Cholecystectomy or conservative management for uncomplicated symptomatic gallstones (biliary pain) or cholecystitis ?

A Health Technology Assessment in India

Policy Brief

Health Technology Assessment in India (HTAIn)
ICMR-National Institute of Epidemiology

Recommendations

- Laparoscopic cholecystectomy to be preferred over open cholecystectomy unless deemed necessary in cases of the complicated gallbladder
- Early LC (within 72 hours of admission or 7 days from symptom onset) to be a preferred treatment option for uncomplicated cholelithiasis and acute cholecystitis
- Evidence should be generated on long-term effectiveness of conservative management and health-related quality of life for gallstone disease in Indian context

About...

Gallstones are stones formed due to concentration of bile which precipitates as sludge and later develops into gallstones

Cholecystectomy is the surgical removal of gallbladder performed either as open cholecystectomy (OC) or laparoscopic cholecystectomy (LC). **Early Cholecystectomy** is performed within 72 hours of hospitalization whereas **Delayed Cholecystectomy** involves initial symptomatic management followed by surgery performed 6-12 weeks later

Conservative management involves symptomatic management with analgesics, antibiotics and lifestyle modifications.

Summary

Gallstone disease is the sixth commonest problem requiring surgery and emergency hospitalization in India thus imposing a significant economic burden in Indian healthcare system[1]. The policy question of whether cholecystectomy or conservative management (CM) should be recommended for gallstone treatment is addressed in this brief. Health Technology Assessment (HTA) been the chosen approach to explore this question.

Clinical effectiveness was assessed through systematic review and metanalysis (SRMA) of randomized control trials investigating the effectiveness of early cholecystectomy compared to CM/delayed cholecystectomy[2]. SRMA findings showed that Early cholecystectomy is effective than CM as it result in a fewer biliary complications and a reduction in reported abdominal pain.

Cost-effectiveness was assessed using decision analytic markov model utilizing data from secondary literature. The results showed that Early laparoscopic cholecystectomy (ELC), compared to Delayed laparoscopic cholecystectomy (DLC), incurred an incremental cost of -₹12,001 (-$161) for 0.0002 QALYs gained, resulting in an ICER of -₹6,43,89,441 ($8,66,755) and is cost-saving. ELC and DLC, compared to CM, incurred an incremental cost of -₹10,948 ($147) and ₹1,054 ($14) for 0.032 QALYs gained. The ICER was -₹3,42,758 ($4,609) for ELC compared to CM, suggesting ELC is cost-saving and ₹33,183 ($446) for DLC compared to CM, suggesting DLC is cost-effective compared to CM. Further, sensitivity & Scenario analysis showed that the results were robust to the changes in the input parameters.

Background

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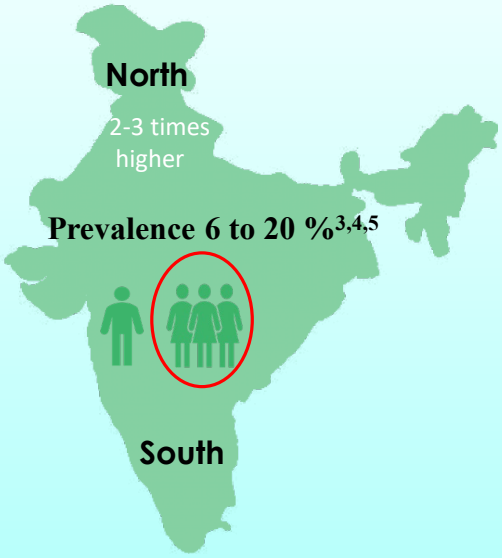
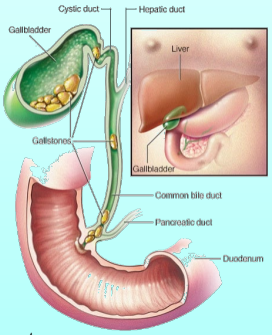


Gallstone disease impose a significant economic burden on the healthcare systems. With the advent of laparoscopic cholecystectomy, it has become the most preferred treatment for cholelithiasis/cholecystitis, proven clinical effectiveness yet seems costly.



Source: Mayo clinic

Conservative management, which involves pain and symptom management, has also shown effectiveness towards cholelithiasis and cholecystitis and carries a low risk of complications and is considered an alternative to surgery in the clinical practice[6]. Therefore, determining cost-effective management options for gallstones for implementation into the Indian health care system is critical. This substantiates the importance of conducting health technology assessment to determine the cost-effectiveness of cholecystectomy compared with conservative management in people presenting with uncomplicated symptomatic gallstones (biliary pain) or cholecystitis.

