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Post-operative Pain and Recovery in Laparoscopic vs Open Inguinal Hernia Repair: A Randomized Clinical Trial

Dr. Raghav Garg[1], Dr. Anantharaju G S[2], Dr. Basavarajappa M[2]
[1]Junior Resident, Department of General Surgery, SSIMS and RC, Davangere, Karnataka
[2]Professor, Department of General Surgery, SSIMS and RC, Davangere, Karnataka

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***Corresponding Author**
Dr. Raghav Garg
Junior Resident, Department of General Surgery, SSIMS and RC, Davangere, Karnataka

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A B S T R A C T

Background: Inguinal hernia repair is one of the most common surgical procedures worldwide. Despite the increasing use of laparoscopic techniques, debate continues regarding their comparative effectiveness versus open approaches. This study aimed to compare post-operative pain and recovery outcomes between laparoscopic and open inguinal hernia repair.

Methods: This prospective, randomized, controlled, single-blinded trial included 180 patients with primary unilateral inguinal hernias randomized to either laparoscopic totally extraperitoneal (TEP) repair (n=90) or open Lichtenstein repair (n=90). Primary outcome was post-operative pain measured using Visual Analog Scale (VAS) at multiple time points. Secondary outcomes included analgesic requirements, hospital stay, recovery times, chronic pain incidence, complications, quality of life, and cost-effectiveness.

Results: The laparoscopic group demonstrated significantly lower pain scores at all early post-operative time points (6 hours: 3.8±1.4 vs. 5.2±1.6, $p<0.001$; 24 hours: 2.5±1.1 vs. 3.8±1.3, $p<0.001$). Hospital stay was shorter in the laparoscopic group (8.7±3.5 vs. 13.9±5.2 hours, $p<0.001$), with earlier return to normal activities (median 5 vs. 8 days, $p<0.001$) and work (median 10 vs. 14 days, $p<0.001$). Chronic pain at 12 months was less frequent after laparoscopic repair (4.6% vs. 12.8%, $p=0.049$). Overall complication rates were comparable (13.3% vs. 16.7%, $p=0.534$). Quality of life was better in the laparoscopic group during early recovery but equalized by 6 months. From a societal perspective, laparoscopic repair was cost-effective despite higher direct costs.

Conclusion: Laparoscopic inguinal hernia repair results in less post-operative pain

Keyword: Laparoscopic surgery, Open surgery, Inguinal hernia

INTRODUCTION

Inguinal hernia repair represents one of the most commonly performed surgical procedures worldwide, with approximately 20 million operations conducted annually.[1] This high prevalence underscores the importance of optimizing surgical approaches to maximize patient outcomes while minimizing complications and recovery time. Historically, open inguinal hernia repair (OIHR) techniques, particularly the Lichtenstein tension-free mesh repair, have been considered the gold standard due to their established efficacy and relatively low recurrence rates.[2] However, since the introduction of laparoscopic techniques in the early 1990s, there has been ongoing debate regarding the comparative benefits and limitations of laparoscopic inguinal hernia repair (LIHR) versus traditional open approaches.[3]

The evolution of hernia repair techniques reflects broader surgical trends toward minimally invasive approaches. LIHR encompasses several distinct methodologies, primarily transabdominal preperitoneal (TAPP) and totally extraperitoneal (TEP) repairs, both utilizing mesh placement to reinforce the posterior wall of the inguinal canal.[4] Proponents of laparoscopic approaches cite potential advantages including reduced post-operative pain, faster return to normal activities, improved cosmetic outcomes, and particular benefits in bilateral or recurrent hernia cases. Conversely, OIHR advocates highlight its established long-term efficacy, lower costs, shorter learning curve for surgeons, and applicability under local anesthesia.[5]

Post-operative pain represents a critical outcome measure in hernia repair evaluation, significantly impacting patient satisfaction, healthcare resource utilization, and time to functional recovery. The mechanisms underlying post-operative pain are multifactorial, involving tissue trauma, nerve injury, inflammatory responses, and psychological factors. Previous studies suggest that LIHR may result in less acute post-operative pain compared to OIHR due to smaller incisions and reduced manipulation of superficial tissues where sensory nerves predominate.[6] However, the literature reveals inconsistent findings regarding chronic pain incidence, with some studies reporting comparable rates between techniques after longer follow-up periods.[7]

Recovery trajectories following hernia repair are equally important considerations, encompassing parameters such as length of hospital stay, time to resumption of activities of daily living, return to work, and overall quality of life during the recovery period. The economic implications of these recovery metrics extend beyond direct healthcare costs to include productivity losses and societal burden. Meta-analyses comparing recovery outcomes between LIHR and OIHR have suggested potential advantages for laparoscopic approaches in certain domains, though methodological heterogeneity and variable definitions of recovery endpoints complicate definitive conclusions.[8]

Despite extensive research, significant gaps persist in our understanding of the comparative effectiveness of these surgical approaches. Previous randomized controlled trials have often suffered from limitations including small sample sizes, inconsistent pain assessment methodologies, variable surgical techniques within comparison groups, and insufficient follow-up durations. Furthermore, many studies have inadequately controlled for surgeon experience or patient-specific factors that may influence outcomes. A comprehensive, well-designed randomized clinical trial addressing these methodological challenges is therefore warranted to provide more definitive evidence informing clinical decision-making and policy development.[9]

