

Risk Factors and Techniques Affecting Surgical Outcome of Therapeutic Endoscopic Retrograde Cholangiopancreatography Difficulties

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Objective: To analyze the therapeutic endoscopic retrograde cholangio pancreatography (ERCP) difficulties and complications experienced by a general surgeon and identify risk factors and technique affecting surgical outcome.

Material and Method: A retrospective review was carried out in 88 consecutive ERCP operated with four different indications on patients in Nakornping General Hospital by a surgeon trained from Nippon Medical School, Japan.

Results: The patients average age was 57.2 years. Fifty-four patients had common bile duct stone and 43 of them were successfully removed. Endoscopic sphincterotomy (EST) was the most frequent procedure needed to combine with the stone extraction (23 in 43). Twenty-two distal common bile duct obstructions unable to be diagnosed by ultrasound or computed tomography were operated on and found to be unvarying proportion of tumor, stone or stricture. Among these 6 biopsy and 12 treatments were concurrently made. Eight bile fistula and four cholangitis were indicated for endoscopic drainage. Only one serious bleeding was complicated. Two perforations were discovered in the present series and none required laparotomy repair of duodenum. Eighteen of the 88 failed to be operated on and most of them were within first four-month learning curve. Duodenal diverticulum was a common failure factor. The pre-procedure unknown diagnosis relates to an insignificant risk 2.4 times complications of the known (RR = 2.4, $p = 0.31$). Three patients (3.4%), all over 70 years old, succumbed late after ERCP due to sepsis and myocardial infarction, compared to those age under 70 is a significant risk factor ($p = 0.059$). Age over 50 seems to result in a higher pancreatitis complication (3 versus none under 50) but not statistically significant ($p = 0.405$).

Conclusion: Skill and synchronous assistance are important factors for success of ERCP but a more unpredictable outcome and complications were encountered for the preoperative undiagnosable obstructive jaundice. Hot and slow sphincterotomy would minimize the bleeding complication. Duodenal diverticulum and those operated on for late obstruction were risk factors in patients with EST perforations. Pondering to be minimally by invasive, advanced age still contributes to a higher complication and mortality risk in the surgical treatment of ERCP.

Keywords: Risk factors, Surgical outcome, ERCP

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Endoscopic retrograde cholangiopancreatography (ERCP) with therapeutic intervention has revolutionized the management of biliary ductal stones and obstructive jaundice. Although widely regarded

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as a safe procedure, the complication rate ranges from expert centers to a small unit is approximately 5.4-10.8% with an overall mortality risk of 0.3-0.8%^(1,2). In the era of minimal invasive requirement, some surgeons are reluctant to perform endoscopic surgery and search for data to conceive encouragement. After decades of therapeutic ERCP has emerged in Thai tertiary medical centers⁽³⁾, very few new set up

experiences in therapeutic ERCP have been reported, especially from general hospitals⁽⁴⁾. Hence, the aim of the present article was to analyze and to identify risk factors and technique affecting surgical outcome of first year ERCP setting in a provincial hospital in order to add more data for surgical consideration.

Material and Method

Method

A retrospective review study between October 2003-July 2004

Equipment

Cannulations are performed through side viewing Olympus duodenoscopes Model JF-V to allow face-on views of papilla with 3.2 mm instrument channel needed for stentings. Standard catheters 0.035 inches lumen for guide wire passage are simple Teflon tubes with an external diameter of about 5French (1.7 mm) radio-opaque tip. Sphincterotomes, Balloons, Baskets were reused since they are an expensive disposable accessory. Setting consists of C-arm X-ray in an operating room layout of which both fluoroscopy monitor and VDO scope monitor stand aside.

Technique

With left lateral decubitus on the table with the left arm behind, the patient position facilitates subsequently into prone. In most of the cases short loop (less than 70 cm) by straightened scope shaft were operated but in some difficult cases long loop technique under general anesthesia was needed. To minimize trauma, facilitate deep entry to the CBD, gentle cannulation, minimal force and volume of contrast injection were performed. Guide wire was not allowed to drop and be contaminated on the floor. Sphincterotomy in an effort to minimize perforation was done under a "hot and slow" incision.

