

**Patient-Reported Outcome Measures after Endoscopic Retrograde
Cholangiopancreatography: A Prospective, Multicenter Study**

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Conflicts of Interest and Source of Funding: There are no conflicts of interest related to this study and its publication. The Regional Health Trust of South-Eastern Norway and the Regional Health Trust of Western Norway provided financial support to the *Gastronet* group. This study was also funded and supported in part by the Folke Hermansens Cancer Research Fund, Stavanger (StHF # 424501) and the Norwegian Gastroenterological Association.

Running head: Many patients report ERCP as painful

Mini-abstract

Endoscopic retrograde cholangiopancreatography is a procedure that is often associated with pain, particularly in females. Reported pain is associated with a longer procedure duration time or the performance of a sphincterotomy and is dependent on the performing hospital. Sedation influences the pain experienced, which is a predictor of dissatisfaction.

Abstract

Objective: This study sought to document patient satisfaction and specifically pain related to endoscopic retrograde cholangiopancreatography (ERCP) procedures and to identify predictors for these experiences.

Background: While patient-reported outcome measures (PROMs) in ERCP are scarce, these reports are important for making improvements in quality of care.

Methods: From 2007 through 2009, prospective data from consecutive ERCP procedures at 11 hospitals during normal daily practice were recorded. Information regarding undesirable events that occurred during a 30-day follow-up period was also reported. The patient-reported pain, discomfort and general satisfaction with the ERCP were recorded.

Results: Data from 2808 ERCP procedures were included. Patient questionnaires were returned for 52.6% of the procedures. Moderate or severe pain was experienced in 15.5% and 14.0% of the procedures during the ERCP and in 10.8% and 7.7% of the procedures after the ERCP, respectively. In addition, female gender, endoscopic sphincterotomy (EST), and longer procedure times served as independent predictors of increased pain during the ERCP. The performing hospitals and sedation regimens were independent predictors of the procedural pain experience. In 90.9% of the procedures, the patients were satisfied with the information overall, and in 98.3% of the procedures, the patients were satisfied with the treatment provided. Independent predictors of dissatisfaction with the treatment included the occurrence of specific complications after ERCP and pain during or after the procedure.

Conclusions: Female gender, the performance of EST and longer procedure times were independent predictors for increased procedure-related pain. The individual hospital and sedation regimen predicts the patient's pain experience.

Introduction

Patient satisfaction, including the degree of pain experienced, is specifically an important part of quality assurance (QA) for endoscopic retrograde cholangiopancreatography (ERCP).¹⁻⁴ However, variations in the definitions and variables applied have made comparisons among studies difficult,^{1,5,6} and well-designed, validated instruments for proper evaluation are lacking.

Endoscopists generally agree that the ERCP procedure is associated with significant discomfort and pain for most patients, and appropriate sedation is typically justified. Nevertheless, even though the ERCP procedure has been performed for four decades, systematic studies assessing patient feedback and satisfaction as a quality measure are scarce. According to a British report titled "High-Quality Care for All,"⁷ patient safety, patient experience and effectiveness of care should represent the three main dimensions of quality in healthcare. Thus, the mandatory use of patient-related outcome measures (PROMs)⁸ has been suggested for quality improvement programs.^{2,9}

As part of a national quality improvement program for endoscopic procedures,¹⁰ this study was conducted to evaluate the patient pain experience and satisfaction related to ERCP procedures. The main objective involved evaluating self-reported patient pain and satisfaction; additionally, this study sought to identify possible predictors for these measures.

Methods

Protocol

The national quality assurance program for endoscopic activity in Norway was organized by Gastronet.¹⁰ The voluntary reporting of consecutive ERCP procedures from several hospitals and their collection into a clinical database is part of the official QA platform for the Norwegian Gastroenterological Association (NGA).¹¹

Study population and selection

All consecutive patients aged 18 years or older who were scheduled for planned or emergency ERCP were included in this study. Information regarding the total number of ERCPs performed at each hospital in the country during the study period was available.¹² Updated activity figures were supplemented and confirmed by each participating endoscopy unit. During the 36-month study period, the hospitals began their prospective reporting at different times. Consequently, several hospitals reported their ERCP activity for a shorter time period. With respect to the completeness of the data, 11 hospitals fulfilled the inclusion criteria for this study, and they reported prospectively on 2808 consecutive ERCP procedures.¹³

