Cost Effectiveness Analysis of IPOM (Intraperitoneal Onlay Mesh) technique for Laparoscopic Ventral Hernia Repair

(Outcome Report)

Submitted to;
Technical Advisory Committee,
Health Technology Assessment in India (HTAIn),
Department of Health Research,
Ministry of Health and Family Welfare,
Government of India

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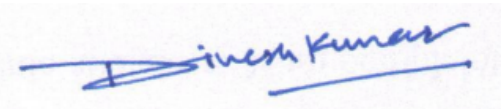
Acknowledgements

We would like to sincerely thanks, Department of Health & Research, Ministry of Health and Family Welfare, Govt. of India for designating Dr. Rajendra Prasad Government Medical College (DRPGMC), Kangra, Himachal Pradesh as HTAIn resource centre. We would further like to thank the entire DHR team who are always geared upto provide assistance related to any query pertaining to the topics assigned and providing us valuable inputs to complete the study. The comments and feedback provided by the technical appraisal committee are always treasured.

We would further like to acknowledge Dr. Som Raj Mahajan, Assistant Professor, Department of Surgery, DRPGC, Tanda, for providing us valuable information related to Laparoscopic ventral hernia repair. Lastly, our sincere thanks to all unnamed who have helped us in various ways for performing this cost effectiveness analysis.



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List of Abbreviations

BIA:	Budget Impact Analysis
EHS:	European Hernia Society
CEA:	Cost-Effectiveness Analysis
CEAC:	Cost-effective Acceptability Curve
CHSI:	Cost of Health Services in India
eMILOS:	Endoscopic Mini Open Sublay
eTEP:	extended Total Extraperitoneal
HBP:	Health Benefit Package
HTAIn:	Health Technology Assessment India
ICER:	Incremental Cost Effective Ratio
IEHS:	International Endohernia Society
IPOM:	Intraperitoneal Onlay Mesh
TAPP:	Trans abdominal Preperitoneal Patch
QALYs:	Quality Adjusted Life Years
SSI:	Surgical Site Infection
VAS:	Visual Analogue Scale
OT:	Operation Theatre
NHSCD:	National Health System Costing Database
JBI:	Joanna Briggs Institute
WTP:	Willingness to Pay

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Executive Summary

Background

Laparoscopic repair of ventral hernia has become a preferred procedure for the surgeons considering minimal-invasive treatment regime that it offers in the patient's benefit. Besides, it is known to reduce the length of the patient stay, less surgical site infections, low levels of post operative pain along with better cosmesis. Intraperitoneal Onlay Mesh (IPOM) is one of such technique that is commonly used for treating ventral hernia both primary as well as incisional. The intraperitoneal plane of mesh placement in IPOM offers little limitation as it may lead to adhesion to the bowels and mesh infection. Newer laparoscopic techniques using a preperitoneal or extraperitoneal plane of mesh placement and different mesh types confers additional benefit in reducing post operative complications and overall health cost. However, ease of performing laparoscopic IPOM compared to the other techniques makes it a potential candidate in continuing treating ventral hernias until there is strong evidence recommending other laparoscopic techniques like Total abdominal Preperitoneal Patch Plasty and extended totally extraperitoneal (eTEP) for ventral hernia repair. The current study thus assessed the cost-effectiveness analysis (CEA) of IPOM technique for laparoscopic ventral hernia repair using a health system approach for costing.

Methods

For clinical-effectiveness, systematic review and meta-analysis was conducted from literature available globally. The following PICOT criteria were defined for analysis:

- **Population**: Adult patients with diagnosis of small Ventral Hernia defect inclusive of incisional hernia, irrespective of size of defect.
- **Intervention**: IPOM (Intraperitoneal Onlay Mesh)
- **Comparator**: Open Hernioplasty
- **Outcome**: Wound infections, seroma, hernia recurrence, duration of surgery, unit costs of the intervention and comparator**,** ICER
- **Time horizon:** 5 years

For cost effectiveness analysis, the cost for intervention and comparator were obtained from National Health System Costing Database (NHSCD) for India. Whereas, outcome data was obtained from randomized control trails (RCTs) from worldwide.

Results

Clinical effectiveness evidence indicated that ventral hernia repair using IPOM results in significantly lesser wound infection compared to open hernioplasty. However, no significant difference was observed for other outcomes including hernia recurrence, seroma, and duration of surgery.

At current capacity, simulations estimated the mean costs for open hernioplasty as INR 36,166 and for Laparoscopic IPOM repair as INR 58,872. The unit costs were higher when estimated at 80 percent and 100 percent capacity utilization. Simulation using 10,000 samples predicted the mean ICER value as INR 5,023 per wound infection averted per patient at current capacity. It was observed that almost 36% simulated costs per one wound infection averted were cost-effective falling in the top-right dominant quadrant. It was not changed much at costs for 80.0% and 100.0% capacity utilization. Budget impact analysis done for Himachal Pradesh estimated the overall cost of implementing the intervention in the state of Himachal Pradesh to be INR 60,63,816/- The positive value of budget impact indicates that inclusion of Laparoscopic IPOM is going to be costly as compared to open VHR.

Conclusion and Recommendation:

The study findings potentially indicate that the intervention IPOM for ventral hernia repair is cost effective in India, though only 36% of the simulations were cost effective and below the WTP threshold for India. It further gives better outcomes in terms of lesser wound infection. However, a higher budget allocation would be required for making the intervention available to a larger population. Till date the most popular laparoscopic technique for treating ventral hernia repair is IPOM. There is lack of substantial cost effectiveness evidence in support of different types of ventral hernia techniques in India. However, newer laparoscopic techniques should be explored as they might offer added benefit in improving overall patient's quality of life.

1. Introduction

Ventral hernias-a common patient presentation faced by surgeons has an overall incidence between 6-22% (1).It is a condition where a protrusion of the underlying intestine or any other abdominal tissue occurs through a gap or weakness in the abdominal wall. They are non-inguinal, non-hiatal defects in the fascia of the abdominal lining and are observed to be more prevalent in females and elderly persons between 40-60 years of age (1,2).The conventional method of hernia repair uses an open surgical technique without mesh insertion for repairing the anatomical layers or structure which leads to a higher rate of recurrence (3) hence imposing a significant economic burden on our health care system(4,5).Consecutively, the surgeries were managed using open mesh hernioplasty technique (6)involving inlay, onlay, sublay, and underlay mesh placement technique. As per the Guidelines of the International Endohernia Society (IEHS) mesh repair is recommended for abdominal hernias with defects large than 1cm and laparoscopic repair for those larger than 4 cm (7).

Laparoscopic ventral hernia repair technique has been established as an effective treatment option which is less invasive, results in fewer wound complications, gives faster recovery, low rate of recurrence along with improved cosmesis. In recent years, Intraperitoneal onlay mesh (IPOM) repair has emerged as a simple and safe laparoscopic method where the hernia defect is bridged from the peritoneal side using a composite mesh. Despite being a treatment of choice, intraperitoneal placement of the mesh offers certain short comings such as small bowel obstruction due to adhesion and mesh infection due to interaction of the mesh with the visceral organs (8).To address these issues, newer advancements in the laparoscopic technique for ventral hernia repair such as Trans abdominal Pre-peritoneal Patch (TAPP) technique extended Total Extraperitoneal (eTEP) technique have emerged. These differ from others in the type of mesh used and plane of mesh placement which is either pre-peritoneal or extra peritoneal. Further, they confer a low treatment cost and reduced post-surgery complications compared to other laparoscopic techniques (9–11)

However, keeping in mind the superior expertise required to perform the above technically demanding surgeries and sparse literature evidence, still laparoscopic IPOMs have an upper edge in treating small and medium-sized hernias in hospital

settings with fewer complications. This fact is well supported by International Endohernia Society (IEHS) guidelines which describe both pre-peritoneal and intra-peritoneal repairs as adequate procedures to treat small to medium-sized ventral and incisional hernias (EHS classification W1 and W2) (12).However, society also recommends that the primary closure of the hernial defect is desirable, though it is technically complex. Any how the primary goal of ventral hernia repair is to relieve the patient's symptoms and/or cure of the hernia with minimization of recurrence rates.

Therefore, it was intriguing to investigate the cost-effectiveness analysis of IPOM technique for laparoscopic ventral hernia repair through the current study. Firstly, clinical effectiveness was established through evidence from literature. A health system costing approach was followed to compare the intervention of interest under study with open hernioplasty for treating ventral hernia. Costs were derived from the NHSCD site for ventral hernia repair. Probabilistic sensitivity analysis (PSA) using Monte Carlo simulation was performed to obtain the point estimates for cost-effectiveness plot (CE) and cost effectiveness acceptability curve (CEAC). Further, a budget impact analysis was also performed to have a holistic estimate of the expenditure. The findings of the study will thus provide evidence-based recommendations for either considering or opting out laparoscopic IPOM procedure in the country's health benefit package.

2. Objectives:

Aim of the current study is to perform cost-effectiveness analysis of Laparoscopic IPOM (Intraperitoneal Onlay Mesh) as compared to open surgical technique for ventral hernia repair (VHR). The objectives of the study are:

i. To assess clinical effectiveness of laparoscopic IPOM compared to open hernioplasty from literature available worldwide.

ii. To calculate the cost per unit delivery of laparoscopic surgical procedure IPOM compared to open surgery for VHR using NHSCD for India.

iii. To compare outcomes such as wound infection, seroma, recurrence, duration of surgery and length of hospital stay between IPOM and open hernioplasty for VHR.

iv. To calculate incremental cost-effectiveness ratio (ICER) and cost-effectiveness acceptability curve (ICER) for laparoscopic IPOM.

3. Methodology:

3.1 Evaluating Clinical Effectiveness of Laparoscopic IPOM compared to open hernioplasty

To assess clinical effectiveness of the intervention (Laparoscopic IPOM) compared to the open hernioplasty, a thorough search of clinical evidence was conducted from both nationally and internationally available sources of literature which includes reports from HTA agencies, published systematic reviews and cost effective analysis (CEAs), randomized controlled trials (RCTs) and other newly published clinical evidence.

The following PICO framework was defined for the search:

- **Population**: Adult patients with diagnosis of small Ventral Hernia defect inclusive of incisional hernia, irrespective of size of defect.
- **Intervention**: IPOM (Intraperitoneal Onlay Mesh)
- **Comparator**: Open Hernioplasty
- **Outcome**: Wound infection, hernia recurrence, seroma, duration of surgery, length of hospital stay and Unit costs of the intervention and comparator**,** ICER.
- **Time horizon**: 5 years

Thereafter, studies were searched on frequently available databases like PUBMED, EMBASE, SCOPUS, Google Scholar, Web of Science, The Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews. In addition, databases and registries maintaining published CEAs were also considered. Broadly, the keywords like—Laparoscopic Ventral Hernia Repair, IPOM for ventral hernia repair, Open Hernioplasty, Cost-effectiveness analysis of IPOM, Outcomes, Quality of life, Recurrence, India, worldwide, Unit cost etc were used.

The literature search resulted in a relevant, recently published systematic review and meta-analysis by Martins et al; 2024 (13) but it did not include studies related to incisional hernia. Thus, a separate systematic review and meta analysis was conducted for assessing clinical effectiveness data or outcomes, using only randomized control trails (RCTs) mentioning IPOM and open ventral hernia, inclusive of incisional hernia repair. Studies which were full text articles, published between years 2005-2024 in English language were considered for screening. However, protocols, editorials, abstracts, commentaries, communication, brief highlights, model-based studies and all articles published in languages other than English were excluded.

The inclusion criteria used for literature search were as follows:

- Adult patients (>18years) with a diagnosis of small Ventral Hernia defect inclusive of incisional hernia and irrespective of the defect size
- Laparoscopic Intraperitoneal onlay mesh (IPOM) as the intervention procedure along with open ventral hernia repair as comparator.
- RCTs studies reporting various outcomes like hernia recurrence, wound infection, seroma, duration of surgery, length of hospital stay etc.
- Studies published between 2005-2024

Exclusion criteria for the studies were as follows:

- Laparoscopic techniques other than IPOM or if the laparoscopic technique is unclear
- Studies with cost prediction models
- Conference abstracts, short communications, protocols, case reports

The consort diagram depicting the selection of articles is described in Figure 1.

