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Research article

# Surgery A survey of patients' perceptions and experiences of intervention for gallstone disease during pregnancy



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#### ARTICLE INFO

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#### ABSTRACT

*Background:* Gallstones intervention during pregnancy might be a stressful event for both mother and fetus and stress might affect outcome. The aim of this study was to identify factors that might improve the care of pregnant patients in need of intervention for gallstone disease.

*Methods:* By crossmatching the Swedish Registry of Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks) and the Swedish Medical Birth Registry, we identified patients with gallstone intervention during pregnancy. A questionnaire covering patient experience before, during and after surgery and the Beck Depression Inventory II (BDI-II) were distributed.

**Results:** In total, 275 patients subjected to cholecystectomy, endoscopic retrograde cholangiopancreatography (ERCP) or both were identified, and 146 (54%) patients responded. Surgery was in median performed in pregnancy week 16 (12–20), and 62 (42%) patients had symptoms of gallstone disease before pregnancy, with 17 of these patients scheduled for surgery before pregnancy. Thirty-four (24%) patients felt that the information regarding the upcoming surgery was inadequate, with differences comparing patients with overall favorable versus overall non-favorable experiences (103 (89%) vs. 8 (27%) p < 0.001) and similar differences regarding information on disease/symptoms (95 (84%) vs. 12 (43%), p < 0.001). A majority (57%) were very worried about their expected child, and 51% thought that no measures were taken to relieve their worries. Recurring as suggested improvements was more information about the disease and the surgical procedure.

*Conclusion:* Intervention due to gallstone disease during pregnancy is a stressful event that impacts many patients negatively, both before and after surgery. Patient education might positively affect patient experience.

#### 1. Introduction

Nonobstetric surgery occurs in 1–2% of all pregnancies [1]. After appendectomies, cholecystectomy is the second most common procedure, with an incidence of 0.05% and an increasing trend [1, 2]. Previously avoided because of safety concerns, endoscopic retrograde cholangiopancreatography (ERCP) has recently become more frequently used during pregnancy [3, 4]. Gallstone complications such as cholecystitis, pancreatitis or choledocholithiasis are potentially dangerous to the fetus. With a growing body of knowledge concerning the safety of cholecystectomies and ERCP during pregnancy, these procedures are expected to increase [5].

Prenatal stress is a known factor that might negatively affect pregnancy outcome measures ranging from lower birth weight and gestational age to behavioral problems and neuropsychiatric disorders [6, 7].

Acute medical conditions and surgery are serious events in any patient's life that might trigger stress reactions and even depression, affecting not only the general wellbeing of the patients but also postoperative outcomes [8]. There is reason to believe that nonobstetric surgery during pregnancy might impact the psychological wellbeing of the pregnant patient, possibly affecting both pregnancy outcome and postpartum wellbeing and even the conditions for the expected child. To the authors' knowledge, the psychological impact of surgery during pregnancy has not been studied previously.

The aim of this study was to retrospectively evaluate the subjective experience of patients who have undergone gallstone intervention during pregnancy using a targeted questionnaire and the Beck Depression Inventory II (BDI-II), to identify important areas with a possibility for improvement in care.

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Table 1. Comparison of responders and non-responders.

	$\begin{array}{l} Responders \\ N=146 \end{array}$	$\begin{array}{l} Non\text{-responders} \\ N=129 \end{array}$	p-Value
Age at time of surgery	38 (33–41)	35 (32–40)	0.004
Age at intervention	31 (27–35)	28 (25–33)	0.002
Time from surgery to survey (months)	75 (57–99)	74 (55–99)	0.865
LOS (days)	1 (1–2)	2 (1–2)	0.226
Number of procedures >1	24 (16%)	10 (8%)	0.029
Any adverse event (yes)	13 (9%)	7 (5%)	0.268

Data is presented as absolute number (percentage) for categorical variables and median (interquartile range) for continuous variables. N, number of available data.

