

The burden of endoscopic retrograde cholangiopancreatography (ERCP) performed with the patient under conscious sedation

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Received: 22 May 2011 / Accepted: 5 January 2012 / Published online: 1 February 2012
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Abstract

Background Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive procedure that proves burdensome to patients. Nevertheless, very little data are available on patient tolerance of this procedure that may improve practice guidelines and could aid in decreasing the burden of ERCP. This study therefore investigated the burden of ERCP performed with the patient under conscious sedation.

Methods Consecutive patients receiving ERCP under conscious sedation between November 2007 and December 2008 at the University Medical Center Utrecht and Erasmus MC Rotterdam (The Netherlands) were asked to participate in this study. The patients completed questionnaires on demographics, medical history, burden of ERCP (mental health, discomfort, and pain), symptoms and the EuroQol-5D (EQ-5D), including the EQ-VAS (lower EQ-5D scores and higher EQ-VAS scores represent a better quality of life). The paired *t*-test, the Kruskal–Wallis test, Pearson

correlation, and logistic regression were used to evaluate the results.

Results The questionnaire was returned by 149 (54%) of 276 eligible patients, 139 of whom completed the entire questionnaire (54% males; mean age, 60 ± 14 years). Throat ache ($p < 0.001$) was the only symptom higher than baseline value 1 day after the ERCP. On day 1, about one-tenth of the patients experienced moderate to severe mental health problems, which were associated with a higher EQ-5D score before ERCP ($p = 0.01$). Slightly fewer than half of the patients experienced pain and discomfort during and immediately after ERCP. More discomfort was experienced by patients who underwent therapeutic ERCP ($p < 0.05$) and those with a higher EQ-5D score ($p < 0.001$) or lower VAS ($p < 0.01$). Pain was associated with younger age ($p < 0.01$), higher EQ-5D score ($p < 0.001$), and lower VAS ($p < 0.01$).

Conclusion One-third to one-half of patients experience pain and discomfort during and immediately after ERCP when it is performed with conscious sedation for the patient. Other sedation strategies, such as the use of general anesthesia or propofol, may well reduce the burden of ERCP, particularly for patients with a higher EQ-5D score, younger age, or therapeutic ERCP treatment. However, randomized trials are warranted.

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Keywords Conscious sedation · Endoscopic retrograde cholangiopancreatography · ERCP

Endoscopic retrograde cholangiopancreatography (ERCP) is a frequently used procedure for pancreatic and biliary diseases. The most common indications for ERCP include removal of common bile duct (CBD) stones and management of malignant or benign CBD strictures. Complications after

ERCP occur for 5% to 10% of patients [1–3], particularly for patients with pancreatitis (2–5%), cholangitis (1–5%), hemorrhage (1%), or perforation (1–2%) [4–6]. Previous studies have suggested that upper endoscopy is an invasive procedure that proves burdensome for patients because it is associated with anxiety, pain, and discomfort [7].

Because ERCP is considered to be a more invasive procedure than upper endoscopy, a patient's perceptions may be different. Data on patient tolerance of ERCP are only minimally available, with studies mainly focusing on patient satisfaction [8–10]. These studies have shown that pain experienced during ERCP determines, to a great extent, patient satisfaction. However, discomfort and mental health, probably also important variables that determine the burden of ERCP, were not investigated.

In the current study, we determined the burden of ERCP using questionnaires on mental health, discomfort, pain, and symptoms during and after ERCP. Empirical data on the burden of ERCP can be used to optimize the information for patients undergoing ERCP, which may contribute to improvement of a patient's tolerance because such data enable better preparation of patients for the procedure. In addition, the data may improve practice guidelines such as provision for the type of sedation that prevents pain and discomfort as well as other types of patient support, an important issue stated by the American Society for Gastrointestinal Endoscopy (ASGE) [11].

Patients and methods

Patients

Consecutive patients referred for ERCP between November 2007 and December 2008 at two academic hospitals, the University Medical Center (UMC) Utrecht and Erasmus MC-University Medical Center Rotterdam (The Netherlands), were asked to participate in this prospective study. Both centers are large tertiary referral hospitals for therapeutic endoscopy. Patients referred from other hospitals were excluded due to the risk of incomplete follow-up data. Patients were asked to complete a questionnaire on the burden of ERCP. All the patients gave written informed consent. The study was approved by the Medical Ethical Committees of the UMC Utrecht and Erasmus MC Rotterdam.

