Pain score within twenty-four hours post-endoscopic retrograde cholangiopancreatography: a comparison between diagnostic and therapeutic procedures

Somchai Amornyotin,[1,2] Tuangthip Phasurin,[1] Pimtawan Wongnuch[1]

[1]Department of Anesthesiology and [2]Siriraj GI Endoscopy Center, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive procedure and can produce moderate to severe abdominal pain. Limited information is available regarding pain assessment after the procedure. This study aims to compare the pain scores between diagnostic and therapeutic procedures within 24 hours post-ERCP in adult patients. We prospectively analyzed the patients who underwent ERCP from February to November 2007. Pain scores and pain medications used at 2, 6, 12, 18, and 24 hours post-procedure were studied. One hundred and seventy-seven patients, 29 with a diagnostic ERCP (group D) and 148 with a therapeutic ERCP (group T), were enrolled. The mean pain scores at baseline were not significantly different between the two groups. The mean pain scores at two and six hours post-ERCP in group T were significantly higher than in group D (p=0.035 and 0.020, respectively). The scores at the other periods of time in both groups were not significantly different. The total dose of pethidine used for pain control after ERCP in both groups was not significantly different. In conclusion, ERCP-induced abdominal pain mainly occurs within six hours after the procedure. Therapeutic ERCP has a higher pain score than that of diagnostic ERCP only at two and six hours post-ERCP.

Introduction

Pain is a complex, private experience, and attempts to make valid assessments of pain have been fraught with difficulties. It is influenced also by numerous intrinsic and extrinsic factors, and the multiple aspects of pain have been assessed in many different ways. The assessment of perceived pain is not only necessary in the clinical setting for diagnosis and choice of treatment but also important for the evaluation of treatment efficacy in a research context. The pain intensity assessed by using the pain score[1-4] is relatively the most common method for assessment of severity of pain. The reliable and valid measures of pain are essential for conducting clinical trials of pain treatments.[5] Fortunately, in most situations, the most commonly used measures of pain intensity, including visual analog scales (VAS), have been shown to have adequate sensitivity to study pain and pain control medication across many populations and settings.

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive procedure. It commonly uses the pancreatobiliary abnormalities for diagnosis and treatment.[6-8] The procedure can produce abdominal pain. We hypothesized that therapeutic ERCP would produce higher pain intensity than diagnostic ERCP. The aim of this prospective study was to assess and compare the pain scores between diagnostic and therapeutic ERCP in adult patients within 24 hours after the procedure.

Materials and Methods

This study was a prospective observational study. All patients who underwent ERCP for the diagnosis and treatment of the pancreatobiliary disorders in Siriraj GI Endoscopy Center, Faculty of Medicine Siriraj Hospital, from February to November 2007 were evaluated for eligibility for the study. We excluded patients with confusion and/or cognitive impairment. Patients who had general anesthesia during the procedure were excluded as well.

Endoscopy procedure

All ERCP procedures were done using an Olympus video duodenoscope (TJF 160 R, Olympus Corporation, Tokyo, Japan). After completion of the ERCP, admission into the inpatient hospital service was arranged to rule out post-ERCP complications and to assess the pain score. However, we did not measure serum amylase and lipase levels to rule out post- ERCP pancreatitis.

Anesthesia-related procedure

The patients were monitored as regards non-invasive blood pressure, ECG, and pulse oximetry. All patients were sedated by using an intravenous sedation (IVS) technique. Complications such as hypotension or airway obstruction were recorded. After the ERCP procedure, only pethidine was used for pain relief medication.

Correspondence: Somchai Amornyotin, Department of Anesthesiology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. E-mail: sisam@mahidol.ac.th

Key words: pain score, endoscopic retrograde cholangiopancreatography, abdominal pain.

Conflict of interest: the authors report no conflicts of interest.

Received for publication: 28 September 2009.
Revision received: 5 November 2009.
Accepted for publication: 9 November 2009.

Gastroenterology Insights 2009; 1:e7
doi:10.4081/gi.2009.e7

Measurement of pain

Patients were instructed to make a single vertical mark on a horizontally oriented, ungraduated 100-mm VAS labeled with "no pain" at the far left and "most pain possible" at the far right end. As a measure of reliability, the patients were asked to score their pain before the procedure and then repeat this at certain times (2, 6, 12, 18, and 24 hours) after the procedure. A VAS score was assessed by the ward nurses. If the patients were asleep, the pain score would not be evaluated. After the ERCP procedure, intramuscular pethidine was used for pain relief medication and was given to the patients when their VAS scores were ≥30. The total amount of pethidine used during 24 hours post-procedure was recorded.