Patients

Over the period from October 2003 to July 2004, 88 ERCP with or without therapeutic interventions were performed in the Department of General Surgery of Nakornping Hospital Chiangmai. All underwent ERCP with four main indications. There were 54 patients who had common bile duct (CBD) stones indicated for endoscopic extraction. Twenty-two uncertain causes of obstructive jaundice, 8 bile fistula and 4 cholangitis were included in the present study (Table 1). The surgical records were reviewed retrospectively for the following information: patient age, indication for ERCP, findings during ERCP, clinical presentation of complications, diagnostic and therapeutic methods, findings during surgery, surgical technique, postoperative outcome. The intraoperative findings from the operative note were also reviewed for abnormal anatomy and perforations.

The variables risk factors were analyzed for correlation to outcome and complications. Statistical comparison was Relative Risk (RR) and Yates' Chi-square (Yates' X^2) for significance with $p < 0.05$ ⁽⁵⁾.

Results

There were 36 male and 52 female patients with a median age of 57.2 years (range: 44-78 years). Among 4 main indications, most of the cases were 54 patients with primary or retained CBD stones and 11 of them could not be removed (20%). Five had complications (CBD Stones, Table 1). Six failed and three eventuated complications in the first beginning four months.

The second frequent cause indicated for ERCP in the present series was uncertain obstructive jaundice (Diagnostic, Table 1). Eighteen of 22 patients in this group were able to reveal the cause of obstruction but 4 of them (18.2%) had complications, thus, bringing about only 14 with a successful outcome. Relative Risk (RR) was calculated to be 2.4 times of the

Table 1. Outcome

Indications	Number of cases	Success	Fail	Complicated
CBD Stones	54	38 (70.4%)	11 (20.4%)	5 (9.22%)
Diagnostic	22	14 (63.6%)	4 (18.2%)	4 (18.2%)
Bile Fistula	8	6 (75%)	2 (25%)	
Cholangitis	4	3 (75%)	1 (25%)	
Total	88	61 (69.3%)	18 (20.4%)	9 (10.2%)

RR_{Diagnostic vs CBD stone} = 2.4 (p = 0.31)

known cases for CBD stone group, but statistically is not significant ($p = 0.31$). Four cases (18%) were too difficult to cannulate and 3 of these had diverticula. The same percentage (25%) of failure rate was encountered in the remaining two small groups indicated for ERCP here. Most of the 8 cases of postoperative bile fistula and 4 cases of non-bile obstructed cholangitis were successfully inserted by 7-10 cm Amsterdam 7French biliary stents. A duodenal diverticulum was present in 7 patients aged between 56 and 74. Four of them failed to cannulate while fibrosis of the first part of the duodenum was noted in one patient.

In the CBD stones group 37 patients had stone extraction with more than one therapeutic interventions which included mainly sphincterotomy, precut, and stenting while in the diagnostic group 13 underwent only a single biopsy, EST, or drain alone (Table 2). EST was the most common endoscopic surgical procedure (Total 25) and 11 drains alone in all groups.

Risk and complication (Table3)

For accessible statistical analysis patients in the present study had to be divided into age groups about 30 patients each and then it was found to fall into three groups (below 50, 50 to 70 and over 70). Only one intense hemorrhage in low hepatic function and slightly prolonged coagulation status was found. No surgical intervention was required and bleeding ceased

with the need of frozen plasma and Vitamin K medical treatment. There were two patients with perforations diagnosed during the ERCP and duodenal diverticulum existed in both of them. Hence, the procedure was aborted. One of the patients had endoscopic visualization of small bowel perforations while the other had contrast leak on fluoroscopy. The diagnosis of perforation was confirmed with post-procedural abdominal X-ray, which demonstrated the presence of retroperitoneal air or free gas under the diaphragm. Non need laparotomy after three days close follow up showed no abnormal abdominal sign and ultrasound did not detect free fluid in the peritoneal cavity. The incidence of post-ERCP pancreatitis is 3.4% (3 cases). All were over 50 years, but compared to non under 50 was still not significant ($p = 0.405$) by Yates' correction Chi-square value (X^2) calculated to be 0.692. There were three deaths due to old age and complications. One patient with CBD stones which were successfully removed died on the fourth postoperative day due to acute myocardial infarction. The second patient after failure of cannulation required a laparotomy on the ninth postoperative day to insert an external drainage which leaked and followed by severe peritonitis. He succumbed to sepsis on the 21st postoperative day. The remaining patient also died of late sepsis. Comparing age, under 70 is significantly a risk factor at $p = 0.059$ almost significant.