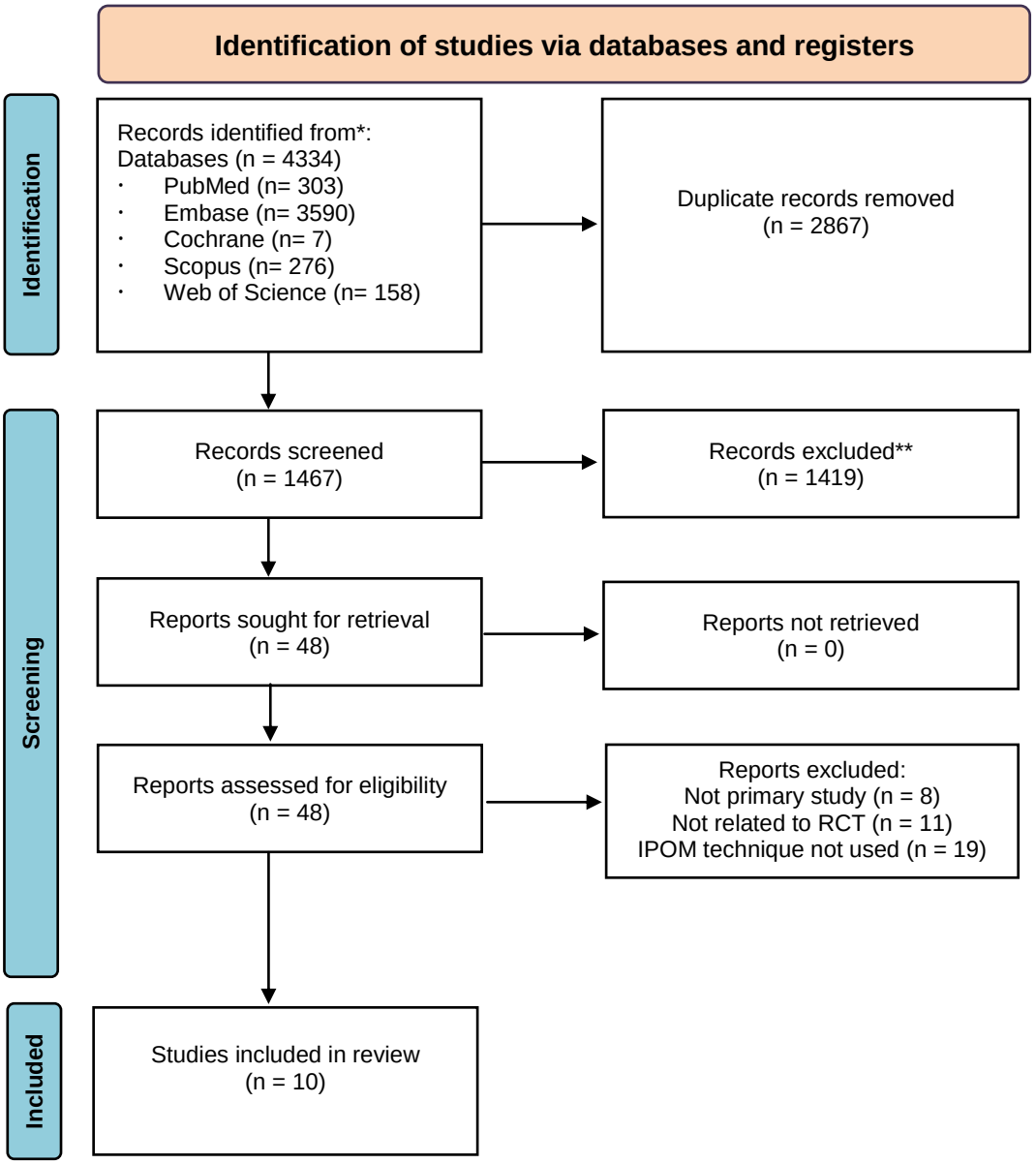


Figure 1: PRISMA format for the studies reviewed for systematic review and meta-analysis.

The quality of the shortlisted studies was then independently assessed by JBI (Joanna Briggs Institute) critical appraisal tool for the assessment of risk of bias for randomized controlled trials (14). The assessment was performed independently by two reviewers. The third reviewer was consulted in case of any discrepancy of decision between the first two reviewers. The specific validity constructs in the revised JBI critical appraisal tool for RCTs include internal validity and statistical conclusion validity. Questions that have been organized under the internal validity construct are further organized according to the domain of bias that they are specifically addressing. The domains include bias related to selection and allocation; administration of intervention/exposure; assessment, detection and measurement of the outcome; and participant retention. The detail of the tool assessment is described in Annexure Table 1 & 2.

Data collection/ extraction was done using Microsoft excel. Extracted data consisted of study design, sample size, defect size, type of hernia, follow up period and outcomes measured. The main assessed outcomes were Hernia recurrence, duration of surgery, length of hospital stay, post operative pain scores, surgery complications such as wound infection/dehiscence, seroma and patients with successful outcomes.

All the results were measured on the same scale or units for conducting the meta-analysis. Risk Ratio (RR) were calculated for all the dichotomous outcomes using 95% confidence intervals. Data was entered in Microsoft excel and analyzed using R Studio (4.3.1) using "meta" package. Data was analyzed for RR to compare dichotomous outcomes: wound infection and seroma, and hernia recurrence. Mean difference was reported for continuous outcomes mainly for duration of surgery (minutes) and length of hospital stay (days). For all the continuous outcomes mean with standard deviation considered for meta-analysis. The I^2 statistics was calculated to assess the heterogeneity. An I^2 value <25% was considered as minimal or no heterogeneity, between 25 and 50% as mild to moderate, within 50 to 75% as moderate to substantial and >75% as substantial heterogeneous (15). As the numbers of primary studies included were less sub-group analysis could not be performed.

The systematic review protocol was also registered on PROSPERO (CRD42024603106), which is an international Prospective register on systematic review (supplementary section).

3.2 Estimating Unit costs of Laparoscopic IPOM compared to open hernioplasty

The unit cost was calculated using cost estimates from NHSCD for India. The cost estimates were available for both intervention and comparator. It was generated under cost of health services (CHSI) in India which was formed from surveys across 11 states of India.

In database, cost data is given as average (mean and median) cost under general surgery for OPD, IPD, and operation theatre (OT). It was different for district and tertiary hospitals. Costs of OPD, IPD, and OT were given for current level of capacity which was again estimated at 80.0% and 100.0% capacity utilization. It was done to measure extent of productive capacity of hospitals.

The current study used mean cost for analysis for all cost centers (OPD, IPD, and OT) from tertiary level of hospitals only at all the three levels of capacity utilization. The mean costs from the district level were excluded from analysis as cost for laparoscopic ventral hernia was not available for district hospitals in the database. The probable reason might be that district hospital being a secondary setting caters less laparoscopic repairs of ventral hernia. Subsequently, data extraction was done using Microsoft excel in the format for mean cost with measures of dispersion. While estimating cost parameters for IPD, length of hospital stay for both procedures were estimated from systematic review of literature and pooled estimate was used to calculate total IPD cost of both procedures (Supplementary Table 1 & supplementary figure 1 & 2). Additionally, as the NHSCD Data did not include the mesh cost, the costs for the mesh and tackers was obtained from the Himachal Pradesh state's government setting at its retail price and was added to the final cost for analysis. Cost simulations was done using R studio package (4.3.1) where extracted mean and standard deviation of cost and summary outcomes (based on metanlysis) were simulated 10,000 times using probabilistic model.

3.3 Cost effectiveness analysis of Laparoscopic IPOM compared to open hernioplasty

As none of studies included for this review reported any QALY estimate, the final measure of effect was preferred as—the outcome which reported significant relative risk between the intervention and comparator. Consecutively, ICERs were calculated considering the incremental costs and incremental effects as follows:

$$ICER = \Delta Cost / \Delta \text{ Outcome}$$

Where; ICER= Incremental cost effective Ratio, ΔCost =Incremental cost, ΔOutcome = Incremental outcome

After extracting costs and outcomes, simulations (10,000) for costs and outcomes were performed on included studies to estimate costs and outcomes. Thereafter, incremental costs and outcomes were estimated followed by incremental cost effectiveness ratio

(ICER).The ICERs were then compared to the available cost-effective thresholds/benchmarks or willingness to pay threshold (WTP) for India. It was considered as INR 2,00,000/-using per capita income of India. ICERs close to or below the threshold were considered cost-effective while the above would likely not be.

Cost-effectiveness acceptability curve (CEAC) at different thresholds for willingness to pay (WTP) was also calculated.

3.4 Budget Impact Analysis

In addition to cost effectiveness, the budget impact analysis (BIA) was also conducted to assess the affordability. It involved estimating the current spending on the standard of care and calculating how much spending would change by introducing the intervention of choice. To have a better estimate from our own state, BIA parameters were selected from a study which was done in a government hospital (IGMC) in Shimla, Himachal Pradesh (17). The crude Budget estimate for the state of Himachal Pradesh was then calculated:

Budget Estimate (per year) = (Number of ventral hernia patients per year x Laparoscopic IPOM Cost)

4. Results:

4.1 Evidence on Clinical Effectiveness of Laparoscopic IPOM compared to open hernioplasty

The systematic literature search for outcome data resulted in 4334 articles related to laparoscopic and open ventral hernia repair. Majority of the articles were not included as they did not match the inclusion criteria. A total of 48 articles were further reviewed for the current study. Of these 19 were excluded as they did not mention the type of laparoscopic technique (IPOM, IPOM+, etc.) used for repair, 11 RCTs did not report any randomization technique and 8 were not primary study. A total of 10 RCTs were finally included and assessed for quality according to JBI critical appraisal tool of risk assessment.

The included studies were published between year 2005 – 2023 and were conducted in India (17,18), Egypt (19), Pakistan (20,21) and Europe (22-26). Majority of these trials were multi-centric (20,21,23-26). All the trials focused on primary (epigastric, umbilical, paraumbilical) as well as incisional ventral hernia repair. The major outcomes reported in these RCTs were: Intra/post operative complications such as wound infection, dehiscence, seroma etc, Operative time, Hospital stay duration, time until return to work, recurrence rate and pain scores. The details of the included studies with all the relevant information are described in annexure table 3.

Total 1204 patients were included in the systematic review, 600 were randomized to the IPOM Laparoscopic repair group and 604 were randomized to the open hernioplasty group with a follow-up period ranging between 1 month and 2 years. The quality of the RCTs assessed using JBI tool showed that all studied had overall score of more than 50.0 percent. Three studied had score between 50.0-60.0%, four had between 61.0-70.0%, and three had more than 70.0%. Depending of the assessment, no study was observed with severe risk of bias. Domain wise assessment indicated 50% (n=5) of the studies with a moderate risk in bias related to selection and allocation and 2 studies with low risk in bias related to administration of intervention. All the 10 studies demonstrated a low risk of bias related to measurement of outcome and participant retention.

Clinical Effect Estimates:

The major outcomes reported in these studies were assessed and it was found that most of them reported wound infections, seroma, hernia recurrence, duration of surgery, post-operative pain scores and length of hospital stay (Table 1).

Pain Score:

The current meta-analysis was performed using all the outcomes as mentioned in the table 1 except post operative pain scores and length of hospital stay. The pain score assessment varied in terms of post-operative day of assessment across extracted studies. One of the study reported VAS pain scores at day1, day 2 and day 3 (17). Another study reported pain scores at 1 month after the surgery (23). Two studies mentioned pain scores at only Day 2 of surgery (18,25) and not considered for meta-analysis. One study observed chronic pain upto 12 months after the procedure.