Data collection and definitions

Data regarding patient demographics, clinical characteristics, sedation regimes and complications were recorded prospectively. Information concerning undesirable events that occurred during a 30-day follow-up period was obtained by examining hospital records or outpatient clinic notes or by contacting patients as necessary. All information was reported consecutively to the registry from each hospital by a responsible endoscopist, as was described previously in greater detail.^{11,13} On the first day after the procedure, all patients were asked to complete a short questionnaire.¹⁴ The form, which included a four-point verbal rating scale for pain (4-VRS), was previously validated¹⁵ and has been used for patient assessment following colonoscopy.¹⁴ An English translation of the form is provided as an appendix (see *Appendix 1*).

The patients were categorized according to the hospital type, annual hospital ERCP volume and the ASA (American Society of Anesthesiologists) physical status classification system.¹⁶ In addition, the type and severity of the complications¹⁷ encountered during and

after the ERCP and during the 30-day follow-up period were recorded by the responsible endoscopist. No particular instructions were given regarding the ERCP procedure, including the sedation procedures, at the participating hospitals.

Primary study outcomes

The PROMs used for this study included patient-reported pain (as experienced during and after the procedure but reported on the first day after the ERCP) and general patient-reported satisfaction regarding the information provided about the examination and the overall management of the procedure (please see *Questionnaire* at an appendix at the end of the manuscript).

Ethical considerations and legislation

This study was approved by the Norwegian Social Science Data service and the National Data Inspectorate. This study is also part of the Gastronet QA program. Thus, further evaluation and approval by the Regional Ethics Committee for Medical and Health Research was not required.

Statistical analysis

PASW Statistics 18.0 for Mac (SPSS Inc., Chicago, IL, USA) was used for the statistical analysis. Descriptive statistics, with numbers, percentages, medians and interquartile ranges (IQRs), were used to characterize the study population and demographic data. For comparisons of categorical variables, the chi-square or Fisher's exact tests were applied as appropriate. To identify significant independent variables for patient satisfaction, pertinent clinical risk factors were analyzed by univariate logistic regression analysis. Variables with a $P < 0.25$ in the univariate analyses were included in the multivariate logistic regression

model. Stepwise forward and backward selection procedures were used to identify the variables for inclusion in the final model. In the final multivariable models, adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were calculated, and the relevant interactions were tested. Case-wise deletion of cases with missing values was used, and goodness of fit was verified using the Hosmer-Lemeshow test. All tests were two-tailed, and statistical significance was defined as $P < 0.05$.

Results

Completeness of data, demographics and procedures

Fourteen hospitals reported their ERCP procedures to the registry between January 2007 and December 2009. However, only 11 hospitals, including two university hospitals, five central hospitals, and four general district hospitals, met the inclusion criteria. High quality data recorded from 2808 procedures were available for further evaluation, which comprised 94.6% of the performed procedures at the hospitals during the time of registration.^{11,13} Patients' self-reported questionnaires were received for 1477 procedures (52.6%) (**Figure 1**), and the age and sex distributions were similar for responders and non-responders (**Table 1**). However, a significantly lower response rate ($P < 0.001$) was observed for patients with higher ASA scores (**Table 1**).

The main indication for ERCP was biliary therapy (91.6% of the procedures) (**Table 1**) and bile duct obstructions, with common bile duct stones (CBDSs) (1359, 48.5%) and bile duct strictures (892, 31.8%) being the most common findings. Successful CBD cannulation was achieved in 91.1% of the procedures. These procedures were performed by 48 endoscopists, and the majority (i.e., >80%) of the ERCPs were performed as in-patient procedures. Conscious sedation using midazolam, diazepam, or these drugs in combination

with pethidine was employed in most cases. Complications and definitions are reported in a former publication.¹³

Main complications

Various complications were encountered in 327 (11.6%) of the procedures, as reported recently.¹³ The main complications included post-ERCP cholangitis in 100 (3.6%) procedures, post-ERCP pancreatitis in 88 (3.1%) procedures, and recorded bleedings during 48 (1.7%) and after 24 (0.9%) procedures. Of note, 33 of the reported bleedings did not have any clinical consequences, such as transfusions or therapeutic measures.