Procedure

All the ERCP procedures were performed by experienced endoscopists assisted by a gastrointestinal training fellow according to standardized protocols. Conscious sedation

including midazolam, pethidin, and fentanyl was given to all the patients, and all were admitted overnight after ERCP.

Questionnaires and measurements

The patients were asked to complete questionnaires at three different time points. On day 0, before their ERCP, the patients completed questionnaires on their demographics, medical history, symptoms, and quality of life. On day 1, before their discharge after the ERCP, the patients filled out questionnaires on symptoms and the burden of ERCP. On day 7, only the symptoms questionnaire was completed. The occurrence and type of complications were collected when patients were still in the hospital through telephone contact with the patients on day 1 (after discharge), on day 7, and on day 30. If a complication had occurred and the patients were seen for this or readmitted, specific details were obtained from the hospital information system.

Burden of ERCP

The questionnaire on the burden of ERCP consisted of the following items: mental health, discomfort, pain, and overall burden. The mental health portion included questions on how patients felt during the ERCP. Discomfort was assessed during seven steps of the procedure: (1) the period during which the patients had nothing by mouth before ERCP, (2) the administration of conscious sedation, (3) the introduction of the endoscope, (4) the ERCP procedure itself, (5) the removal of the endoscope, (6) the recovery period (waking up after sedation), and (7) the period directly after ERCP. Pain was assessed during four steps: (1) the administration of conscious sedation, (2) the introduction of the endoscope, (3) the ERCP procedure itself, and (4) the period directly after ERCP.

The overall burden of ERCP was rated by patients describing the procedure as not burdensome, somewhat burdensome, or very burdensome. Items were adapted from earlier studies investigating the burden of upper endoscopy [7, 12, 13]. The patients were offered three response options to these questions: no, quite, and very.

Quality of life

To measure quality of life (QoL), we used the EuroQol-5D (EQ-5D), including the EQ-VAS [14]. The EQ-5D measures quality of life in six domains: mobility, self-care, usual activities, pain, anxiety and depression, and memory. The patients were offered three responses: no, some, and severe/complete limitations. The EQ-VAS is a self-classifying summary score on quality of life ranging from 0 (worst) to 100 (best). For each domain, a total score is

determined, which, using linear transformation, results in a scale ranging from 0 to 100, with a lower score on the EQ-5D and a higher visual analog score (VAS) representing a better health status.

Symptoms

The symptom questionnaire consisted of a symptom scale of eight symptoms associated with upper endoscopy to detect whether ERCP caused physical symptoms. The items included were throat ache, heartburn, regurgitation, flatulence or a bloated feeling, vomiting, hematemesis, diarrhea, and constipation. The patients were offered a scale of 0 (no symptoms) to 10 (many symptoms).

Statistical analysis

The scores for mental state, discomfort, and pain items were combined. The symptoms were compared before and after ERCP using a paired *t*-test. The association of patient and treatment characteristics (age, gender, education level, quality of life, procedure type, and previous ERCP experience) with mental state, discomfort, and pain was evaluated using the Kruskal–Wallis test for categorical variables. The Pearson correlation test was used for continuous variables, and logistic regression was used for categorical variables with two options.

All analyses were corrected for type and dosage of sedation used. Finally, each significant variable also was analyzed as a categorical variable (3 groups) to give clinicians guidance in their decision to perform an ERCP for a particular patient using general anesthesia. The association with burden of ERCP was evaluated using the Kruskal–Wallis test. A two-sided *p* value less than 0.05 was considered significant. Calculations were performed using SPSS 16 (SPSS Inc., Chicago, IL, USA).

Results

Patients

Of the 732 patients available, 276 fulfilled the inclusion and exclusion criteria of the study, and 149 (54%) of these patients returned the questionnaire. Of these 149 questionnaires, 139 could be evaluated (54% males; mean age, 60 ± 14 years). A total of 98 patients (66%) had previously undergone one or more ERCPs. The most common indications for ERCP were CBD stones (34%) and malignant or benign obstruction of the hepaticobiliary ducts (35%). The mean EQ-5D score was 17.9 ± 18.2 , and the mean VAS was 62.9 ± 18.6 on day 0.

The medications administered during ERCP included midazolam, administered to 145 patients (97%) (mean dosage, 6.6 ± 2.7 mg), combined with pethidine for 42 patients (28%) (mean dosage, 47.6 ± 16.4 mg) and with fentanyl for 104 patients (70%) (mean dosage, 0.08 ± 0.03 mg). The characteristics of the patients are shown in Table 1.

