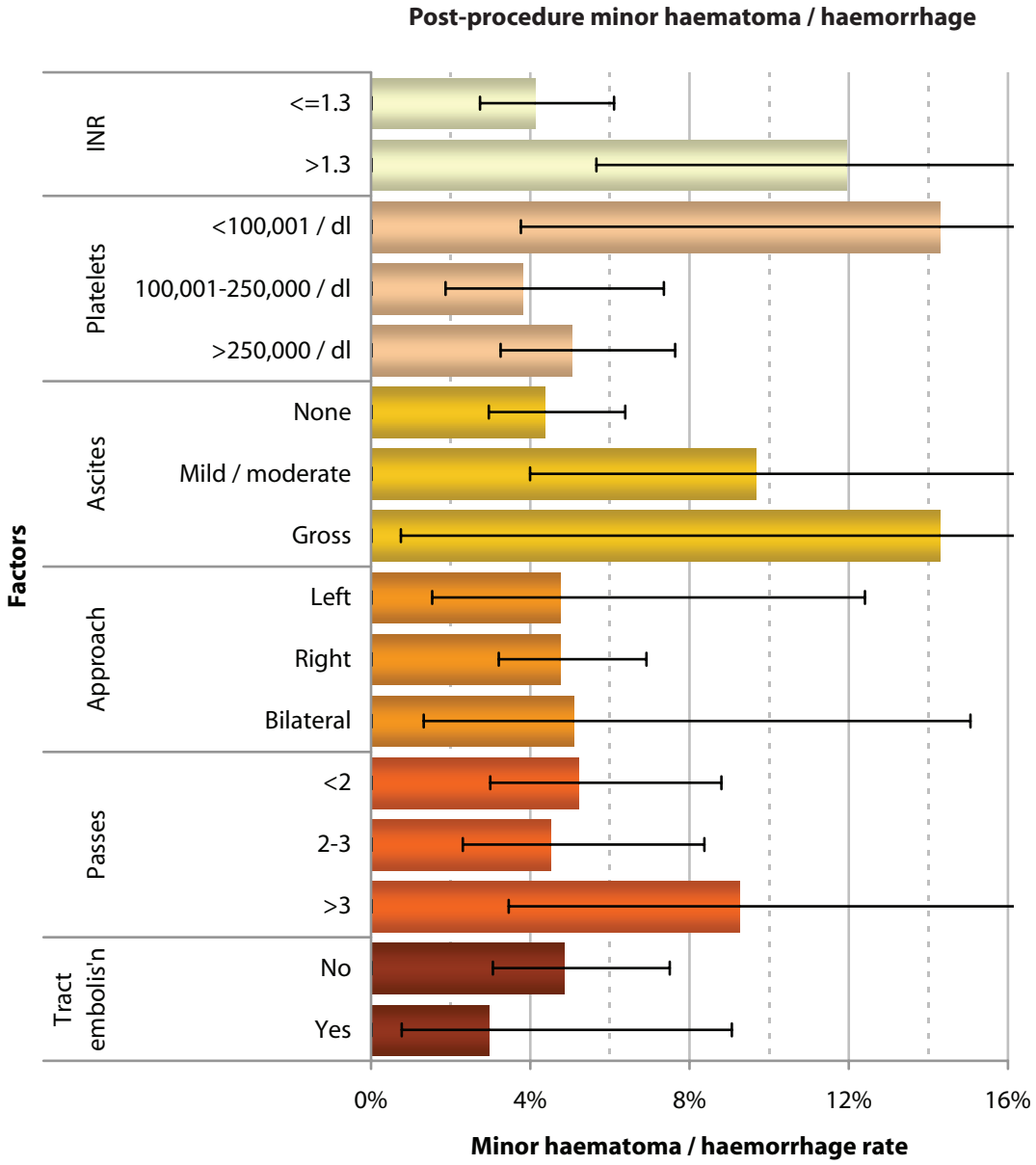
Analysis of potential associated factors for minor haemorrhage was conducted looking at 5 key factors. Both the recorded blood parameters have some association with this outcome: increased INR levels demonstrate a significant association with increased haematoma / haemorrhage rates (p=0.012) and reduced platelet counts a mild association with increased rates of haematoma / haemorrhage (p=0.087).

The difference in rates of haematoma / haemorrhage associated with the presence of ascites (None *versus* Yes) also reaches statistical significance (p=0.036). Gross ascites seems to be associated with a non-significant increase in the incidence of minor haemorrhage. Neither approach, number of passes or tract embolization demonstrated a significant association with this outcome.

Minor haematoma / haemorrhage complication: post-procedure haematoma / haemorrhage and selected factors

			Post-procedure minor haematoma / haemorrhage			
			No	Yes	Unspecified	Rate
Selected factors	INR	≥1.3	582	25	63	**4.1%**
		>1.3	59	8	9	**11.9%**
		Unspecified	43	1	43	**2.3%**
	Platelets	<100,001 dl^{-1}	18	3	4	**14.3%**
		100,001-250,000 dl^{-1}	227	9	26	**3.8%**
		>250,000 dl^{-1}	415	22	47	**5.0%**
		Unspecified	24	0	38	**0.0%**
	Ascites	None	590	27	63	**4.4%**
		Mild / moderate	56	6	9	**9.7%**
		Gross	6	1	2	**14.3%**
		Unspecified	32	0	41	**0.0%**
	Approach	Left	80	4	5	**4.8%**
		Right	542	27	63	**4.7%**
		Bilateral	56	3	8	**5.1%**
		Unspecified	6	0	39	**0.0%**
	Passes[i]	<2	254	14	20	**5.2%**
		2-3	212	10	18	**4.5%**
		>3	49	5	5	**9.3%**
		Unspecified	169	5	72	**2.9%**
	Tract embol'n	No	393	20	26	**4.8%**
		Yes	98	3	13	**3.0%**
		Unspecified	193	34	76	**15.0%**

i Passes through the liver capsule


Post-procedure minor haematoma / haemorrhage
Factors
INR
<=1.3
>1.3
Platelets
<100,001 / dl
100,001-250,000 / dl
>250,000 / dl
Ascites
None
Mild / moderate
Gross
Approach
Left
Right
Bilateral
Passes
<2
2-3
>3
Tract embolis'n
No
Yes
0%
4%
8%
12%
16%
Minor haematoma / haemorrhage rate

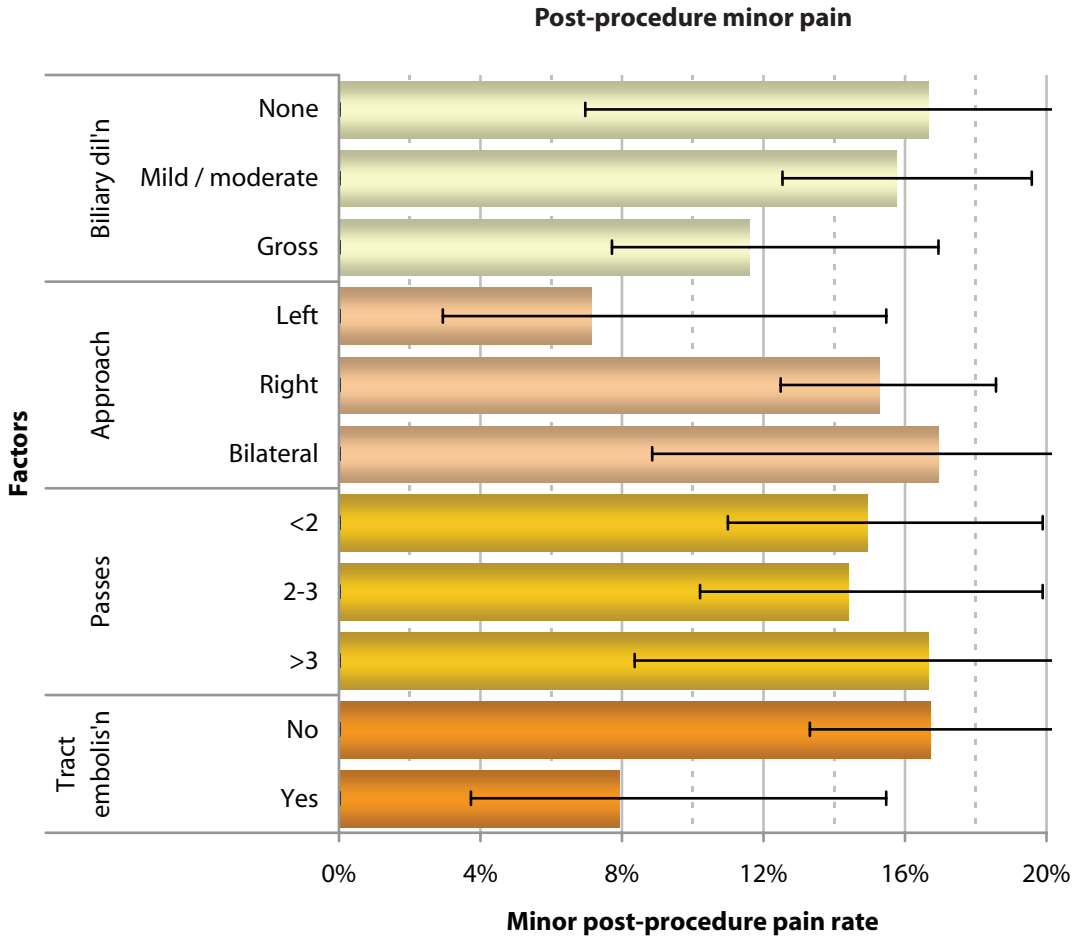
Minor complication: pain

Although the number of passes and the occurrence of tract embolization may influence the likelihood of minor bile / blood leaks to the liver capsule, analysis did not reveal any significant association. Grossly dilated biliary systems are likely to be technically easier to enter and therefore potentially reduce procedure time; while analysis did show less pain associated with gross dilatation the difference did not attain statistical significance.