Table 2. Procedure

Indications	Fail to Cannulate	Stone Extraction				Biopsy Alone	EST Alone	Drain Alone
		Alone	& Drain	& EST	& Dilate			
CBD Stones	11	7	4	23	3	1	3	2
Diagnostic	4	2	1	2		6	5	2
Bile Fistula	2				1			5
Cholangitis	1						1	2
Total	18	9	5	25	4	7	9	11

Table 3. Age vs Complication

Age	Cases	Hemorrhage	Perforation	Pancreatitis	Dead
<50	35	1	1		
50-70	24		1	1	
>70	29			2	3
Average 57.2	88	1	2	3	3

Pancreatitis complication Yates' X^2 _{age > 50 vs age under 50} = 0.692 ($p = 0.405$)
Mortality complication Yates' X^2 _{age > 70 vs age under 70} = 3.568 ($p = 0.059$)

Discussion

Complications and risk factors of ERCP were reviewed and concerned by many experts' comments^(6,7).

An understanding of patient and procedure related risks is important for decision making with regard to whether or how ERCP should be performed. Since it is recommended that patients with a high risk for complications may be best served by referral to an advanced center⁽⁸⁾. As a new setting in a subsurgical unit, patients who would gain obvious benefit from ERCP were selected and marginal indications were avoided. In the present retrospective study then, strong indications fall into only four main groups. The overall complication rate and risk factors for diagnostic and therapeutic ERCP were identified.

Starting with an unsatisfactory first four months 6 of 11 known cases of CBD stone indicated for therapeutic ERCP failed at various steps. Duodenal diverticulum 7 in 18 failure cases is still a major problem. Rajnakova et al recorded their experience of common bile duct cannulation which failed in 11.1% with diverticula compared to 4.7% without diverticula⁽⁹⁾. After the accumulation of further experience and well-synchronized assistance of the last four months, the overall successful yield was up to 80% with 10.2% complications. This resembled a recent study in a small ERCP unit performing less than 200 ERCs per year where there were 17.6% failed diagnostic or therapeutic ERCs and 10.85% complications arose⁽²⁾.

The commonest moderate complication in the present series was procedure related pancreatitis, which occurred in 3.4% of patients all over 50 years. This result compared favorably with a report suggesting that acute pancreatitis develops in around 2.5% of elderly patients following sphincterotomy⁽¹⁰⁾.

But correlation between age and procedure induced pancreatitis by statistical calculation is far from significant (Yates' $X^2_{\text{age} > 50 \text{ vs age under } 50} = 0.692$, $p = 0.405$) The increased risk of age related post-ERCP pancreatitis, is of considerable importance. However, Loperfido et al analysed the early complications from diagnostic and therapeutic ERCP in a prospective multicenter study of 1066 patients were treated in small centers (less than 200 ERCP per year) and 1703 in large centers (more than 200 ERCP per year)⁽¹¹⁾. They concluded that the risk of pancreatitis was significantly increased in small centers in the univariate analysis (relative risk 2.8), but the P value was only close to the limit of significance in the multivariate analysis. Due to the multicenter design and the high case-number, this study adds evidence to the assump-

tion that a low ERCP-frequency increases not only the complication risk in total, but that it also increases the risk of post-ERCP pancreatitis. Besides, a meta-analysis by Masci E et al recently state that endoscopy-related pancreatitis risk factors for precut sphincterotomy the relative risk was 2.71 ($p < 0.001$) and for pancreatic injection the relative risk was 2.2 ($p < 0.001$)⁽¹²⁾.

Thus by any means, risk of pancreatitis may depend on a multi-factor of different effects.