Length of Hospital Stay:

Further, as mean estimates of "length of hospital stay" for IPOM and open hernioplasty were included for evaluating total cost in inpatient department for both the procedures. The meta-analytic estimates were used to estimate total IPD cost of both procedures while simulating costs for analysis. (Supplementary Figure: 1 and 2)

Table 1: The overall outcomes with details reported in the included studies for laparoscopic and open ventral hernioplasty.

Authors	Wound infections	Seroma	Hernia Recurrence	Duration of surgery	Post operative pain scores	Length of Hospital stay
Misra et al.; 2006	✓	✓	✓	-	✓	✓
Olmi et al.; 2007	✓	✓	✓	✓	-	✓
Ascencio et al.; 2008	✓	-	✓	✓	✓	✓
Khan et al.; 2012	-	-	-	✓	✓	✓
Rogmark et al.; 2013	✓	✓	✓	✓	✓	✓
Shah et al.; 2021	✓	-	✓	✓	-	✓
Miserez et al.; 2021	✓	✓	✓	✓	✓	✓
Elashry et al.; 2022	✓	✓	✓	✓	✓	✓
Parihar et al.; 2023	✓	✓	-	✓	✓	✓
Veenderal et al.; 2023	✓	✓	✓	✓	-	✓
Total	**9**	**7**	**8**	**9**	**7**	**10**

Wound Infection:

Wound infection was reported by 9 studies (17-20,22-26). The meta-analysis finding is demonstrated in Figure 2 below. The pooled estimate has a risk ratio of 0.31 with a 95% CI = 0.18 to 0.54 indicating a significant difference in wound infection rates between the two groups. The results suggest that in IPOM there is a significantly low risk of wound infection compared the open group with low level of heterogeneity (I^2 = 7.3%).

The proportions were then estimated and presented as forest plots. The proportion in Laparoscopic IPOM was; 0.02 with 95 % CI: 0.00-0.03 and mild heterogeneity I^2=35 % and in open hernioplasty was; 0.10 with 95 % CI: 0.05-0.16 with moderate to severe heterogeneity I^2=80.3% (Supplementary figure 3 & 4).

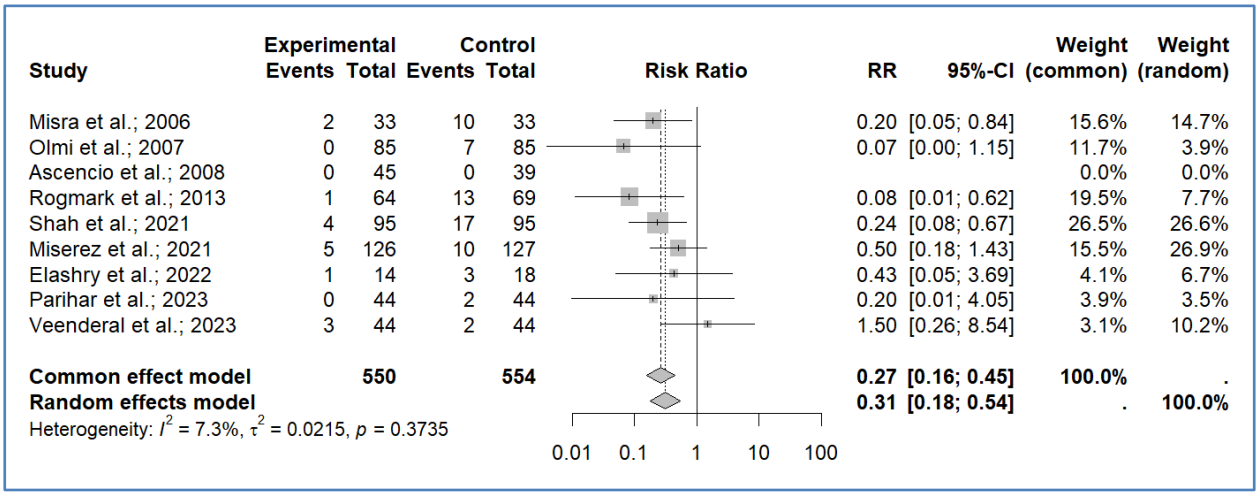


Figure 2: Forest plot of comparison of wound infection: Intraperitoneal Onlay Mesh (Experimental) and Open Hernioplasty (Control) (Yes: Event; No: No event).

Seroma:

Seven of the studies reported seroma (17-19,22-26) demonstrating the pooled estimate (figure 3) of risk ratio: 1.22 with a 95% CI from 0.63 to 2.35 indicating a non-significant difference in seroma rates between the two groups. The heterogeneity (I^2 = 36.55%) observed suggests moderate variability across studies.

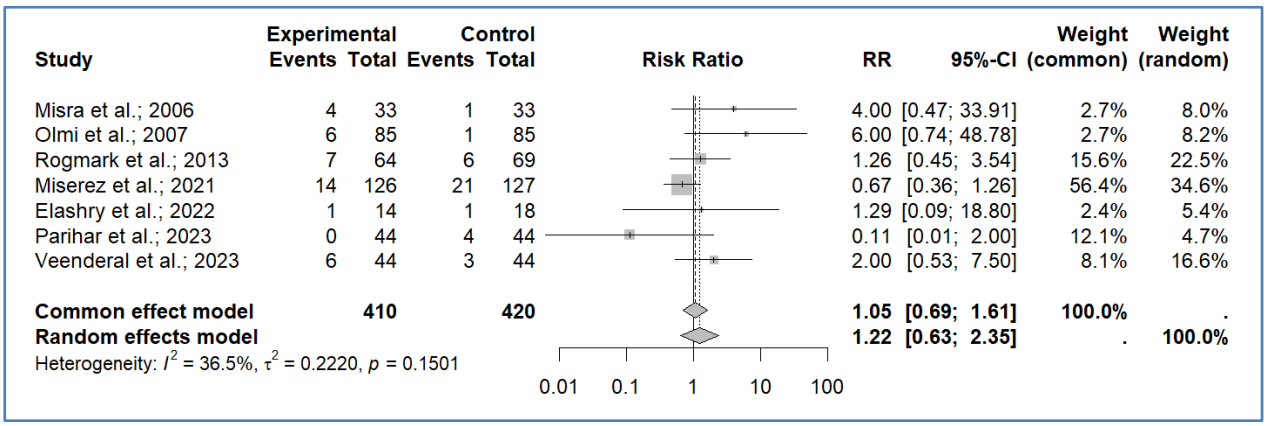


Figure 3: Forest plot of comparison of seroma: Intraperitoneal Onlay Mesh (Experimental) and Open Hernioplasty (Control).

Hernia Recurrence:

Eight studies evaluated hernia recurrence (17,19,20,21,22-26). Figure 4 below demonstrates the forest plot for hernia recurrence rates between IPOM and open hernioplasty estimating the relative risk. The pooled estimate demonstrates a risk ratio of 1.28 with a 95% CI from -0.81 to 2.04, indicating no significant difference in recurrence rates between the two groups. The low heterogeneity (I^2 = 0%) suggests that the studies are consistent, indicating reliability in the combined effect size. The meta-analysis does not show a significant difference in hernia recurrence rates between IPOM and open hernioplasty approaches.

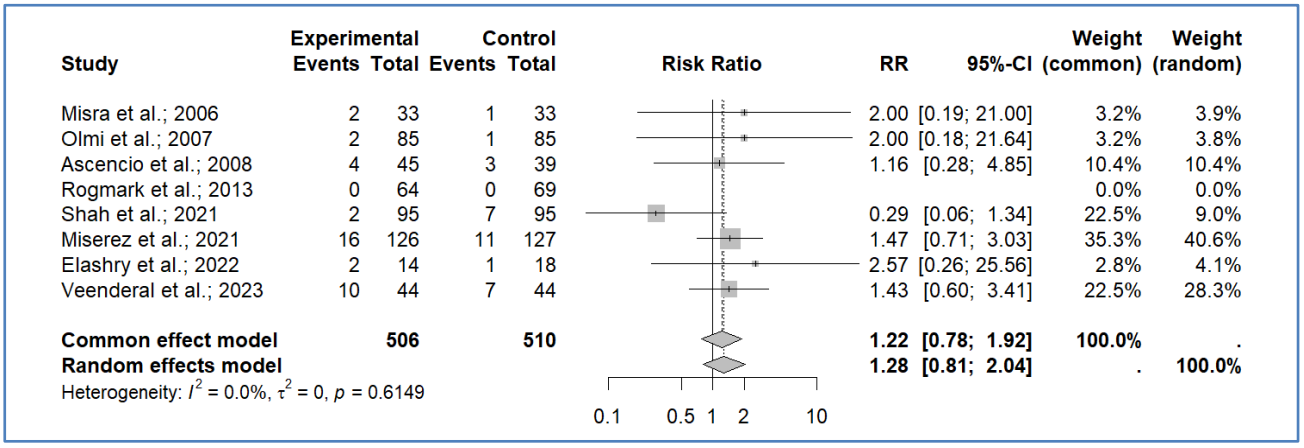


Figure 4: Forest plot of comparison of hernia recurrence: Intraperitoneal Onlay Mesh (Experimental) and Open Hernioplasty (control).

Duration of surgery:

Nine studies reported duration of surgery as an outcome (18-26). The overall mean difference (MD) observed was -12.30 (95% CI: -34.87 to 10.27) indicating that there is no significant difference in the duration of surgery between IPOM and Open hernioplasty procedure. A high heterogeneity (I^2 = 99.9%) indicates substantial variability in the study data (figure 5).

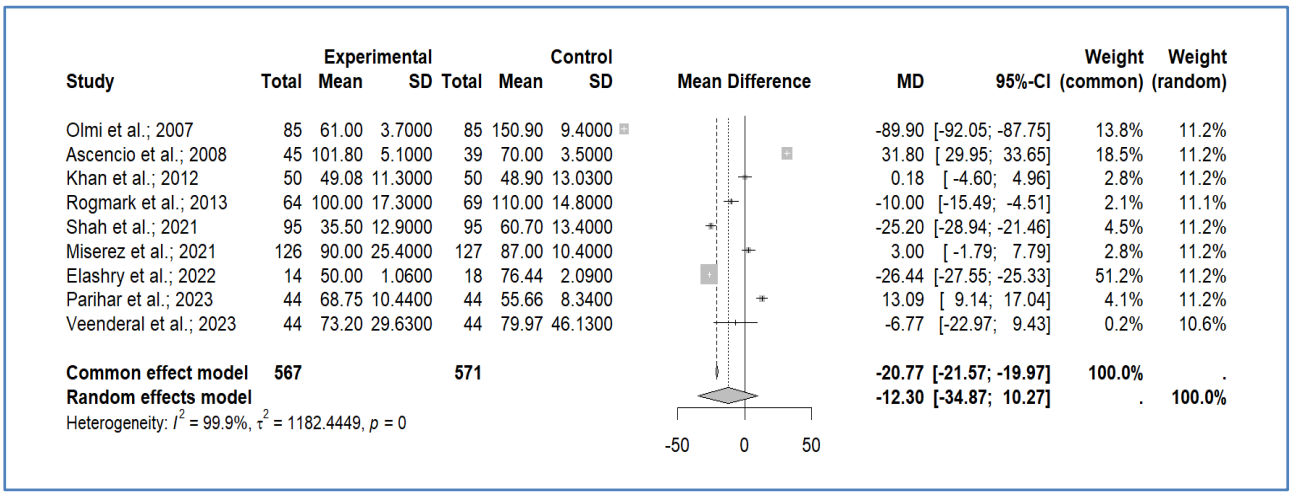


Figure 5: Forest plot of comparison of Duration of surgery: Intraperitoneal Onlay Mesh (Treatment) and Open Hernioplasty (Control).

Other Post-Operative Complications:

Meta-analysis of least reported/observed complications was not done and they were mainly MESH infection, flap necrosis, urinary retention, Adhesiolysis, neuralgia, bowel obstruction/paralytic ileus, caval thrombosis, pulmonary embolism, post-operative heammorhage, hematoma, bulging, trochar herniation, blood loss, and mortality. Only one to two studied reported one or more of these outcomes.