Minor pain complication: post-procedure pain and selected factors

			Post-procedure minor pain			
			No	Yes	Unspecified	Rate
Selected factors	Biliary dilatation	None	30	6	3	**16.7%**
		Mild / moderate	369	69	45	**15.8%**
		Gross	183	24	28	**11.6%**
		Unspecified	33	4	39	**10.8%**
	Approach	Left	78	6	5	**7.1%**
		Right	482	87	63	**15.3%**
		Bilateral	49	10	8	**16.9%**
		Unspecified	6	0	39	**0.0%**
	Passes[i]	<2	228	40	20	**14.9%**
		2-3	190	32	18	**14.4%**
		>3	45	9	5	**16.7%**
		Unspecified	152	22	72	**12.6%**
	Tract embol'n	No	344	69	26	**16.7%**
		Yes	93	8	13	**7.9%**
		Unspecified	178	26	76	**12.7%**

i Passes through the liver capsule


Post-procedure minor pain
Factors
Biliary dil'n
None
Mild / moderate
Gross
Approach
Left
Right
Bilateral
Passes
<2
2-3
>3
Tract embolis'n
No
Yes
0%
4%
8%
12%
16%
20%
Minor post-procedure pain rate

Major complications

The vast majority of patients had no major complications (92.1%). Of the 7.9% of patients where a major complication was reported, most frequently these were due to sepsis (3.5%), renal failure (1.8%) or haemorrhage (1.6%).

1.0% of patients (6 of 592) with normal pre-procedure renal function and 9.8% (6 of 61) with moderately raised creatinine went on to develop renal failure as a major complication following biliary intervention. This highlights the need to maintain optimal hydration pre- and post-procedure in this patient group to minimize the risk of this complication.

Major complications

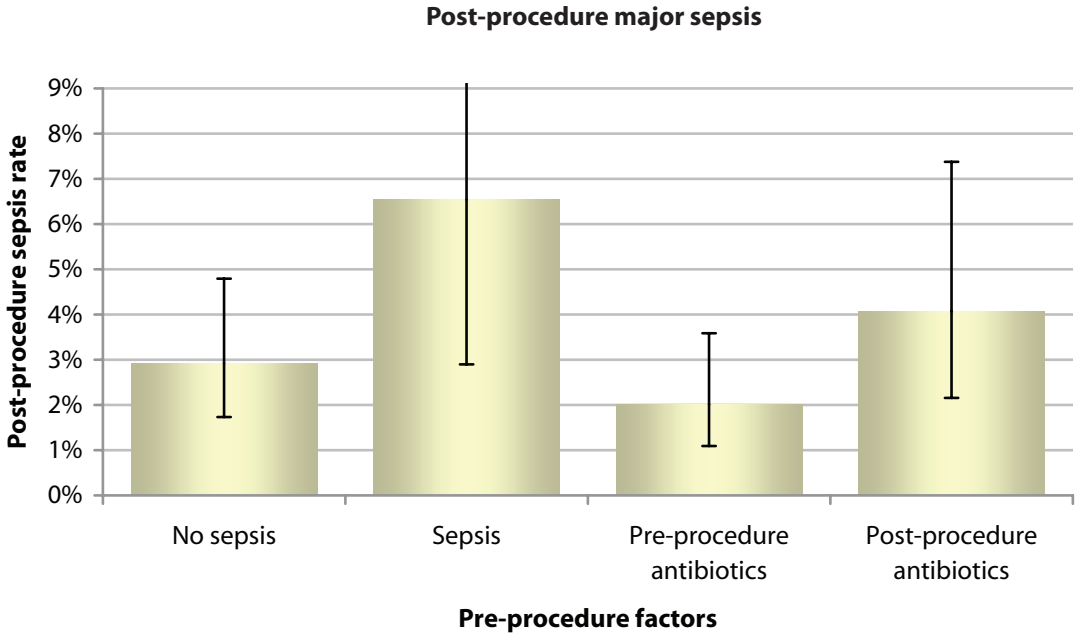
		Data	
		Count	**Percentage**
Major complications	None	631	**92.1%**
	Abscess	1	**0.1%**
	Pancreatitis	1	**0.1%**
	Renal failure	12	**1.8%**
	Sepsis	24	**3.5%**
	Peritonitis	3	**0.4%**
	Pneumothorax	0	**0.0%**
	Haemorrhage / haematoma	11	**1.6%**
	Colecystitis	0	**0.0%**
	Pleural fistula	2	**0.3%**
	Pain	6	**0.9%**
	Unspecified	148	
	All	**833**	

Major complication: sepsis

The incidence of a major overall sepsis complication was low (3.5%). The rate seems to be higher in the drainage-only (5.2%) group *versus* the drainage and stenting groups (3.0%). This difference was not statistically significant. However, a significantly higher proportion of patients who underwent drainage only (26.6%) had pre-procedural sepsis compared to patients who underwent combined drainage & stenting. This is likely to be the result of active patient selection.

Major sepsis complication: post-procedure sepsis and selected factors

			Post-procedure sepsis			
			No	Yes	Unspecified	Rate
Selected factors	Pre-procedure sepsis	No	533	16	91	**2.9%**
		Yes	100	7	14	**6.5%**
		Unspecified	28	1	43	**3.4%**
		All	**661**	**24**	**148**	**3.5%**
	Antibiotics	Pre-procedure antibiotics	585	12	84	**3.6%**
		Post-procedure antibiotics	259	11	23	**4.1%**
		Unspecified	63	1	60	**1.6%**
		All	**661**	**24**	**148**	**3.5%**



Major complication: haematoma / haemorrhage

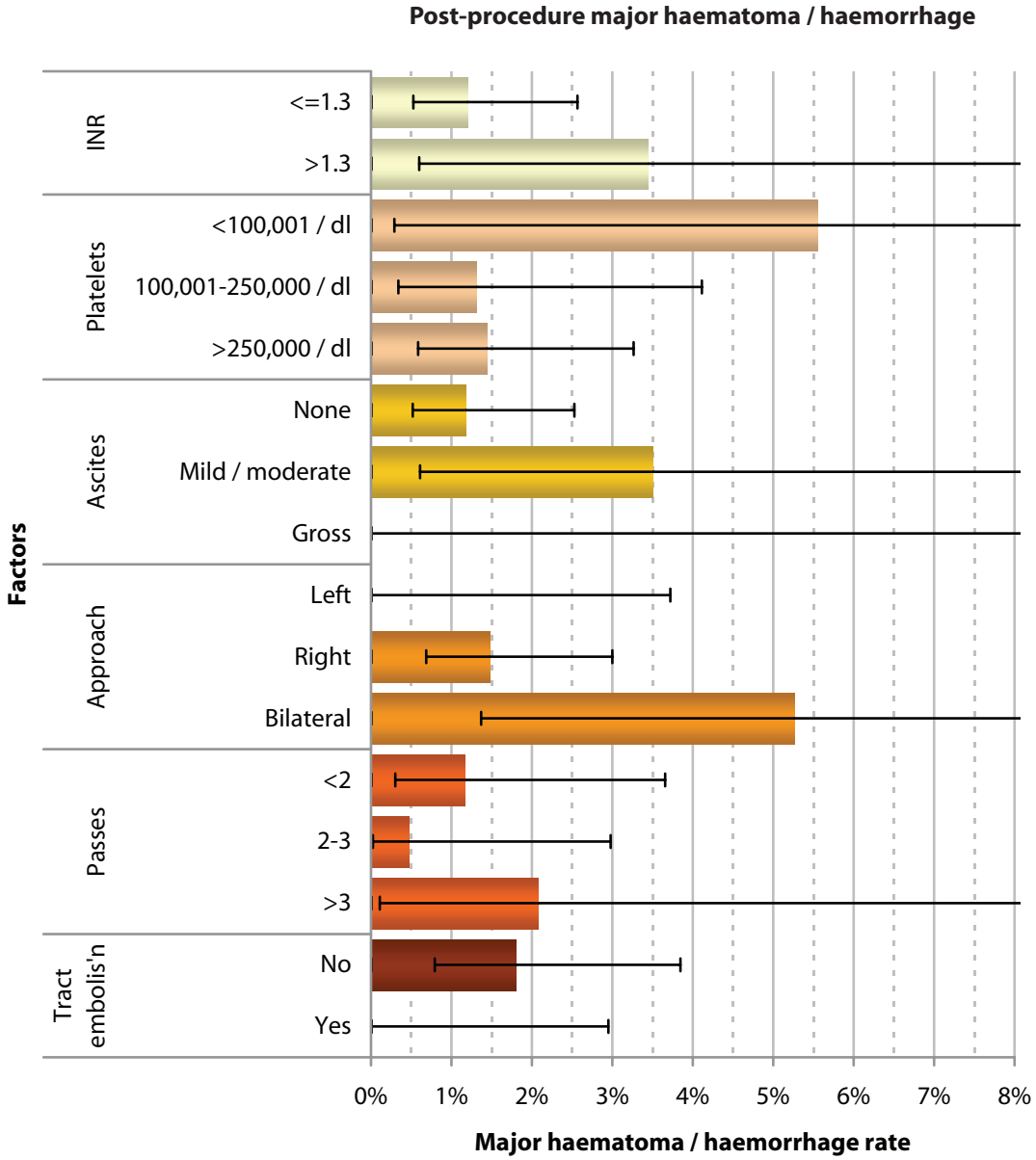
There was no clear correlation between post-procedural haemorrhage / haematoma and the following factors: abnormal INR, reduced platelets, ascites, approach, number of liver passes and tract embolisation.

This is not, perhaps, surprising as the number of these complications is small.