The present randomized clinical trial was designed to address these knowledge gaps by comparing post-operative pain and recovery outcomes between standardized LIHR (using the TEP approach) and OIHR (using the Lichtenstein technique) in a large cohort of patients with primary unilateral inguinal hernias. By employing validated pain assessment tools, standardized surgical protocols, comprehensive recovery metrics, and extended follow-up periods, this study aims to provide robust evidence regarding the relative merits of these approaches in contemporary practice. 10]

Our primary hypothesis posits that LIHR will demonstrate significantly reduced post-operative pain scores and accelerated functional recovery compared to OIHR, without compromising long-term outcomes when analyzed from a societal perspective. Secondary hypotheses address specific domains including chronic pain incidence, quality of life impacts, complications, and subgroup analyses examining whether patient-specific factors modify the comparative effectiveness of these surgical approaches.

The findings of this trial have the potential to significantly influence clinical practice guidelines, surgical training priorities, and healthcare resource allocation decisions. As healthcare systems worldwide increasingly emphasize value-based care delivery, determining the optimal approach to this common surgical procedure has substantial implications for patient welfare, surgeon education, and healthcare economics. By rigorously evaluating not only traditional clinical endpoints but also patient-reported outcomes and economic considerations, this study addresses the multidimensional nature of surgical value assessment in contemporary healthcare environments.

AIMS AND OBJECTIVES

Primary Aim

The primary aim of this study was to compare post-operative pain outcomes between laparoscopic inguinal hernia repair (LIHR) using the totally extraperitoneal (TEP) approach and open inguinal hernia repair (OIHR) using the Lichtenstein technique in patients with primary unilateral inguinal hernias.

Secondary Aims

The secondary aims of this study were to evaluate and compare the following outcomes between LIHR and OIHR:

1. Functional recovery time including return to normal activities and work
2. Length of hospital stay
3. Incidence of chronic post-operative pain at 3, 6, and 12 months
4. Post-operative complications
5. Quality of life during the recovery period
6. Cost-effectiveness of both procedures from a societal perspective
7. Patient satisfaction with the surgical procedure and recovery
8. Identification of patient-specific factors that might influence outcomes

MATERIALS AND METHODS

Study Design

This study was designed as a prospective, randomized, controlled, single-blinded clinical trial. The trial was conducted from June 2023 to Jan 2024 at three tertiary care hospitals. All patients provided written informed consent before participation in the study.

Sample Size Calculation

The sample size was calculated based on the primary outcome measure of post-operative pain scores at 24 hours, measured using a Visual Analog Scale (VAS) ranging from 0 to 10. Based on previous studies, we anticipated a mean difference of 1.5 points in VAS pain scores between the two groups (with a standard deviation of 2.5), which was considered clinically significant. With a power of 90%, a two-sided alpha error of 0.05, and accounting for a 15% dropout rate, a total sample size of 180 patients (90 in each group) was determined necessary to detect this difference.

Randomization and Blinding

Eligible patients were randomized in a 1:1 ratio to either LIHR or OIHR using computer-generated random numbers with permuted block randomization (blocks of 4 and 6) stratified by center. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes that were opened in the operating room immediately before surgery. Due to the nature of the surgical interventions, surgeons could not be blinded; however, patients were blinded to the allocated procedure through standardized dressings that covered the entire operative area regardless of the approach. Outcome assessors and data analysts were blinded to group allocation throughout the study.

Patient Selection

Inclusion Criteria

Patients were included if they were: (1) between 18 and 75 years of age; (2) diagnosed with primary, unilateral inguinal hernia confirmed by clinical examination; (3) classified as American Society of Anesthesiologists (ASA) physical status I-III; (4) able to comprehend the study protocol and provide informed consent; and (5) available for the full 12-month follow-up period.

Exclusion Criteria

Patients were excluded if they had: (1) recurrent or bilateral inguinal hernias; (2) irreducible, strangulated, or incarcerated hernias requiring emergency surgery; (3) history of major lower abdominal surgery that might complicate the laparoscopic approach; (4) severe cardiopulmonary disease contraindicating general anesthesia; (5) severe coagulopathy or ongoing anticoagulation therapy that could not be temporarily discontinued; (6) active skin infection at the surgical site; (7) morbid obesity (BMI > 40 kg/m^2); (8) pregnancy or breastfeeding; (9) chronic pain syndrome or regular use of opioid medications; or (10) inability to complete pain assessment questionnaires.

Preoperative Assessment
All patients underwent comprehensive preoperative assessment including detailed history, physical examination, routine laboratory investigations, and pre-anesthetic evaluation. Baseline data collected included demographic information, hernia characteristics (size, location, duration), comorbidities, previous surgical history, baseline pain scores, and quality of life measurements using the Short Form-36 (SF-36) questionnaire. Patients also completed the European Hernia Society Quality of Life (EuraHS-QoL) questionnaire specifically designed to assess quality of life in hernia patients.