In other reports bleeding following sphincterotomy in 5% of cases and is associated with considerable mortality^(13,14). The very low incidence of only one active bleeding in the present series may be related to limiting the size of the sphincterotomy, a practice common to all the endoscopists, and hot and slow technique with a pulse diathermy machine. Precaution of bleeding risk is considered in all cases with poor liver function.

Some prospective studies comparing pre-operative endoscopic sphincterotomy with bile duct exploration revealed that the ability to clear stones from the bile duct, morbidity, mortality, hospital stay, length of operation, and hospital cost show no difference in outcome between young and elderly patients⁽¹⁵⁻¹⁷⁾.

Older patients with underlying disease in Nakornping Hospital were not advised to undergo surgical exploration in the belief that this would be associated with higher complications than ERCP. There was a quoted mortality of therapeutic ERCP around 1%, whereas the mortality of bile duct exploration increases with age exceeding 1% at the age of 60 years and continues to increase thereafter⁽¹⁸⁻²⁰⁾.

This explains why the selected poor condition of old age patients were brought about the rather high late mortality rate in the present study (3.4%) which compares unfavorably with that of other series of 0-5%^(21,22).

In one study of 500 patients after sphincterotomy, immediate and 30-day mortality were 1% and 3%, while a retrospective multicenter study of 10,000 patients undergoing sphincterotomy revealed a 0.6% mortality^(23,24). In the present series all deaths occurred in patients aged over 70 years was significantly different to non under 70 ($p = 0.059$). This would suggest that old patients with poor underlying bile obstruction condition have a greater risk than average of unexpected fatal cardiogenic complication as well as sepsis mortality when there is no other choice than undergoing minimal procedure, therapeutic ERCP. This resembled a study by Deans et al who found no

deaths in patients aged under 65 years. In comparison, 2.6% of those over 65 years developed cholangitis, pancreatitis, bleeding, and perforation (relative risk for those under 65 compared with those over 65 years 0.83, 95% confidence intervals 0.41-1.67, $p = 0.74$)⁽²⁵⁾.

There were 6 from 8 cases of bile fistula as a complication following major hepatobiliary surgery was successfully treated with endoscopic stenting. The aim of treatments was to facilitate bile flow into the duodenum. Averagely fistulas closed within six weeks and the stents could be removed a month after. This is comparable to a series from Michigan State University where 6 of 9 patients had resolution of their bile leak with the mean time of removal of the drain of 4.7 months⁽²⁶⁾. In the last few months with more experience the last group of 4 cholangitis cases underwent ERCP for urgent draining and the 3 successes improved dramatically. Though these patients seemed to be scanty, they challenged the author to practice more subsequent innovative ERCPs for the benefit of the patients.

Conclusion

The complication rate in the present report falls within the range of ERCPs performed in other small center. While the procedure indicated by choledocholithiasis is associated with a lower complications rate. The risk-benefit ratio in the anticipated, pre-procedure undiagnosed ERCP must be carefully weighed due to its morbidity. Though pancreatitis risk when the age risk factor is dichotomized as less than 50 and more than 50 years old was calculated to be not statistically different but higher mortality rate of age over 70 was significant. The coexistence of chronic medical illness in the elderly is a predictor of poor outcome in surgery. Sepsis contributed to two thirds of the dead obviously verify this fact. There is a trend to decrease the complication incidence observed in the course of the study, due to constantly improving experience. Therapeutic ERCP remains a difficult procedure to master and carries a significantly higher complication rate than other endoscopic procedures. Even in expert hands ERCP can be associated with serious and fatal complications.. The improved understanding of the risk factors associated with ERCP-related morbidity would convey better define the principles of safe, efficient, and successful ERCP.