Major haematoma / haemorrhage complication: post-procedure haematoma / haemorrhage and selected factors

			Post-procedure major haematoma / haemorrhage			
			No	Yes	Unspecified	Rate
Selected factors	INR	≥1.3	577	7	86	**1.2%**
		>1.3	56	2	18	**3.4%**
		Unspecified	41	2	44	**4.7%**
	Platelets	<100,001 dl^{-1}	17	1	7	**5.6%**
		100,001-250,000 dl^{-1}	225	3	34	**1.3%**
		>250,000 dl^{-1}	411	6	67	**1.4%**
		Unspecified	21	1	40	**4.5%**
	Ascites	None	586	7	87	**1.2%**
		Mild / moderate	55	2	14	**3.5%**
		Gross	3	0	6	**0.0%**
		Unspecified	30	2	41	**6.3%**
	Approach	Left	79	0	10	**0.0%**
		Right	535	8	89	**1.5%**
		Bilateral	54	3	10	**5.3%**
		Unspecified	6	0	39	**0.0%**
	Passes[i]	<2	254	3	31	**1.2%**
		2-3	213	1	26	**0.2%**
		>3	47	1	11	**2.1%**
		Unspecified	160	6	80	**3.6%**
	Tract embol'n	No	381	7	51	**1.8%**
		Yes	100	0	14	**0.0%**
		Unspecified	193	4	83	**2.0%**

i Passes through the liver capsule


Post-procedure major haematoma / haemorrhage
Factors
INR
<=1.3
>1.3
Platelets
<100,001 / dl
100,001-250,000 / dl
>250,000 / dl
Ascites
None
Mild / moderate
Gross
Approach
Left
Right
Bilateral
Passes
<2
2-3
>3
Tract embolis'n
No
Yes
0%
1%
2%
3%
4%
5%
6%
7%
8%
Major haematoma / haemorrhage rate

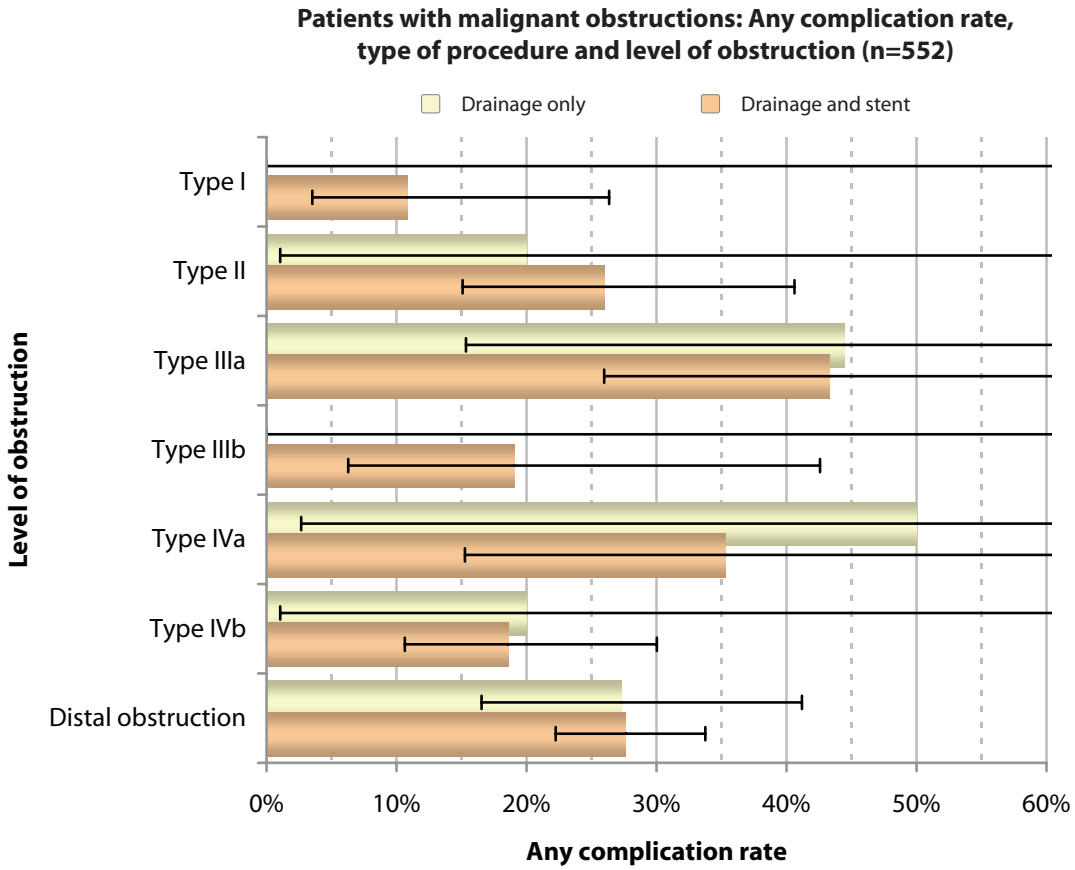
Overall complications

Overall complications and level of obstruction

Complex hilar lesions are the most technically demanding lesions to treat, and may require several punctures as well as a more prolonged procedure time. Although one would have expected this group of patients to have had the highest complication rates, analysis did not demonstrate any clear link between the level of biliary obstruction and outcome (neither overall complications nor any of the individually-specified complications).

Patients undergoing procedures for malignant obstructions: any complications

		Type of procedure and any complications							
		Drainage only				Drainage and stent			
		No	Yes	Unspecified	Rate	No	Yes	Unspecified	Rate
Level of obstruction	Type I	2	0	1	**0.0%**	33	4	10	**10.8%**
	Type II	4	1	3	**20.0%**	37	13	17	**26.0%**
	Type IIIa	5	4	3	**44.4%**	17	13	4	**43.3%**
	Type IIIb	3	0	1	**0.0%**	17	4	1	**19.0%**
	Type IVa	1	1	1	**50.0%**	11	6	3	**35.3%**
	Type IVb	4	1	3	**20.0%**	57	13	14	**18.6%**
	Distal obstruction	40	15	12	**27.3%**	178	68	25	**27.6%**
	Unspecified	3	2	4	**40.0%**	19	3	11	**13.6%**
	All	**62**	**24**	**28**	**27.9%**	**367**	**124**	**85**	**25.2%**


Patients with malignant obstructions: Any complication rate, type of procedure and level of obstruction (n=552)
Drainage only
Drainage and stent
Level of obstruction
Type I
Type II
Type IIIa
Type IIIb
Type IVa
Type IVb
Distal obstruction
0%
10%
20%
30%
40%
50%
60%
Any complication rate

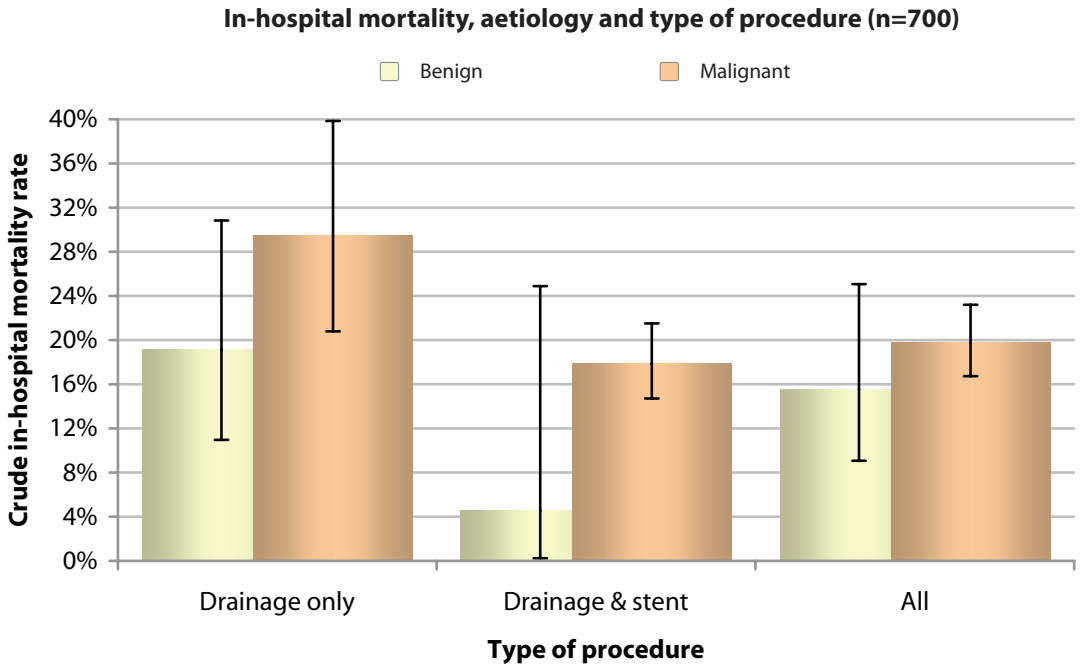
In-hospital mortality

In-hospital mortality and aetiology

The in-patient mortality rate at almost 20% is high for biliary drainage and stenting, particularly when compared to the many other interventional procedures performed by radiologists. Although the mortality was highest in patients with malignancy (19.8%), there was also an unexpectedly high mortality associated with patients who had benign disease (15.6%). As reported major complications for this procedure were around 7.9%, this high mortality cannot be entirely attributable to the procedure. This most likely also reflects the multiple pre-existing comorbities of the patients who present for biliary drainage and stenting. This is key information that will need to be discussed with patients as part of the process of gaining informed consent for these procedures.

In-hospital mortality, aetiology and procedure

			In-hospital mortality			
			Alive	Died	Unspecified	Rate
Aetiology and type of procedure	Benign	Drainage only	55	13	4	**19.1%**
		Drainage and stent	21	1	1	**4.5%**
		Unspecified	0	0	0	**NA**
		All	**76**	**14**	**5**	**15.6%**
	Malignant	Drainage only	67	28	19	**29.5%**
		Drainage and stent	423	92	66	**17.9%**
		Unspecified	1	1	0	**50.0%**
		All	**491**	**121**	**85**	**19.8%**



In-hospital mortality and pre-procedure bilirubin

For patients with malignant disease, there was no significant difference in mortality rates associated with pre-procedure levels of bilirubin within the each of the two main procedure groups. In patients with the highest levels of pre-procedure bilirubin levels (>299 µmol l^{-1}), the mortality rate for the drainage-only group was significantly higher than that seen in the combined drainage & stent group (p=0.027). This almost certainly represents patient selection, with sicker patients undergoing a drainage-only procedure.