Summary of the evidence on clinical effectiveness between IPOM and open hernioplasty

The key findings of the meta-analysis are summarized as follows and depicted in table 2.

1. **IPOM significantly reduces the risk of wound infections** compared to open hernioplasty (RR = 0.31, 95% CI: 0.18, 0.54).
2. IPOM increases the risk of seroma (RR = 1.22, 95% CI: 0.65, 2.35). However, the finding was not observed to be statistically significant.
3. Higher risk of hernia recurrence is associated with IPOM compared to OH (RR = 1.28, 95% CI: 0.81, 2.04), although it was not observed to be statistically significant.
4. IPOM is associated with shorter mean duration of surgery compared to OH (Mean Difference = -12.30 minutes, 95% CI: (-34.87, 10.27), but was not statistically significant.

Table 2: Summary of outcomes from meta-analysis between IPOM and Open Hernioplasty in ventral hernia surgery

Outcomes	**Findings**	**Interpretations**
Wound infection [RR (95%CI)]	0.31 (0.18, 0.54)	**IPOM significantly reduces the risk of wound infection**
Seroma [RR (95%CI)]	1.22 (0.65, 2.35)	No significant difference
Hernia recurrence [RR (95%CI)]	1.28 (0.81, 2.04)	No significant difference
Duration of surgery in minutes [Mean Diff (95%CI)]	-12.30 (-34.87, 10.27)	No significant difference

4.2 Cost estimates of the IPOM and open hernioplasty

Costs parameters were drawn from NHSCD for India for intervention (Laparoscopic VHR) and comparator (Open VHR). In present analysis, based on NHSCD data, cost per visit in outpatient and in-patient department stay was assumed to be the same for open hernioplasty and Laparoscopic ventral repair. Whereas, the cost of operation theatre was different for both procedures (Table: 3).

Table 3: Cost for open and laparoscopic ventral hernia repair from tertiary care hospitals from India derived from NHSCD for India.

Level	Capacity	Open Hernioplasty	Laparoscopic Ventral Repair
		Mean Unit cost in INR (Range)	
OPD	Current	364 (214- 563)	
	80%	574 (264- 1,514)	
	100%	481 (217- 1,220)	
IPD	Current	1,671 (566- 3,545)	
	80%	1,704 (598- 2,755)	
	100%	1,515 (517- 2,675)	
OT	Current	*23,558 (8654-50,257)	29,544 (7,030-49,913)
	80%	*41,703 (7143-1,28,661)	64,148 (5,712-186,617)
	100%	*35,124 (6716-1,04,827)	53,055 (5,341-149,641)

* The overall mean estimates of open procedure in Tertiary hospital are derived from individual estimates from **Umbilical, Epigastric and Spigelian and incisional hernia** from the database.
Cost of MESH was estimated to be INR 4,000 and tacker INR 20,000/- at market price.

The total IPD Cost for both the laparoscopic IPOM and open hernioplasty was calculated by factoring mean days of length of the hospital stay estimated from systematic review in both the groups. The mean days estimated were 2.65 days for laparoscopic IPOM and 4.39 days for open hernioplasty (Supplementary figure 1 & 2).

- Total IPD Cost of Laparoscopic IPOM = Mean cost x 2.65 days
- Total IPD Cost of Open hernioplasty = Mean cost x 4.39 days

The final cost of the Laparoscopic IPOM and Open hernioplasty procedure constituted the cost of the procedure as obtained from NHSCD database and cost of Prolene mesh & Tackers.

- Total cost of Laparoscopic IPOM = Mean Cost from NHSCD + Mesh cost + Tacker cost
- Total cost of open hernioplasty = Mean Cost from NHSCD + Mesh cost

4.3 Cost-Effectiveness Analysis of laparoscopic IPOM

For ICER calculation, wound infection was considered as the outcome measure and final costs of the procedures taken up as discussed in the previous section. After simulations, the mean cost estimates along with ICERs were estimated at current, 80% and 100% capacity utilization (Table 4). The mean costs calculated for open hernioplasty at **current capacity utilization** was INR 36,166 and for laparoscopic IPOM was INR 58,872. Simulation using 10,000 samples predicted the mean ICER value as INR 5023 per **wound infection averted**. The obtained ICER was compared to India's willingness to pay (WTP) threshold at INR 2,00,000/-.It was observed that 36% of simulated costs per one wound infection averted were cost-effective falling in the dominant top and bottom right quadrants (Figure:6)

The mean costs calculated for open hernioplasty at **80 percent capacity utilization** was INR 55,110.0 and for laparoscopic IPOM was INR 95,044.0, with mean ICER value of INR 29,206. The obtained ICER was compared to India's willingness to pay (WTP) threshold and was observed that 34.8% of simulated costs per one successful outcome were cost-effective (Figure: 7).

Further, the mean costs were also calculated at **100 percent capacity utilization**. It was INR 47,324 for open hernioplasty and INR 83,061 for Laparoscopic IPOM with mean ICER value of INR 1637. The obtained ICER was then compared to India's willingness to pay (WTP) threshold at INR 2,00,000/- and was observed that 36.8% of simulated costs per one successful outcome were cost-effective (Figure: 8).

The Cost Effectiveness Acceptability Curve (CEAC) demonstrated that 36% of the simulations were cost effective below the WTP threshold of INR 2,00,000 at current capacity of resources. At 5,000/- about 35.0% of simulations were cost-effective at current capacity utilization, achieving saturation from within a range of INR 3,000 to 5,000 (Figure; 9)

Table 4: Unit cost estimates and ICER values at different levels of hospital capacity utilization for Laparoscopic IPOM and Open hernioplasty

Capacity	Laparoscopic IPOM Unit Cost (INR)	Open Hernioplasty Unit Cost (INR)	ICER	Percent Cost-Effectiveness
Current	58,872	36,166	5,023	36.0
80 percent	95,044	55,110	29,206	34.8
100 percent	83,061	47,324	1,637	36.8

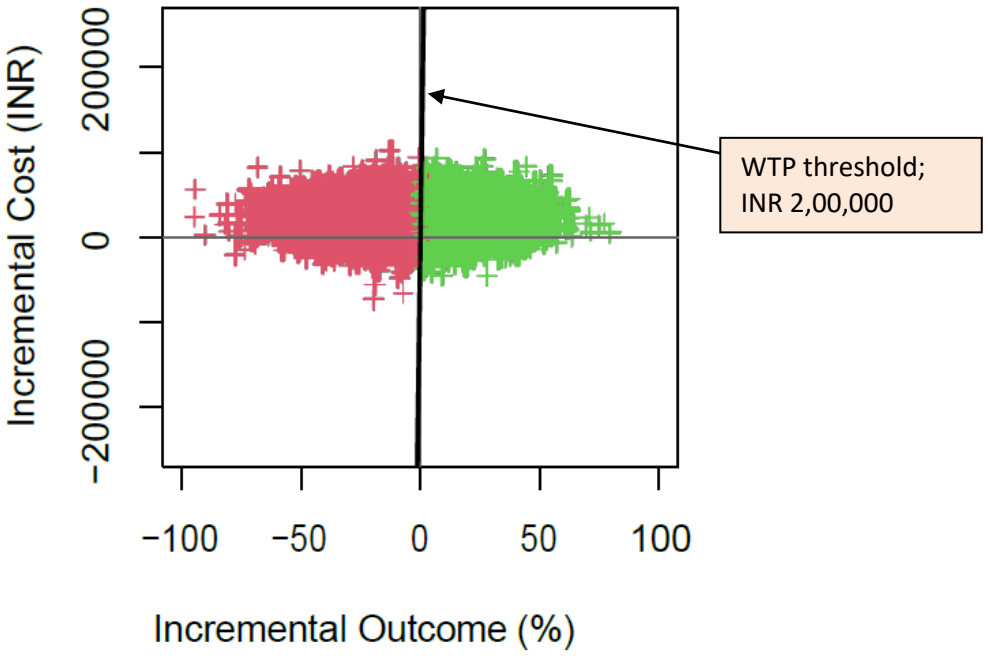


Figure 6: Incremental Cost Effectiveness Planes for laparoscopic IPOM and open ventral hernioplasty at current utilization using NHSCD for India at **current capacity utilization**.
(Green: ICER estimates below WTP threshold; Red: ICER estimates above WTP threshold)

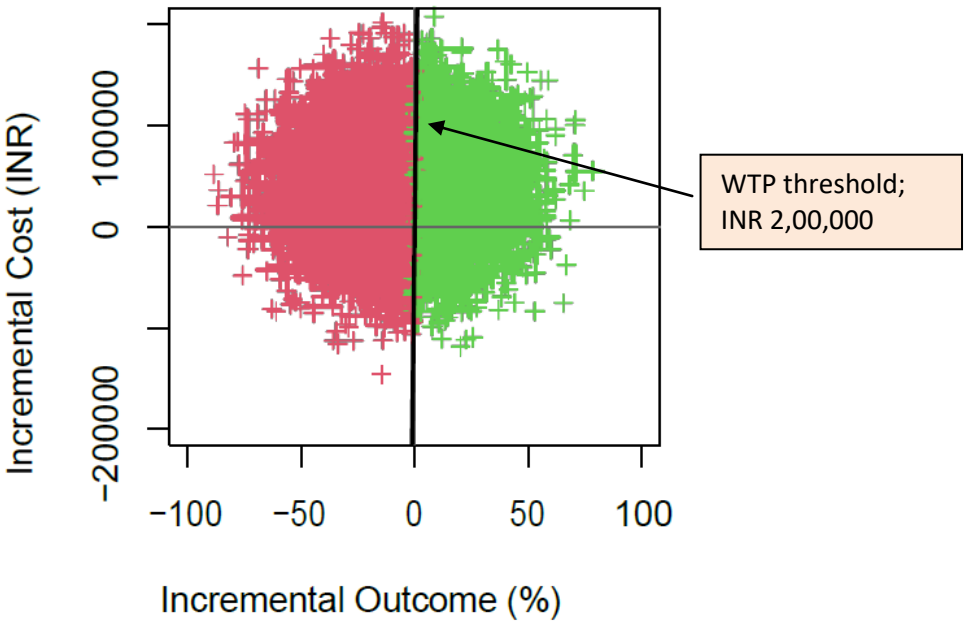


Figure 7: Incremental Cost Effectiveness Planes for laparoscopic IPOM and open ventral hernioplasty at current utilization using NHSCD for India at **80.0% capacity utilization**.
(Green: ICER estimates below WTP threshold; Red: ICER estimates above WTP threshold)

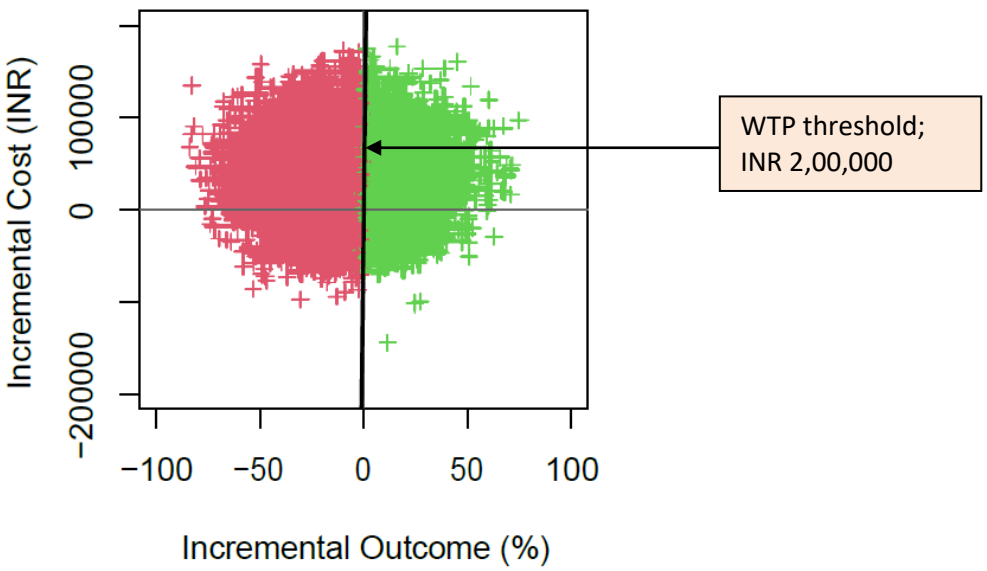


Figure 8: Incremental Cost Effectiveness Planes for laparoscopic and open ventral hernioplasty at current utilization using NHSCD for India at **100.0% capacity** utilization.
(Green: ICER estimates below WTP threshold; Red: ICER estimates above WTP threshold)