#### 2. Materials and methods

By searching the Swedish Registry of Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks) and crossmatching the entries with the Swedish Medical Birth Registry (https://www.socialstyrelsen.se/en/statistics-and-data/registers/registe r-information/the-swedish-medical-birth-register/), we were able to identify 277 pregnant patients (including two twin pregnancies) in both registries. We excluded one patient who was deceased and one patient whose child was deceased. The 275 remaining patients were subjected to cholecystectomy (n = 223), ERCP (N = 18) or both (N = 34) between January 1, 2009, and March 12, 2016. A questionnaire with 35 questions, comprising simple yes/no questions, multiple choice questions and free text questions was constructed, covering baseline data, pre-pregnancy status, experience of pregnancy and gallstone disease, experience of birth, immediate postpartum period and current status (Supplement 1). There were no questions regarding socioeconomic status or race. Great care was taken to formulate the questions to ensure that they were easily answered and covered most aspects of pregnancy and disease. The questionnaire and the Beck Depression Index II (BDI-II) were sent by mail with a prepaid return envelope [9]. In the cover letter, patients were instructed to prioritize the question-naire and omit the BDI-II if it felt more comfortable. For nonresponders, an additional two mailings were sent, and finally attempts were made to reach the patients by phone. Data collection was performed between March 1 and September 31, 2019. Text answers were scrutinized individually by both authors (JH, BA) to minimize the risk of misinterpretation. All answers were anonymous to the authors, and no information about surgical outcome was linked to the respondents at this stage. The answers were then entered into a database and linked to register parameters from GallRiks.

One of the questions was on the overall experience with the care, graded as very good, good, neutral, poor or very poor. By combining the two satisfied categories and the two dissatisfied categories, we divided the patients into two groups and compared parameters between them. No patients answered "neutral" on this question.

Missing data for items in the questionnaire were handled by omitting these data, and calculations were made on available data. Incomplete BDI-II questionnaires (n = 6) were excluded.

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist was used during the study design and manuscript write up.

#### 2.1. Statistical analysis

Descriptive data are presented as number (n) and percentage (%) and median and interquartile range (IQR), as appropriate. Differences between groups were evaluated by Chi<sup>2</sup> test for categorical variables and Mann–Whitney U-test for continuous variables.

All statistical analysis were two-sided. A p value < 0.05 was considered significant. Statistical analysis was performed using Stata MP statistical package version 14.1, 2015 (StataCorp LP, College Station, Texas, USA).

The Regional Ethics Committee in Lund approved the study (Dnr 2014/177).

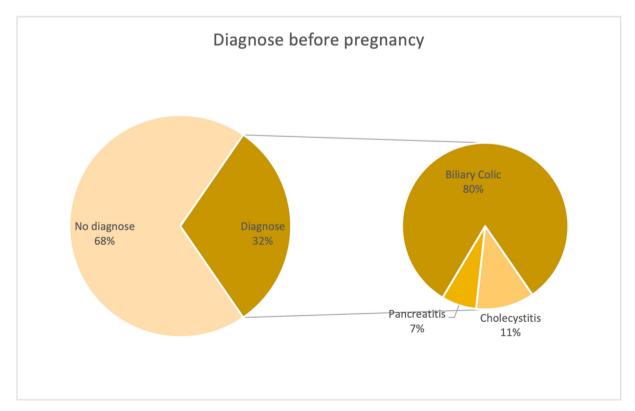


Figure 1. Frequency of patients with known gallstones prior to pregnancy, frequency of gallstone related symptoms/disease before pregnancy.