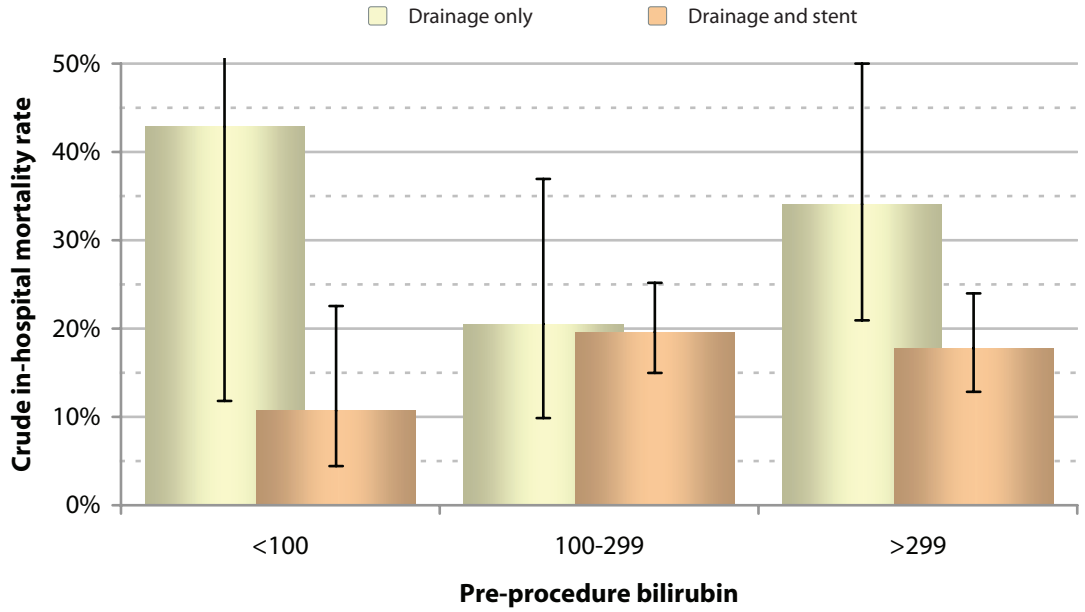
There are 95 entries for benign disease. The mortality rates for drainage-only procedures are15.0% for bilirubin <100 µmol l^{-1} (n=38), 26.3% for levels 100-299 µmol l^{-1} (n=19) and 20.0% for levels >299 µmol l^{-1} (n=10); for combined drainage & stent procedures the rates are 0.0% (n=14), 0.0% (n=3) and 20.0% (n=5) respectively.

There were very few patients with benign disease in the database; not surprisingly, pre-procedure bilirubin levels showed no significant associations with mortality in this group.

Patients undergoing procedures for malignant disease: in-hospital mortality & pre-procedure bilirubin

		Type of procedure and in-hospital mortality							
		Drainage only				Drainage and stent			
		Alive	Died	Unspecified	**Rate**	Alive	Died	Unspecified	**Rate**
Pre-procedure bilirubin	<100 µmol l^{-1}	4	3	1	**42.9%**	50	6	7	**10.7%**
	100-299 µmol l^{-1}	31	8	7	**20.5%**	201	49	24	**19.6%**
	>299 µmol l^{-1}	29	15	9	**34.1%**	162	35	25	**17.8%**
	Unspecified	3	2	2	**40.0%**	10	2	10	**16.7%**
	All	**67**	**28**	**19**	**29.5%**	**423**	**92**	**66**	**17.9%**

Patients with malignant disease: In-hospital mortality, type of procedure and pre-procedure bilirubin levels (n=593)

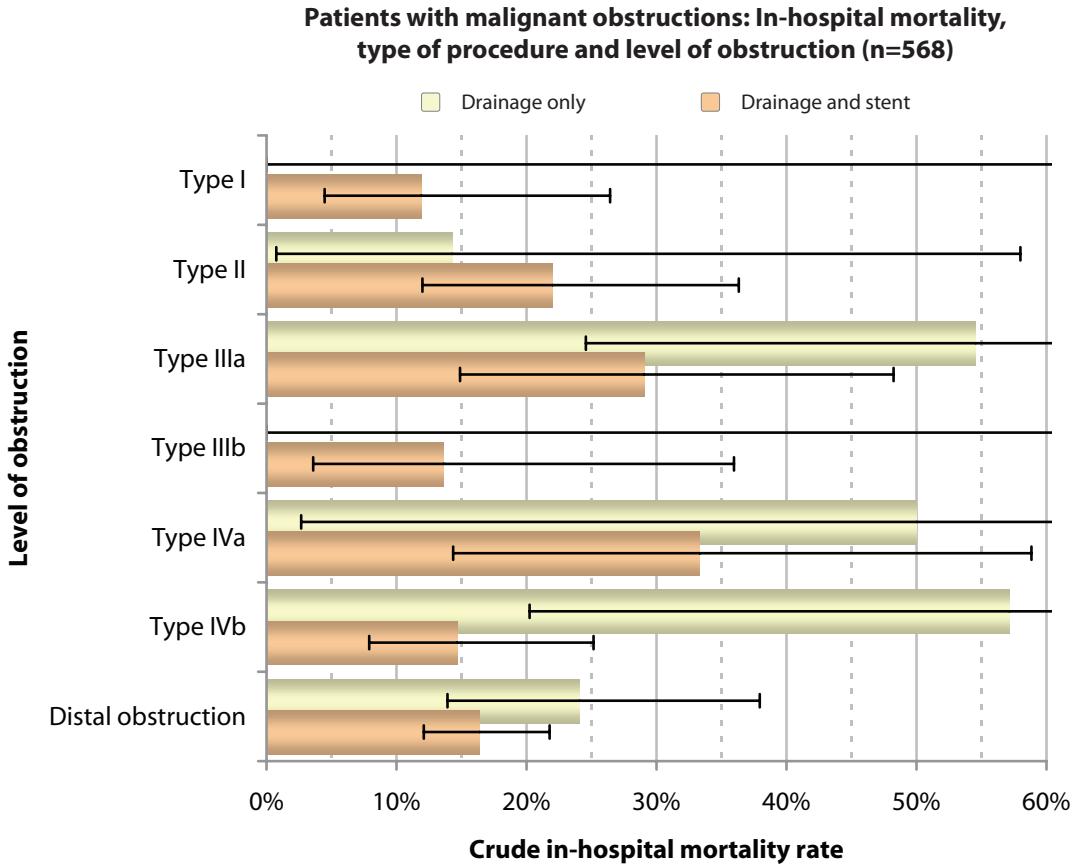


In-hospital mortality and level of obstruction

For patients with both benign and malignant disease, there was no clear association between in-hospital mortality and the level of obstruction. It is re-assuring that in trying to treat the more complex proximal lesions, in-patient mortality of these patients is not significantly increased following drainage. This, taken with clinical improvement obtained by many of these patients following drainage and / or stenting, justifies the attempts to palliate these patients.

Patients undergoing procedures for malignant obstructions: in-hospital mortality and level of obstruction

		Type of procedure and in-hospital mortality							
		Drainage only				Drainage and stent			
		Alive	Died	Unspecified	**Rate**	Alive	Died	Unspecified	**Rate**
Level of obstruction	Type I	2	0	1	**0.0%**	37	5	5	**11.9%**
	Type II	6	1	1	**14.3%**	39	11	17	**22.0%**
	Type IIIa	5	6	1	**54.5%**	22	9	3	**29.0%**
	Type IIIb	3	0	1	**0.0%**	19	3	0	**13.6%**
	Type IVa	1	1	1	**50.0%**	12	6	2	**33.3%**
	Type IVb	3	4	1	**57.1%**	64	11	9	**14.7%**
	Distal obstruction	41	13	13	**24.1%**	204	40	27	**16.4%**
	Unspecified	6	3	0	**33.3%**	25	6	2	**19.4%**
	All	**67**	**28**	**19**	**29.5%**	**422**	**91**	**65**	**17.7%**


Patients with malignant obstructions: In-hospital mortality, type of procedure and level of obstruction (n=568)
Drainage only
Drainage and stent
Level of obstruction
Type I
Type II
Type IIIa
Type IIIb
Type IVa
Type IVb
Distal obstruction
0%
10%
20%
30%
40%
50%
60%
Crude in-hospital mortality rate

In-hospital mortality and pre-procedure INR

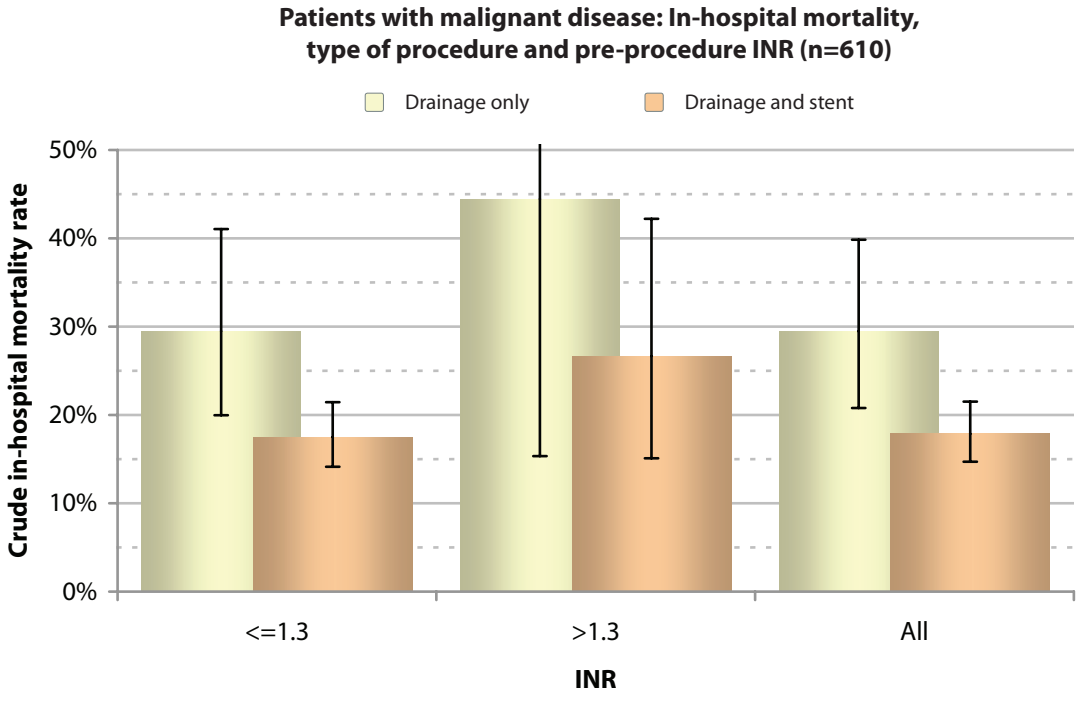
For patients with malignant disease, there was a significant difference in in-hospital mortality rates for drainage *versus* combined drainage & stent procedures for the patients with the lowest pre-procedural INR levels (p=0.021). Similarly, the data for patients with a raised INR also suggest a higher mortality in the drainage-only group, although this difference did not attain significance. This most likely results from patient selection and sicker patients being offered drainage only.