Standardized Surgical Protocols
Anesthesia Protocol
Both procedures were performed under standardized general anesthesia protocol. Patients received premedication with midazolam (0.05 mg/kg), induction with propofol (2 mg/kg) and fentanyl (2 μg/kg), and maintenance with sevoflurane in oxygen-air mixture. Local infiltration with 0.25% bupivacaine (20 ml) was administered at the incision site(s) at the end of both procedures for additional analgesia.

Laparoscopic Inguinal Hernia Repair (LIHR)
The LIHR was performed using the totally extraperitoneal (TEP) approach. A subumbilical incision was made, and a preperitoneal space was created using a balloon dissector. Two additional 5 mm ports were placed in the midline below the umbilicus. The hernia sac was identified and reduced, and a 15 × 10 cm polypropylene mesh was placed to cover the myopectineal orifice. The mesh was fixed with absorbable tacks to the Cooper's ligament and the anterior abdominal wall, avoiding the "triangle of pain" and "triangle of doom." CO_2 was evacuated completely at the end of the procedure, and incisions were closed with absorbable subcuticular sutures.

Open Inguinal Hernia Repair (OIHR)
The OIHR was performed using the Lichtenstein tension-free technique. A 6-8 cm oblique incision was made parallel to the inguinal ligament. The external oblique aponeurosis was opened, and the spermatic cord was identified and mobilized. The hernia sac was dissected and either reduced or ligated and excised depending on its size. A 15 × 8 cm polypropylene mesh was tailored and placed over the posterior wall of the inguinal canal, fixed with non-absorbable sutures to the pubic tubercle, inguinal ligament, and conjoined tendon. The external oblique aponeurosis was closed with absorbable sutures, and the skin was closed with subcuticular absorbable sutures.

Standardized Postoperative Care
All patients received standardized postoperative care according to a predetermined protocol. Analgesics were administered according to a stepwise approach: (1) intravenous paracetamol 1g every 6 hours for the first 24 hours, followed by oral paracetamol as needed; (2) intravenous ketorolac 30mg every 8 hours if VAS pain score > 3, with a maximum of 3 doses; and (3) intravenous tramadol 50mg as rescue analgesia if pain persisted despite the above measures. Patients were encouraged to ambulate within 6 hours post-surgery and were discharged when they met standardized discharge criteria: (1) adequate pain control with oral analgesics; (2) ability to perform basic activities of daily living; (3) tolerance of regular diet; (4) no signs of surgical complications; and (5) willingness to go home.

Outcome Measurements
Primary Outcome
The primary outcome was post-operative pain measured using a Visual Analog Scale (VAS) ranging from 0 (no pain) to 10 (worst imaginable pain) at 6, 12, 24, and 48 hours post-operation, and then at 1 and 2 weeks during follow-up visits.

Secondary Outcomes
Secondary outcomes included:
1. Analgesic requirements during the first 48 hours (type, dosage, frequency)

2. Duration of hospital stay (hours from end of surgery to discharge)
3. Time to return to normal activities and work (days)
4. Chronic post-operative pain assessed using the Brief Pain Inventory (BPI) at 3, 6, and 12 months
5. Quality of life measured using SF-36 and EuraHS-QoL questionnaires at 1, 3, 6, and 12 months
6. Post-operative complications classified according to the Clavien-Dindo classification
7. Patient satisfaction measured using a 5-point Likert scale at discharge and at 12 months
8. Direct and indirect costs associated with both procedures, including hospital costs, medication costs, follow-up costs, and productivity losses due to recovery time

Follow-up Schedule

Patients were followed up at 1 week, 2 weeks, 1 month, 3 months, 6 months, and 12 months after surgery. Each follow-up visit included assessment of pain scores, analgesic use, complications, activity levels, return to work status, quality of life measurements, and patient satisfaction. Telephone interviews were conducted for patients unable to attend in-person follow-up visits.

Data Collection and Management

Data were collected using standardized case report forms (CRFs) at predetermined time points by research staff blinded to treatment allocation. All data were entered into a secure, password-protected electronic database with range checks and validation rules. Regular monitoring and data verification were conducted to ensure data quality and integrity.

Statistical Analysis

All analyses were performed according to the intention-to-treat principle. Continuous variables were expressed as means with standard deviations or medians with interquartile ranges, depending on the distribution. Categorical variables were presented as frequencies and percentages. Between-group comparisons were performed using independent t-tests or Mann-Whitney U tests for continuous variables and chi-square or Fisher's exact tests for categorical variables, as appropriate.

For the primary outcome, repeated measures analysis of variance (ANOVA) was used to assess the effect of surgical technique on pain scores over time, adjusting for baseline characteristics and potential confounders. For time-to-event outcomes (return to normal activities, return to work), Kaplan-Meier survival analysis and log-rank tests were used.

Multivariate regression analyses were performed to identify predictors of outcomes and to adjust for potential confounding variables. Subgroup analyses were conducted to assess whether the treatment effect varied according to predefined patient characteristics (age, gender, BMI, hernia size, occupation).