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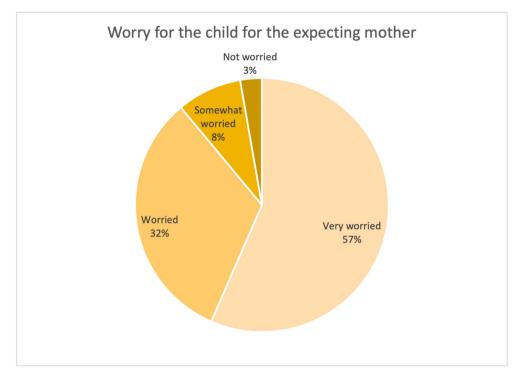


Figure 2. Frequency of degree of worry for the child for the expectant mother.

#### 3. Results

A total of 146 (53%) patients answered the survey. An analysis was performed comparing responders and nonresponders. Differences were seen in age, both at surgery and survey, and with a higher frequency of postoperative complications in the responders' group (Table 1). Completion of the BDI-II was made by 113 patients (41% of all patients, 77% of questionnaire responders).

Some items had missing data in the questionnaire, and the completion of specific items was between 94% (n = 137) and 100% (n = 146).

Of the responders, 113 (77%) patients were subjected to only cholecystectomy, and 15 (10%) were subjected to cholecystectomy and intraoperative ERCP. Four patients underwent postoperative ERCP, one

patient underwent preoperative ERCP, and four patients underwent two ERCP procedures in addition to cholecystectomy. ERCP as the only intervention was performed in 9 (6.2%) patients. Laparoscopic technique were used in 116 (85%) of the cholecystectomies, and 20 (15%) patients underwent open surgery. No conversion from laparoscopic to open surgery took place. No intraoperative complications were recorded, and 13 (8.9%) patients had one or more complications recorded at the 30-day follow-up.

The median (IQR) time for symptom debut was pregnancy week 12 (7–17). The frequency of symptom debut per trimester was as follows: 1st trimester (weeks 0–13) 57% (n = 80), 2nd trimester (weeks 14–26) 38% (n = 54) and 3rd trimester (27–40) 5% (n = 7). The median pregnancy week of surgery was 16 (12–20), the 1st trimester was 33% (N = 48), the

Table 2. Patients that were overall positive compared to patients that were overall negative with the general care.\*

	N	Overall positive $N=116$ (82%)	Overall negative $N=26$ (18%)	P
Age at treatment	142	31 (27–34)	30 (27–34)	0.638
Age at survey	142	38 (33.5–41.5)	36 (33–40)	0.617
Pregnancy week	142	16 (12–20)	17.5 (14–20)	0.490
BDI-II score	111	9 (2–19.5)	6.5 (1–16)	0.384
Sick leave (yes)	138	80 (70%)	15 (60%)	0.351
Total sick leave (days)	125	11 (0–21)	14 (1.5–41)	0.317
Affecting wish for future children (yes)	137	12 (11%)	7 (27%)	0.032
Measurements to relieve worry (yes)	136	56 (50%)	12 (48%)	0.825
Sufficient information on surgical procedure (yes)	137	95 (84%)	10 (42%)	< 0.001
Sufficient information on disease/symptoms (yes)	142	103 (89%)	5 (19%)	< 0.001
Things could have been done better (yes)	136	39 (35%)	22 (85%)	< 0.001
Time from surgery to survey (months)	142	75 (58–99.5)	77.5 (50–101)	0.881
Any postoperative complication (yes)	142	8 (7%)	5 (19%)	0.049
No procedures >1	142	20 (17%)	3 (11%)	0.881
Time from decision to surgery >7 days	140	49 (43%)	15 (58%)	0.174

Data is presented as absolute number (percentage) for categorical variables and median (interquartile range) for continuous variables. N, number of available data. Abbreviations: BDI-II; Becks Depression Index II.

<sup>\*</sup> Patients that answered "good" or "very good" were considered positive, patients that answered "poor" or "very poor" were considered negative.

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**Table 3.** Patients with no symptoms of depression (Becks Depression Index II score between 0 and 13) compared to patients with any symptom of depression (Becks Depression Index II score 14–54).