There are 95 entries for benign disease. The mortality rates for drainage-only procedures are 17.0% for INR ≤1.3 (n=53) and 44.4% for levels >1.3 (n=9); for combined drainage & stent procedures the rates are 5.9% (n=17) and 0.0% (n=4) respectively

There was an increased mortality associated with elevated INR levels in both the benign and malignant groups, but the differences were not statistically significant. The elevated INR may reflect not just an increased bleeding tendency, but also represents a marker for greater liver dysfunction and overall poor patient health.

Patients undergoing procedures for malignant disease: in-hospital mortality & pre-procedure INR

		Type of procedure and in-hospital mortality							
		Drainage only				Drainage and stent			
		Alive	Died	Unspecified	Rate	Alive	Died	Unspecified	Rate
Pre-procedure INR	≤1.3	55	23	14	**29.5%**	363	77	50	**17.5%**
	>1.3	5	4	3	**44.4%**	33	12	6	**26.7%**
	Unspecified	7	1	2	**12.5%**	27	3	10	**10.0%**
	All	**67**	**28**	**19**	**29.5%**	**423**	**92**	**66**	**17.9%**



In-hospital mortality and pre-procedure platelet levels

For patients with malignant disease, there was a significant difference in in-hospital mortality rates for drainage *versus* combined drainage & stent procedures for patients with platelet counts in the range 100,000-250,000 dl^{-1} (p=0.021). There were also apparent differences in mortality rates for patients with both higher and lower platelet levels (<100,000dl^{-1} and >250,000 dl^{-1}), but these differences were not statistically significant. It is likely that sicker patients were being selected to have drainage only.

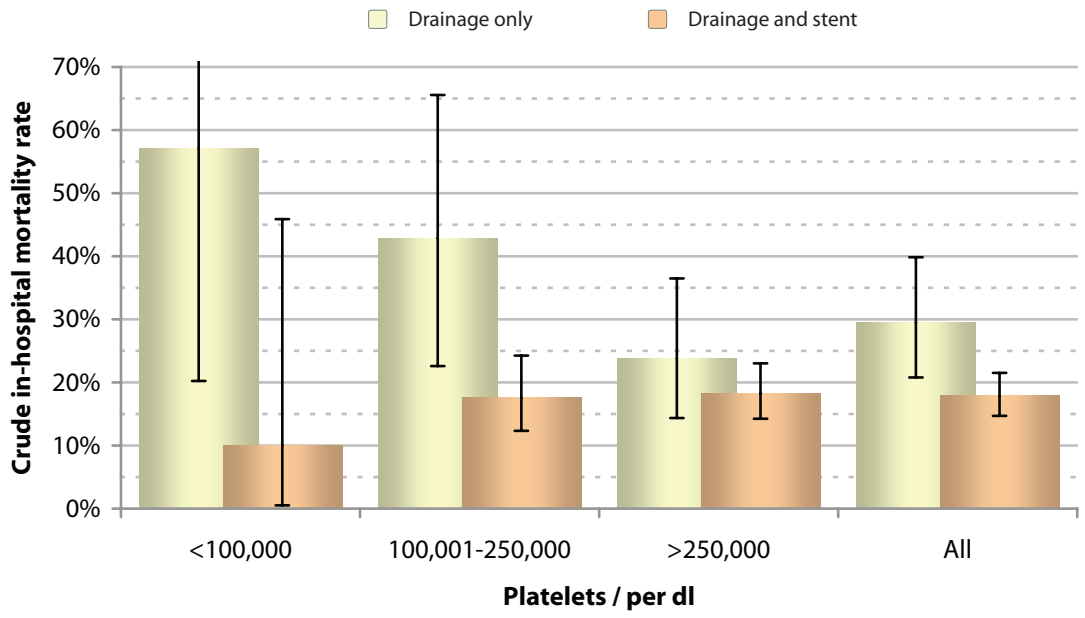
There are 95 entries for benign disease. The mortality rates for drainage-only procedures are 33.3% for platelet level <100,000 dl^{-1} (n=3), 22.6% for levels 100,000-250,000 dl^{-1} (n=31) and 16.1% for levels >250,000 dl^{-1} (n=31); for combined drainage & stent procedures the rates are 0.0% (n=1), 14.3% (n=7) and 0.0% (n=14) respectively.

As with raised INR levels, low platelet levels are a marker of poor patient health, putting them at increased risk of dying in addition to the small increase in risk of minor bleeding demonstrated in this registry

Patients undergoing procedures for malignant disease: in-hospital mortality & pre-procedure platelets

		Type of procedure and in-hospital mortality							
		Drainage only				Drainage and stent			
		Alive	Died	Unspecified	**Rate**	Alive	Died	Unspecified	**Rate**
Pre-procedure platelet level	<100,000 dl^{-1}	3	4	1	**57.1%**	9	1	3	**10.0%**
	100,000-250,000 dl^{-1}	12	9	7	**42.9%**	141	30	17	**17.5%**
	>250,000 dl^{-1}	48	15	9	**23.8%**	260	58	38	**18.2%**
	Unspecified	4	0	2	**0.0%**	13	3	8	**18.8%**
	All	**67**	**28**	**19**	**29.5%**	**423**	**92**	**66**	**17.9%**

Patients with malignant disease: In-hospital mortality, type of procedure and pre-procedure platelet levels (n=610)



In-hospital mortality and pre-procedure renal disease

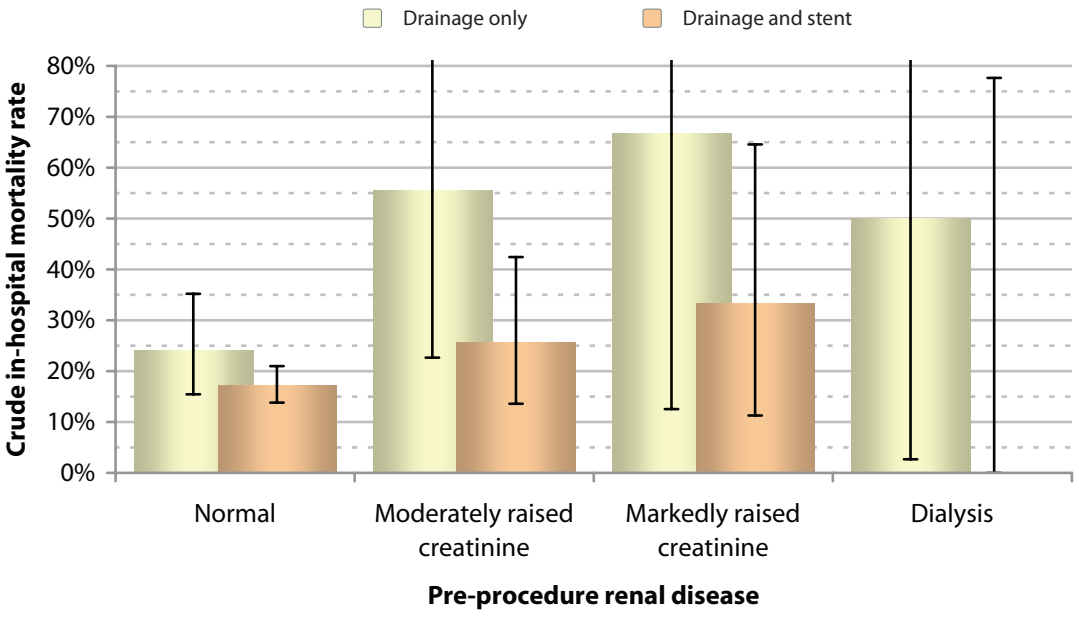
For the group of patients with malignant disease, although there was an association between increased mortality and worsening pre-procedural renal failure this finding was not statistically significant.

There are 95 entries for benign disease; the mortality rates for drainage-only procedures are19.6% for no renal disease (n=51), 9.1% for moderately raised creatinine (n=11) and 40.0% for markedly raised creatinine (n=5); for combined drainage & stent procedures the rates are 0.0% (n=21), 50.0% (n=2) and NA (n=0) respectively. None of the apparent differences in this group attained statistical significance.

Patients undergoing procedures for malignant disease: in-hospital mortality & pre-procedure renal disease

		Type of procedure and in-hospital mortality							
		Drainage only				Drainage and stent			
		Alive	Died	Unspecified	Rate	Alive	Died	Unspecified	Rate
Pre-procedure renal disease	None	60	19	16	**24.1%**	373	77	53	**17.1%**
	Moderately raised creatine	4	5	0	**55.6%**	29	10	6	**25.6%**
	Markedly raised creatine	1	2	0	**66.7%**	8	4	1	**33.3%**
	Dialysis	1	1	0	**50.0%**	2	0	0	**0.0%**
	Unspecified	1	1	3	**50.0%**	11	1	6	**8.3%**
	All	**67**	**28**	**19**	**29.5%**	**423**	**92**	**66**	**17.9%**

Patients with malignant disease: In-hospital mortality, type of procedure and pre-procedure renal disease (n=596)