ERCP-related mortality was encountered in 39 (1.4%) patients.

Patient-reported pain

Pain during the ERCP procedure

While “no pain” or “slight pain” was reported for 557 (38.4%) and 467 (32.2%) procedures, respectively, “moderate” or “severe pain” was experienced during the remaining 225 (15.5%) and 203 (14.0%) ERCPs, respectively.

The univariate regression analysis revealed that female gender, younger age, annual ERCP volume less than 50 procedures, university hospital type, performance of endoscopic sphincterotomy (EST), treatment of CBDs, and longer procedure times were all associated with increased pain. In addition, significant differences between hospitals ($P < 0.001$) with regard to pain experiences during the procedure were observed.

In the multivariate regression analysis, female gender, the performance of EST, and longer procedure times were independent predictors of increased pain related to the procedure (**Table 2**). In addition, the hospital category independently ($P < 0.001$) predicted the reported pain experience.

Pain after the ERCP procedure

“No pain” or “slight pain” after the procedure was reported in 724 (49.8%) and 462 (31.8%) procedures, respectively, which comprised the majority (81.6%) of the procedures. Nevertheless, “moderate pain” or “severe pain” was experienced after 157 (10.8%) and 112 (7.7%) ERCP procedures, respectively. The pain lasted less than 1 h in 123 patients (17.9%), between 1 and 3 h in 157 patients (22.9%), between 3 and 6 h in 115 patients (16.8%), and at least 6 h in 291 patients (29.6%). The univariate regression analysis revealed that female gender, younger age, university hospital, pre-cut sphincterotomy (EST), use of a guide-wire, biliary self-expanding metal stent (SEMS) placement, biliary leakage, post-ERCP pancreatitis (PEP), post-procedure cholangitis, longer procedure time, and pain during the procedure served as predictive factors for moderate to severe pain after the ERCP. Patients who suffered from moderate or severe pain after the ERCP were significantly less satisfied with the patient information and the ERCP treatment in general compared to those who did not report pain.

In the multivariate regression analysis (**Table 3**), female gender, younger age, pre-cut EST, use of a guide-wire, insertion of a SEMS, and the occurrence of PEP or a post-procedure cholangitis predicted moderate to severe pain after the ERCP. Undergoing the procedure at a university hospital was an independent predictor of increased pain experienced after the procedure.

Pain experience according to sedation

A univariate regression analysis showed significant ($P < 0.001$) differences between sedation regimens and pain experienced during ERCP procedures. Differences regarding routine sedation procedures and analgesia between the participating hospitals were also observed.

Intravenous administration of midazolam (≤ 5 mg) and pethidine (≤ 50 mg) was employed in 904 ERCP procedures (32.4%), and this combination was most commonly used. In the multivariate regression analysis, this combination was associated with significantly ($P = 0.015$) less patient-reported pain, compared with other options and combinations.

Moreover, pain after the ERCP procedure was experienced to significantly different degrees ($P = 0.002$) among sedation regimes, but it was impossible to identify a specific pattern.

Patient-reported satisfaction

A total of 1301 patients (90.9%) reported a high level of satisfaction with the information received from their health professionals related to the ERCP procedure. Sixty-seven patients (4.7%) rated that they were “not quite satisfied” with the information received, and 64 patients (4.5%) reported that they were “dissatisfied” with the information received. Significant independent factors for dissatisfaction with received information, as reported by 131 patients (4.6%), included the administration of a pre-cut EST ($P = 0.001$, OR 3.13 [95% CI: 1.61-6.09]) and either moderate to severe pain during ($P < 0.001$, OR 2.40 [95% CI: 1.55-3.72]) or after the ERCP procedure ($P = 0.006$, OR 1.90 [95% CI: 1.21-3.00]). Moreover, significant differences with respect to the experience of pain between the participating hospitals ($P = 0.008$) were observed.