N BDI-II score 0-13 N = 76 (67		
110 215 (275 245)		
Age at treatment (years) 113 31.5 (27.5–34.5)	) 32 (26–35) 0.8	.897
Age at survey (years) 113 38 (34–41)	37 (32–43) 0.9	.976
Pregnancy week (weeks) 113 15.5 (11–20)	17 (13–20) 0.5	.561
Sick leave (yes) 110 56 (76%)	21 (58%) 0.0	.063
Total sick leave (days) 102 10 (1.5–21)	10 (0–28)	.779
Affecting wish for future children (yes) 109 12 (16%)	9 (25%) 0.4	.419
Measurements to relieve worry (yes) 111 38 (51%)	14 (38%) 0.3	.179
Sufficient information on surgical procedure (yes) 110 62 (84%)	23 (64%) 0.0	.019
Sufficient information on disease/symptoms (yes) 113 64 (84%)	24 (65%) 0.0	.020
Things could have been done better (yes) 109 32 (43%)	19 (54%) 0.2	.281

Data is presented as absolute number (percentage) for categorical variables and median (interquartile range) for continuous variables. N, number of available data. Abbreviations: BDI-II; Becks Depression Index II.

2nd trimester was 58% (N = 85) and the 3rd trimester was 8.9% (N = 13)

Of all patients, 62 (42%) had experienced symptoms of gallstone disease before pregnancy. Almost one-third were diagnosed with gallstones (n = 47, 32%) prior to their pregnancy. Of these patients, the symptoms were pain/biliary colic in 36 (80%) patients, cholecystitis/cholangitis in 5 (11%) patients, and acute pancreatitis in 3 (6.6%) patients (Figure 1). A majority (n = 26, 55%) with a diagnosis had discussed surgery with their physician before pregnancy, and 17 (71%) of those patients were scheduled for surgery.

During pregnancy, the waiting time from the onset of symptoms until the decision to undergo surgery was >7 days in 65 (45%), 2–7 days in 33 (23%) and less than 2 days in 45 (31%).

Almost a quarter (35, 24%) did not think they were provided with enough information about their condition preoperatively, and an equal number (34, 24%) felt that information about the upcoming surgical procedure was inadequate.

A majority of 82 patients (57%) were very worried about their expected child, and only 4 (2.8%) were not worried (Figure 2).

Approximately half of the patients, 70 (51%), experienced that no certain measurements were taken to relieve them from their worries, and the most common free text answer on what they would have wanted was more information from surgeon/medical staff and, to a lesser extent, more follow-up.

Almost half of the patients, 63 (45%), were of the opinion that "things could have been done better". In the free text answers following this question, we recurrently noted a wish for a better and more thorough conversation with the surgeon and/or other medical staff, as well as an appeal for fetal examination with ultrasound.

A majority of patients (103, 73%) were not able to work because of the symptoms of gallstone disease and/or surgery. The median (IQR) time of sick leave was 7 (4–14) days for 49 (48%) patients on sick leave before surgery. The median (IQR) time of sick leave after surgery was 14 (7–21) days for the 89 (86%) patients in this group. Thirty-five (34%) patients were on sick leave both before and after surgery. The total median (IQR) sick leave time in this group was 14.5 (8–28) days.

Modes of delivery were normal vaginal birth in 74% (n = 103), assisted vaginal birth (suction or forceps) in 7.1% (n = 10), planned cesarian section in 11% (n = 15) and emergency cesarian section in 9.2% (n = 13). Only 14 (10%) patients felt that the actual birth was affected by the gallstone disease/procedure.

In the postpartum period, 24 (17%) patients thought much or very much about the surgical procedure that occurred during pregnancy. When asked if the patients thought that their child was affected by the procedure, 81 (57%) did not think it was affected, 27 (19%) thought it was somewhat affected, 3 (2.1%) thought it was much affected, 7 (4.9%) thought it was very much affected and 25 (17%) thought it was uncertain.