Symptoms

At baseline, the majority of patients had no overt post-endoscopy-like symptoms. However, among the 139 patients, a score of 5 or higher was reported for throat ache for 8 patients (6%), heartburn for 12 patients (9%), regurgitation for 23 patients (17%), flatulence or bloated

Table 1 General and treatment characteristics of patients receiving endoscopic retrograde cholangiopancreatography (ERCP) under conscious sedation

Characteristics measured at baseline	<i>n</i>	%	Response (<i>n</i>)
Mean age (years)	60 ± 14		149
Male (%)	81	54	149
Education (<i>n</i>)			142
None	1	1	
Primary	23	21	
Secondary	86	57	
Tertiary	32	21	
Civil status (<i>n</i>)			142
Living together/no children at home	79	55	
Living together with children	30	21	
Living alone/no children at home	28	20	
Living alone with children	5	4	
ERCP number			149
First	50	34	
Second or more	98	66	
Mean EQ-5D score		18 ± 18	142
Procedure (<i>n</i>)			149
Therapeutic	124	83	
Diagnostic	25	17	
Sedation during ERCP: <i>n</i> (mean dosage)			149
Midazolam (mg)	145 (6.6 ± 2.7)	97	
Analgesics during ERCP: <i>n</i> (mean dosage)			149
Pethidine (mg)	42 (47.6 ± 16.4)	28	
Fentanyl (mg)	104 (0.08 ± 0.03)	70	

feeling for 36 patients (26%), vomiting for 11 patients (8%), hematemesis for 2 patients (1%), diarrhea for 14 patients (10%), and constipation for 14 patients (10%). On day 1, the mean score for throat ache (0.5 on day 0 vs 2.5 on day 1; $p < 0.001$) was higher than on day 0. On day 7, throat ache was again comparable with baseline, whereas heartburn, regurgitation, flatulence, and vomiting were lower than baseline ($p = 0.01$).

Burden of ERCP: Mental health

On day 1, about 10% of the patients stated that they had experienced moderate to severe mental health problems during ERCP. More than half of the patients did not feel nervous or felt rather nervous, confused, or worried (Table 2). The patients with a higher EQ-5D score experienced more mental health problems ($p = 0.01$, Fig. 1). Analysis of EQ-5D as a categorical variable (score <7 vs $7-10$ vs >10) confirmed its significant association with mental health ($p = 0.02$).

Table 2 Mental health state of patients ($n = 140$) receiving endoscopic retrograde cholangiopancreatography (ERCP) under conscious sedation

Mental state	No <i>n</i> (%)	Rather <i>n</i> (%)	Quite <i>n</i> (%)	Very <i>n</i> (%)
I feel calm	20 (14)	46 (33)	46 (33)	28 (20)
I feel nervous	82 (59)	40 (29)	14 (10)	4 (2)
I am confused	121 (86)	14 (10)	2 (2)	3 (2)
I am relaxed	28 (20)	44 (32)	39 (28)	28 (20)
I am satisfied	24 (17)	47 (34)	46 (33)	22 (16)
I am worried	54 (38)	50 (36)	28 (20)	8 (6)

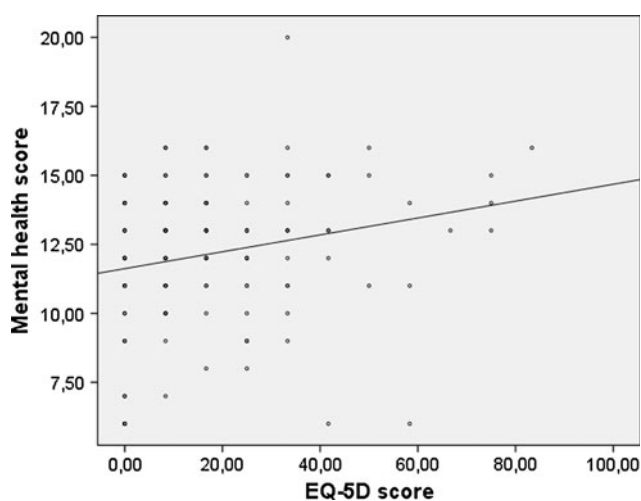


Fig. 1 Relationship between mental health and EQ-5D score according to the Kruskal–Wallis test ($p = 0.01$) for patients receiving endoscopic retrograde cholangiopancreatography (ERCP) under conscious sedation

In contrast, female gender, younger age, therapeutic ERCP, lower VAS, previous ERCP(s), and lower education level did not have a significant effect on mental health. The association of mental health with patient and treatment characteristics did not depend on type or dosage of the sedation used.

