**Journal of Cardiovascular Disease Research**

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

**ORIGINAL RESEARCH**

# A multi centre comparative study of interval cholecystectomy versus early cholecystectomy for obstetric cholecystitis

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Received: 2nd November, 2023 Accepted: 10th December, 2023

**Abstract**:

Background:

Cholecystitis during pregnancy poses a significant medical challenge, necessitating a careful examination of optimal management strategies. This multi-center comparative study investigates the efficacy and safety of interval cholecystectomy versus early cholecystectomy for obstetric cholecystitis, encompassing both antenatal and postpartum periods. The study focuses on women aged 22 to 35 years, aiming to provide comprehensive insights into the outcomes associated with these surgical approaches.

Materials and Methods:

This multi-center study involves a diverse cohort of women aged 22 to 35 years, diagnosed with obstetric cholecystitis. The participants will be recruited from Karpagam faculty of medical sciences and research, Nalan Gastro Centre and One care medical centre, Karpagam, Coimbatore, ensuring a representative sample reflecting the broader population. Patients will be randomly assigned to either the early cholecystectomy group or the interval cholecystectomy group. Baseline characteristics, including age, gestational age, and medical history, will be recorded. The primary outcome measures include surgical complications, maternal morbidity, and fetal outcomes. For antenatal cholecystitis, participants in the early cholecystectomy group will undergo surgery during pregnancy, while those in the interval cholecystectomy group will receive conservative management initially, with surgery scheduled postpartum. In the postpartum cholecystitis arm, early cholecystectomy will be performed within the first few days after delivery, while the interval cholecystectomy group will receive conservative management initially, with surgery scheduled at a later postpartum period. Data will be collected regarding the incidence of complications such as preterm labor, fetal distress, and maternal complications. Surgical outcomes, including operative time, blood loss, and postoperative recovery, will be meticulously documented.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

**Results:**

Preliminary analysis reveals that both early and interval cholecystectomy demonstrates favorable outcomes in terms of maternal and fetal well-being. The early cholecystectomy group exhibits a lower incidence of acute complications during pregnancy, such as preterm labor and fetal distress, suggesting that timely surgical intervention may mitigate the progression of the disease. On the other hand, the interval cholecystectomy group demonstrates a lower overall incidence of surgical complications, emphasizing the safety of delaying surgery until after delivery. This group also shows a reduced rate of postoperative morbidity, indicating that deferring cholecystectomy does not compromise maternal health. Operative times are comparable between the two groups, dispelling concerns regarding prolonged surgery during pregnancy. Blood loss is also within acceptable limits for both cohorts. Postoperative recovery is generally uneventful, with no significant differences observed in terms of hospital stay and time to return to normal activities.

Conclusion:

In conclusion the findings suggest that early cholecystectomy may be particularly beneficial in reducing acute complications during pregnancy, providing a timely resolution to the inflammatory process. On the other hand, interval cholecystectomy appears to be a safe alternative, avoiding surgery during pregnancy and demonstrating favorable postoperative outcomes.

Keywords:

Obstetric cholecystitis, early cholecystectomy, interval cholecystectomy, antenatal cholecystitis, postpartum cholecystitis, maternal morbidity, fetal outcomes, surgical complications, pregnancy, gallbladder.

## Introduction

In recent years, the management of cholecystitis during pregnancy has become a subject of increased attention within the medical community, given its potential impact on both maternal and fetal health. Cholecystitis, characterized by inflammation of the gallbladder, poses unique challenges when occurring in the obstetric population, necessitating a careful evaluation of optimal treatment strategies. The traditional approach of early cholecystectomy, considered the standard of care, has raised concerns regarding the potential risks associated with surgery during pregnancy, leading to the exploration of alternative interventions such as interval cholecystectomy. This multi-center comparative study aims to contribute valuable insights into the effectiveness and safety of these surgical approaches, focusing on women aged 22 to 35 years and encompassing both antenatal and postpartum periods.The choice between early and interval cholecystectomy warrants thorough examination, considering the diverse physiological changes occurring during pregnancy and postpartum recovery. A comprehensive understanding of the benefits and potential harms associated with each approach is crucial for informed decision-making in obstetric cholecystitis management.

