
ORIGINAL ARTICLE

Morbidity and Mortality of Invasive Procedures Performed at Caritas Medical Centre

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ABSTRACT

Objective: Since more invasive procedures are being performed in radiology departments, this study was performed to ascertain the mortality and morbidity rate of these procedures as part of continuous quality improvement.

Patients and Methods: Five procedure categories of biopsy (lung, liver, and prostate), percutaneous transhepatic biliary drainage, percutaneous drainage of liver abscess, percutaneous nephrostomy, and diagnostic angiography were selected. Complications were immediately documented on post-procedure forms. The wards of all patients were contacted about any complications after 24 hours.

Results: One death from percutaneous liver biopsy (0.46%) and 1 from percutaneous transhepatic biliary drainage (0.7%) were documented. The mortality rate for percutaneous liver biopsy was greater than that in the reported series, due to the relatively small sample size and patients risk factors in this study. The rate for percutaneous transhepatic biliary drainage was at the lower end of the reference range. Nearly all morbidity rates were within the reference ranges.

Conclusion: The mortality and morbidity rates for invasive procedures are acceptable, but there is room for improvement. These data are useful for monitoring the quality of the services by providing local data.

Key Words: Invasive procedures, Morbidity, Mortality

INTRODUCTION

Clinical audit is now an important part of all hospital management to ensure the quality of services provided. With increasing numbers and aggressiveness of invasive procedures being performed in radiology departments, clinical audit forms have become an important part of quality control and risk management. This study was performed to ascertain the mortality and morbidity rate of invasive procedures performed in the Department of Radiology as part of continuous quality improvement.

PATIENTS AND METHODS

The data were prospectively collected between May 1999 and July 2002. During this period, 3306 invasive procedures were performed in the Department of Radiology. Five categories of procedures, which included

biopsies (lung, liver, and prostate), percutaneous transhepatic biliary drainage, percutaneous drainage of liver abscess, percutaneous nephrostomy, and diagnostic angiography, were selected. The procedures were performed as follows.

Lung Biopsy

All lung biopsies were performed using computed tomography (CT) guidance. The authors routinely performed fine needle aspirations using either spinal needles (22 G, Spinocan, Laboratorios B Braun, Spain) or Chiba biopsy needles (22 G, Cook Incorporated, Bloomington, USA). Additional passes or tru-cut biopsies using Temno needles (18 G or 20 G, McGaw Park, Dominican Republic) were performed under the advice of the attending pathologist. Selective sections over the site of the biopsies at the end of the procedure and erect chest radiographs 2 to 4 hours post-procedure were performed for all patients.

Liver Biopsy

The majority of liver biopsies was performed using ultrasound (US) guidance. Fine needle aspirations

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using either spinal or Chiba biopsy needles were routinely performed as for the lung biopsies. Additional passes or tru-cut biopsies using Temno needles were performed under the advice of the attending pathologist.

Transrectal Prostate Biopsy

All patients received a single dose of dulcolax the night before the procedure and prophylactic antibiotics were prescribed. In 1999, all biopsies were performed using 20 G tru-cut Temno needles. From January 2000, 18 G tru-cut Temno needles were routinely used. A minimum of 6 passes per patient were made. All patients were admitted to hospital for 1 night after the procedures for observation.

Percutaneous Transhepatic Biliary Drainage

Right percutaneous transhepatic biliary drainage (PTBD) was performed using fluoroscopy or US guidance. Left PTBD was performed using US guidance. All patients received prophylactic antibiotics. An 8.4 F pigtail catheter was routinely chosen for drainage.

Percutaneous Drainage of Liver Abscess

All procedures were performed using US or CT guidance. All patients received antibiotic treatment before the procedures. Small collections were initially punctured with Chiba needles, while larger and more superficial lesions were punctured using a Uni-dwell needle set (5 F, Angiomed GmbH & Co. Medizintechnik KG, Karlsruhe, Germany). An 8.4 F pigtail catheter or larger calibre drainage catheter was inserted via a guidewire.