Overall satisfaction with the ERCP management

The level of overall satisfaction with the ERCP treatment was reported by 1416 responders (98.3%). While no significant differences among hospitals were identified in the univariate regression analysis, several factors predicted a decreased overall satisfaction.

In the multivariate regression analysis, the occurrence of perforation ($P = 0.043$, OR 13.4 [95% CI: 1.08-166.14]), cardio-respiratory complications after ERCP ($P = 0.010$, OR 21.2 [95% CI: 2.06-217.52]), and moderate to severe pain during ($P = 0.003$, OR 4.1 [95% CI: 1.65-10.43]) or after ($P < 0.001$, OR 6.1 [95% CI: 2.54-14.60]) the procedure were independent predictive factors for a decreased patient-reported satisfaction with the treatment received.

Discussion

To the best of our knowledge, this report is currently the largest study on the patient-reported pain experience and satisfaction related to an ERCP procedure in a general unselected multicenter practice reported. Pain and discomfort during and after this procedure is common, and many different measures to prevent or ease these undesired side-effects are being utilized among institutions and countries.

While reports on ERCP outcomes regarding PROMs have not been published to date, the aspect of patient satisfaction in relation to the ERCP procedure has been addressed in three previous multicenter studies.^{1,5,6} However, neither the study by Colton et al.⁶ nor that by Williams et al.⁵ included pain evaluation as a part of the assessment. Moreover, the Italian study¹ was restricted to patients with gallstone disease only. All reports were biased by low response rates or selection bias.

Most clinicians would agree that patient satisfaction is of great importance.^{2,4,18} However, the availability of reliable high-quality measurements and instruments for the appropriate recording of information remains a major challenge. Moreover, high-quality assessment techniques are difficult to implement for many reasons. First, the timing of the assessment and the patient reporting may be of importance; second, methods for such

evaluation vary across studies. Furthermore, sedation may impact both the patient's experience and how he or she recalls and describes the experience.

The study by Cohen et al.¹⁹ addressed problems related to the reliability of patient satisfaction measurements and showed that the answers collected from patient surveys depended on how the questions were presented. To address the challenges associated with patient self-reporting, a questionnaire originally consisting of nine items was designed by the Group Health Association of America (GHAA-9).² This instrument was designed to fit the US health care system,² but other versions were subsequently introduced,²⁰ including a modified European version with amended pain-related questions.¹

According to patient assessments that have measured patient satisfaction following GI endoscopy procedures, pain and discomfort are regarded as highly important.²⁰ Using a validated version of the GHAA-9 for use in ERCP patients, Yacavone et al.²⁰ concluded that the GHAA-9 had inadequate content validity for measuring patient satisfaction with endoscopy because pain control was not assessed. Furthermore, Masci et al.¹ claimed in their recent study that no validated patient evaluation questionnaire for ERCP procedures currently exists.

We chose a very simple form comprising five questions (*Appendix 1*) related to pain experience and a validated 4-VRS.¹⁵ This form has previously been validated for colonoscopy examinations in more than 10,000 colonoscopy procedures.^{14,15,21} ERCP is regarded as the endoscopic gastrointestinal procedure that is associated with the highest risk of complications,^{22,23} and this procedure is performed on patients with a wide range of symptoms and conditions.^{11,24,25} Our study population consisted of two major groups of patients, those patients with CBDS disease and those patients with a malignant disease related to or affecting the biliary tract. The CBDS group was largely targeted for curative treatment, whereas most patients with malignancy were targeted for palliative intention. The

heterogeneity of the patient population made it difficult to survey or to procure appropriate information for all patients. Additionally, the patients' clinical conditions on the day following the procedure, including their mental states and cognitive capacities, may have affected their self-assessed reports. We observed that patients treated with biliary stent procedures (i.e., the majority had a stent for palliation for malignant disease) or with severe comorbidity were less likely to respond to the questionnaire.