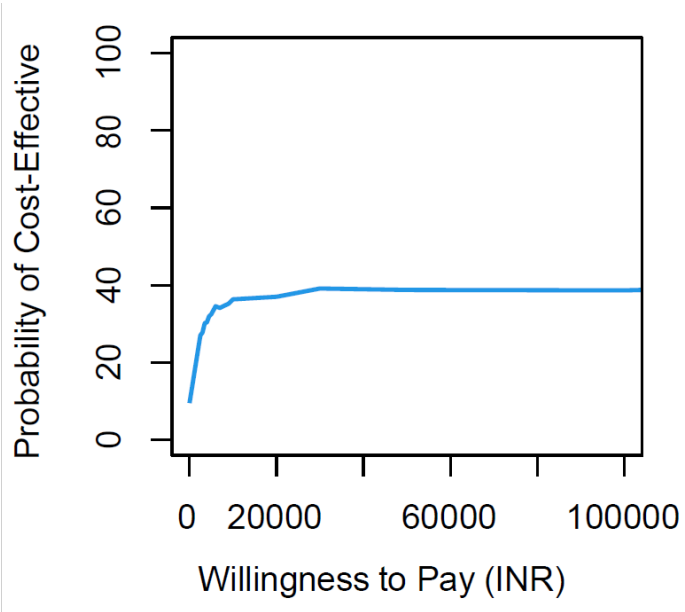


Figure 9: Cost effectiveness acceptability curve (CEAC) for laparoscopic and open ventral hernioplasty using NHSCD for India.

Consequentially, crude Budget estimate was also calculated at the current, 80 percent and 100 percent capacity utilization for the state of Himachal Pradesh (Table: 5). It reflects the overall cost of implementing the intervention laparoscopic IPOM in the state of Himachal Pradesh. The positive value of budget impact indicates that inclusion of Laparoscopic is going to be costly as compared to open VHR. It is quite indicative that Laparoscopic IPOM is going to be costly at national level as well.

Table 5: Budget Impact Analysis calculated for state of Himachal Pradesh.

	Parameters	**Population**	**Reference**
	Estimated number of Eligible Patients with ventral hernia (Incidence)	103 (annual)	Parmar et al. 2020
	Estimated Annual Cost for Himachal Pradesh between IPOM and Open procedure:		NHSCD for India
A. B.	Current Capacity Utilization (IPOM) Current Capacity Utilization (Open) Net Difference (A-B)	(58,872* 103)= 60,63,816 (36,166*103) = 37,25,098 = **INR 23,38,718**	Current analysis
C. D.	80 percent Capacity Utilization (IPOM) 80 percent Capacity Utilization (Open) Net Difference (C-D)	(95,044* 103)= 97,89,532 (55,110*103) = 56,76,330 **= INR 41,13,202**	Current analysis
E. F.	100 percent Capacity Utilization (IPOM) 100 percent Capacity Utilization (Open) Net Difference (E-F)	(83,061* 103) = 85,55,283 (47,324* 103) = 48,74,372 **= INR 36,80,911**	Current analysis

5. Discussion:

Healthcare facilities are expanding by bringing newer modalities, providing better care, and fewer complications at a better cost. The current review thus was conducted to calculate the cost-effectiveness analysis of a laparoscopic ventral hernia procedure Intraperitoneal Onlay Mesh (IPOM) over the conventional open Hernioplasty. A total of 10 RCTs were included for meta-analysis which provided evidence for the clinical effectiveness. The results revealed that wound infection was significantly less likely to be present in patients who underwent laparoscopic IPOM approach. The findings are in sync with previous studies. For all other outcomes no significant difference was observed between the two approaches. However, comparison of mean estimates between the groups depicted lower length of stay and duration of surgery in patients undergoing laparoscopic surgery, although was not found to be statistically significant. In this regard, it is worth mentioning that laparoscopic IPOM for ventral hernia in terms of clinical outcomes is beneficial and advantageous.

For cost effectiveness analysis, cost data was obtained from NHSCD for India and RCTs from India were reviewed for outcomes. In current study, a simulated average cost of open hernioplasty at current capacity utilization is INR 36,166/-and INR 58,872/- for laparoscopic IPOM with ICER of INR 5023/- per percent of wound infection averted per patient. The unit costs estimated at 80 and 100 percent utilization were comparably high although the percentage simulations that remained cost effective below the WTP were almost similar. Further, cost for management of various complications (during and after operation) was not given in database so the cost per complication was not carried out. Inferring this in our Indian scenario, the difference is considerable compared to per capita income. However, all of these studies did also report less complications post operatively in IPOM specifically lesser wound infections pointing to IPOM being superior compared to open surgery. Keeping in mind the cosmesis related demand of the patients now a days, laparoscopic ventral hernia surgery being a minimal invasive technique, is a preferred procedure by choice over conventional open repair.

As per the cost-effectiveness planes, 36% of point estimates appear to be cost-effective below WTP threshold for India; INR 2,00,000/-. This depicts that the intervention is cost-effective in India. The BIA was based on one article from where parameters were drawn. However, PSA was done using those parameters suggesting costly intervention with an annual budget of about INR 60,63,816 (Laparoscopic VHR, at current

capacity) in Himachal Pradesh. Thus, an additional budget of INR 23,38,718 would be required over open hernioplasty cost to implement the laparoscopic IPOM in state.

The current review encountered a few limitations as well. Since costs were derived from NHSCD whereas outcomes were obtained from RCT. It might be not representative of full HTA where we assess outcomes where costing is being carried out. Except one study, sample size in other studies was less expecting low power and increased variability. Further, analysis using different types of mesh could not be performed. We were limited by the data available from the secondary settings hospitals in our state that use only prolene mesh in supply. Accordingly, the estimates were deduces using cost of cost of Prolene mesh alone. Lastly, the data on yearly estimation of laparoscopic ventral hernia repair cases was not available for India. We could deduce an approximate estimate for our state from data available in a study conducted in a medical college, at Shimla, India (17).

6. Policy Implication and Recommendation:

The cost-effectiveness analysis of IPOM for ventral hernia repair depicts that there is a considerable difference in the unit costs of both the open hernioplasty and laparoscopic IPOM in Indian Scenario. Despite, given costs of two procedures, laparoscopic IPOM significantly demonstrated lesser post operative wound infection. Additionally, mean estimates indicated lesser duration of surgery and length of hospital stay but higher relative risk (RR) of seroma formation and hernia recurrence rate in laparoscopic IPOM. However, the results were not significant.

Like other surgeries, laparoscopic VHR aims to improve patient's quality of life. Laparoscopic IPOM could become a preferred procedure owing to its minimal invasive nature but at a bit higher costs than open hernioplasty. With the advent of time, different variations in laparoscopic techniques for ventral hernia repair have come up, which require greater expertise to carry out the surgery. These might provide an edge over limitations of the previous laparoscopic techniques and hence patient's quality of life. However, there is a lack of evidence supporting different laparoscopic VHR techniques.

For the policymakers, the practice of Laparoscopic ventral repair may be standardized

which may decrease the number of open surgeries performed by the surgeons. Secondly, the quality of the mesh used for IPOM or laparoscopic surgery accounts for majority of its costs in case of composite mesh. Present analysis could only include the cost of Prolene mesh as per the data availability while costs for other different types of mesh were not considered. Nevertheless government can emphasize conducting an estimate on the available mesh in the market which eventually will lead to employing good quality composite mesh at subsidized rates in the future thereby cutting more cost.

Thus, from the current analysis, we state that Laparoscopic ventral hernia repair in comparison to open repair is cost effective in averting wound infection in patients which undergo Laparoscopic ventral hernia repair keeping in view only 36% of the cost effectiveness achieved below WTP threshold. However, there is a lack of cost-effectiveness data on Laparoscopic ventral hernia repair from India to support our findings.

7. Conclusions:

- Simulated average cost of open hernioplasty at current capacity utilization is INR 36,166 and for laparoscopic IPOM is INR 58,872 per patient.
- Simulated average cost at 100 percent capacity utilization for open hernioplasty is INR 47,324 and for laparoscopic IPOM is INR 83,061 per patient.
- The simulated costs were higher at 80 percent capacity utilization: open hernioplasty is INR 55,110 and for laparoscopic IPOM is INR 95,044 per patient.
- Mean ICER value was highest at 80 percent capacity: INR 29,206 followed by INR: 5,023.0 at current capacity and INR 1,637.0 at 100 percent capacity. It showed that nearly 36% of simulated observations of laparoscopic IPOM are cost-effective as compared to open ventral hernioplasty at WTP of INR 2,00,000/-.
- Budget impact analysis is proved the inclusion of laparoscopic ventral hernioplasty as a costly intervention with an additional annual budget of INR 60,63,816.0 /- for the state.

References

1. Gaur S, Sharma DK. Epidemiology and management of ventral hernia in a tertiary healthcare centre- a prospective observational study. Int Surg J. 2022 ;9 (2):401.

2. Rodrigues J, Anoop K, Rodrigues FCS, Cormoli G. A Clinical Study of Ventral Hernias in Tertiary Hospital, Goa Medical College. Clin Surg. 2023 ;8 (1):1–6.

3. Luijendijk RW, Hop WCJ, VanDenTol MP, DeLange DCD, Braaksma MMJ, IJzermans JNM, et al. A Comparison of Suture Repair with Mesh Repair for Incisional Hernia. N Engl J Med. 2000 10; 343 (6):392–8.

4. Davila DG, Parikh N, Frelich MJ, Goldblatt MI. The increased cost of ventral hernia recurrence: a cost analysis. Hernia J Hernias Abdom Wall Surg. 2016 ;20 (6):811–7.

5. Gillion JF, Sanders D, Miserez M, Muysoms F. The economic burden of incisional ventral hernia repair: a Multicentric cost analysis. Hernia. 2016 ;20 (6):819–30.

6. Elrifai AY, Elfouly MG, Farrag AM. Laparoscopic intraperitoneal onlay mesh versus open hernioplasty in ventral hernia treatment: a non randomized controlled trial. The egyptian Journal of Surgery. 2022;41 (2):496-501.

7. Bittner R, Bain K, Bansal VK, Berrevoet F, Bingener-Casey J, Chen D, et al. Update of Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS))—PartA. Surg Endosc. 2019 ;33 (10):3069–139.

8. Robinson TN, Clarke JH, Schoen J, Walsh MD. Major mesh-related complications following hernia repair: events reported to the Food and Drug Administration. Surg Endosc. 2005;19 (12):1556–60.

9. Megas IF, Benzing C, Winter A, Raakow J, Chopra S, Pratschke J, et al. A propensity-score matched analysis of ventral-TAPP vs. laparoscopic IPOM for small and mid-sized ventral hernias. Comparison of perioperative data, surgical outcome and cost-effectiveness. Hernia. 2022; 26 (6):1521–30.

10. Bilsel Y, Abci I. The search for ideal hernia repair; mesh materials and types. Int J Surg. 2012;10(6):317–21.

11.Jain M, Krishna A, Prakash O, Kumar S, Sagar R, Ramachandran R,et al. Comparison of extended totally extraperitoneal (eTEP) vs intraperitoneal onlay mesh (IPOM) repair for management of primary and incisional hernia in terms of early outcomes and cost effectiveness—a randomized controlled trial. Surg Endosc. 2022;36 (10):7494–502.