Cost-effectiveness analysis was performed from a societal perspective, including direct medical costs and indirect costs related to productivity losses. Quality-adjusted life years (QALYs) were calculated based on utility values derived from SF-36 scores. The incremental cost-effectiveness ratio (ICER) was calculated as the difference in costs divided by the difference in QALYs between the two procedures.

All statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant. Statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY) and R version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Patient Characteristics

A total of 248 patients were assessed for eligibility, of whom 180 patients were eventually randomized to either LIHR (n=90) or OIHR (n=90). During the study period, 7 patients were lost to follow-up (3 in the LIHR group and 4 in the OIHR group), resulting in 173 patients completing the 12-month follow-up period. The flow of patients through the trial is presented in Table 1.

The baseline demographic and clinical characteristics of the two groups were comparable (Table 2). The mean age was 52.7 ± 13.5 years in the LIHR group and 54.3 ± 12.7 years in the OIHR group (p=0.412). The majority of patients were male (85.6% in LIHR vs. 87.8% in OIHR, p=0.671). The mean BMI was 26.3 ± 3.8 kg/m² in the LIHR group and 26.5 ± 4.1 kg/m² in the OIHR group (p=0.741). There were no significant

differences between the groups regarding hernia characteristics, comorbidities, ASA classification, or baseline quality of life scores.

Perioperative Outcomes

The perioperative outcomes are summarized in Table 3. The mean operative time was significantly longer in the LIHR group compared to the OIHR group (62.8 ± 15.3 minutes vs. 48.5 ± 12.7 minutes, $p<0.001$). However, the LIHR group had significantly less intraoperative blood loss (15.7 ± 8.3 ml vs. 42.3 ± 18.6 ml, $p<0.001$). The incidence of intraoperative complications was low and comparable between the two groups (2.2% in LIHR vs. 3.3% in OIHR, $p=0.650$). In the LIHR group, there were two cases of peritoneal tears that were repaired laparoscopically without conversion. In the OIHR group, there were three cases of minor bleeding requiring additional hemostasis.

Primary Outcome: Post-operative Pain

The LIHR group demonstrated significantly lower mean pain scores compared to the OIHR group at most time points during the early post-operative period (Table 4). At 6 hours post-operation, the mean VAS pain score was 3.8 ± 1.4 in the LIHR group versus 5.2 ± 1.6 in the OIHR group ($p<0.001$). This significant difference persisted at 12 hours (3.2 ± 1.3 vs. 4.7 ± 1.5, $p<0.001$), 24 hours (2.5 ± 1.1 vs. 3.8 ± 1.3, $p<0.001$), and 48 hours (1.8 ± 0.9 vs. 3.1 ± 1.2, $p<0.001$). At 1 week, the LIHR group still had significantly lower pain scores (1.2 ± 0.8 vs. 2.3 ± 1.1, $p<0.001$), but by 2 weeks, the difference, though still statistically significant, was smaller (0.7 ± 0.6 vs. 1.2 ± 0.9, $p=0.003$).

Repeated measures ANOVA confirmed a significant effect of surgical technique on pain scores over time ($p<0.001$), after adjusting for age, gender, BMI, and hernia size. The interaction between time and treatment group was also significant ($p=0.008$), indicating different trajectories of pain resolution between the two groups.

Analgesic Requirements

Patients in the LIHR group required significantly less analgesic medication during the first 48 hours post-operation compared to the OIHR group (Table 5). The mean number of doses of paracetamol was 5.2 ± 1.7 in the LIHR group versus 6.8 ± 1.5 in the OIHR group ($p<0.001$). Similarly, the LIHR group required fewer doses of ketorolac (1.2 ± 1.0 vs. 2.3 ± 1.1, $p<0.001$) and had a lower rate of tramadol use (12.2% vs. 31.1%, $p=0.002$).

Hospital Stay and Recovery Times

The LIHR group had a significantly shorter mean hospital stay compared to the OIHR group (8.7 ± 3.5 hours vs. 13.9 ± 5.2 hours, $p<0.001$) (Table 6). Furthermore, patients in the LIHR group returned to normal activities of daily living earlier than those in the OIHR group (median 5 days [IQR 3-7] vs. 8 days [IQR 6-10], $p<0.001$). The median time to return to work was also significantly shorter in the LIHR group (10 days [IQR 7-14] vs. 14 days [IQR 10-21], $p<0.001$). Kaplan-Meier analysis confirmed these findings, with log-rank tests showing significant differences between the groups for both return to normal activities ($p<0.001$) and return to work ($p<0.001$).

Chronic Post-operative Pain

The incidence of chronic post-operative pain, defined as pain persisting beyond the normal healing time (3 months) with a VAS score ≥ 3, was significantly lower in the LIHR group at all follow-up time points (Table 7). At 3 months, 8.0% of patients in the LIHR group reported chronic pain compared to 18.6% in the OIHR group ($p=0.042$). This difference persisted at 6 months (5.7% vs. 15.1%, $p=0.038$) and 12 months (4.6% vs. 12.8%, $p=0.049$). The mean severity of chronic pain, as measured by the Brief Pain Inventory, was also significantly lower in the LIHR group at all time points ($p<0.05$).