Rather than restricting the criteria for successful ERCP treatments to factors such as cannulation rates, stent patency, or specific complications, additional information should be obtained to evaluate outcomes from the patient's perspective.²⁶ Female patients demonstrated an increased risk for reporting pain both during and after the ERCP procedure; this finding is in agreement with previous observations related to colonoscopy.²⁷ Moreover, longer procedure times also served as a risk factor for increased pain. Whereas younger age was not an independent risk factor for pain during the procedure, younger age was an independent significant risk factor for pain after the ERCP procedure. In addition, EPT was an independent risk factor for pain during the ERCP procedure, which indicates that patients with CBDSSs, many of whom receive an EPT, are at increased risk for pain compared with patients with a malignant stricture.

This multi-center study mirrors routine clinical ERCP practices in Norway, which include university, central and general district hospitals. High endoscopist compliance for reporting consecutive data added to the reliability, validity, and significance of this study.

One limitation of this study was that only 52.6% of the patients provided feedback by returning their questionnaires; however, this response rate is not very different from the 66% response rate achieved in a study from the USA⁶ and the 45% response rate achieved in a previous British study.⁵ In contrast, a higher response rate of 81.6% was reported for the study by Masci et al.,¹ although this study examined 700 procedures with gallstones that were

performed at 15 different hospitals with generous exclusion criteria. Nonetheless, selection bias may to some extent have influenced the reliability and validity of this study. However, the study population comprised all patients over 18 years of age in unselected multicenter general practice. In addition, 851 of the included patients were at least 80 years of age, and 408 (47.8%) of these patients responded by forms. Some patients had several ERCP procedures at different times, which may also explain why some patients did not respond after every procedure. While a higher response rate would have been an advantage, we are unaware of any comparable study with a higher response rate. The challenges and difficulties encountered when these questions are addressed in a clinical research setting, as in this study, should not be underestimated.

To elucidate potential hidden biases, we analyzed the patterns of missing data and the proportions of missing patient form data according to the included variables (**Table 1**). The missing data were relatively similar for all patient groups, and unsurprisingly, we observed lower response rates for elderly patients and for those patients with significant co-morbidities (i.e., higher ASA grades), which has previously been emphasized as a general challenge with these types of studies.^{5,6}

Our questionnaire included only five questions. To more accurately identify the grade of satisfaction, additional questions related to the specific ERCP procedure are likely warranted. Moreover, grading related to the difficulty of the procedure^{22,28} would have been of interest, but this aspect was not included in the registration form. Finally, the logistics related to the collection of patient feedback should also be reconsidered in future studies. Nevertheless, as emphasized by Naylor et al.,²⁹ only factors of particular importance should be included in the evaluation to achieve simple and complete reporting. Furthermore, limiting the number of variables is also important for analysis and statistical calculations and for the

prevention of challenges regarding confounders and over-fitting. Accordingly, due to these methodological concerns, any conclusions from this study should be interpreted with caution.

Adequate sedation is of particular importance for technically demanding endoscopic procedures.³⁰ Moreover, appropriate attention to proper pain relief would likely improve patient satisfaction. Additionally, regarding the association between complications and postoperative pain, a reduced complication rate would likely translate into an increased proportion of satisfied patients. Depending on the difficulty and complexity of the procedure,²⁸ along with the desires, co-morbidities and disease patterns of the patients, the sedation technique should be tailored and individualized. Moreover, ERCP should be regarded as a true surgical procedure, and more attention should be paid to procedure-related aspects, as suggested by the World Health Organization in the surgical checklist of safe surgery.³¹

A paradox exists in that most patients generally report that they are satisfied despite a painful procedure. However, our study shows that patient satisfaction related to the ERCP procedure was related to the patients' experiences of pain during and after the procedure. Some caution should be taken in this interpretation because only small numbers of patients were dissatisfied with the treatment. Improved instruments for the appropriate reporting of patient-reported outcomes after ERCP should be developed and assessed by including study populations from various institutions and in different countries. In addition, increased compliance in patient reporting, as difficult it may be to achieve in routine practice, will contribute to the available knowledge on this important aspect of treatment.

Acknowledgements

Data collection was organized and coordinated by the Gastronet, and the contributions made by the Gastronet secretariat and the staff and nurses at the participating hospitals and ERCP units are very much appreciated. We also acknowledge support and funding offered by the Norwegian Gastroenterological Association (NGA) and the Folke Hermansens Cancer Research Fund, Stavanger (StHF # 424501).

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