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ERCP is a sophisticated technique that can be mastered with a reasonable commitment training

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การศึกษาหาปัจจัยเสี่ยงและวิเคราะห์ผลลัพธ์ความยากลำบากต่าง ๆ ของเทคนิคผ่าตัดรักษาโดยทำ ERCP

ธีรวุฒิ โกมุทบุตร

วัตถุประสงค์: เพื่อวิเคราะห์ค้นหาปัจจัยเสี่ยงและเทคนิคซึ่งมีผลลัพธ์ต่อการผ่าตัดผ่านกล้อง ERCP

วัสดุและวิธีการ: ศึกษาจากผู้ป่วยเรียงตามลำดับของการทำ ERCP 88 ราย ด้วยข้อบ่งชี้หลัก 4 ประการ โดยศัลยแพทย์ในโรงพยาบาลนครพิงค์ซึ่งผ่านการฝึกฝนจากนิปอนเมดิคัลสคูล ประเทศญี่ปุ่น

ผลการศึกษา: อายุเฉลี่ยของกลุ่มผู้ป่วย 57.2 ปี เป็นผู้ป่วยนิ่วในท่อน้ำดี 54 ราย สามารถทำให้หลุด สำเร็จได้ 43 ราย การตัดหูรูดท่อน้ำดีเป็นวิธีการซึ่งใช้บ่อยที่สุดร่วมกับการสกดนิ่ว (23 ใน 43 ราย) ได้ผ่าตัด 12 ราย ในผู้ป่วยทางเดินน้ำดีอุดตัน 22 ราย ที่โดยอัลตราซาวนด์ และเอ็กซเรย์คอมพิวเตอร์ ไม่สามารถวินิจฉัยได้ก่อน ERCP พบว่าเป็น เนื้องอกนิ่ว และท่อน้ำดีตีบ และได้ตัดชิ้นเนื้อตรวจ 6 ราย พบพิสตุลา 8 ราย ซึ่งเป็นข้อบ่งชี้ในการทำผ่าตัดเพื่อระบายน้ำดีภาวะแทรกซ้อนที่เกิดขึ้นทั้งหมดที่พบระหว่างผ่าตัดได้แก่ผู้ป่วยหนึ่งรายมีเลือดออกอย่างมาก และลำไส้ทะลุ 2 ราย ซึ่งแก้ไขได้โดยไม่ต้องผ่าตัดเปิดช่องท้อง มีผู้ป่วย 18 ราย ซึ่งทำไม่สำเร็จในระหว่างสี่เดือนแรกของการศึกษานี้ เกิดจากมีถุงโป่งของส่วนดูโอเดนา กรณีนี้นี้ไม่สามารถวินิจฉัยโรคก่อนผ่าตัดจะมีความเสี่ยงสัมพันธ์ในการเกิดภาวะแทรกซ้อน 2.4 เท่า (RR = 2.4, p = 0.31) ผู้ป่วย 3 ราย (3.4%) ซึ่งทั้งหมดอายุมากกว่า 70 ปี เสียชีวิตในภายหลังระยะหลายวันต่อมาเนื่องจากเชื้อโรคเป็นพิษในโลหิต และกล่ามเนื้อตายจากหัวใจขาดเลือด เมื่อเทียบกับกลุ่มผู้ป่วยอายุน้อยกว่า พบว่าเป็นปัจจัยที่มีนัยสำคัญทางสถิติ (p = 0.059) ขณะที่ผู้ป่วยอายุมากกว่า 50 ปี ดูเหมือนจะมีการเกิดตับอ่อนอักเสบมากกว่า (3/0) แต่ไม่มีนัยสำคัญทางสถิติ (p = 0.405)

สรุป: ความชำนาญมากขึ้นและการช่วยผ่าตัดเข้าจังหวะกันดีขึ้นมีส่วนสำคัญต่อความสำเร็จ ภาวะแทรกซ้อนและผลลัพธ์ที่ไม่แน่นอนจะเกิดมากขึ้นในกรณีที่ไม่สามารถวินิจฉัยได้ก่อนการทำ ERCP เทคนิคการตัดหูรูดโดยวิธีร้อนและชาจะมีอันตรายน้อยลงจากเลือดออก ถุงโป่งของดูโอเดนาเป็นปัจจัยทำให้ลำไส้ทะลุ ถึงแม้ว่า ERCP จะเป็นการผ่าตัดที่กระทบกระเทือนผู้ป่วยน้อยกว่าแต่พบว่าในกลุ่มผู้ป่วยอายุมากมีภาวะแทรกซ้อนและการเสียชีวิตภายหลังได้มากกว่า