## Materials and Methods:

This multi-center comparative study was designed to investigate the effectiveness and safety of interval cholecystectomy versus early cholecystectomy in the management of obstetric cholecystitis.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

Study Design:

A prospective randomized controlled trial was conducted to compare the outcomes of early cholecystectomy and interval cholecystectomy in women diagnosed with obstetric cholecystitis. The study encompassed both antenatal and postpartum periods, aiming to provide a comprehensive evaluation of these surgical approaches.

Participants:

The study included women aged 22 to 35 years, diagnosed with obstetric cholecystitis, recruited from Karpagam faculty of medical sciences and research, Nalan Gastro Centre and One care medical centre, Karpagam, Coimbatore.

Randomization:

Participants were randomly assigned to either the early cholecystectomy group or the interval cholecystectomy group using computer-generated random numbers. The randomization process was concealed to ensure allocation concealment and minimize selection bias.

Baseline Characteristics:

Baseline demographic information, including age, gestational age, parity, and medical history, was collected for each participant. This information was crucial for stratification and subsequent analysis.

Interventions:

For antenatal cholecystitis, participants in the early cholecystectomy group underwent surgical intervention during pregnancy, whereas those in the interval cholecystectomy group received conservative management initially, with surgery scheduled postpartum. In the postpartum cholecystitis arm, early cholecystectomy was performed within the first few days after delivery for the early cholecystectomy group, while the interval cholecystectomy group received conservative management initially, with surgery scheduled at a later postpartum period.

Outcome Measures:

The primary outcome measures included surgical complications, maternal morbidity, and fetal outcomes. Surgical complications encompassed factors such as operative time, blood loss, and postoperative recovery. Maternal morbidity included any adverse events related to the surgical procedure or the postoperative period. Fetal outcomes comprised measures such as preterm labor and fetal distress.

Data Collection:

Data were collected through a combination of medical records review and direct patient assessments. Operative times, blood loss, and postoperative recovery were meticulously documented. Additionally, information on complications, both maternal and fetal, was recorded to provide a comprehensive overview of the safety and efficacy of each surgical approach.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

Statistical Analysis:

Statistical analysis was performed using appropriate tests, including chi-square tests for categorical variables and t-tests for continuous variables. A p-value of less than 0.05 was considered statistically significant. Subgroup analyses were conducted to explore variations in outcomes based on different variables.

**Results:**

The study enrolled a total of 300 women aged 22 to 35 years diagnosed with obstetric cholecystitis. They were randomly assigned to either the early cholecystectomy group (n=150) or the interval cholecystectomy group (n=150). Baseline characteristics, including age, gestational age, and medical history, were comparable between the two groups, minimizing potential confounding factors.

Antenatal Cholecystitis:

In the antenatal cholecystitis subgroup, participants in the early cholecystectomy group underwent surgery during pregnancy, while those in the interval cholecystectomy group received conservative management initially, with surgery scheduled postpartum. (Table 1)

Table 1

| **Outcome Measure** | **Early Cholecystectomy (n=75)** | **Interval Cholecystectomy (n=75)** | **p-value** |
|---|---|---|---|
| Preterm Labor (n, %) | 5 (6.7%) | 10 (13.3%) | 0.21 |
| Fetal Distress (n, %) | 3 (4%) | 4 (5.3%) | 0.74 |
| Maternal Complications (n, %) | 8 (10.7%) | 6 (8%) | 0.53 |

The early cholecystectomy group demonstrated a lower incidence of preterm labor (6.7% vs. 13.3%) compared to the interval cholecystectomy group, although the difference was not statistically significant (p=0.21). Rates of fetal distress and maternal complications were comparable between the two groups (p=0.74 and p=0.53, respectively).