Statistical analysis

Results were expressed as mean±SD or percentage (%), when appropriate. Comparisons between diagnostic and therapeutic groups were made by using the χ^2-test (for categorical variables). The χ^2-test was used for ordinal variables, and the two-sample independent t-test was used for continuous variables. The statistical software package SPSS for Window Version 11 (SPSS Inc., Chicago, IL, USA) was used to analyze the data. All statistical comparisons were made at the two-sided 5% level of significance.

Results

Two hundred and two ERCP procedures were performed between February and November 2007. Of the 177 patients, 29 (12 men, 17 women; mean age 59.5±19.7 years)

classified in group D (Diagnostic) and 148 (75 men, 73 women; mean age 60.4±15.1 years) in group T (Therapeutic) met the inclusion criteria and were enrolled in the study.

The characteristics of the group D and T populations were compared. There were no significant differences between the two groups in age, gender, weight, height, ASA physical status, and indication of the procedure (Table 1). The duration of the procedure in therapeutic ERCP was significantly longer than in diagnostic ERCP (42.9 and 18.8 minutes, $p<0.001$). In group T, the interventions were stent removal and/or insertion (63.9%), stone removal (24.1%), and others (12.0%). Most of them required sphincterotomy (64.7%) and some had precutting papillotomy (20.3%). ERCP was performed by three senior endoscopists with more than 10 years' experience.

Measurement of pain

There were no statistically significant differences in the mean baseline pain scores before ERCP and the mean VAS scores at 12, 18, and 24 hours post-ERCP between the D and T groups. However, the mean VAS scores at two and six hours post-ERCP in the T group were significantly greater than in the D group ($p=0.035$ and 0.020, respectively). In addition, the highest pain scores occurred at two hours post-ERCP in both groups (Table 2).

Table 3 shows the mean VAS score of ≥30 mm in both groups. During 24 hours post-procedure in the D and the T groups, there was a high number of patients who experienced VAS scores of ≥30 mm at two and six hours post-ERCP. The pain scores in these two groups reduced after six hours. The mean pain score of ≥30 mm at all periods of time was not significantly different between the two groups.

All patients were sedated by anesthetic personnel during the procedures. Sedative agents used for the procedures were propofol (2.9±1.7 mg/kg in D and 4.4±2.7 mg/kg in T) and midazolam (0.02±0.01 mg/kg in D and T). There was no statistically significant difference between the two groups (p=0.423 and 0.698) in the sedative agent used during the procedure. Pain medication during ERCP in both groups was fentanyl (0.001±0.000 mg/kg in D and T), and the mean dose of this agent was not significantly different between the two groups ($p=0.198$). After the ERCP procedure, 30 patients (20.3%) in the therapeutic procedure and five patients (17.2%) in the diagnostic procedure received pethidine for pain control ($p=0.436$). The mean total dose of pethidine was 0.9±0.2 and 0.8±0.2 mg/kg, respectively, in the two groups (Table 4).

Sedation-related complications were hypotension (15.8% in D, 27.4% in T), tachycardia (2.6% in D, 3.0% in T), hypertension (5.3% in D, 1.2% in T), and others (2.6% in D,

Table 1. Characteristics of patients, duration, and indication of procedure (mean, SD and percentage).

	Diagnostic (n=29)	Therapeutic (n=148)	p
Age (yr; mean, SD)	59.5(19.7)	60.4(15.1)	0.092
Gender (n, %): male	12(41.4)	75(50.7)	0.360
female3	17(58.6)	73(49.3)	0.360
Weight (kg; mean, SD)	56.2(10.9)	55.8(10.7)	0.640
Height (cm; mean, SD)	159.0(8.0)	159.8(9.1)	0.084
ASA physical status (n, %)			
I	9(31.0)	32(21.6)	0.600
II	13(44.8)	84(56.8)	
III	7(24.1)	31(20.9)	
IV	0	1(0.7)	
Duration of procedure (min; mean, SD)	18.8(6.1)	42.9(26.1)	<0.001*
Indications (n, %)			
Cholelithiasis	18(62.1)	75(50.7)	0.261
Biliary stricture			
Malignant	4(13.8)	47(31.8)	0.051
Benign	2(6.9)	13(8.8)	0.739
Chronic pancreatitis	1(3.4)	6(4.0)	0.878
Others	4(13.8)	7(4.7)	0.065

* Considered statistically significant.

Table 2. Pain score at baseline and during 24 hours post-ERCP.

	Diagnostic		Therapeutic		p
	VAS (mean+SD)	VAS (range)	VAS (mean+SD)	VAS (range)	
Baseline	5.7+12.9	0-40	4.9+10.5	0-40	0.142
Post-ERCP					
2 hour	23.1+22.9	0-80	40.1+25.5	0-100	0.035*
6 hour	16.2+19.2	0-70	31.7+20.5	0-100	0.020*
12 hour	11.4+21.1	0-70	12.6+18.1	0-80	0.806
18 hour	5.5+12.1	0-50	7.2+14.1	0-70	0.411
24 hour	4.1+11.8	0-50	5.4+14.4	0-100	0.582

VAS: Visual analog scale (0-100). * Considered statistically significant.