12.Bittner R, Bingener-Casey J,Dietz U, Fabian M, Ferzli G, Fortelny R, et al. Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society [IEHS])-PartIII. Surg Endosc. 2014 ;28 (2):380–404.

13. Martins M.R., Santos-Sousa H., do Vale, M.A. Pinto BS. Comparison between the open and the laparoscopic approach in the primary ventral hernia repair: a systematic review and meta-analysis. Langenbecks Arch Surg **409**, 52 (2024).

14. Barker TH, Stone JC, Sears K, Klugar M, Tufanaru C, Leonardi-Bee J, Aromataris E, Munn Z. The revised JBI critical appraisal tool for the assessment of risk of bias for randomized controlled trials. JBI Evidence Synthesis. 2023;21(3):494-506

15. Higgins JPT, Altman DG, Gotzsche PC, Junni P, Moher D, Oxman AD et al. The Cochrane collaboration's tool for assessing risk of bias in randomized trials. BMJ; 2011; 343: d5928.

16. Parmar V, Jhobta R.S., Parmar G, Thakur V, Kaundal R. Spectrum of Ventral Hernia in Patients Presenting at Indira Ghandhi Medical College Shimla. European Journal of Pharmaceutical and Medical Research. 2020; 7: 617-20.

17. Misra MC, Bansal VK, Kulkarni MP, Pawar DK. Comparison of laparoscopic and open repair of incisional and primary ventral hernia: results of a prospective randomized study. Surg Endosc. 2006;20(12):1839-45.

18. Parihar APS, Sharma OK, Seth S, Goel R. Open retromuscular sublay mesh repair versus laparoscopic Intraperitoneal Onlay mesh Repair for ventral hernias-randomized controlled trial. J of cardiovascular disease research. 2023: 14(3); 1441-46.

19. Elashry MA, Rady M, Abdelaziz AM, Abbas M, Nasr M, Taleb HA et al. Laparoscopic (IPOM And IPOM Plus) Versus Open Para-Umbilical Hernia Mesh Repair. J of Pharm Neg Res. 2022: 13(7); 1728-39.

20. Shah RU, Shah S, Sharif G, Badar A, Azeem SM, Hussain A et al. Comparison of the outcomes of laparoscopic approach with open method for primary ventral hernia repair. Pak J Med Health Sci. 2021:15(6):1626–28

21. Khan JS, Qureshi U, Farooq U, Hassa ZF, Hassan H. The comparison of open and laparoscopic ventral hernia repairs. J Postgrad Med Inst. 2012: 26(4):397–401

22. Olmi S, Scaini A, Cesana GC, Erba L, Croce E. Laparoscopic versus open incisional hernia repair: an open randomized controlled study. Surg Endosc. 2007 ;21(4):555-9.

23. Asencio F, Aguiló J, Peiró S, Carbó J, Ferri R, Caro F et al. Open randomized clinical trial of laparoscopic versus open incisional hernia repair. Surg Endosc. 2009 ;23(7):1441-8.

24. Rogmark P, Petersson U, Bringman S, Eklund A, Ezra E, Sevonius D et al. Short-term outcomes for open and laparoscopic midline incisional hernia repair: a randomized multicenter controlled trial: the ProLOVE (prospective randomized trial on open versus laparoscopic operation of ventral eventrations) trial. Ann Surg. 2013 ;258 (1):37-45.

25. Miserez M, Lefering R, Famiglietti F, Mathes T, Seidel D, Sauerland S et al. Synthetic Versus Biological Mesh in Laparoscopic and Open Ventral Hernia Repair (LAPSIS): Results of a Multinational, Randomized, Controlled, and Double-blind Trial. Ann Surg. 2021; 273(1):57-65.

26. Van Veenendaal N, Poelman M, Apers J, Cense H, Schreurs H, Sonneveld E et al. The INCH-trial: a multicenter randomized controlled trial comparing short- and long-term outcomes of open and laparoscopic surgery for incisional hernia repair. Surg Endosc. 2023;37(12):9147-58.

Annexures

Annexure Table 1: Quality scores of RCTs based on JBI critical appraisal tool for randomized control trials. (Revised tool 2023)

	INTERNAL VALIDITY										Statistical conclusion validity				
	A. Bias related to Selection & Allocation			B. Bias related to Administration of Intervention/exposure			C. Bias related to Assessment/detection/ Measurement of Outcome			D. Bias related to Participant Retention				Scores	
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Total	Percent
Misra et al 2006	Y	Y	Y	Y	N	Y	UN	Y	Y	Y	Y	Y	Y	(11/13)	85%
Parihar et al 2023	UN	UN	Y	UN	UN	Y	UN	Y	Y	N	Y	Y	Y	(7/13)	54%
Elashry et al 2022	UN	UN	Y	UN	UN	Y	UN	Y	Y	UN	Y	Y	Y	(7/13)	54%
Shah et al 2021	UN	UN	Y	UN	UN	Y	UN	Y	Y	UN	Y	Y	Y	(7/13)	54%
Khan et al 2012	Y	UN	Y	UN	UN	Y	UN	Y	Y	N	Y	Y	Y	(8/13)	62%
Olmi et al 2007	UN	UN	Y	UN	UN	Y	UN	Y	Y	Y	Y	Y	Y	(8/13)	62%
Ascencio et al 2008	UN	UN	Y	UN	UN	Y	UN	Y	Y	Y	Y	Y	Y	(8/13)	62%
Rogmark et al 2013	Y	Y	Y	N	Y	Y	UN	Y	Y	Y	Y	Y	Y	(11/13)	85%
Miserez et al 2021	Y	UN	Y	UN	UN	Y	Y	Y	Y	Y	Y	Y	Y	(10/13)	77%
Veenedaal et al 2023	Y	UN	Y	UN	UN	Y	UN	Y	Y	Y	Y	Y	Y	(9/13)	69%

Annexure Table 2: Domain wise analysis of the RCTs based on JBI critical appraisal tool for randomized control trials. (Revised tool 2023)

	A. Bias related to selection and Allocation (Internal Validity)									
	Misra et al 2006	**Parihar et al 2023**	**Elashry et al** 2022	**Shah et al 2021**	**Khan et al 2012**	**Olmi et al 2007**	**Ascencio et al 2008**	**Rogmark et al 2013**	**Miserez et al 2021**	**Veenedaal et al 2023**
Q1	Y	UN	UN	UN	Y	UN	UN	Y	Y	Y
Q2	N	UN	UN	UN	UN	UN	UN	Y	UN	UN
Q3	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Low risk	Moderate risk	Moderate risk	Moderate risk	Low risk	Moderate risk	Moderate risk	Low risk	Low risk	Low risk

Y: Yes **N**: No **UN**: Unclear

	B. Bias related to administration of intervention / exposure (Internal Validity)									
	Misra et al 2006	**Parihar et al 2023**	**Elashry et al** 2022	**Shah et al 2021**	**Khan et al 2012**	**Olmi et al 2007**	**Ascencio et al 2008**	**Rogmark et al 2013**	**Miserez et al 2021**	**Veenedaal et al 2023**
Q4	Y	UN	UN	UN	UN	UN	UN	N	UN	UN
Q5	N	UN	UN	UN	UN	UN	UN	Y	UN	UN
Q6	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Low risk	Moderate risk	Moderate risk	Moderate risk	Moderate risk	Moderate risk	Moderate risk	Low risk	Moderate risk	Moderate risk

Y: Yes **N**: No **UN**: Unclear

	C. Bias related to Assessment/detection/ Measurement of Outcome (Internal Validity)									
	Misra et al 2006	**Parihar et al 2023**	**Elashry et al** 2022	**Shah et al 2021**	**Khan et al 2012**	**Olmi et al 2007**	**Ascencio et al 2008**	**Rogmark et al 2013**	**Miserez et al 2021**	**Veenedaal et al 2023**
Q7	UN	UN	UN	UN	UN	UN	UN	UN	Y	UN
Q8	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Q9	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk

Y: Yes **N**: No **UN**: Unclear

	D. Bias related to Participant retention (Internal Validity)									
	Misra et al 2006	**Parihar et al 2023**	**Elashry et al** 2022	**Shah et al 2021**	**Khan et al 2012**	**Olmi et al 2007**	**Ascencio et al 2008**	**Rogmark et al 2013**	**Miserez et al 2021**	**Veenedaal et al 2023**
Q10	Y	N	UN	UN	N	Y	Y	Y	Y	Y
	Low risk	High risk	Low risk	Low risk	High risk	Low risk	Low risk	Low risk	Low risk	Low risk

Y: Yes **N**: No **UN**: Unclear

	Statistical conclusion validity									
	Misra et al 2006	**Parihar et al 2023**	**Elashry et al** 2022	**Shah et al 2021**	**Khan et al 2012**	**Olmi et al 2007**	**Ascencio et al 2008**	**Rogmark et al 2013**	**Miserez et al 2021**	**Veenedaal et al 2023**
Q11	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Q12	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Q13	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk

Y: Yes **N**: No **UN**: Unclear

Annexure Table 3: Background Information of the Indian studies included for the Outcome data

Author, Country, Year	Hernia Type	Laparoscopic technique	Study Duration	Population	Intervention	Comparator	Outcome (OPEN)	Outcome (Laparoscopic)
Misra et al. India (2006)[17]	Primary + Incisional	IPOM	2003- 2005 (2 years)	Adults (>18 yrs) with primary, Incisional, recurrent hernia	Laparoscopic VHR (n=33)	Open VHR (n=33)	**Intraoperative complications=** 0 **Post operative complications** =14 Deep wound infection (1), Superficial wound infection (9), mesh infection (1), flap necrosis (1), urinary retention (1), seroma (1) **Mean Hospital stay**= 3.43 (1-34) **Recurrence**: 3.33% (1/30) **VAS Pain score post op day 3**: 2.16 **Patient satisfaction:** 7.6 **Cost:** INR 1536.66 , S.D=1062.53	**Intraoperative complications=** 0 **Post operative complications** = 7 Deep wound infection (0), Superficial wound infection (2), mesh infection (0), flap necrosis (0), urinary retention (1), seroma (4) **Mean Hospital stay**= 1.47 (1-3) **Recurrence**: 6.25% (2/32) **VAS Pain score post op day 3**: 2.16 **Patient satisfaction:** 8.27 **Cost:** INR 13,786.90 , S.D=6792
Parihar et al India (2023)[18]	ventral hernia (Umbilical, Epigastric, Lumbar, Incisional)	IPOM	2020-2021	Adults (>18 yrs) for elective primary ventral hernia repair (Umbilical, Epigastric, Lumbar, Incisional)	Laparoscopic IPOM (n=44)	Open VHR (n=44)	**Duration of Surgery (mean, SD):** 55.66 ± 8.34 **Duration of Hospital stay (Mean, SD):** 6.50 ± 1.68 **VAS score for pain 48 HRS (Mean, SD):** 4.52 ± 0.66 **Wound Infection:** 2 **Seroma:** 4 **Cosmetic Satisfaction:** 38	**Duration of Surgery (mean, SD):** 68.75±10.44 **Duration of Hospital stay (Mean, SD):** 3.61 ± 2.28 **VAS score for pain 48 HRS (Mean, SD):** 2.36 ± 0.61 **Wound Infection:** 0 **Seroma:** 0 **Cosmetic Satisfaction:** 42
Elashry Egypt (2022)[19]	Paraumbilical heria	IPOM	2021-2022	Adults (>18 years) with paraumbilical hernia repair	Laparoscopic IPOM (n=14)	Open VHR (n=18)	**Operating time:** 76.44±2.09 **Estimated blood loss:** 18 (100%) **Post operative seroma:** 1(5.6%) **Infection:** 3(16.7%) **Time off work:** 11.06±0.38 **Post op pain:** 7.06±0.22 **Recurrence:** 1 (5.6%) **Hospital stay:** 7.12±0.71	**Operating time:** 50±1.06 **Estimated blood loss:** 8(57.14%) **Post operative seroma:** 1(7.1%) **Infection:** 1(7.1%) **Time off work:** 6.57±0.44 **Post op pain:** 2.14±0.35 **Recurrence:** 2 (14.3%) **Hospital stay:** 1 day±0