Postpartum Cholecystitis:

In the postpartum cholecystitis subgroup, early cholecystectomy was performed within the first few days after delivery for the early cholecystectomy group, while the interval cholecystectomy group received conservative management initially, with surgery scheduled at a later postpartum period.(Table 2)

Table 2:

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

| Outcome Measure | Early Cholecystectomy (n=75) | Interval Cholecystectomy (n=75) | p-value |
|---|---|---|---|
| Surgical Complications (n, %) | 5 (6.7%) | 3 (4%) | 0.52 |
| Maternal Morbidity (n, %) | 7 (9.3%) | 4 (5.3%) | 0.37 |
| Fetal Outcomes (n, %) | 2 (2.7%) | 1 (1.3%) | 0.78 |

Both groups exhibited low rates of surgical complications, with no significant differences observed (p=0.52). Maternal morbidity rates were also comparable between the early and interval cholecystectomy groups (p=0.37). Fetal outcomes, including preterm labor and fetal distress, showed minimal variations with no statistically significant differences (p=0.78).(Table 3)

Table 3: Overall Surgical Outcomes:

| Outcome Measure | Early Cholecystectomy (n=150) | Interval Cholecystectomy (n=150) | p-value |
|---|---|---|---|
| Operative Time (mean ± SD, min) | 50.3 ± 8.7 | 51.8 ± 9.2 | 0.29 |
| Blood Loss (mean ± SD, mL) | 75 ± 15 | 78 ± 14 | 0.41 |
| Postoperative Recovery (days) | 3.2 ± 0.8 | 3.5 ± 1.0 | 0.12 |

Operative times, blood loss, and postoperative recovery were comparable between the early and interval cholecystectomy groups, indicating no significant differences in the overall surgical outcomes (p>0.05).

The results of this study suggest that both early and interval cholecystectomy demonstrate favorable outcomes in the management of obstetric cholecystitis. The choice between the two approaches should be individualized, considering specific clinical contexts and patient preferences.

**Discussion:**

The findings of this multi-center comparative study contribute to the ongoing discourse on the management of obstetric cholecystitis, offering insights into the efficacy and safety of early cholecystectomy versus interval cholecystectomy in women aged 22 to 35 years.

The antenatal cholecystitis subgroup revealed that early cholecystectomy was associated with a lower, albeit non-significant, incidence of preterm labor compared to interval cholecystectomy. This aligns with previous studies suggesting the potential benefits of early surgical intervention in mitigating the progression of cholecystitis during pregnancy (1). However, the rates of fetal distress and maternal complications were similar between the two groups, emphasizing the need for a nuanced approach in decision-making.

ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

In the postpartum cholecystitis subgroup, both early and interval cholecystectomy demonstrated low rates of surgical complications and maternal morbidity, with no statistically significant differences observed. These results are consistent with studies advocating for the safety of deferring surgery until after delivery, allowing for a more favorable postoperative course (2-5).

The overall surgical outcomes, including operative time, blood loss, and postoperative recovery, were comparable between the two intervention groups. The similarity in these parameters indicates that the timing of surgery did not significantly impact the technical aspects and recovery process, supporting the feasibility of both approaches.

The study's strengths include its prospective randomized controlled design, a diverse cohort, and comprehensive outcome assessments. However, several limitations should be acknowledged. The relatively modest sample size may limit the generalizability of the findings, and variations in surgical expertise across different centers could introduce biases.

The decision between early and interval cholecystectomy in obstetric cholecystitis management remains a complex one, requiring careful consideration of individual patient factors and preferences. While early cholecystectomy may offer potential advantages in reducing the risk of preterm labor, interval cholecystectomy emerges as a safe alternative, avoiding surgery during pregnancy and demonstrating favorable postoperative outcomes.

This study aligns with previous research advocating for individualized treatment strategies in obstetric cholecystitis, considering factors such as gestational age, severity of symptoms, and maternal-fetal well-being (3-9). The results underscore the importance of shared decision-making between healthcare providers and patients, emphasizing the need for personalized care plans tailored to the specific clinical context.

## Conclusion

In conclusion, the findings of this study contribute valuable insights to the evolving landscape of obstetric cholecystitis management. The debate between early and interval cholecystectomy continues, and further research with larger cohorts and longer-term follow-up is warranted to refine our understanding and establish evidence-based guidelines for optimal patient care.

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ISSN: 0975-3583, 0976-2833 VOL14, ISSUE 12, 2023

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