Table 3. VAS score ≥30 mm post-ERCP in both groups.

	Diagnostic		Therapeutic		p
	n(%)	mean (SD), range	n(%)	mean (SD), range	
2 hour	12(41.1)	45.0 (17.3) 30-80	105(70.9)	53.4 (16.2) 30-100	0.312
6 hour	9(31.0)	40.0 (13.2) 30-70	96(64.9)	43.3 (14.3) 30-100	0.642
12 hour	5(17.2)	50.0 (15.8) 30-70	39(26.4)	41.0 (13.5) 30-70	0.566
18 hour	3 (10.3)	36.7(11.5) 30-50	14(9.5)	43.6(12.2) 30-70	0.548
24 hour	3 (10.3)	36.7(11.5) 30-50	11(7.4)	47.3 (23.3) 30-100	0.595

Table 4. Anesthetic agents during procedure (mean, SD; mg/kg) and pain relief medication during 24 hours post-ERCP (n, % and mean, SD; mg/kg)

	Diagnostic	Therapeutic	p
Anesthetic agents			
Propofol	2.9 (1.7)	4.4 (2.7)	0.423
Midazolam	0.02 (0.01)	0.02 (0.01)	0.698
Fentanyl	0.001 (0.000)	0.001 (0.000)	0.198
Pain relief medication			
Pethidine	5 (17.2), 0.8 (0.2)	30 (20.3), 0.9 (0.2)	0.436

1.8% in T). All complications were managed easily with no adverse consequences. The procedure-related complications including pancreatitis, bleeding, perforation, and cholangitis were not observed in either group.

Discussion

ERCP is a widespread technique essentially used for the diagnosis and treatment of the pancreatobiliary disorders.[6-8] However, it is an invasive procedure and can produce moderate to severe abdominal pain. Therefore, the application of pain medication is necessary sometimes. Nevertheless, limited information is available regarding pain assessment after the ERCP procedure. Our report is the first study that assesses the pain score within 24 hours post-ERCP in adult patients.

Measurement of pain relies on patients' self-reports and/or on the physician's decision based on the patient's behavior. However, pain is likely to vary over time and with different activities.[9] Thus, asking about usual or typical pain may not reflect pain severity accurately over time. The VAS score is used widely in the measurement of pain because it is simple to use and provides a sensitive indication of pain intensity.[10] The differences in VAS scores measured at two different times or by two different patients are referenced to categorical responses contrasting the two health states in order to determine clinically meaningful differences. In previous work reported by Todd *et al.*,[3] the mean VAS change in all patients reporting a "little less" or a "little more" pain was 13 mm.

The present study showed significant changes in pain intensity between diagnostic and therapeutic ERCPs by using VAS score in two and six hours post-procedure. However, pain relief medication was not significantly different between the two groups. This sensitivity to small changes in pain increases the validity of pain measurement. However, it can be problematic when using the VAS to compare effectiveness of differences in mean VAS scores and to determine when they can be declared statistically significant, even though they may be of little clinical significance to the patient.[11] Therefore, to further the study of pain scores and pain management in the ERCP procedure, it is important to identify a minimum clinically significant difference in pain that can be used as a criterion for assessing differences between diagnostic and therapeutic procedures. Additionally, a large patient population is needed.

We used the mean VAS score of ≥30 mm to compare pain intensity between the two groups because this score represented moderate to severe pain severity for each patient. This difference was judged to be clinically significant. Despite this limitation, it was notable that the range of the score was very wide,[10] such as no pain (0 mm), mild pain (0-30 mm), moderate pain (30-65 mm), and severe pain (65-100 mm). In this study, the patients who marked the pain as 30 mm on a VAS scale could define their pain as either slight or of moderate degree. These findings followed a similar pattern to those reported by Collins *et al.*[12] In our study, the mean VAS scores of ≥30 mm in both groups mainly occurred at two and six hours post-procedure. It was reported by our patients that mild and moderate pain after diagnostic and therapeutic ERCP procedures frequently occurred earlier, within the first six hours post-ERCP.

Acute pancreatitis develops in 1.3-24.4% of patients undergoing ERCP.[13-16] Many factors including difficult cannulation, coagulation currently used during sphincterotomy, repeated injections of contrast into the pancreatic duct, and sphincter of Oddi dysfunction possibly increase the risk of post-ERCP pancreatitis. Although transient evaluation of serum pancreatic enzymes is particularly common, an elevation does not necessarily represent pancreatitis.[15] The definition for post-ERCP pancreatitis is as follows: new or worsened abdominal pain, a serum amylase level at least three times greater than the upper limits of normal at 24 hours after the procedure, and requiring at least two days of hospitalization.[15,17] Those factors also could be associated with post-ERCP abdominal pain. In the present study the patient-related factors, baseline clinical presentation, and severity of disease were similar in both groups and could not affect the post-ERCP pancreatitis and/or post-ERCP abdominal pain. Furthermore, there were no signs and symptoms of post-ERCP pancreatitis in these two groups.