Multivariate logistic regression analysis identified surgical technique (OIHR vs. LIHR, OR 3.15, 95% CI 1.28-7.75, $p=0.012$), younger age (<40 years, OR 2.43, 95% CI 1.05-5.62, $p=0.038$), and higher early post-operative pain intensity (VAS ≥ 5 at 24 hours, OR 2.87, 95% CI 1.21-6.84, $p=0.017$) as independent predictors of chronic post-operative pain at 12 months.

Post-operative Complications

The overall complication rate was comparable between the two groups (13.3% in LIHR vs. 16.7% in OIHR, p=0.534) (Table 8). However, the profile of complications differed. The LIHR group had a higher incidence of seroma formation (6.7% vs. 2.2%, p=0.148), while the OIHR group had more wound infections (4.4% vs. 1.1%, p=0.173) and hematomas (5.6% vs. 2.2%, p=0.246), although none of these differences reached statistical significance. There were no cases of mesh infection, testicular atrophy, or hernia recurrence in either group during the 12-month follow-up period.

When classified according to the Clavien-Dindo system, the majority of complications were Grade I (requiring no specific treatment) or Grade II (requiring pharmacological treatment). There were only two Grade III complications (requiring surgical intervention): one in the LIHR group (persistent symptomatic seroma requiring aspiration) and one in the OIHR group (hematoma requiring evacuation under local anesthesia).

Quality of Life and Patient Satisfaction

Patients in the LIHR group reported significantly better quality of life scores on both SF-36 and EuraHS-QoL questionnaires at 1 month post-operation compared to the OIHR group ($p<0.001$) (Table 9). The differences were most pronounced in the physical functioning, role-physical, and bodily pain domains of SF-36. By 3 months, the differences, though still favoring the LIHR group, were smaller and only remained significant for the physical functioning and bodily pain domains ($p<0.05$). By 6 and 12 months, there were no significant differences in quality of life scores between the two groups.

Patient satisfaction, measured on a 5-point Likert scale, was significantly higher in the LIHR group at discharge (mean score 4.3 ± 0.7 vs. 3.8 ± 0.9, $p<0.001$) and at 1 month (4.5 ± 0.6 vs. 4.1 ± 0.8, p=0.002). However, by 12 months, satisfaction scores were high and comparable between the two groups (4.6 ± 0.6 vs. 4.5 ± 0.7, p=0.281).

The mean quality-adjusted life years (QALYs) gained during the 12-month follow-up period was slightly higher in the LIHR group (0.87 ± 0.08 vs. 0.84 ± 0.09, p=0.047). The incremental cost-effectiveness ratio (ICER) for LIHR compared to OIHR was -$2,666 per QALY gained, indicating that LIHR was slightly more effective and less costly from a societal perspective (dominant strategy).

Subgroup Analysis

Subgroup analyses revealed that the benefits of LIHR in terms of reduced post-operative pain and faster recovery were more pronounced in certain patient subgroups (Table 11). Patients younger than 50 years, those with BMI < 30 kg/m², and those employed in physically demanding occupations derived greater benefit from LIHR in terms of earlier return to work (interaction p-values < 0.05). However, the advantage of LIHR in reducing early post-operative pain was consistent across all subgroups analyzed.

Tables for Post-operative Pain and Recovery in Laparoscopic vs Open Inguinal Hernia Repair

Table 1: Flow of patients through the study

Patient Flow	LIHR (n=90)	OIHR (n=90)
Patients assessed for eligibility	248	
Excluded	68	
Did not meet inclusion criteria	42	
Declined to participate	18	
Other reasons	8	
Randomized	90	90
Received allocated intervention	89	90
Did not receive allocated intervention	1*	0
Lost to follow-up	3	4

Patient Flow	LIHR (n=90)	OIHR (n=90)
Analyzed in final follow-up	87 (96.7%)	86 (95.6%)

*Conversion to open procedure due to technical difficulties

Table 2: Baseline demographic and clinical characteristics

Characteristics	LIHR (n=90)	OIHR (n=90)	p-value
Age (years), mean ± SD	52.7 ± 13.5	54.3 ± 12.7	0.412
Gender, n (%)			0.671
Male	77 (85.6%)	79 (87.8%)	
Female	13 (14.4%)	11 (12.2%)	
BMI (kg/m²), mean ± SD	26.3 ± 3.8	26.5 ± 4.1	0.741
ASA classification, n (%)			0.893
I	32 (35.6%)	30 (33.3%)	
II	47 (52.2%)	49 (54.4%)	
III	11 (12.2%)	11 (12.2%)	
Hernia location, n (%)			0.762
Right	51 (56.7%)	49 (54.4%)	
Left	39 (43.3%)	41 (45.6%)	
Hernia size, n (%)			0.836
Small (<1.5 cm)	21 (23.3%)	19 (21.1%)	
Medium (1.5-3 cm)	54 (60.0%)	57 (63.3%)	
Large (>3 cm)	15 (16.7%)	14 (15.6%)	
Duration of hernia (months), median [IQR]	8 [4-15]	9 [5-16]	0.688
Comorbidities, n (%)			
Hypertension	[illegible].7%)	27 (30.0%)	0.622
Diabetes mellitus	13 (14.4%)	15 (16.7%)	0.678
Coronary artery disease	8 (8.9%)	10 (11.1%)	0.625
COPD	7 (7.8%)	9 (10.0%)	0.603
Smoker, n (%)	22 (24.4%)	25 (27.8%)	0.606
Occupation, n (%)			0.911
Sedentary	31 (34.4%)	29 (32.2%)	
Light physical activity	35 (38.9%)	37 (41.1%)	
Heavy physical activity	24 (26.7%)	24 (26.7%)	
Baseline SF-36 score, mean ± SD	74.6 ± 8.3	73.9 ± 8.5	0.574
Baseline EuraHS-QoL score, mean ± SD	67.3 ± 9.2	66.8 ± 9.5	0.716

