## Appendix

# The Questionnaire

1. **In general, are you satisfied with the endoscopic treatment?**

   ☐ yes
   ☐ no

2. **Did you find the examination to be painful?**

   ☐ no
   ☐ yes, but only slightly painful
   ☐ moderately painful
   ☐ very painful

3. **Did you experience pain or other discomfort after the examination? ***

   ☐ no
   ☐ yes, but only minimal pain
   ☐ moderate pain
   ☐ severe pain

   a. **If you answered "yes" on question #3, please indicate the duration of the pain**

      ☐ less than one hour
      ☐ 1–3 hours
      ☐ 3–6 hours
      ☐ more than 6 hours

4. **Are you satisfied with information provided regarding the examination? ****

   ☐ yes
   ☐ not quite
   ☐ no

* Patients were invited to explain or describe additional problems in greater detail on the back side of the sheet.

** Patients were invited to explain or describe additional problems in greater detail on the back side of the sheet and were also asked to suggest improvements.

**Table 1. Demographics and characteristics of 2808 ERCP procedures**

| Variable | Procedures N = 2808 (% of total) | Responders N = 1477 (% within each variable) | Non-Responder N = 1331 (% within each variable) | *P* value* |
|---|---|---|---|---|
| **Sex** | | | | 0.996 |
| Male | 1253 (44.6) | 658 (52.5) | 595 (47.5) | |
| Female | 1546 (55.1) | 812 (52.6) | 734 (47.4) | |
| Not reported | 9 (0.3) | | | |
| **Age-groups** | | | | 0.148 |
| < 30 years | 104 (3.7) | 56 (53.8) | 48 (46.2) | |
| 30 - 49 years | 374 (13.4) | 207 (53.3) | 167 (44.7) | |
| 50 - 69 years | 812 (29.0) | 430 (53.0) | 382 (47.0) | |
| 70 - 89 years | 1379 (49.3) | 722 (52.4) | 657 (47.6) | |
| > 90 years | 130 (4.6) | 55 (42.3) | 75 (57.7) | |
| **ASA score** | | | | **< 0.001** |
| 1 | 650 (23.1) | 379 (58.3) | 271 (41.7) | |
| 2 | 1270 (45.2) | 724 (57.0) | 546 (43.0) | |
| 3 | 756 (26.9) | 328 (43.4) | 428 (56.6) | |
| 4/5 | 90 (3.2) | 22 (24.4) | 68 (75.6) | |
| Not reported | 42 (1.7) | | | |
| **Procedure time**** | | | | **0.004** |
| 0 - 20 minutes | 1081 (38.5) | 590 (54.6) | 491 (45.4) | |
| 21 - 40 minutes | 1025 (36.5) | 555 (54.1) | 470 (45.9) | |
| 41 - 60 minutes | 464 (16.5) | 214 (46.1) | 250 (53.9) | |
| > 60 minutes | 162 (5.8) | 74 (45.7) | 88 (54.3) | |
| Not reported | 76 (2.7) | | | |
| **Procedure***** | | | | |
| Sphincterotomy of the bile duct | 1525 (54.4) | 856 (56.1) | 669 (43.9) | **< 0.001** |
| Treatment of CBDSs | 1215 (43.4) | 699 (57.6) | 516 (42.4) | **< 0.001** |
| Dilatation of the bile duct | 25 (0.9) | 17 (68) | 8 (32) | 0.119 |
| Placement of stent in the CBD | 790 (28.1) | 381 (48.2) | 409 (51.8) | **0.005** |
| Placement of self-expanding stent | 92 (3.2) | 48 (52.2) | 44 (47.8) | 0.975 |
| Exchange of stent in the CBD | 303 (10.8) | 135 (44.6) | 168 (55.4) | **0.004** |
| Removal of stent of the CBD | 183 (6.5) | 101 (55.2) | 82 (44.8) | 0.448 |
| Taking specimen from the CBD | 232 (8.3) | 127 (54.7) | 105 (45.3) | 0.472 |
| Emergency ERCP | 56 (2.0) | 74 (51.4) | 33 (58.9) | 0.081 |
| Pre-cut sphincterotomy | 144 (5.1) | 1018 (53.2) | 70 (48.6) | 0.875 |
| Guide-wire for cannulation | 1912 (68.1) | 313 (49.4) | 894 (46.8) | 0.110 |

* *P* values apply to comparisons between responders and non-responders.
** Median procedure time was 25 minutes (IQR 18 - 40).
*** Several therapeutic procedures may have been performed during a single ERCP procedure.

**Table 2. Evaluation of risk for moderate to severe pain during the ERCP procedure by a multivariable regression analysis**

| Risk factors* | n/N** | *P* value | Adjusted OR | 95% CI for OR |
|---|---|---|---|---|
| **Gender** | | | | |
| Male | 154/644 | | 1.00 | reference |
| Female | 272/801 | **< 0.001** | 1.83 | 1.41 - 2.37 |
| **Procedure time** | | **< 0.001** | | |
| 0-20 minutes | 129/580 | | 1.00 | reference |
| 21-40 minutes | 163/542 | **0.078** | 1.30 | 0.97 - 1.75 |
| 41-60 minutes | 88/213 | **< 0.001** | 2.67 | 1.83 - 3.91 |
| > 60 minutes | 32/74 | **0.009** | 2.09 | 1.20 - 3.63 |
| **Biliary EPT performed** | | | | |
| No | 106/603 | | 1.00 | reference |
| Yes | 266/842 | **0.013** | 1.40 | 1.07 - 1.83 |

*The sedation regimen (*P = 0.015)*, including the combined or single use of midazolam, diazepam and pethidine, and ERCP hospital ($P < 0.001$) were also independent risk factors for pain during the procedure.
** Proportion according to category (1405 cases included in analyses).