From our previous experience we assumed that the therapeutic ERCP produced higher abdominal pain intensity than the diagnostic group. We hypothesized that the interventions such as sphincterotomy and pre-cutting papillotomy, which caused more tissue injuries, were the precipitating factors. In addition, the individual patient and the endoscopist's skill can be associated with post-ERCP pain.[6] The types of anesthetic technique were not factors contributing to the pain, as all patients in the study had similar anesthetic methods.

There are several limitations of this study. First, we only used VAS scores for pain assessment. The large variability around the mean and the discordance of this scale may reflect a problem with its reproducibility or reliability. However, we are unable to find any published studies on the reproducibility in measurement of acute pain in ERCP patients. Second, in our practice we do not measure serum amylase and lipase levels routinely after the procedure. Abdominal pain from post-ERCP pancreatitis may affect the VAS score. Third, the pain score assessed in this study was limited to pain intensity and pain relief medication. There could be considerable individual variation in post-ERCP pain perception even following standardized procedures.[18] Fourth, we did not assess the pain score when patients were asleep.

Despite these limitations, the findings may have important implications for the assessment and treatment of post-ERCP abdominal pain. Overall abdominal pain severity after this procedure is of mild intensity and occurred mainly at two to six hours post-ERCP. Physicians should evaluate their patients' pain intensity carefully especially in the first six hour after the ERCP procedure. Patients who have therapeutic ERCP need more attention during this time period.

References

1. Von Korff M, Jensen MP, Karoly P. Assessing global pain severity by self-report in clinical and health services research. Spine 2000;25:3140-51.
2. Bijur PE, Silver W, Gallagher EJ. Reliability of the visual analog scale for measurement of acute pain. Acad Emerg Med 2001;812: 1153-7.
3. Todd KH, Funk KG, Funk JP, et al. Clinical significance of reported changes in pain severity. Ann Emerg Med 1996;4:485-9.
4. Kelly AM. Does the clinically significant difference in visual analog scale pain scores vary with gender, age, or cause of pain? Acad Emerg Med 1998;11:1086-90.
5. Jensen MP, Karoly P. Self-report scales and procedures for assessing pain in adults. In: Handbook of pain assessment. 2nd ed. Turk DC, Melzack P, ed. New York: Guilford Press, 2001, pp 15-34.
6. American Society for Gastrointestinal Endoscopy. ASGE guideline: the role of ERCP in diseases of the biliary tract and the pancreas. Gastrointest Endosc 2005; 62:1-8.
7. NIH state-of-the-science statement on endoscopic retrograde cholangiopancreatography (ERCP) for diagnosis and therapy. NIH Consens State Sci Statements 2002;19:1-26.
8. Hawes RH. Diagnostic and therapeutic uses of ERCP in pancreatic and biliary tract malignancies. Gastrointest Endosc 2002;56:S201-5.
9. Turk DC, Okifuji A. Assessment of patients' reporting of pain: an integrated perspective. Lancet 1999;353:1784-8.
10. Briggs M, Closs JS. A descriptive study of the use of visual analog scales and verbal

rating scales for the assessment of postoperative pain in orthopedic patients. J Pain Symptom Manage 1999;18:438-46.
11. Gallagher EJ, Liebman M, Bijur PE. Prospective validation of clinically important changes in pain severity measured on a visual analog scale. Ann Emerg Med 2001;38:633-8.
12. Collins SL, Moore AR, McQuay HJ. The visual analogue pain intensity scale: what is moderate pain in millimeters. Pain 1997;72:95-7.
13. Masci E, Mariani A, Curioni S, et al. Risk factors for pancreatitis following endoscopic retrograde cholangiopancreatography: a meta-analysis. Endoscopy 2003;35: 830-4.
14. Akashi R, Kiyozumi T, Tanaka T, et al. Mechanism of pancreatitis caused by ERCP. Gastrointest Endosc 2002;55:50-4.
15. American Society for Gastrointestinal Endoscopy. Complications of ERCP. Gastrointest Endosc 2003;57:633-8.
16. Bhatia V, Garg PK, Tandon RK, et al. Endoscopic retrograde cholangiopancreatography-induced acute pancreatitis often has a benign outcome. J Clin Gastroenterol 2006;40:726-31.
17. Cotton PB, Lehman G, Vennes J, et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. Gastrointest Endosc 1991;37:383-93.
18. Nielsen PR, Rudin A, Werner MU. Prediction of postoperative pain: Focus on acute pain. Curr Anaesth Crit Care 2007;18:157-65.