At the time of the survey, 41 (28%) patients were still having gallstone-related symptoms, and 28 (20%) were still experiencing some issues related to the surgical procedure. Almost half (65, 45%) were still thinking about the gallstone-related issues they had during pregnancy, and 19 (13%) answered that their experience affected their wish for more children.

The answers to the question on overall experience with care were as follows: 49 (35%) patients graded it very good, 67 (47%) good, 0 neutral, 13 (9.1%) poor and 13 (9.1%) very poor. No answer was given by four patients, which we excluded. Combining these categories put 116 (82%) patients in the positive group and 26 (18%) in the negative group. Comparing these two groups showed significant differences in satisfaction with the information given (Table 2).

Common free text answers about general care regarded the feeling of not being taken seriously, delayed diagnosis and treatment due to misinterpretation of symptoms and difficulty in differentiating symptoms of gallstone disease from normal pregnancy-related issues.

The median (IQR) BDI-II score was 8 (2–18), with a range from 0 to 54. No depression (score 0–13) was detected in 76 (67%), mild depression (score 14–19) in 10 (8.8%), moderate depression (score 20–28) in 13 (11%) and severe depression (score 29–63) in 14 (12%). Comparing the group scoring 0–13 (no depression) with the group scoring 14–54 (mild to severe depression) showed similar results regarding overall satisfaction, but significant differences were noted for the opinion of whether sufficient information was given, both related to the disease (n = 64 (84%) vs. n = 24 (65%), p = 0.020) and the planned procedure (n = 62 (84%) vs. n = 23 (64%), p = 0.019) (Table 3).

#### 4. Discussion

In this study, we found that a majority of patients subjected to cholecystectomy and/or ERCP during pregnancy worried about their child being affected negatively by the procedure and experienced that medical professionals made too little effort to meet their needs. A substantial portion of the women felt that they received inadequate information about both their condition and the upcoming surgery. In retrospect, almost half is of the opinion that things could have been done better by the medical professionals.

Suggested improvements in the free text answers were a wish for more knowledge and awareness about gallstone disease in pregnancy by health-care providers. Patients in general wanted more information about disease and treatment. Additionally, a postoperative fetal ultrasound, more follow-up and more attention to the psychological impact of surgery during pregnancy are desired.

The main adjustable factor seems to be lack of preoperative information about the disease, the procedure and specifically the impact of

these on the fetus, thus providing us a possibility to improve care of pregnant patients in need of surgery.

A third of the patients in our study were diagnosed with bile stones prior to pregnancy, and 17 were scheduled for surgery. For these patients, surgery during pregnancy might have been avoided if they had been given higher priority for intervention before pregnancy.

It is known from the literature and previous studies that general preoperative anxiety levels vary greatly depending on the patient group, underlying disease, type of anesthesia and procedure [10]. It is estimated that 25–80% experience some degree of anxiety preoperatively [11]. Female gender is generally considered a risk factor for elevated levels of anxiety preoperatively [12, 13]. Young age has also shown significance as a risk factor in some studies, although contradictory results exist [11]. Both of these risk factors were present in the pregnancy group, and additional worry about the fetus in 97% of our study group probably contributed to higher preoperative anxiety levels.

Postoperative subjective outcome following laparoscopic cholecystectomy is a complex issue, especially regarding the term "post-cholecystectomy syndrome". Some persistent gastrointestinal symptoms are present in 5–47% of patients after cholecystectomy in the general population [14]. In our survey, 20% and 28% were still having symptoms of gallstone disease or surgery, respectively. This study was not specifically designed to capture postoperative symptoms, so this number should be seen more as a general sign of incomplete satisfaction with the procedure.

The fact that 45% of our patients were still thinking about the biliary procedure they underwent during pregnancy at the time of survey and that it affected the wish for more children in 13% shows the impact this benign disease has for this patient group. This information hopefully can be used as a wake-up call to health care professionals to strengthen the information and care during a pregnancy that is complicated by gallstone problems.