**Table 3. Evaluation of risk factors for moderate to severe pain after the ERCP procedure by multivariable regression analysis**

| Risk factors* | n/N | *P* value | Adjusted OR | 95% CI for OR |
|---|---|---|---|---|
| **Gender** | | | | |
| Male | 102/643 | | 1.00 | reference |
| Female | 166/805 | **< 0.001** | 1.41 | 1.04 -1.91 |
| | | | | |
| **Age group** | | **< 0.001** | | |
| < 30 years | 15/54 | | 1.00 | reference |
| 30-49 years | 58/205 | 0.720 | 1.14 | 0.55 - 2.39 |
| 50-69 years | 84/427 | 0.311 | 0.69 | 0.34 - 1.41 |
| 70-89 years | 104/709 | **0.041** | 0.48 | 0.23- 0.97 |
| > 90 years | 7/53 | **0.016** | 0.22 | 0.06 - 0.75 |
| | | | | |
| **Hospital category** | | **0.010** | | |
| University hospital | 84/354 | | 1.00 | reference |
| Central hospital | 157/926 | **0.003** | 0.540 | 0.36 - 0.81 |
| General community hospital | 28/175 | 0.450 | 0.794 | 0.44 - 1.45 |
| | | | | |
| **Metal stent** | | | | |
| No | 243/1336 | | 1.00 | reference |
| Yes | 16/48 | **0.001** | 1.44 | 1.15 - 1.80 |
| | | | | |
| **Biliary pre-cut** | | | | |
| No | 237/1316 | | 1.00 | reference |
| Yes | 22/73 | **0.007** | 2.29 | 1.26 - 4.17 |
| | | | | |
| **Guide-wire use** | | | | |
| No | 59/413 | | 1.00 | reference |
| Yes | 205/1004 | **0.007** | 1.67 | 1.15 - 2.42 |
| | | | | |
| **Post-ERCP pancreatitis** | | | | |
| No | 242/1416 | | 1.00 | reference |
| Yes | 27/39 | **< 0.001** | 10.59 | 4.93 – 22.72 |
| | | | | |
| **Post-ERCP cholangitis** | | | | |
| No | 251/1413 | | 1.00 | reference |
| Yes | 18/42 | **< 0.001** | 5.17 | 2.52 - 10.60 |

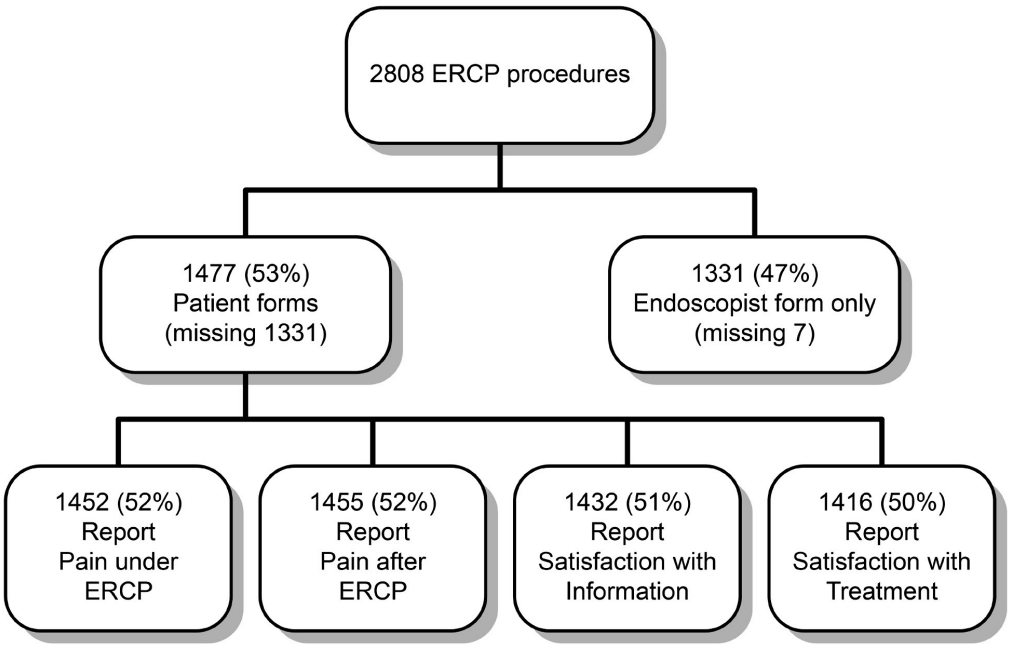
*The sedation regimen (*P = 0.002)*, including the combined or single use of midazolam, diazepam and pethidine, was an independent risk factor for pain after the procedure.

## Figure legend

**Figure 1.**

Flow chart used to describe completeness of patients´ responses following 2808 procedures

**Figure 1.**


2808 ERCP procedures
1477 (53%)
Patient forms
(missing 1331)
1331 (47%)
Endoscopist form only
(missing 7)
1452 (52%)
Report
Pain under
ERCP
1455 (52%)
Report
Pain after
ERCP
1432 (51%)
Report
Satisfaction with
Information
1416 (50%)
Report
Satisfaction with
Treatment