Assessment of clinical and cost-effectiveness

We systematically searched randomized control trials investigating the effectiveness of early cholecystectomy compared to conservative management/delayed cholecystectomy. We pooled the risk ratios with a 95% confidence interval, also estimated adjusted number needed to treat to harm. We conducted a cost-utility analysis using the decision-analytic Markov model to calculate and compare the costs and QALY of Early laparoscopic cholecystectomy vs. Delayed laparoscopic cholecystectomy, Early laparoscopic cholecystectomy vs. Conservative management and Delayed laparoscopic cholecystectomy vs. Conservative management in patients with symptomatic uncomplicated gallstone/cholecystitis. We adopted a lifetime time horizon with one-year cycle length from an Indian health system perspective. Clinical, cost and utility data were obtained possibly through systematic review and metanalysis or from secondary literature. Both costs and outcomes were discounted at a 3% annual discount rate. Incremental cost-effectiveness ratio was calculated, and the cost-effectiveness was determined with India's 2020 GDP/capita as the willingness to pay threshold. The cost values are reported in INR and USD (1USD=74.37 INR). One-way and probabilistic sensitivity analyses were performed to test parameter uncertainties.

Key Findings

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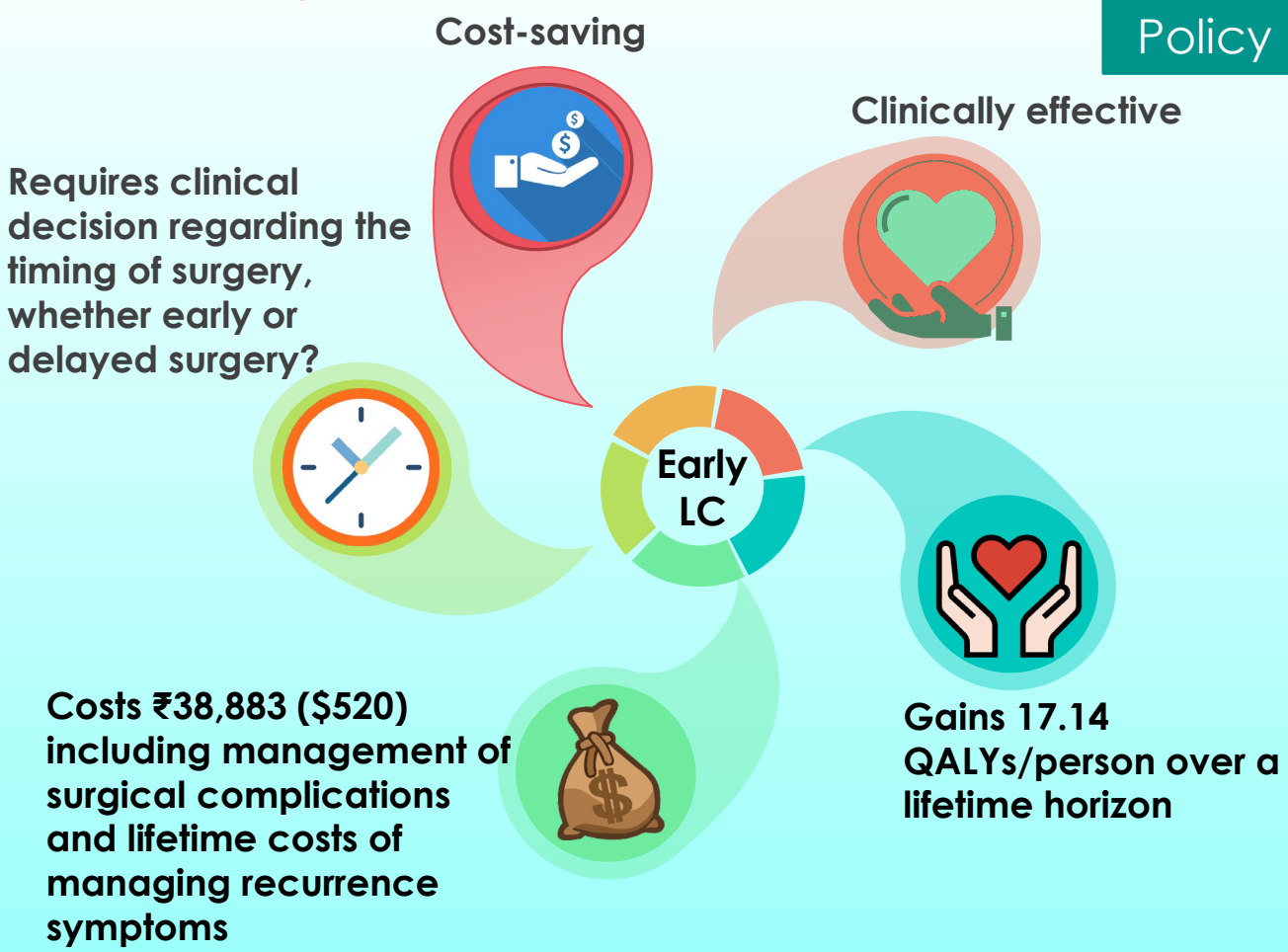