Several different strategies have been proposed to overcome or modulate preoperative anxiety. Among these are the identification of patients at risk of developing anxiety using proper instruments, such as the VAS-A (Visual Analog Scale – Anxiety) or APAIS (The Amsterdam Preoperative Anxiety and Information Scale) [12, 15]. As previously mentioned, pregnant patients subjected to nonobstetric surgery are probably at higher risk of having preoperative anxiety, and even without structured questionnaires, a high rate of suspicion that the pregnant patients have some preoperative anxiety should be acknowledged. Preoperative information has been shown to be beneficial in reducing preoperative anxiety [16, 17]. An individual assessment of specific patients' need for expanded information should be performed, and surgeons, anesthesiologists, nurses, midwives and other medical staff should be properly educated about surgery during pregnancy [11].

The prevalence of some degree of depression (BDI-II scores >14) was 33% in our study. In a study by Arnau et al. (2001) of BDI-II in a primary health care setting, depression was prevalent in 23.2% of all patients, male and female, aged 18–74, with a higher mean BDI-II score for women. A large study of college students by Whisman et al. (2015) showed a median BDI-II score of 7, close to the median of 8 in our group [18].

Fetal ultrasound is routinely performed after surgery in pregnancy in the authors' hospital, but there are no national guidelines, and the availability may vary locally. It seems to be welcomed by the pregnant patients as a reassuring measure and was repeatedly asked for in the free text answers.

Comparing the mode of delivery in the general population in Sweden with our group, the incidence is similar, with normal vaginal birth in 76% versus 73%, cesarean section in 18% versus 20% and instrumental assisted birth in 6% versus 7% [19].

#### 5. Limitations

Despite efforts to increase the response rate, it was relatively low. A low response rate might make the results unreliable. There is a possibility of nonresponse bias due to differences in the responders and nonresponders in factors such as socioeconomic status and physical and mental health [20]. Age at intervention and age at survey differed between responders and nonresponders, possibly affecting the results. The time from surgery to completion of the questionnaire varied between 37 and 123 months. Although the time was similar between responders and nonresponders, time itself may have affected the perception of the care given. Interpretation of our patient scores in the BDI-II needs to be taken cautiously. Cutoff limits of no, mild, moderate and severe depression are taken from the original manual. There are, however, reasons to assume that these cutoff levels are affected by demographics and setting-specific factors that make them unreliable for general use [9, 21].

#### 6. Conclusion

To our knowledge, this is the first study of patient experience of gallstone intervention in pregnancy. Gallstone disease during pregnancy is a serious event that might impact not only the physical but also the psychological wellbeing of the patients and thus possibly the outcome. Our study shows that patients are concerned about the risks of surgical intervention and that the suggested solution to this is more information. Patient education is a low-cost intervention that can affect the patient experience. Surgeon and staff education on surgery during pregnancy should be considered.

## Two-sentence article summary

Pregnant patients undergoing intervention for bile stone disease were identified in a national database and answered a survey on perceptions and experience of the care received. The importance of this study is to identify patient factors that might be improved for this patient group, and by doing so, possibly improve outcome for mother and child.

The difference between the groups with no depressive symptoms (measured by BDI-II scores) and the group with any depressive symptoms regarding the information given should be interpreted as an example of how individual differences in psychiatric status might affect the need for more information. No reliable conclusions about causality between BDI-II scores and previous gallstone surgery during pregnancy can be drawn from our data.

#### **Declarations**

#### Author contribution statement

Jonas Hedström and Bodil Andersson: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the

data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

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#### Data availability statement

Data will be made available on request.

#### Declaration of interest's statement

The authors declare no conflict of interest.

#### Additional information

Supplementary content related to this article has been published online at https://doi.org/10.1016/j.heliyon.2022.e11184.

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