Shah UR Pakistan (2021)[20]	Primary vetral hernia	IPOM	2017-2019	Adults (>18 yrs) with primary ventral hernia (umbilical, paraumbilical, epigastric)	LVHR (N=95)	OVHR (N=95)	**Operative time (mins):** 60.7 **Hospital days:** 4.4 ± 1.5 **Wound infection:** 12 **Wound dehiscence: 5** **Recurrence:** 7	**Operative time (mins):** 35.5 **Hospital days:** 2.45 ± 0.60 **Wound infection:** 4 **Wound dehiscence:** 0 **Recurrence:** 2
Khan JS Pakistan (2012)[21]	Ventral hernia	IPOM	3 years	Adults (>18 yrs) with uncomplicated ventral hernia (umbilical, paraumbilical, epigastric)	Laparoscopic VHR (n=50)	Open VHR (n=50)	**Duration of surgery:** 48.9 ± 13.03 **Post operative Pain scores at 2 Hrs:** 6 ± 0.78 **Post operative pain score at 24 hrs:** 3.6 ± 0.66 **Post operative hospital stay:** 39 ± 7.36	**Duration of surgery:** 49.08 ± 11.25 **Post operative Pain scores at 2 Hrs:** 4.9 ± 0.99 **Post operative pain score at 24 hrs:** 2.4 ± 0.49 **Post operative hospital stay:** 31± 5.8
Olmi et al. Italy (2007)[22]	Incisional	IPOM	2001-2004 (3 years)	Adults (>18 yrs) with Incisional hernia	Laparoscopic VHR (n=85)	Open VHR (n=85)	**American society of Anaesthesiologist (ASA) Score**: No difference **Mean Operative time:** 150.9 (132.1–169.7) **Adhesiolysis:** 2 **Use of drainage:** 97.6% **Mean length of hospitalization:** 9.9 (5.2–14.6) **Return to work in days:** 25 (16–30) **Relapse:** 1.1~~%~~ **Complications:** 29.4% (n=25) **Cost:** Euro 3100	**American society of Anaesthesiologist (ASA) Score**: No difference **Mean Operative time:** 61.0 (54.1–68.9) **Adhesiolysis:** 80 **Use of drainage:** 0% **Mean length of hospitalization:** 2.7 (2.2–3.2) **Return to work in days:** 13 (6–15) **Relapse:** 2.3% **Complications:** 16.4% (n=14) **Cost:** Euro 2700
Ascencio et al. Spain (2008)[23]	Incisional	IPOM	2007-2008	Adults (>18 yrs) with Incisional hernia	Laparoscopic VHR (n=45)	Open VHR (n=39)	**Operative Time:** 70 min **Operative complications:** 0% **Local Complications:** 5.12% (n=2) **Mortality rate at 30 days:** 0 **Total mean length of stay:** 3.33 days **Recurrence after 1 year:** 7.89% **Health VAS mean (1 month):** 84.53 **Pain VAS mean (1 month):** 10.43 **QOL (1 month):** 0.95	**Operative Time:** 101.88 min **Operative complications:** 6.66% (n=3) **Local Complications:** 33.33% (n=15) **Mortality rate at 30 days:** 0 **Total mean length of stay:** 3.46 days **Recurrence after 1 year:** 9.75% **Health VAS (1 month):** 83.88 **Pain VAS (1 month):** 17.48 **QOL (1 month)**: 0.90

Rogmark et al Sweden (2013)[24]	Incisional	IPOM	2005-2009	Adults (>18 yrs) with Incisional hernia	Laparoscopic VHR (n=64)	Open VHR (n=69)	**Operative time:** 110 (78–137) min **Hospital stay: 2 (1.5–3)** **Recurrence:** 0 **Patients without any event:** 40 **No complications (Clavien Dindo class.):** 42 **Non severe complications (CD Severity):** 21 **Severe complications (CD severity):** 6	**Operative time:** 100 (70–139) min **Hospital stay:** 2 (1–3) **Recurrence:** 0 **Patients without any event:** 43 **No complications (Clavien Dindo** 45 **Non severe complications (CD Severity):** 18 **Severe complications (CD severity):** 1
Miserez et al Europe (2021)[25]	Ventral abdominal hernia	IPOM	2005-2009	Adults (>18 yrs) for elective of primary or Incisional hernia	Lap Synthetic mesh (n=64) Lap Biological mesh (n=62)	Open Synthetic mesh (n=61) Open Biological mesh (n=66)	**Operative Time**: 87 (63.5–105) **Length of stay in hospital**: 5 (4–7) **Time untill return to work:** 32 days **Reccurence:** 11 **Mesh Infection**: 2 **Reoperation**: 15 **At least one major complication** : 21 **Post operative Local morbidity**: 73 (Wound dehiscence, wound infection, hematoma,seroma, intraabdominal abscess,peritonitis, ielus, bulging) **Serious adverse events related to mesh:** 4 **Serious adverse events related to procedure:** 12	**Operative Time:** 90 (65–166.5) **Length of stay in hospital:** 4 (3–6) **Time untill return to work:** 26 days **Reccurence**: 16 **Mesh Infection**: 2 **Reoperation**: 16 **At least one major complication** : 24 **Post operative Local morbidity**: 67 (Wound dehiscence, wound infection, hematoma,seroma, intraabdominal abscess,peritonitis, ielus, bulging) **Serious adverse events related to mesh:** 7 **Serious adverse events related to procedure:** 14
Veenendaal et al Netherlands (2023)[26]	Primary + incisional recurrent	IPOM	5 years	Adults (>18 yrs) with primary, reccurrent Incisional hernia	Laparoscopic VHR (n=44)	Open VHR (n=44)	**Operative time (mean, SD):** 79.97 (46.13) **Length of hospital stay:** 3 (1-36) **No complications (Clavien Dindo classification)**: 22 **Complications (Clavien Dindo classification):** 13 **Mortality at 28 days**: 0% **Reccurence:** 16% **QOL scores**: no difference **Patient Satisfaction:** Impaired	**Operative time (mean, SD)**: 73.20 (29.63) **Length of hospital stay:** 3 (1-12) **No complications (Clavien Dindo classification)**: 21 **Complications (Clavien Dindo classification)**: 18 **Mortality at 28 days:** 0% **Reccurence:** 23% **QOL scores:** no difference **Patient Satisfaction**: Satisfactory

Supplementary Section

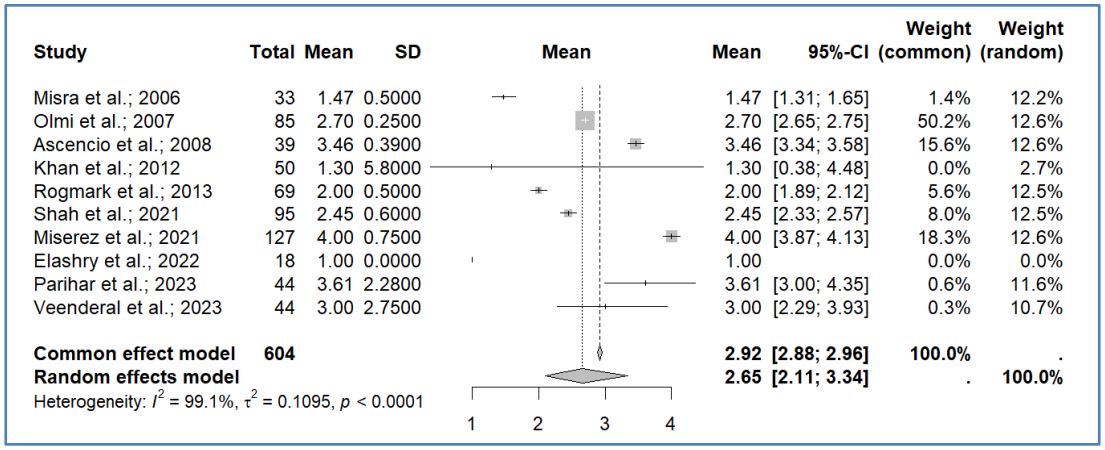
Lengths of Hospital stay as outcome:

Length of hospital stay was reported as outcome in all the 10 RCTs (Supplementary Table: 1). The mean days of hospital stay post surgery were higher for open group: 4.39 days as compared to laparoscopic repair which were 2.65 days (Supplementary figure 1 & 2). This pooled estimates outcome of this outcome was used to calculate total IPD cost of both procedures.

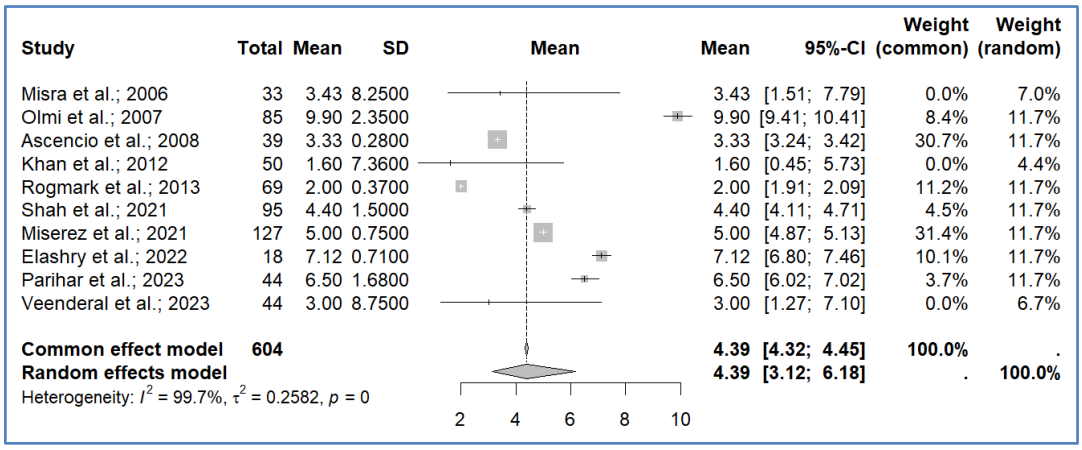
Supplementary Table 1: Length of hospital stay data reported in the studies.

Author	Total Patients		Length of hospital stay (Days)	
	IPOM	Open	IPOM	Open
Misra et al.; 2006	33	33	1.47 ± 0.5	3.43 ± 8.25
Olmi et al.; 2007	85	85	2.7 ± 0.25	9.9 ± 2.35
Ascencio et al.; 2008	45	39	3.46 ± 0.39	3.33 ± 0.28
Khan et al.; 2012	50	50	1.3 ± 5.8	1.6 ± 7.4
Rogmark et al.; 2013	64	69	2 ± 0.5	2 ± 0.37
Shah et al.; 2021	95	95	2.5 ± 0.6	4.4 ± 1.5
Miserez et al.; 2021	126	127	4 ± 0.75	5 ± 0.75
Elashry et al.; 2022	14	18	1 ± 0	7.12 ± 0.71
Parihar et al.; 2023	44	44	3.61 ± 2.3	6.50 ± 1.68
Veenderal et al.; 2023	44	44	3 ± 2.75	3 ± 8.75

Length of hospital stay: Mean estimates

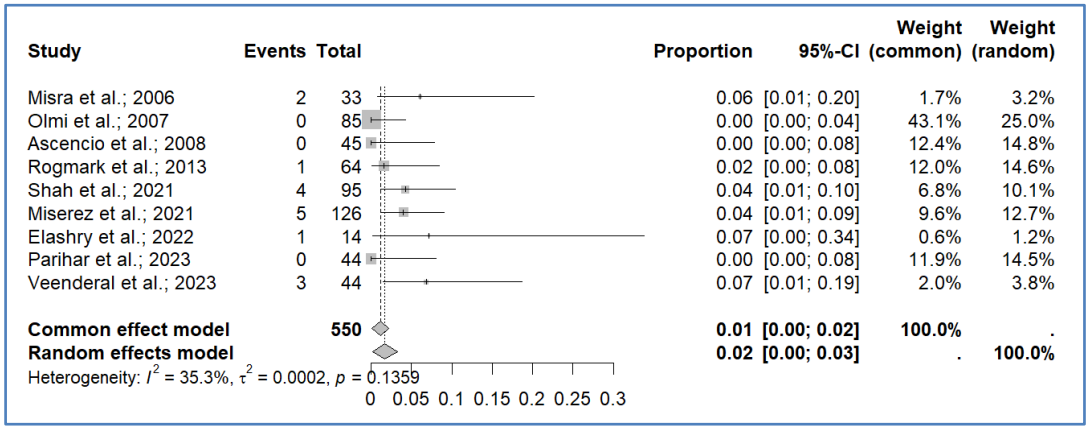


Supplementary figure 1: Forest plots depicting mean estimates of length of hospital stay in Laparoscopic IPOM.