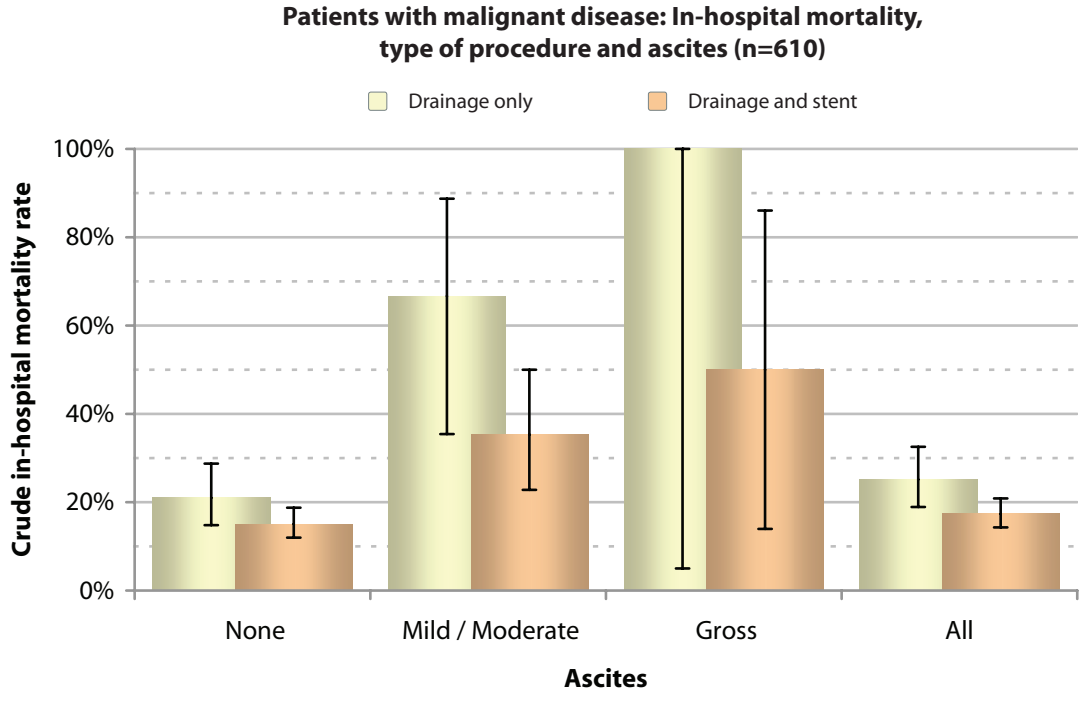
In-hospital mortality and ascites

For patients with malignant disease and mild / moderate ascites pre-procedure, the mortality rate following drainage alone is significantly higher than that following combined drainage & stent (p=0.016). Mortality rates are significantly higher for patients with malignant disease and mild / moderate acsites *versus* patients with malignant disease and no ascites in both the drainage-only group (p=0.002) and the combined drainage & stent group (p<0.001).

The overall higher mortality for patients with ascites for both the benign and malignant groups almost certainly reflects the poor state of the patients' overall health at the time they have their biliary interventional procedure. The presence of ascites is also likely to increase the risk of bleeding in these patients (the bleeding risk only translated to a significant increase in the risk of minor bleeding according to the data in this registry). The higher mortality in the drainage-only group as a whole most likely reflects selection of patients who were either too ill or died before a stent could be placed.

Patients undergoing procedures for malignant disease: in-hospital mortality & ascites

		Type of procedure and in-hospital mortality							
		Drainage only				Drainage and stent			
		Alive	Died	Unspecified	**Rate**	Alive	Died	Unspecified	**Rate**
Ascites	None	62	18	16	**22.5%**	365	67	57	**15.5%**
	Mild / moderate	1	6	0	**85.7%**	33	18	5	**35.3%**
	Gross	0	1	0	**100.0%**	3	3	1	**50.0%**
	Unspecified	4	3	3	**42.9%**	22	4	3	**15.4%**
	All	**67**	**28**	**19**	**29.5%**	**423**	**92**	**66**	**17.9%**



In-hospital mortality and pre-procedure sepsis

For patients with malignant disease and no pre-procedural sepsis, there is a significant difference in the mortality rate following drainage alone *versus* combined drainage & stenting (p=0.032).

There are 95 entries for benign disease. The mortality rates for drainage-only procedures are 10.3% for patients with no sepsis (n=39) and 32.0% for patients with pre-procedure sepsis (n=25); for combined drainage & stent procedures the rates are 0.0% (n=15) and 14.3% (n=7) respectively. As with many of the other parameters, this would be consistent with selection of sicker patients for drainage-only procedures. These findings were not statistically significant.

Patients undergoing procedures for malignant disease: in-hospital mortality & pre-procedure sepsis

		Type of procedure and in-hospital mortality							
		Drainage only				Drainage and stent			
		Alive	Died	Unspecified	Rate	Alive	Died	Unspecified	Rate
Sepsis	No	50	21	15	**29.6%**	354	77	57	**17.9%**
	Yes	13	4	1	**23.5%**	49	11	6	**18.3%**
	Unspecified	4	3	3	**42.9%**	20	4	3	**16.7%**
	All	**67**	**28**	**19**	**29.5%**	**423**	**92**	**66**	**17.9%**

In-hospital mortality and approach

For patients with both malignant disease and benign disease there are no significant differences in in-hospital mortality rates according to the approach used.

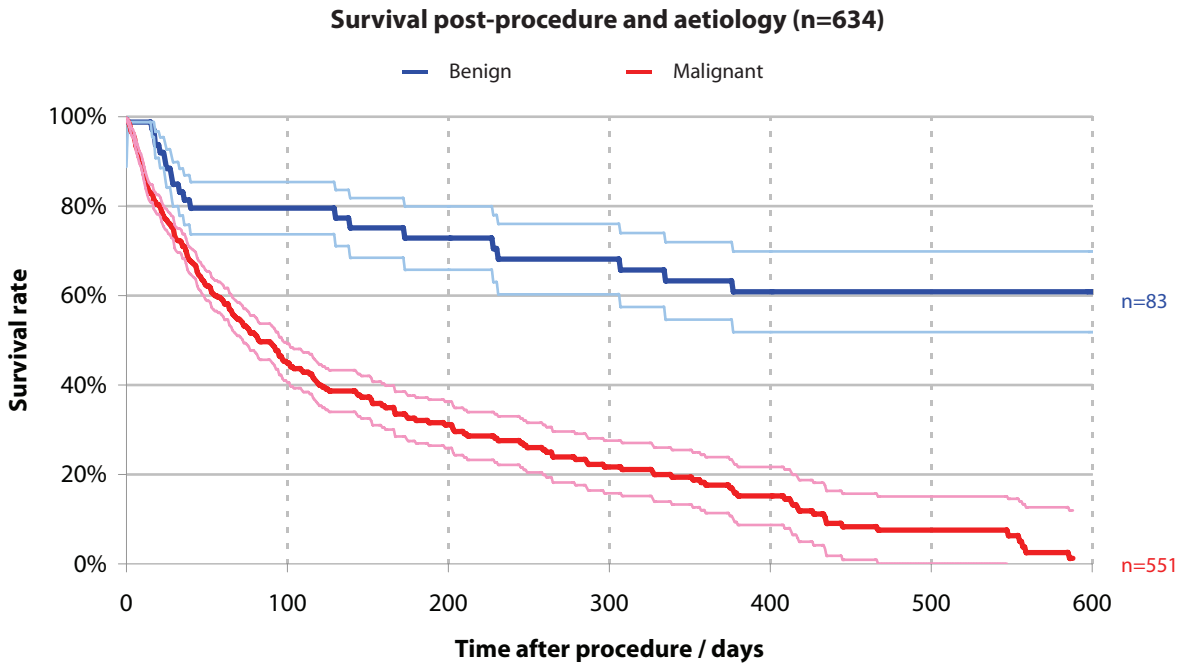
There are 95 entries for benign disease. The mortality rates for drainage only procedures are 22.2% for left-sided (n=9) and 19.0% for right-sided (n=58); for combined drainage & stent procedures the rates are 0.0% (n=2) and 5.0% (n=20) respectively.

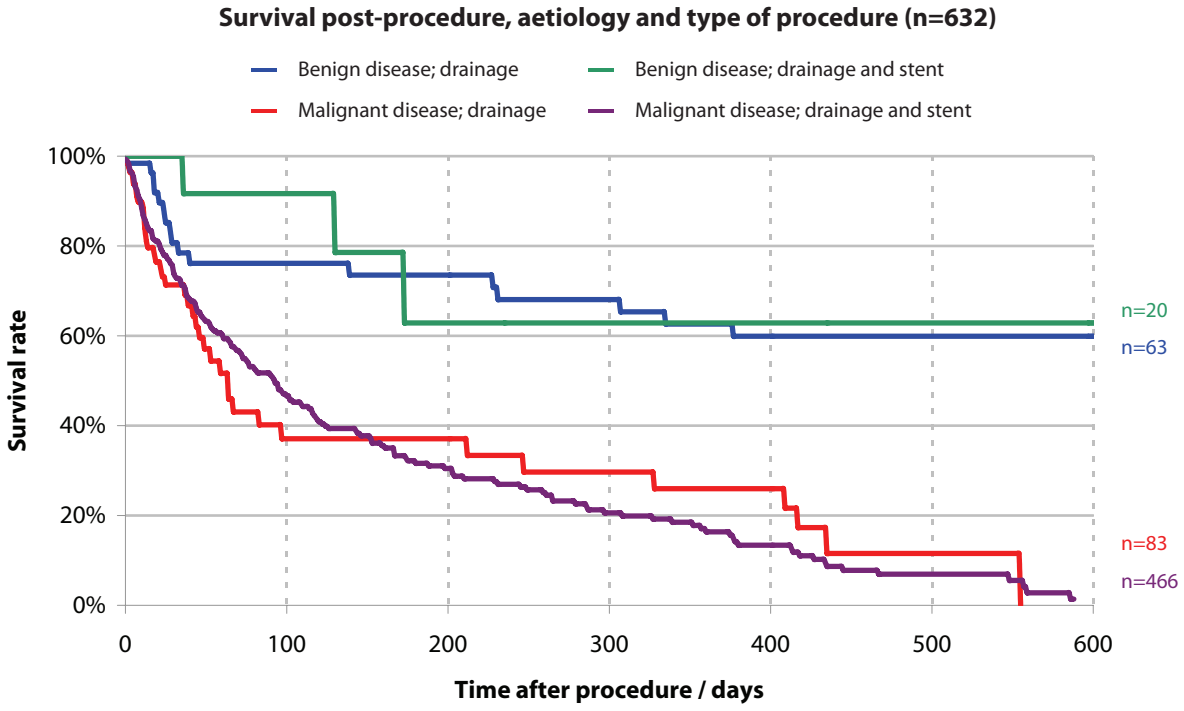
Patients undergoing procedures for malignant disease: in-hospital mortality & approach

		Type of procedure and in-hospital mortality							
		Drainage only				Drainage and stent			
		Alive	Died	Unspecified	Rate	Alive	Died	Unspecified	Rate
Approach	Left	11	5	1	**31.3%**	44	13	3	**2.8%**
	Right	54	20	15	**27.0%**	333	66	51	**16.5%**
	Bilateral	2	3	2	**60.0%**	40	13	7	**24.5%**
	Unspecified	0	0	1	**NA**	6	0	5	**0.0%**
	All	**67**	**28**	**19**	**29.5%**	**423**	**92**	**66**	**17.9%**

Long-term outcomes

The numbers of patients with long-term follow up data are relatively small, and the analyses based upon these data need to be treated with some caution. Those patients with follow up data recorded are almost certainly a highly-selected group undergoing regular follow up, *i.e.*, patients with benign disease, or patients re-presenting with complications. This does show, however, that the survival rate for patients with malignant disease at 1 year is low at <20%. However, within the group of patients with benign disease survival at one year is also very low at <60%, irrespective of whether the patient underwent drainage alone or combined drainage & stent. As might be expected, there is a steady decline in survival for the malignant group with 0% survival at 600 days.