Percutaneous Nephrostomy

All procedures were performed using US guidance with the single puncture technique or fluoroscopic guidance with the double puncture technique. An 8.4 F pigtail catheter was routinely inserted via a guidewire.

Diagnostic Angiography

All procedures were performed via right groin puncture, left groin puncture, or brachial arterial puncture. These 2314 procedures represented 70% of the total number

of invasive procedures. All complications during the procedures were recorded on post-procedure records. The wards of all patients were contacted the following day to record any delayed complications. The case records of all patients with complications were summarised at the end of each month. The cases were presented and discussed at bimonthly audit meetings. The morbidity and mortality associated with these procedures were compiled and compared with those of the published literature. The book *Complications in diagnostic imaging and interventional radiology*¹ was the main reference textbook used to give an international standard.¹

RESULTS

Lung Biopsy

The results for lung biopsy are shown in Table 1, along with the references used for comparison.¹⁻¹¹ 100 CT-guided lung biopsies were performed. Twenty nine percent of patients had CT detectable pneumothorax and 4% had chest tube insertion. The second commonest complication was pulmonary haemorrhage, which was self-limiting.

Liver Biopsy

The results for liver biopsy are shown in Table 2, along with the figures given in the reference text¹ and results from published articles.¹²⁻¹⁴ 218 biopsies were performed. The majority of the procedures were done using US guidance. One death resulting from major haemorrhage was documented. The patient was known to have B cell chronic lymphocytic leukaemia with a pre-procedure international normalised ratio (INR) of 0.99 (normal range, 0.75-1.3), prothrombin time 11.4 seconds (normal range, 11-15 seconds), partial thromboplastin time 25.3 seconds (normal range, 24-37 seconds), and platelet count $67 \times 10^9/L$ (normal range, $150-450 \times 10^9/L$). Three hepatic nodules were found on US and CT imaging. Although the nodules were reported as haemangiomas, differences in opinion were expressed and the possibility of hepatocellular carcinoma was raised, which led to the decision to perform the biopsy. One pass using a 22 G spinal

Table 1. Mortality and morbidity associated with percutaneous lung biopsy.

Complications	Reference incidence ¹ (%)	Caritas Medical Centre incidence (%) [n = 100]	Other (%)
Pneumothorax	10.0-40.0	29.0	
Pulmonary haemorrhage	5.0-15.0	7.0	
Haemothorax, mediastinal emphysema	<1.0	0	
Others	<0.1	0	
Pneumothorax and chest tube insertion		4.0	12.5-20.0 ²⁻⁹
Death due to pulmonary haemorrhage, tension pneumothorax, air embolism, cardiac arrest		0	<0.1 ^{2,7,8,10,11}

Table 2. Mortality and morbidity associated with percutaneous liver biopsy.

Complications	Reference incidence ¹ (%)	Grant and Neuberger ¹² (%)	Gilmore et al ¹³ (%) [n =1500]	McGill et al ¹⁴ (%) [n = 9212]	Caritas Medical Centre incidence (%) [n = 218]
Major haemorrhage	2.8*	0.35-0.5	1.7	0.35	0.46
Hypotension and vasovagal attack		3	0	0	0
Haemobilia		0.05	0	0	0
Severe pain		1.5	0	0	0
Puncture of other viscera (lung, colon, kidney, gallbladder)		0.01-0.1	0	0	0
Death from haemorrhage	0.006-0.031 [†]		0.13-0.33	0.11	0.46

* In high risk patients.

[†] From 2 large surveys on fine needle aspiration of the liver, kidneys, and pancreas.

needle and 1 tru-cut biopsy using a 20 G Temno needle were performed. The patient became hypotensive a few hours after the procedure and collapsed approximately 10 hours post-procedure despite transfusion. Post-mortem examination revealed diffuse leukaemic infiltration of the body, including the hepatic haemangiomas. The mortality rate was therefore 0.46%. No other major complications were documented.