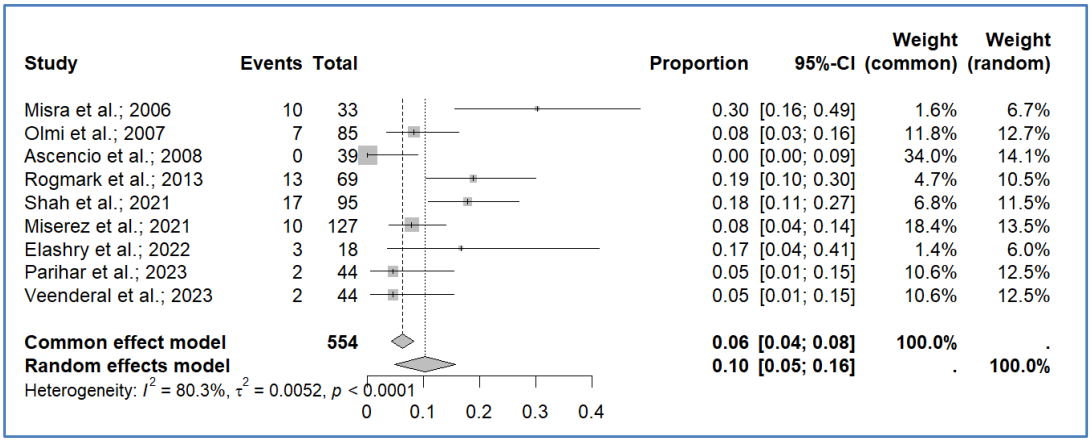


Supplementary figure 2: Forest plots depicting mean estimates of length of hospital stay in Open hernioplasty.

Wound Infection: Proportions



Supplementary figure 3: Forest Plot of Wound infection depicting proportions in Laparoscopic IPOM Repair



Supplementary figure 4: Forest Plot of Wound infection depicting proportions in open hernioplasty

PROSPERO Registration Protocol

Review title
Comparative Effectiveness of Intraperitoneal Onlay Mesh (IPOM) vs. Open Hernioplasty in Small Ventral Hernia Repair: A Systematic Review and Meta-Analysis of RCTs

Review question
What is the comparative effectiveness of Intraperitoneal Onlay Mesh (IPOM) versus open hernioplasty in small ventral hernia repair, specifically in terms of hernia recurrence rates and postoperative complications?

Searches

We will conduct a comprehensive search across multiple databases to identify relevant studies comparing the clinical effectiveness of Intraperitoneal Onlay Mesh (IPOM) versus open hernioplasty for small ventral hernia repairs. The search will be conducted up to October 2024 and will adhere to a predefined PICO framework (Population, Intervention, Comparator, Outcome). The databases to be Searched will be PubMed, Embase, Scopus, The Cochrane Central Register of Controlled Trials (CENTRAL), and Clinical trial registries, includingClinicalTrials.gov, and WHO International Clinical Trials Registry Platform (ICTRP).

Search strategy: Attached.

Condition or domain being studied

Ventral hernia is a common patient presentation faced by surgeons with an overall incidence between 6-22%.It is a condition where a protrusion of the underlying intestine or any other abdominal tissue occurs through a gap or weakness in the abdominal wall. They are non-inguinal, non-hiatal defects in the fascia of the abdominal lining and are observed to be more prevalent in females and elderly persons between 40-60 years of age.The conventional method of hernia repair uses an open surgical technique without mesh insertion for repairing the anatomical layers or structure which often results in a higher rate of recurrence imposing a significant economic burden on the health care system.The laparoscopic ventral hernia repair technique has been established as an effective, less invasive treatment option, that results in fewer wound complications, gives faster recovery, low rate of recurrence along with improved cosmesis. In recent years, Intra-peritoneal onlay mesh (IPOM) repair has emerged as a simple and safe laparoscopic method where the hernia defect is bridged from the peritoneal side using a composite mesh.

Participants/population
Adult patients with a diagnosis of small ventral hernia defects, inclusive of incisional hernias, regardless of the size of the defect

Intervention(s), exposure(s)

Intraperitoneal Onlay Mesh (IPOM)

Comparator(s)/control
Open hernioplasty

Types of study to be included

The Randomized Controlled Trials (RCT) will be only included.

Context

The review focuses on evaluating the comparative effectiveness of Intraperitoneal Onlay Mesh (IPOM) versus open hernioplasty in the context of small ventral hernia repairs. It includes randomized controlled trials (RCTs) that involve adult patients undergoing surgical repair of ventral hernias smaller than 4 cm. The inclusion criteria are limited to studies that specifically compare IPOM with open hernioplasty, assessing key outcomes such as hernia recurrence rates and postoperative complications (e.g., wound infection, seroma formation). Studies involving larger hernias, pediatric populations, or those using other surgical techniques or mesh types are excluded to maintain a focused analysis on the target patient group and interventions.

Main outcome(s)

Recurrence rate of hernia post-surgery, Rate of post-operative complications (e.g., wound infections, seroma, chronic pain), Recovery time (e.g., return to normal activities, length of hospital stay), Number of successful outcomes which includes patients without any complications.

Measures of effect **(Please specify the effect measure(s) for your main outcome(s) e.g., relative risks, odds ratios, risk difference, and/or 'number needed to treat.)**

To quantify and compare the outcomes of Intraperitoneal Onlay Mesh (IPOM) and open hernioplasty in adult patients with small ventral hernia defects, the following effect measures will be used. Hernia Recurrence Rate after Surgery using Risk Ratio (RR) or Relative Risk (RR) with 95% Confidence Intervals (CI). The recurrence rate will be calculated as the proportion of patients who have a hernia recurrence after surgery in each group (IPOM versus open hernioplasty). A Risk Ratio < 1 indicates fewer recurrences in the IPOM group compared to open hernioplasty. A Risk Ratio > 1 indicates a higher recurrence rate in the IPOM group. If recurrence rates are low, Odds Ratios (OR) may be used as an alternative.

Wound infections, seroma, chronic pain, and other surgical complications may occur at a risk ratio (RR) or odds ratio (OR) with 95% confidence intervals (CI). The complication rate will be calculated as the percentage of patients in each group who experience post-operative complications. IPOM has a lower complication rate than open hernioplasty, as indicated by a Risk Ratio or Odds Ratio of less than one.

Risk of bias (quality) assessment

The quality assessment/ risk of bias (RoB) in the included articles will be assessed independently and in duplicate by all authors based on the JBI checklist for systematic review and meta-analysis of RCT.The overall certainty of evidence for each outcome will be assessed using the GRADE method.

Strategy for data synthesis

Our study will adhere to the PRISMA guidelines for systematic review methodology, ensuring transparency and rigour in reporting our findings.

The data synthesis for the systematic review and meta-analysis comparing Intraperitoneal Onlay Mesh (IPOM) to open hernioplasty for small ventral hernia repairs will be structured. First, we will conduct a qualitative synthesis of all relevant studies, summarising key findings on recurrence rates, post-operative complications, and recovery time.

A quantitative synthesis (meta-analysis) will be carried out on studies that report similar outcome measures. We will use appropriate statistical models to pool effect sizes: Risk Ratios (RR) or Odds Ratios (OR) for dichotomous outcomes like recurrence and complication rates, and Mean Differences (MD) for continuous outcomes like recovery time. If there is significant heterogeneity, a random-effects model will be used; otherwise, a fixed-effects model will be used. Heterogeneity will be evaluated using the I^2 statistic and Cochran's Q test.

Analysis of subgroups or subsets

Subgroup analyses will be conducted based on key study characteristics such as hernia defect size and follow-up duration. Sensitivity analyses will be performed to assess the robustness of the results, excluding studies with a high risk of bias or missing data. Where possible, funnel plots and the Egger's test will be used to assess publication bias.

Dissemination plans

We plan to disseminate the findings among the key stakeholders working on policy decision making and program implementation.

Keywords

IPOM, Laparoscopic ventral hernia repair, Open hernioplasty, Recurrence

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Data extraction

Titles and/or abstracts of the studies retrieved from the databases and additional sources will be screened independently by two review authors. The studies that meet the inclusion will be identified and selected. The full text of these potentially eligible studies will be retrieved and independently assessed by review team members. A standardized, pre-piloted excel datasheet will be used to extract data from the included studies for assessment of study quality and evidence synthesis. Extracted information will include: study setting; PICO framework defining study population intervention, comparator, outcomes and times of measurement; information for assessment of the risk of bias. Two review authors will extract data independently, discrepancies will be identified and resolved through discussion (with a third author where necessary).

Search strategies

Database: PubMed, Embase, Scopus, Cochrane Central Register of Controlled Trials (CENTRAL), ClinicalTrials.gov, and WHO International Clinical Trials Registry Platform (ICTRP)

PubMed	As on Date: 16th October 2024	
	Query	Items found
#4	#1 AND #2 AND #3	304
#1 Ventral Hernia	('Ventral Hernia' [MeSH] OR 'Abdominal Hernia' [MeSH] OR "Hernia, Ventral" OR "Hernia, Abdominal" OR "Small Ventral Hernia" OR "Primary Ventral Hernia")	31,329
#2 IPOM OR Open Hernia Repair	("Intraperitoneal Onlay Mesh" OR "IPOM" OR "Intraperitoneal Mesh" OR "Mesh Repair") OR ("Open Hernioplasty" OR "Open Hernia Repair" OR "Open Surgery" OR "Open Mesh Repair")	32,540
#3 RCTs	("Randomized Controlled Trial"[Publication Type] OR "Randomised Control Trials" OR "RCT" OR 'Clinical Trial' [MeSH])	1,014,670

Embase	As on Date: 16th October 2024	
	Query	Items found
#4	#1 AND #2 AND #3	
#1 Ventral Hernia	(exp "'Ventral Hernia'"/ OR exp "'Abdominal Hernia'"/ OR "Hernia, Ventral" OR "Hernia, Abdominal" OR "Small Ventral Hernia" OR "Primary Ventral Hernia")	
#2 IPOM OR Open Hernia Repair	("Intraperitoneal Onlay Mesh" OR IPOM OR "Intraperitoneal Mesh" OR "Mesh Repair") OR ("Open Hernioplasty" OR "Open Hernia Repair" OR "Open Surgery" OR "Open Mesh Repair")	
#3 RCTs	("Randomized Controlled Trial".pt. OR "Randomised Control Trials" OR RCT OR exp "'Clinical Trial'"/)	

Scopus	As on Date: 16th October 2024	
	Query	Items found
#4	#1 AND #2 AND #3	
#1 Ventral Hernia	(INDEXTERMS("'Ventral Hernia'") OR INDEXTERMS("'Abdominal Hernia'") OR "Hernia, Ventral" OR "Hernia, Abdominal" OR "Small Ventral Hernia" OR "Primary Ventral Hernia")	
#2	("Intraperitoneal Onlay Mesh" OR IPOM OR "Intraperitoneal Mesh" OR "Mesh Repair") OR ("Open Hernioplasty" OR "Open Hernia Repair" OR "Open Surgery" OR "Open Mesh Repair")	