Conclusions and Glasgow Biliary Audit

Conclusions and Glasgow Biliary Audit

Commentary and recommendations

Commentary

The collection of over 800 patient-records within this registry demonstrates the commitment of the British Society of Interventional Radiology and its members to improving the quality of data available on interventional procedures. Voluntary registries are, however, subject to varying degrees of incomplete data capture, and throughout this report there are references to incomplete data entry. Such shortfalls in the data collection process hamper accurate data-interpretation and statistical analysis, and can radically affect the results of analyses designed to compare performance between either individuals or hospitals. In part, this is a reflection of the limited resources available to most of the specialist operators to support participating in these kinds of voluntary audits. It is imperative for all hospital units to do all they can to facilitate participation in these invaluable registries. In practical terms sufficient time and resources should be made available to operators to collect and enter data on all the patients that they treat.

Although there are suggestions of significant associations between certain risk factors and both complications and mortality, only a few reach statistical significance. Some of these results will become clearer as more and more data are accumulated in the registry. Indeed, the shape of some of the analyses might change as the currently missing data are chased up and completed. Creating a data dictionary to drive increased understanding of the terminology used in the registry and strongly encouraging members to complete their data should both work in concert to drive improvements in data quality.

Recommendations

- Further audit of this cohort is required to determine the timing of death, the cause of death and also to determine whether nor not there are any risk factors significantly associated with this outcome.
- It is important to sustain the work that is currently underway to begin risk modelling for this patient group.
- Given the high mortality in this cohort of patients, further data collection will be required. Significant improvements in data completeness are also required.
- Data submission remains voluntary, but NHS services should consider how they could make appropriate resources available to support data collection by individual operators.
- Re-design of the parts of the dataset would help to reduce any potential ambiguity in the questions and therefore help to improve data quality.
- Developing a data dictionary would make the terminology clear for all the operators who are entering data into the registry.
- There should be ongoing effort to establish the Biliary Drainage and Stenting Registry as the second BSIR index procedure.

Glasgow BIliary Audit

Voluntary registries must contend with concerns regarding data completeness and the potential for data submission that may represent only a small selection of members practice. Ideally central data linkage would enable key outcomes to be validated, both in terms of total numbers of procedures and accuracy. Unfortunately, this is not available at the present time. An alternative approach would be to audit a collection of units to compare key outcomes within the registry with complete capture of activity for these units.

The Glasgow Interventional Radiology Unit has undertaken an audit of activity over the period of this current registry report. These data come from 5 hospitals; 3 of which submitted data to the registry.

Number of patients; data covering the period 1st November 2006 to 19th August 2009

		Local data	BDSR data	Completion rate in the BDSR
Hospital	Glasgow General Hospital	56	29	**51.8%**
	Glasgow Royal Infirmay	70	3	**4.3%**
	Victoria Hospital, Glasgow	39	5	**12.8%**
	Southern Hospital , Glasgow	38	0	**0.0%**
	Stobhill Hospital, Glasgow	32	0	**0.0%**
	All	**235**	**37**	**15.7%**

30-day mortality; data covering the period 1st November 2006 to 19th August 2009

		Local data		Registry data	
		Number of patients	30-day mortality	Number of patients	30-day mortality
Hospital	Glasgow General Hospital	56	20 (35.7%)	29	6 (20.7%)
	Glasgow Royal Infirmay	70	18 (25.7%)	3	0 (0.0%)
	Victoria Hospital, Glasgow	39	11 (28.2%)	5	1 (20.0%)
	Southern Hospital , Glasgow	38	10 (26.3%)	0	0
	Stobhill Hospital, Glasgow	32	10 (31.3%)	0	0
	All	**235**	**69 (29.4%)**	**37**	**7 (19.0%)**

Complete data for a total of 37 patients were entered into the Biliary Drainage & Stent Registry (total of 38 patients, but one set of data was incomplete). 30-day mortality in these registry patients was 7 of 37 (18.9%).

However, by analysing the Radiology Information System throughout Glasgow, a total of 235 patients in Glasgow had a biliary drainage or stenting procedure in the same time-period (one set of data incomplete, therefore complete data for 235 patients). Mortality data for this entire patient-group was validated *via* the Community Health Index system. In the total number of patients, 30-day mortality rate was 29.4% (69 of 235 patients).

In summary, only 15.7% (37 of 235) of Glasgow patients were entered into the registry. 30-day mortality amongst the patients entered into the registry was 19.0%, contrasting with an actual 30-day mortality of 29.4% for all patients treated in Glasgow. There were no apparent differences in mortality rates between hospitals that were submitting to the registry and those that were not.

The BSIR are grateful to Ms Moira Ritchie, Dr Chris Hay and Prof. Jon Moss for submitting the data for this audit.

Appendices

Appendices

Database form

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Biliary drainage & Stent Registry
Page 1; Version 1.1

Demographics and other identifiers

Automatically-generated identifier		
Date of birth	dd / mm / yyyy	
Gender	○ Male	○ Female

Initial registry data

Basic procedure data

Date of percutaneous access	dd / mm / yyyy	
Is this a re-intervention	○ No	○ Yes
Type of procedure	○ Drainage only	○ Drainage **and** stent

Patient factors at initial draining

Bilirubin	µmol l^{-1}	
INR	absolute value	
Platelet count	○ <50 × 10^9 l^{-1} ○ 50-100 × 10^9 l^{-1}	○ 101-250 × 10^9 l^{-1} ○ >250 × 10^9 l^{-1}
Platelets given	○ No	○ Yes
Vitamin K	○ No	○ Yes
FFP given	○ No	○ Yes
Renal function	○ Normal ○ Moderately raised creatinine [i] ○ Markedly raised creatinine [ii]	○ Acute renal failure - dialysis ○ Chronic renal failure - dialysis
Acsites	○ None ○ Mild / moderate	○ Gross
Ascitic drain inserted	○ No	○ Yes
Sepsis	○ No	○ Yes
Biliary dilatation	○ None ○ Mild / moderate	○ Gross

Pre-procedure imaging

Ultrasound	○ No	○ Yes
CT	○ No	○ Yes
MRI / MRCP	○ No	○ Yes
ERCP	○ No	○ Yes

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i Creatinine 120-200 µmol l^{-1}
ii Creatinine >200 µmol l^{-1}; no treatment

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Biliary drainage & Stent Registry
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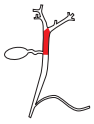
Automatically-generated identifier	
Date of percutaneous access	dd / mm / yyyy

Indication for intervention

Reason for intervention	○ Obstruction	○ Leak
Cause of obstruction	○ Presumed malignant ○ Known malignant	○ Presumed benign ○ Known benign
Benign	☐ Calculi ☐ Stricture ☐ Pancreatitis	☐ Unknown ☐ Other
Details of other benign		
Stricture	○ Anastomotic ○ Calculi ○ Ischaemic ○ Post infection (incl. Helminthic)	○ Post duct injury ○ Post pancreatitis ○ Sclerosing cholangitis
Bile leak	○ Iatrogenic	○ Traumatic
Malignant	○ Pancreatic carcinoma ○ Ampullary/duodenal carcinoma ○ Cholangiocarcinoma ○ GB carcinoma	○ Metastases (compression) ○ Hepatocellular cancer ○ Recurrent tumour ○ Unknown primary

Level of obstruction (Bismuth classification)

	○ Type I		○ Type IVa
	○ Type II		○ Type IVb
	○ Type IIIa		○ Pancreatic tumour
	○ Type IIIb		

Reason for PTBD / stenting	○ ERCP failed ○ ERCP not available ○ ERCP contraindicated	○ Hilar lesion ○ Previously failed drain ○ Previous surgery

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Biliary drainage & Stent Registry
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Automatically-generated identifier

Date of percutaneous access: dd / mm / yyyy

Procedure

Primary operator
- ○ Consultant
- ○ Fellow
- ○ SpR

Calman year of SpR
- ○ Year 1
- ○ Year 2
- ○ Year 3
- ○ Year 4
- ○ Year 5

Number of biliary procedures you have performed in the last 12 months
- ○ 0
- ○ 1-5
- ○ 6-10
- ○ 11-20
- ○ >20

Sedation / general anaesthesia
- ○ None
- ○ Conscious sedation
- ○ General anaesthesia

Local / regional analgesia
- ☐ Antibiotics pre-procedure
- ☐ Antibiotics post-procedure

Monitoring

Patient observer
- ○ Operator
- ○ Anaesthetist
- ○ Nurse (endoscopy / radiology)
- ○ Ward nurse
- ○ Trainee
- ○ Radiographer / helper
- ○ Other

Monitoring equipment
- ○ None
- ☐ pulse oximetry
- ☐ 3-lead ECG
- ☐ Blood pressure
- ☐ EEG (BIS)
- ☐ CO_2

Supplemental oxygen
- ○ No
- ○ Yes

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Biliary drainage & Stent Registry
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Automatically-generated identifier