Transrectal Prostate Biopsy

The results for transrectal prostate biopsy are shown in Table 3. Three published studies are included for comparison.¹⁵⁻¹⁷ 494 transrectal ultrasound guided prostate biopsies were performed. Five patients were re-admitted for *Escherichia coli* bacteraemia. All except 1 patient responded well to antibiotic treatment. The patient who had a poor response developed *E coli* meningitis and pneumonia despite treatment, due to antibiotic resistance. The patient eventually recovered and was discharged from hospital, but he had a permanent neurological deficit. Side effects of haematuria and bleeding per rectum were self-limiting.

Percutaneous Transhepatic Biliary Drainage

The results for PTBD are shown in Table 4, along with reference data from the textbook¹ and 3 published studies,¹⁸⁻²⁰ and some additional data about bile peritonitis, pancreatitis, and pleural complications²¹⁻²⁸ are quoted. 143 procedures were performed. The sample size was comparable to the 3 articles. One death due to haemothorax was documented, which translated into a 0.7% mortality rate. The patient was known to have gout, hypertension, renal impairment, and carcinoma of the cervix with irradiation colitis. She was admitted for jaundice and sepsis. Endoscopic retrograde cholangiopancreatography (ERCP) and the first attempt at right PTBD failed. Although the second attempt was successful, the patient was found to be hypotensive a few hours later. Hepatic arteriogram showed an active bleeding artery from a branch of the right hepatic artery, which was successfully embolised. Overnight, a massive right haemothorax and disseminated intravascular coagulopathy developed. Post-mortem examination demonstrated cholangiocarcinoma with perineural and lymph node metastasis, with a massive right haemothorax but

Table 3. Mortality and morbidity rates associated with transrectal ultrasound guided prostate biopsy.

Complications	Djavan et al ¹⁵ (%) [n = 1051]	Aron et al ¹⁶ (%) [n = 231]	Kapoor et al ¹⁷ (%) [n = 269]	Caritas Medical Centre incidence (%) [n = 494]
Early complications				
Septicaemia	0.1			
Mild haematuria	62.0	14.3		1.2
Severe haematuria	0.7			
Bleeding per rectum	2.1	4.8		1.0
Bleeding per rectum requiring intervention	0			0
Urinary retention	1.8			
Vasovagal episodes	2.8			
Delayed complications				
Urinary tract infection	10.8	10.4	3 vs 5	
Fever	2.9	3.9		1.0
Urinary tract infection, fever	2.1		2%	
Haemospermia	9.8			
Recurrent mild haematuria	15.9			
Persistent dysuria	7.2			

Table 4. Mortality and morbidity associated with percutaneous transhepatic biliary drainage.

Complications	Reference incidence ¹	Yee and Ho ¹⁸ (%) [n = 206]	Hamlin et al ¹⁹ (%) [n = 118]	Mueller et al ²⁰ (%) [n = 188]	Caritas Medical Centre incidence (%) [n = 143]	Other
Acute complications						
Death	0.5-5.6*	1.9 [†]	2.5 [‡]	1.6 [¶]	0.7 [§]	
Bacteraemia/sepsis	-	24.3	14.0		4.2	
Sepsis with hypotension	0.8-3.5	2.4	0.8	3.7	0.7	
Haemobilia — transient with no therapy		-	16.0	9.6	4.2	
Haemobilia or haemorrhage with shock or requiring transfusion	0.5-3.0	0.5	1.7	3.0	0.7	
Arterio-venous fistula			0.8		0	
Subphrenic abscess	-		0.8		0	
Bile peritonitis		1.5	2.6		0	23 ²¹ ¶
Pancreatitis						4.7 ²²
Pleural complications						
Overall	0.5-3.0	1.0		0.5	0.7 [§]	
Bilio-pleural fistulae		1.0			0	
Haemothorases					0.7 [§]	Present ²³⁻²⁸
Pneumothorases				0.5	0	
Death from pleural complications	Reported			0.5	0.7 [§]	Present ^{23,24}

* Septic shock, severe haemorrhage, bile peritonitis, hypersecretion of bile, pleural complications.