Burden of ERCP: Discomfort

Discomfort was most frequently experienced during the period when patients received nothing by mouth before ERCP (32%), during ERCP (42%), and the period directly after ERCP (37%) (Table 3). The patients experienced more discomfort during a therapeutic ERCP than during a diagnostic procedure ($p < 0.05$), and when they had a higher EQ-5D score ($p < 0.001$) or a lower VAS ($p < 0.01$). Multivariable analysis showed a significant effect only for a higher EQ-5D score ($p = 0.01$, Fig. 2).

Table 3 Discomfort of patients ($n = 142$) receiving endoscopic retrograde cholangiopancreatography (ERCP) under conscious sedation

Discomfort	No <i>n</i> (%)	Quite <i>n</i> (%)	Very <i>n</i> (%)	NA <i>n</i> (%)
Not allowed to eat or drink	92 (65)	31 (22)	14 (10)	5 (3)
Conscious sedation	124 (87)	10 (7)	5 (4)	3 (2)
Introducing the endoscope	96 (68)	27 (19)	15 (11)	4 (2)
Undergoing ERCP	79 (56)	27 (19)	33 (23)	3 (2)
Removing the endoscope	101 (71)	29 (21)	9 (6)	3 (2)
Recovering of sedation	124 (88)	9 (6)	3 (2)	6 (4)
Period after ERCP	88 (62)	32 (23)	20 (14)	2 (1)

NA not applicable

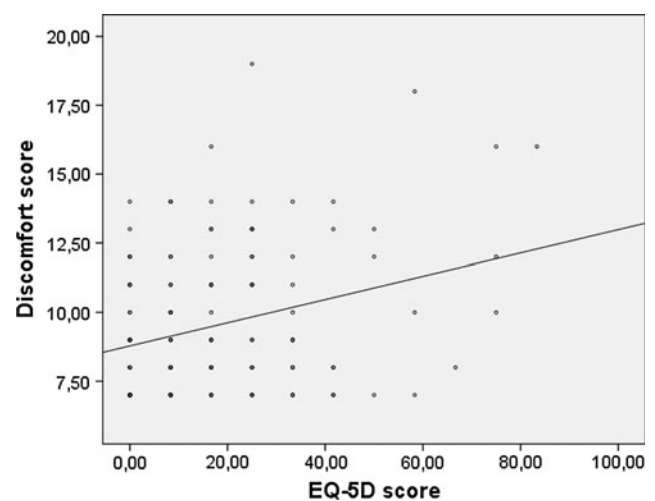


Fig. 2 Relationship between mean discomfort score and EQ-5D score according to the Kruskal–Wallis test ($p < 0.01$) for patients receiving endoscopic retrograde cholangiopancreatography (ERCP) under conscious sedation

Analysis of EQ-5D as categorical variable (score <7 vs 7–10 vs >10) confirmed its significant association with discomfort ($p = 0.03$).

Discomfort was not affected by female gender, younger age, previous ERCP(s), or lower education level. The association of discomfort with patient and treatment characteristics did not depend on the type or dosage of the sedation used.

Burden of ERCP: Pain

The patients experienced pain during the ERCP procedure (31%) and in the period after ERCP (33%) (Table 4). They experienced more pain when they had a higher EQ-5D score ($p < 0.001$), a lower VAS ($p < 0.01$), or a younger age ($p < 0.01$). Multivariable analysis showed a significant effect for a higher EQ-5D score ($p < 0.01$, Fig. 3) and a younger age ($p = 0.01$, Fig. 4). Analysis of EQ-5D (score <7 vs 7–10 vs >10) and age (>60 years vs 45–60 years vs <45 years) as categorical variables confirmed their

Table 4 Pain during and after endoscopic retrograde cholangiopancreatography (ERCP) experienced by patients ($n = 141$) receiving endoscopic retrograde cholangiopancreatography (ERCP) under conscious sedation

Pain	No <i>n</i> (%)	Quite <i>n</i> (%)	Very <i>n</i> (%)	NA <i>n</i> (%)
Conscious sedation	120 (85)	17 (12)	3 (2)	1 (1)
Introducing the endoscope	110 (78)	16 (11)	6 (4)	9 (7)
Undergoing ERCP	93 (66)	22 (16)	21 (15)	5 (3)
Period after ERCP	93 (66)	29 (21)	16 (11)	3 (2)