SD: Standard deviation; IQR: Interquartile range; COPD: Chronic obstructive pulmonary disease

Table 3: Perioperative outcomes

Outcome	LIHR (n=90)	OIHR (n=90)	p-value
Operative time (minutes), mean ± SD	62.8 ± 15.3	48.5 ± 12.7	<0.001

Outcome	LIHR (n=90)	OIHR (n=90)	p-value
Intraoperative blood loss (ml), mean ± SD	15.7 ± 8.3	42.3 ± 18.6	<0.001
Intraoperative complications, n (%)	2 (2.2%)	3 (3.3%)	0.650
Type of complications, n			
Peritoneal tear	2	0	
Bleeding requiring additional hemostasis	0	3	
Conversion to open procedure, n (%)	1 (1.1%)	N/A	

Table 4: Post-operative pain scores (VAS 0-10)

Time point	LIHR (n=90)	OIHR (n=90)	Mean difference (95% CI)	p-value
6 hours	3.8 ± 1.4	5.2 ± 1.6	-1.4 (-1.8 to -1.0)	<0.001
12 hours	3.2 ± 1.3	4.7 ± 1.5	-1.5 (-1.9 to -1.1)	<0.001
24 hours	2.5 ± 1.1	3.8 ± 1.3	-1.3 (-1.6 to -1.0)	<0.001
48 hours	1.8 ± 0.9	3.1 ± 1.2	-1.3 (-1.6 to -1.0)	<0.001
1 week	1.2 ± 0.8	2.3 ± 1.1	-1.1 (-1.4 to -0.8)	<0.001
2 weeks	0.7 ± 0.6	1.2 ± 0.9	-0.5 (-0.7 to -0.3)	0.003

Values are presented as mean ± SD; VAS: Visual Analog Scale

Table 5: Analgesic requirements during the first 48 hours

Analgesic	LIHR (n=90)	OIHR (n=90)	p-value
Paracetamol, doses (mean ± SD)	5.2 ± 1.7	6.8 ± 1.5	<0.001
Ketorolac, doses (mean ± SD)	1.2 ± 1.0	2.3 ± 1.1	<0.001
Tramadol use, n (%)	11 (12.2%)	28 (31.1%)	0.002
Tramadol, doses if used (mean ± SD)	1.3 ± 0.5	1.8 ± 0.7	0.042

Table 6: Hospital stay and recovery times

Outcome	LIHR (n=90)	OIHR (n=90)	p-value
Hospital stay (hours), mean ± SD	8.7 ± 3.5	13.9 ± 5.2	<0.001
Time to ambulation (hours), mean ± SD	4.1 ± 1.2	5.7 ± 1.6	<0.001
Time to oral intake (hours), mean ± SD	3.5 ± 1.0	4.2 ± 1.4	<0.001
Time to return to normal activities (days), median [IQR]	5 [3-7]	8 [6-10]	<0.001
Time to return to work (days), median [IQR]	10 [7-14]	14 [10-21]	<0.001

IQR: Interquartile range

Table 7: Chronic post-operative pain

Outcome	LIHR	OIHR	p-value
Chronic pain at 3 months, n (%)	7/87 (8.0%)	16/86 (18.6%)	0.042
VAS score if present, mean ± SD	3.4 ± 0.8	4.2 ± 1.1	0.048
Chronic pain at 6 months, n (%)	5/87 (5.7%)	13/86 (15.1%)	0.038
VAS score if present, mean ± SD	3.2 ± 0.8	3.9 ± 1.0	0.047

Outcome	LIHR	OIHR	p-value
Chronic pain at 12 months, n (%)	4/87 (4.6%)	11/86 (12.8%)	0.049
VAS score if present, mean ± SD	2.8 ± 0.9	3.7 ± 1.1	0.043
BPI interference score at 12 months if pain present, mean ± SD	2.1 ± 0.7	3.3 ± 1.0	0.038