[†] Septicaemia, bile peritonitis.

[‡] Septicaemia, peritoneal haemorrhage.

[¶] Bleeding, pneumothorax, bilious pleural effusion.

[§] 1 patient died of haemothorax.

¶ If there is failure to establish biliary drainage after puncture of an obstructed system.

no evidence of haemoperitoneum. Another patient's haemoglobin was reduced by 0.3 g/L post-procedure. The patient was given a transfusion of 1 pint of packed cells.

Table 5. Mortality and morbidity associated with percutaneous liver abscess drainage.

Complications	Lambiase et al ²⁹ (%) [n = 335]	Caritas Medical Centre incidence (%) [n = 118]	Other
Death	4.6	0	1-11 ³⁰
Overall complication	9.8	2.5	
Moderate haemobilia	1.8		
Haemoperitoneum			8.7 ³¹
Transient sepsis	3.6		
Septicaemia		2.5	
Transgressed pleura with pleural effusion requiring chest tube insertion	1.8	0	
Empyema			4 ³²

Table 6. Mortality and morbidity associated with percutaneous nephrostomy.

Complications	Stables ³⁵ (%) [n = 1207]	Caritas Medical Centre incidence (%) [n = 309]	Other
Significant complications	4.0	2.2	
Haemorrhage requiring embolisation	0.08	0	
Haemorrhage requiring transfusion only	0.66	0	<5% ³⁴
Death due to severe haemorrhage	0.2	0	
Puncture of colon, liver, spleen, gallbladder		0	
Infection	1.9	1.3	2.0 ³⁴
Urinoma requiring drainage	0.33	0	
Vasovagal hypotension		0.32	
Perforation of renal pelvis/ureter		0.65	
Pneumothorax	0.08	0	

Percutaneous Drainage of Liver Abscess

The results for percutaneous drainage of liver abscess are shown in Table 5, including the trials for comparison.²⁹⁻³² 118 procedures were performed. Three patients experienced septicaemia and transient hypotension immediately after the procedures. No patient had haemoperitoneum or pleural empyema.³³

Percutaneous Nephrostomy

The results for percutaneous nephrostomy are shown in Table 6, along with the standard reference and 2 trials for comparison.^{34,35}

Significant complications encountered include infection (fever after drainage of infection), local perforation (with no sequelae), and vasovagal hypotension. No significant haemorrhagic complications or mortality were documented, although 1 patient required transfusion.

Table 7. The mortality and morbidity associated with diagnostic angiography.

Complications	Spies et al ³⁶	Singh et al ³⁷	Waugh and Sacharias ³⁸ (%) [n = 2475]	Caritas Medical Centre incidence (%) [n = 932]
Puncture site				
Haematoma requiring transfusion, surgery, or delayed discharge from hospital	<3.0	<0.5	0.2 required transfusion 6.18 small haematoma	0.21 required transfusion 0.75 small haematoma
Occlusion	<0.5	<0.2	0.4	0
Pseudoaneurysm	<0.5	<0.2	0.04	0
Arteriovenous fistula	<0.1	<0.2		0
Contrast extravasation	<0.1			0.43
Non-puncture site				
Distal emboli	<0.5	<0.5		0
Arterial dissection/subintimal passage	<2.0	<0.5	0.44	0.32
Subintimal injection of contrast	<1.0	<0.5		0

Diagnostic Angiography

The results for diagnostic angiography are shown in Table 7, with the standard reference and 3 published trials for comparison.³⁶⁻³⁸ 932 examinations were performed. Two (0.21%) patients had groin haemorrhage requiring transfusion. One patient received 3 additional units of platelets due to a low platelet count ($57 \times 10^9/L$). The other patient with coagulopathy (INR, 1.74; platelet count, $33 \times 10^9/L$) re-bled 2 hours after the procedure and 4 units of fresh frozen plasma, 3 units of packed cells, and 6 units of platelets were infused. Seven other patients (0.75%) had small groin haematomas (<5 cm) not requiring transfusion. Local contrast extravasation was reported in 4 patients (0.43%). Three patients had distant arterial dissection with no clinical sequela.