Date of percutaneous access: dd / mm / yyyy

Procedure

Approach
- ○ Left
- ○ Right
- ○ Bilateral

imaging during procedure
- ☐ Fluoroscopy
- ☐ Ultrasound
- ☐ CT
- ☐ MRI

Passes through the liver capsule: number

Gauge of largest needle
- ○ 14 G
- ○ 15 G
- ○ 16 G
- ○ 17 G
- ○ 18 G
- ○ 19 G
- ○ 20 G
- ○ 21 G
- ○ 22 G

	Left	Right
Drainage catheter	○ Proximal external drain ○ Internal / external drain	○ Proximal external drain ○ Internal / external drain
Self locking	○ No ○ Yes	○ No ○ Yes
Drain size	○ 4 Fr ○ 5 Fr ○ 6 Fr ○ 6.5 Fr ○ 7 Fr ○ 8 Fr ○ 8.3 Fr ○ 8.5 Fr ○ 9 Fr ○ 10 Fr ○ 11 Fr ○ 12 Fr ○ 14 Fr ○ 16 Fr	○ 4 Fr ○ 5 Fr ○ 6 Fr ○ 6.5 Fr ○ 7 Fr ○ 8 Fr ○ 8.3 Fr ○ 8.5 Fr ○ 9 Fr ○ 10 Fr ○ 11 Fr ○ 12 Fr ○ 14 Fr ○ 16 Fr
Successful drainage	○ No	○ Yes

Drain outcome

Drain outcome
- ○ Access for subsequent internalisation
- ○ Displaced prior to internalisation
- ○ Intentionally removed

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Biliary drainage & Stent Registry
Page 5; Version 1.1

Automatically-generated identifier	
Date of percutaneous access	dd / mm / yyyy

First stent insertion details

Date of first stent insertion	dd / mm / yyyy
Biliary stenting procedure	○ Primary ○ Combined ○ Staged ○ Repeat for blocked stent
imaging during procedure	☐ Fluoroscopy ☐ Ultrasound ☐ CT ☐ MRI
If blocked stent, how previously placed	○ Percutaneously ○ Endoscopically
Stent	○ Plastic ○ Metal
Stent size (plastic stent)	○ 7 Fr ○ 9 Fr ○ 11 Fr ○ 8 Fr ○ 10 Fr ○ 12 Fr
Stent size (metal stent)	mm
Stent type	○ Covered ○ Uncovered
Balloon expandable stent	○ No ○ Yes
Immediate stent expansion	○ <26% ○ 26-50% ○ 51-75% ○ >75%
Name of balloon expandable stent	○ Megalink ○ Herculink ○ Omnilink
Name of self-expanding stent	○ Absolute ○ Dynalink ○ Ella SX ○ Gore Viabil ○ Life Stent XL SDS ○ Luminex ○ Niti-S ○ Niti-S Y ○ Niti-S T ○ Niti-S PTFE covered ○ Percept ○ Precise ○ Protege ○ Smart ○ Wallstent ○ Zilver ○ Other
Balloon dilatation pre-stent	○ No ○ Yes
Balloon dilatation post-stent	○ No ○ Yes
Cutting balloon	○ No ○ Yes
Stent configuration	○ Unilateral ○ Bilateral ○ Kissing
If bilateral configuration	○ T ○ T coaxial ○ Y
Successful stant placement	○ No ○ Yes
Stent traverses sphincter of Oddi	○ No ○ Yes
Track embolisation	○ No ○ Yes

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Biliary drainage & Stent Registry
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Automatically-generated identifier	
Date of percutaneous access	dd / mm / yyyy

Second stent insertion details

Date of second stent insertion	dd / mm / yyyy
Biliary stenting procedure	○ Primary ○ Combined ○ Staged ○ Repeat for blocked stent
imaging during procedure	☐ Fluoroscopy ☐ Ultrasound ☐ CT ☐ MRI
If blocked stent, how previously placed	○ Percutaneously ○ Endoscopically
Stent	○ Plastic ○ Metal
Stent size (plastic stent)	○ 7 Fr ○ 9 Fr ○ 11 Fr ○ 8 Fr ○ 10 Fr ○ 12 Fr
Stent size (metal stent)	mm
Stent type	○ Covered ○ Uncovered
Balloon expandable stent	○ No ○ Yes
Immediate stent expansion	○ <26% ○ 26-50% ○ 51-75% ○ >75%
Name of balloon expandable stent	○ Megalink ○ Herculink ○ Omnilink
Name of self-expanding stent	○ Absolute ○ Dynalink ○ Ella SX ○ Gore Viabil ○ Life Stent XL SDS ○ Luminex ○ Niti-S ○ Niti-S Y ○ Niti-S T ○ Niti-S PTFE covered ○ Percept ○ Precise ○ Protege ○ Smart ○ Wallstent ○ Zilver ○ Other
Balloon dilatation pre-stent	○ No ○ Yes
Balloon dilatation post-stent	○ No ○ Yes
Cutting balloon	○ No ○ Yes
Stent configuration	○ Unilateral ○ Bilateral ○ Kissing
If bilateral configuration	○ T ○ T coaxial ○ Y
Successful stant placement	○ No ○ Yes
Stent traverses sphincter of Oddi	○ No ○ Yes
Track embolisation	○ No ○ Yes

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Biliary drainage & Stent Registry
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Automatically-generated identifier	
Date of percutaneous access	dd / mm / yyyy

Third stent insertion details

Date of third stent insertion	dd / mm / yyyy
Biliary stenting procedure	○ Primary ○ Combined ○ Staged ○ Repeat for blocked stent
Imaging during procedure	☐ Fluoroscopy ☐ Ultrasound ☐ CT ☐ MRI
If blocked stent, how previously placed	○ Percutaneously ○ Endoscopically
Stent	○ Plastic ○ Metal
Stent size (plastic stent)	○ 7 Fr ○ 9 Fr ○ 11 Fr ○ 8 Fr ○ 10 Fr ○ 12 Fr
Stent size (metal stent)	mm
Stent type	○ Covered ○ Uncovered
Balloon expandable stent	○ No ○ Yes
Immediate stent expansion	○ <26% ○ 26-50% ○ 51-75% ○ >75%
Name of balloon expandable stent	○ Megalink ○ Herculink ○ Omnilink
Name of self-expanding stent	○ Absolute ○ Dynalink ○ Ella SX ○ Gore Viabil ○ Life Stent XL SDS ○ Luminex ○ Niti-S ○ Niti-S Y ○ Niti-S T ○ Niti-S PTFE covered ○ Percept ○ Precise ○ Protege ○ Smart ○ Wallstent ○ Zilver ○ Other
Balloon dilatation pre-stent	○ No ○ Yes
Balloon dilatation post-stent	○ No ○ Yes
Cutting balloon	○ No ○ Yes
Stent configuration	○ Unilateral ○ Bilateral ○ Kissing
If bilateral configuration	○ T ○ T coaxial ○ Y
Successful stant placement	○ No ○ Yes
Stent traverses sphincter of Oddi	○ No ○ Yes
Track embolisation	○ No ○ Yes

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Biliary drainage & Stent Registry
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Automatically-generated identifier	
Date of percutaneous access	dd / mm / yyyy

Overall complications and outcomes at discharge

Minor specific complications	○ None	
	☐ Sepsis	☐ Pancreatitis
	☐ Haemorrhage / haematoma	☐ Pneumothorax
	☐ Abscess	☐ Pleural fistula
	☐ Peritonitis	☐ Renal failure
	☐ Cholecystitis	☐ Pain
Major specific complications	○ None	
	☐ Sepsis	☐ Pancreatitis
	☐ Haemorrhage / haematoma	☐ Pneumothorax
	☐ Abscess	☐ Pleural fistula
	☐ Peritonitis	☐ Renal failure
	☐ Cholecystitis	☐ Pain
Relief of symptoms	○ No change	
	○ Partial	○ Complete
Bilirubin	µmol l^{-1}	
Patient status	○ Alive	○ Dead
Date of discharge / date of death	dd / mm / yyyy	

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Biliary drainage & Stent Registry
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Automatically-generated identifier		
Date of follow up		dd / mm / yyyy

Indication for intervention

Status of stent	○ Functioning	○ Occluded
Bilirubin at follow up	µmol l^{-1}	
Planned surgery of chemotherapy made possible	○ No ○ Yes	○ Not applicable
Adjuvant therapy	○ No	○ Yes
Relief of symptoms	○ No change ○ Partial	○ Complete
Re-intervention within 3 months	○ No	○ Yes
Minor specific complications	○ None ☐ Sepsis ☐ Haemorrhage / haematoma ☐ Abscess ☐ Peritonitis	☐ Cholecystitis ☐ Pancreatitis ☐ Pneumothorax ☐ Pleural fistula ☐ Renal failure
Major specific complications	○ None ☐ Sepsis ☐ Haemorrhage / haematoma ☐ Abscess ☐ Peritonitis	☐ Cholecystitis ☐ Pancreatitis ☐ Pneumothorax ☐ Pleural fistula ☐ Renal failure
Patient status	○ Alive	○ Dead

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Notes

Notes

Notes

Notes

Information on biliary drainage and stenting procedures

Percutaneous biliary drainage and stenting is carried out to relieve the symptoms of obstructions of the bile ducts in the liver, which are most often caused by either cancer, benign strictures or stones. This procedure has become a widely-accepted method for the non-operative relief of biliary obstruction. It is usually performed where endoscopic techniques have failed or are not available or are contra-indicated. Percutaneous treatment is usually performed under conscious sedation using specialised equipment with fluoroscopic and ultrasound guidance, performed by interventional radiologists within the Radiology Department.

This is the first report on this registry produced by the British Society of Interventional Radiology, which should help us understand how well these procedures are being performed in the United Kingdom. In particular:

- To what extent does the procedure improve patients' symptoms.
- How commonly do patients experience complications.
- Is there anything that could be learnt from the data to help improve practice.

This report is primarily for radiologists, but should be of interest to other professionals dealing with patients with hepato-biliary disease, such as gastroenterologist, oncologists and hepato-biliary surgeons.

The report will provide important information to all specialists on the role of percutatenous biliary intervention in the management these difficult patients. Although this is the first attempt at an analysis of the data on this procedure, ultimately it will provide a useful benchmark for individual operators and centres against which to gauge their performance, and will form an important part of revalidation in the future. The BSIR hopes that operators can learn from this report and disseminate areas of best practice to raise standards of patient treatment and care.

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