NA Not applicable

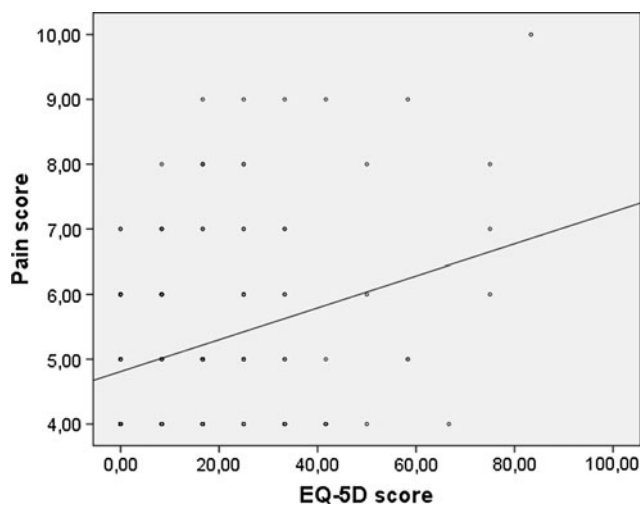


Fig. 3 Relationship between pain and EQ-5D score according to the Kruskal–Wallis test ($p < 0.01$) for patients receiving endoscopic retrograde cholangiopancreatography (ERCP) under conscious sedation

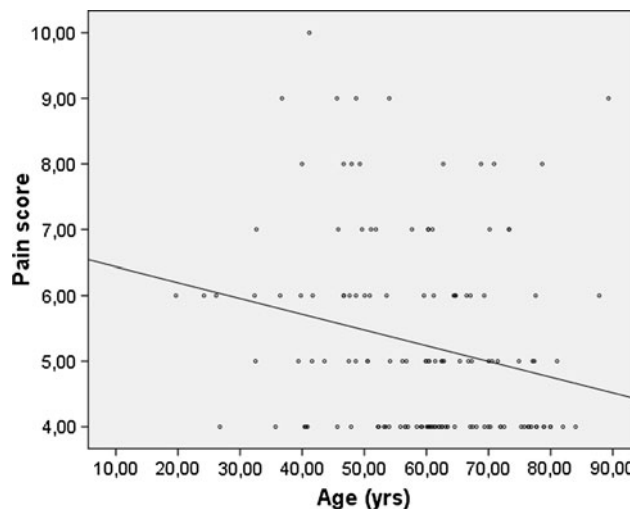


Fig. 4 Relationship between pain and age according to the Pearson correlation test ($p = 0.01$) for patients receiving endoscopic retrograde cholangiopancreatography (ERCP) under conscious sedation

significant association with pain ($p = 0.02$ and 0.02 respectively).

Pain was not affected by female gender, lower education level, therapeutic ERCP, or previous ERCP(s). The association of pain with patient and treatment characteristics did not depend on type or dosage of the sedation used.

Overall burden

Overall, 46% of the patients experienced ERCP as burdensome, with 30% rating it as “very burdensome” and 16% rating it as “quite burdensome.” The procedure received an overall score of 7.3 ± 2.0 . None of the analyzed variables had an effect on overall burden of ERCP.

Discussion

Our results show that between one-third and one-half of the patients receiving ERCP under conscious sedation experienced pain and discomfort not only during the procedure but also in the peri-procedural period. Moreover, these outcomes of the ERCP were affected by the patients’ pre-ERCP quality of life and age, as well as the type (either diagnostic or therapeutic) of ERCP procedure.

Only a few studies on the burden of ERCP are available. A previous study by Menon et al. [9] compared patient satisfaction after magnetic resonance cholangiopancreatography (MRCP) and ERCP. The patients undergoing ERCP reported significantly more pain than those undergoing MRCP. In addition, both Masci et al. [8] and Colton and Curran [10] evaluated patient satisfaction after ERCP using the standardized Group Health Association of America-9 (GHAA-9)

questionnaire. These authors found that better pain control and optimal quality of information before the ERCP positively influenced patient satisfaction. In a study on the burden of colonoscopy, patients reported a mean score of 1.20 for pain and 1.31 for discomfort on a 7-point Likert scale [15]. Although the results of the aforementioned studies cannot be extrapolated to our results, they confirm our findings that ERCP is burdensome to patients.