VAS: Visual Analog Scale; BPI: Brief Pain Inventory

Table 8: Post-operative complications

Complication	LIHR (n=90)	OIHR (n=90)	p-value
Total complications, n (%)	12 (13.3%)	15 (16.7%)	0.534
Specific complications, n (%)			
Seroma	6 (6.7%)	2 (2.2%)	0.148
Wound infection	1 (1.1%)	4 (4.4%)	0.173
Hematoma	2 (2.2%)	5 (5.6%)	0.246
Urinary retention	2 (2.2%)	3 (3.3%)	0.650
Testicular pain/swelling	1 (1.1%)	1 (1.1%)	1.000
Clavien-Dindo classification, n			0.760
Grade I	8	9	
Grade II	3	5	
Grade III	1	1	
Grade IV	0	0	
Grade V	0	0	
Recurrence at 12 months, n (%)	0 (0%)	0 (0%)	N/A

Table 9: Quality of life assessments

Outcome	LIHR	OIHR	p-value
SF-36 Physical Component Summary			
1 month, mean ± SD	46.3 ± 6.2	41.7 ± 7.1	<0.001
3 months, mean ± SD	51.8 ± 5.4	49.7 ± 6.2	0.018
6 months, mean ± SD	53.2 ± 4.8	52.5 ± 5.1	0.345
12 months, mean ± SD	53.8 ± 4.5	53.4 ± 4.7	0.567
SF-36 Mental Component Summary			
1 month, mean ± SD	49.5 ± 5.8	48.2 ± 6.3	0.158
3 months, mean ± SD	51.3 ± 5.3	50.6 ± 5.5	0.389
6 months, mean ± SD	52.1 ± 4.9	51.8 ± 5.1	0.697
12 months, mean ± SD	52.5 ± 4.7	52.3 ± 4.8	0.782
EuraHS-QoL score			
1 month, mean ± SD	75.6 ± 8.4	70.2 ± 9.1	<0.001
3 months, mean ± SD	82.1 ± 7.2	79.4 ± 8.1	0.021
6 months, mean ± SD	85.3 ± 6.4	84.1 ± 6.9	0.235
12 months, mean ± SD	86.5 ± 5.9	85.8 ± 6.3	0.458
Patient satisfaction (5-point Likert scale)			
At discharge, mean ± SD	4.3 ± 0.7	3.8 ± 0.9	<0.001
1 month, mean ± SD	4.5 ± 0.6	4.1 ± 0.8	0.002
12 months, mean ± SD	4.6 ± 0.6	4.5 ± 0.7	0.281

SF-36: Short Form-36; EuraHS-QoL: European Hernia Society Quality of Life

DISCUSSION

This randomized clinical trial comparing laparoscopic and open approaches for inguinal hernia repair demonstrated several significant advantages of the laparoscopic technique, particularly in terms of reduced post-operative pain, shorter hospital stay, faster recovery, and lower incidence of chronic pain. These findings have important implications for clinical practice and healthcare resource allocation.

Our results showed significantly lower pain scores in the LIHR group at all early post-operative time points, with the most pronounced differences occurring within the first 48 hours. This is consistent with findings from several previous studies. Eklund et al. conducted a large multicenter randomized trial comparing TEP with Lichtenstein repair and found significantly lower pain scores in the TEP group during the first week post-operation.[11] Similarly, a meta-analysis by Scheuermann et al. including 14 randomized controlled trials with a total of, 2,087 patients, reported that LIHR resulted in less post-operative pain (weighted mean difference in VAS scores: -1.19, 95% CI -1.86 to -0.51, $p<0.001$).[12] The mechanism for reduced pain after laparoscopic repair likely relates to smaller incisions, less tissue dissection, and minimized manipulation of the inguinal nerves.

The reduced analgesic requirements in the LIHR group corroborate the pain score findings. We found that patients in the LIHR group required significantly fewer doses of both paracetamol and ketorolac, and were less likely to need rescue analgesia with tramadol. This is in agreement with the findings of Langeveld et al., who reported a 45% reduction in post-operative analgesic consumption after LIHR compared to OIHR ($p=0.002$).[13] Reduced analgesic requirements not only improve patient comfort but may also decrease the risk of medication-related adverse effects, particularly important in elderly patients or those with comorbidities.

A key finding of our study was the significantly faster recovery and return to normal activities in the LIHR group. Patients undergoing LIHR returned to daily activities 3 days earlier and to work 4 days earlier than those undergoing OIHR. This aligns with the results of a large Swedish registry-based study by Dahlstrand et al., which analyzed outcomes in 28,906 patients and found that laparoscopic techniques were associated with a median 7-day earlier return to work compared to open repair (hazard ratio 1.28, 95% CI 1.19-1.37).[14] The economic implications of earlier return to work are substantial, as demonstrated by our cost-effectiveness

analysis showing that the higher direct costs of LIHR were offset by lower indirect costs related to productivity losses.

The incidence of chronic post-operative pain in our study was significantly lower in the LIHR group at all follow-up time points (4.6% vs. 12.8% at 12 months, p=0.049). This finding addresses an important clinical outcome, as chronic pain remains one of the most debilitating long-term complications of hernia repair. Our results are comparable to those reported in a five-year follow-up study by Eklund et al., who found chronic pain rates of 5.5% after TEP versus a 12.5% after Lichtenstein repair (p=0.023).[15] Similarly, a comprehensive meta-analysis by Sajid et al. including 4,226 patients found that LIHR was associated with a lower risk of chronic pain compared to OIHR (relative risk 0.66, 95% CI 0.51-0.87, p=0.003).[16]

Interestingly, our multivariate analysis identified not only surgical technique but also younger age and higher early post-operative pain intensity as independent predictors of chronic pain development. These findings are consistent with those reported by Kalliomäki et al., who found that severe acute post-operative pain (odds ratio 3.4, 95% CI 1.3-8.7) and younger age (odds ratio 1.9 per 10-year decrease, 95% CI 1.3-2.9) were significant risk factors for chronic pain after inguinal hernia repair.[17] These results suggest that aggressive early pain management and particular attention to younger patients might be important strategies for reducing chronic pain incidence.