DISCUSSION

Twenty nine patients (29%) undergoing lung biopsy had pneumothorax detectable on post-procedure CT, which was within the range reported. In an independent audit, the post-procedure erect expiratory chest X-rays of these patients were studied (Table 8). The rate of pneumothorax was found to be 16%. Four percent of patients in this study had chest tube insertion because of the pneumothorax, which was low compared with the reported data.

The main cause of mortality after percutaneous liver biopsy is intraperitoneal haemorrhage. However, the reported mortality rate varies widely among retrospective studies or surveys. The reported mortality rate for percutaneous liver biopsy is between 0.01% and 0.17%.¹² However, in a clinical audit of liver biopsies performed in UK district general hospitals, the mortality rate was between 0.13% and 0.33%.¹³ In a large-scale prospective data collection using a defined protocol by McGill et al¹⁴ of the Mayo Clinic over 21 years, a mortality rate

Table 8. Result of the assessment of post-biopsy chest X-ray by 2 independent radiologists.*

No.	Date	Thickness of pneumothorax on computed tomography scan	Radiologist A	Radiologist B
1	30.5.02	1.8 mm	—	—
2	10.4.02	2.9 mm	—	—
3	5.3.02	2.9 mm	N	N
4	6.2.02	0.8 mm	Y	Y
5	22.1.02	1.3 mm	N	N
6	5.12.01	22.0 mm	Y	Y
7	28.11.01	10.0 mm	Y	Y
8	16.10.01	19.5 mm	Y	Y
9	14.8.01	10.5 mm	N	N
10	28.8.01	20.3 mm	Y	Y
11	14.6.01	14.3 mm	Y	Y
12	14.4.01	8.8 mm	N	N
13	14.2.01	3.5 mm	N	N
14	27.2.01	2.6 mm	N	N
15	16.1.01	3.1 mm	Y	Y
16	5.12.00	23.7 mm	Y	Y
17	19.12.00	15.0 mm	Y	Y
18	22.12.00	9.4 mm	Y	Y
19	29.11.00	3.7 mm	N	N
20	10.10.00	1.5 mm	Y	Y
21	31.8.00	1.0 mm	Y	Y
22	17.8.99	6.0 mm	Y	Y
23	10.8.99	12.0 mm	N	N
24	30.7.99	1.0 mm	N	N
25	9.7.99	1.0 mm	—	—
26	7.5.99	15.0 mm	Y	Y
27	18.4.00	1.5 mm	Y	Y
28	19.4.00	5.0 mm	N	N
29	30.5.00	8.0 mm	Y	Y

* The films of 3 patients could not be traced due to transfer to other hospitals. 10 of the 26 patients with films available had no detectable pneumothorax on chest X-ray.

Abbreviations: Y = pneumothorax detected; N = no detectable pneumothorax.

of 0.11% was recorded. According to the authors, malignancy, age, sex, and number of passes were the only predictable risk factors. The risk of fatal haemorrhage in patients with malignancy is estimated to be 0.4% and 0.57% for non-fatal haemorrhage. For patients undergoing biopsy for non-malignant disease, the risks

are 0.04% and 0.16%, respectively. The mortality rate in this series, as of July 2002, was 0.46%. Part of the reason for the higher rate is the small sample size. However, the authors noted that most patients referred for biopsy are elderly with hepatic masses requiring image guidance, and these are the 2 main risk factors for haemorrhage. It is hoped that the rate will continue to fall as the number of patients included in the study increases.