Policy Implications

- Cholecystectomy (open or laparoscopic) is cost-effective than conservative management for symptomatic uncomplicated gallstone disease (biliary colic) and acute cholecystitis.
- **Early cholecystectomy** is **cost-effective** than conservative management for symptomatic uncomplicated gallstone disease
- Early cholecystectomy is cost-effective for acute cholecystitis than conservative management/delayed cholecystectomy. However, it may require a clinical decision regarding the timing of surgery, whether early or delayed surgery with initial symptomatic management followed by cholecystectomy (6-12 weeks later), considering the possible intraoperative complications in early surgery.
- More evidences are needed on Conservative management's effectiveness for symptomatic uncomplicated gallstone disease and acute cholecystitis

Budget Impact for Tamilnadu

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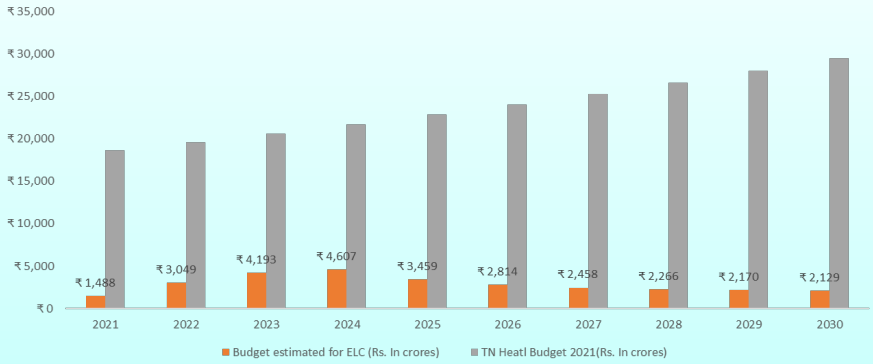
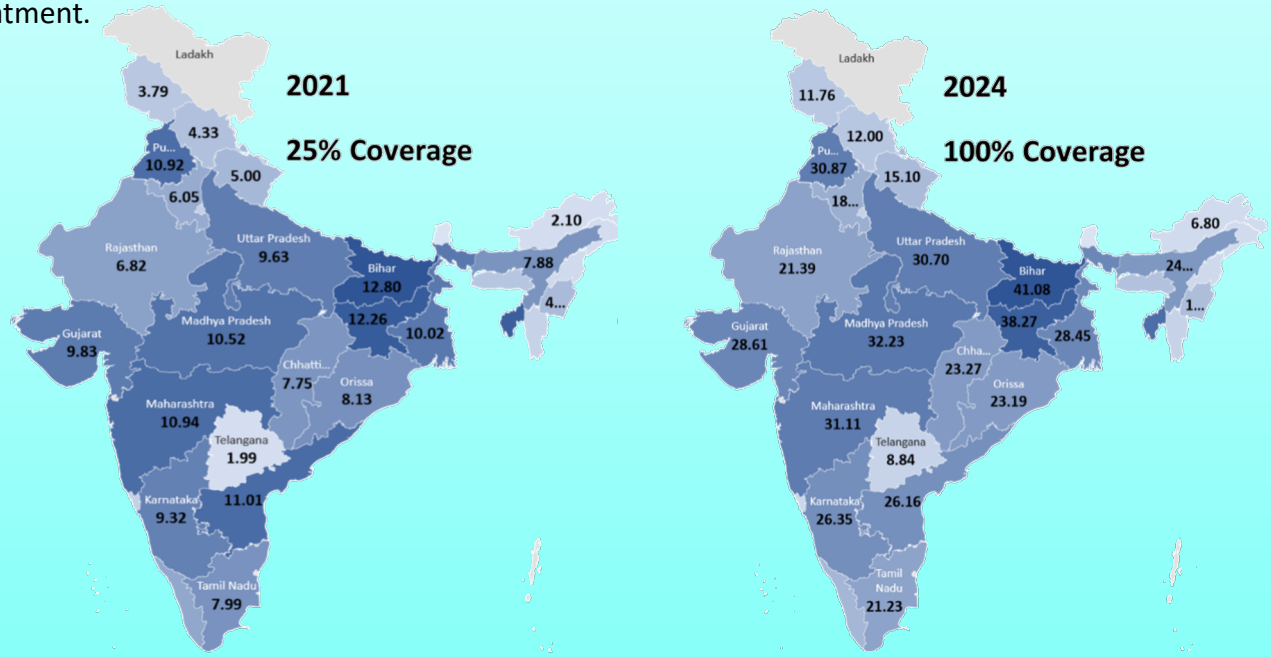


The estimated budget for early cholecystectomy was ₹1,488 crores ($200 million) in 2021 considering 25% treatment coverage. This represents 7.9% of Tamil Nadu's 2021 health budget (₹18,632 crores ($2505 million) and will reach 21.23% of the projected health budget with full (100%) coverage by 2024.

However, the budget requirement reduces in the subsequent years as the number of eligible patients decreases with the increase in yearly coverage, and only the annual new cases would necessitate treatment.



State-wise estimated additional budget (in percentage) for offering Early LC

Conclusion

Cholecystectomy results in fewer biliary complications and a reduction in reported abdominal pain than conservative management. Early Laparoscopic Cholecystectomy is cost saving compared to other treatment options, hence should be the preferable option of gallstone disease management.

References:

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