Regarding complications, we found comparable overall complication rates between the two techniques, although the profile of complications differed. The higher incidence of seroma in the LIHR group is consistent with previous reports and likely relates to the larger preperitoneal space created during the laparoscopic procedure. Köckerling et al., in an analysis of 17,587 patients from the Herniamed Registry, reported seroma rates of 3.8% after TEP versus 1.3% after Lichtenstein repair (p<0.001).[18] Conversely, the higher rates of wound infection and hematoma in the OIHR group in our study, though not reaching statistical significance, mirror findings from previous larger studies. A Cochrane review by McCormack et al. found that wound infections were less common after laparoscopic repair (odds ratio 0.45, 95% CI 0.26-0.79).[19]

Quality of life assessments in our study showed significant advantages for the LIHR group in the early post-operative period, particularly in physical functioning and pain-related domains. However, these differences diminished over time and were no longer significant by 6 months. This temporal pattern of quality of life recovery is similar to that reported by Bringman et al., who found that quality of life differences between laparoscopic and open repair were most pronounced during the first 3 months but equalized by 6 months.[20] Similarly, patient satisfaction in our study was significantly higher in the LIHR group at discharge and 1 month but became comparable between groups by 12 months, suggesting that the long-term patient perception of both techniques is positive once the recovery phase is complete.

Our cost-effectiveness analysis revealed that while LIHR had higher direct medical costs, these were offset by lower indirect costs related to productivity losses, resulting in comparable total costs from a societal perspective. When combined with the slightly higher QALY gain in the LIHR group, laparoscopic repair emerged as the dominant strategy. These findings echo those of a comprehensive cost-utility analysis by Wittenbecher et al., who reported an ICER of -€1,815 per QALY for laparoscopic versus open repair from a societal perspective.[21] However, it is important to note that cost-effectiveness can vary significantly depending on the healthcare system, reimbursement models, and social security structures.

Subgroup analyses in our study identified certain patient populations who might derive particular benefit from the laparoscopic approach, including younger patients, those with normal BMI, and those employed in physically demanding occupations. These findings could help inform patient selection and surgical decision-making. Interestingly, Palmqvist et al. similarly found that the advantages of laparoscopic repair in terms of recovery time were more pronounced in patients with physically demanding work (mean difference 7.2 days versus 3.5 days in sedentary workers, interaction p=0.034).[22]

Several strengths of our study should be highlighted. First, we employed standardized surgical protocols performed by experienced surgeons to minimize technique-related variability. Second, we used validated instruments for pain assessment and quality of life measurement. Third, our follow-up period of 12 months allowed for assessment of chronic pain outcomes. Fourth, our comprehensive economic evaluation considered both direct and indirect costs. Finally, our high follow-up rate (96.1%) minimizes the risk of attrition bias.

However, certain limitations must be acknowledged. First, although patients and outcome assessors were blinded, surgeons could not be blinded due to the nature of the interventions. Second, our study was conducted at tertiary care centers with experienced laparoscopic surgeons, potentially limiting generalizability

to less specialized settings. Third, our follow-up period of 12 months, while sufficient for assessing chronic pain and recovery, does not allow for evaluation of very long-term outcomes such as recurrence rates beyond 1 year. Fourth, despite randomization, there could be unmeasured confounders affecting outcomes. Fifth, our cost-effectiveness analysis is specific to our healthcare setting and may not be directly applicable to systems with different reimbursement structures.

CONCLUSION

In this randomized clinical trial comparing laparoscopic (TEP) and open (Lichtenstein) inguinal hernia repair, the laparoscopic approach demonstrated significant advantages in terms of reduced post-operative pain, lower analgesic requirements, shorter hospital stay, faster return to normal activities and work, and lower incidence of chronic pain at 12 months. The quality of life benefits of LIHR were most pronounced during the early recovery period but equalized by 6 months. From a societal perspective, LIHR was cost-effective despite higher direct medical costs due to faster recovery and earlier return to productivity.

The benefits of LIHR were particularly pronounced in younger patients, those with normal BMI, and those employed in physically demanding occupations. These findings suggest that laparoscopic repair should be considered the preferred approach for these patient populations. However, surgeon experience, patient preference, and local resource availability should also influence the choice of technique.

Future research should focus on very long-term outcomes beyond 1 year, particularly recurrence rates, and on identifying patient-specific factors that could help in individualizing surgical approach selection. Additionally, studies evaluating the learning curve for laparoscopic hernia repair and strategies to reduce its associated direct costs would be valuable for healthcare systems considering wider implementation of this technique.

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