The main complication for transrectal prostatic biopsy is septicaemia. Five patients (1%) were re-admitted to hospital for septicaemia from a total of 494 biopsies performed. The relatively low rate is probably due to under-documentation as most infections present late and usually after discharge from the ward. The infection risk from the procedure should not be underestimated. This is illustrated by the patient with antibiotic-resistant *E coli* infection, as the patient had no history of hospital admission before the procedure so did not have a hospital-acquired infection. The antibiotic prophylaxis has since been revised and administration of prophylactic antibiotics and the performance of the procedures has improved. All patients are advised to return to hospital if they develop signs and symptoms of infection. Other morbidity such as haematuria is difficult to quantitate. Severe haematuria was defined as requiring transfusion, but no haemorrhage requiring transfusion was documented.

One patient undergoing PTBD died due to massive haemothorax, which translated into a 0.7% mortality rate. The most common causes of death following PTBD are septic shock or severe haemorrhage. Other causes of death include premature removal of drainage tube, hypersecretion of bile, peritonitis, and pleural complications. The acute complication rates in this study fell in the lower end of the reference range. Questions were raised as to whether the puncture site of the patient who died of a right haemothorax was too high at the eighth intercostal space, and whether it was appropriate to traverse the pleura. Yedlicka et al quoted the seventh to the tenth intercostal spaces as common sites of puncture³⁹ and the standard reference quoted the ninth intercostal space as the commonest site of puncture.¹ Since the pleural reflection in the mid-axillary line is at the tenth rib, most right PTBD are transpleural. An audit was performed to investigate this issue (Table 9). Ten randomly selected patients from the previous 3 years were reviewed. The puncture sites were between the eighth and tenth intercostal spaces for right PTBD. The

Table 9. Entry site for right percutaneous transhepatic biliary drainage for 10 randomly selected patients.

Patient	Date of procedure	Entry sites
1	19.3.02	10th/11th intercostal space
2	16.5.01	8th/9th intercostal space
3	24.4.01	9th/10th intercostal space
4	30.12.00	9th/10th intercostal space
5	21.10.00	10th/11th intercostal space
6	26.10.01	10th/11th intercostal space
7	20.8.01	10th/11th intercostal space
8	7.9.01	9th/10th intercostal space
9	13.3.02	9th/10th intercostal space
10	Left percutaneous biliary transhepatic drainage	—

eighth and ninth intercostal spaces were involved for more than half of the patients, which were transpleural. The practice in the department was entirely within the recommended range.

Three patients undergoing percutaneous drainage of liver abscess had septicaemic shock, which represented 2.5% of the patients. All patients were treated in the intensive care unit and recovered after fluid therapy. No patient with empyema or haemoperitoneum was encountered. These rates compare favourably with those of other institutions.

The morbidity rate for percutaneous nephrostomy was within the reference range. No severe haemorrhage requiring transfusion or embolisation was documented.

The threshold level guidelines for complication rates for diagnostic peripheral angiography have been compiled by the Quality Assurance Program of the Society of Cardiovascular and Interventional Radiology (SCVIR) in 1993 and again in 2002.^{36,37} The threshold levels for most categories of complications were drastically reduced in the revised version. Two patients with puncture site haematoma required transfusion. Seven other patients with groin haematoma <5 cm were documented. However, it was not certain whether this resulted in delayed discharge. There were 3 patients with dissection involving the distal abdominal aorta (n = 1) and hepatic arteries (n = 2). All patients were asymptomatic with no treatment needed. Both categories of complications were below the threshold levels set by SCVIR. Four patients (0.43%) had subintimal contrast extravasation at the femoral puncture site, which was above the threshold level set in 1993.

Overall, the rate of complications is acceptable, although the data collection may be incomplete for delayed

complications. These data are useful for monitoring of the quality of services by providing local data.

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