In our study, we found that symptoms resulting from the ERCP had disappeared 1 week after the procedure. Nonetheless, 1 day after the ERCP, throat ache still was significantly increased (mean score of 0.5 on day 0 vs 2.5 on day 1; $p < 0.01$). Kruijshaar et al. [7] found similar results for patients undergoing upper endoscopy, with more symptoms, particularly throat ache, 1 day after endoscopy compared with baseline. In many countries, ERCP is already or increasingly being performed with the patient under general anesthesia. It seems likely that this will reduce if not eliminate short-term symptoms. However, this has not been studied objectively.

Patients with higher EQ-5D scores or lower VAS, both reflecting a lower quality of life, experienced more mental health problems, discomfort, and pain during an ERCP. Findings have shown a higher EQ-5D to be common in patients with chronic or malignant disorders [16]. This may at least partly explain our findings. It can be imagined that patients expecting or having perceived after previous ERCP a greater benefit from the procedure may experience its burden as lower. In addition, the long-term prognosis of a patient may have an effect as well. This effect may differ depending on whether a patient has a poor (malignant disorder) or good (benign disorder) prognosis. In the current study, we did not evaluate patient satisfaction or the (expected) prognosis of patients.

We did however correct for post-ERCP complications, such as pancreatitis and cholangitis, because these may have led to a poor condition and may have influenced patients' perception. Although we did not measure a significant effect of complications on the burden of ERCP, probably due to the relatively small study population, it is likely that post-ERCP complications have an effect on the burden of the procedure. Therefore, it can be expected that patients with an increased risk of post-ERCP complications will benefit most from an ERCP performed under alternative sedation methods such as the use of general anesthesia or propofol. This is however unclear and needs to be elucidated in future studies.

More mental health problems, discomfort, and pain during ERCP also may be explained by the time needed for the procedure and difficulty with its performance. We found that patients undergoing therapeutic ERCP experienced more discomfort than patients undergoing diagnostic ERCP. Because a therapeutic ERCP usually involves one or more invasive procedures such as sphincterotomy, stent

placement, removal of CBD stones, and the like, these may increase the burden of ERCP. Surprisingly, multivariable analysis showed no significant effect of a therapeutic procedure on discomfort. However, the number of diagnostic procedures was low, which may well explain this finding.

Patients who underwent ERCP for the first time did not experience a higher or lower burden than those who had undergone one or more previous ERCs. In contrast, Essink-Bot et al. [16] found that patients who had undergone previous surveillance endoscopies for Barrett's esophagus experienced less discomfort, pain, and overall burden than patients who underwent upper endoscopy for the first time. They suggested that these previous surveillance endoscopies had resulted in an adaptation to the procedure. In contrast, our results showed that repeat ERCP still gave anxiety and distress to patients, probably because the patients did not expect the same health benefit as those undergoing surveillance endoscopy for Barrett's esophagus.

Younger patients experienced ERCP as more painful than older patients. A possible explanation could be that the esophageal closure reflex is less pronounced in older patients, making the introduction of the endoscope easier and resulting in less pain [17]. In addition, older patients may be more relaxed than younger patients when undergoing ERCP due previous life experiences.

A limitation of this study was that the questionnaires were completed only by patients who were not severely ill. First, we were not able to include patients with severe cholangitis because these patients often were not able to give informed consent. Second, a positive or a negative outcome for the ERCP procedure may have affected the experiences reported by the patients. Unfortunately, this information was not available, and we did not measure patients' expectations of the ERCP before and after the procedure to correct for this. Third, it would also be of interest to compare mental health, pain, and discomfort during and after ERCP with that before ERCP, but again, we did not measure this in the current study.

In conclusion, our results show that one-third to one-half of patients undergoing ERCP experience discomfort and pain during and after the ERCP procedure under conscious sedation. The burden of ERCP is particularly increased when patients are younger (<45 years), experiencing a suboptimal quality of life (EQ-5D >10), or undergoing a therapeutic ERCP. General anesthesia may improve patients' tolerance in at least these subgroups of patients, although narcotics also have several disadvantages and lead to increased medical costs. Alternatively, a patient's perception may be improved by using adequate combinations of fentanyl and midazolam or propofol and by introducing the endoscope only when an optimal sedative effect is achieved [18–21]. We recommend performing randomized trials to investigate the effect of different

sedation strategies on a patient's perception before, during, and after ERCP.

Disclosures S. M. Jeurnink, E. W. Steyerberg, E. J. Kuipers, and P. D. Siersema have no conflicts of interest or financial ties to disclose.

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