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Original Research Article

Laparoscopic Versus Open Hernia Repair for Indirect Inguinal Hernia in Adolescents: A Retrospective Cohort Study

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Abstract

Introduction: The optimal operative strategy for managing inguinal hernia (IH) in the adolescent population remains undetermined. This investigation sought to analyse and contrast the short-term perioperative results and the durable long-term prognosis among young patients suffering from IH who were treated either with minimally invasive laparoscopic hernia repair (LHR) or conventional open hernia repair (OHR).

Methodology: This was a retrospective cohort study examining historical clinical and pathological characteristics of adolescent IH patients who initially received either LHR or OHR at VIMSAR, Burla between March 2018 and February 2024. Prognostic indicators associated with patient survival and outcome were isolated using univariate and subsequently multivariate Cox regression modelling. To mitigate potential selection bias, Propensity Score Matching (PSM) analysis was implemented to establish equivalent cohorts of patients from the LHR and OHR groups, matching them in a 1:1 ratio.

Results: The initial cohort of adolescent IH patients comprised 122 individuals in the LHR group and 126 individuals in the OHR group. Following the execution of PSM, 94 patients were successfully matched in each study arm. Relative to the OHR cohort, the LHR group exhibited numerous advantages, including a shorter duration of hospital stay, reduced intraoperative haemorrhage, a lower incidence of total postoperative morbidities, and decreased rates of both recurrence and persistent postsurgical pain. Furthermore, the LHR cohort demonstrated markedly improved recurrence-free survival compared to the OHR group, a finding confirmed both prior to and following the PSM procedure.

Conclusion: Laparoscopic management of inguinal hernia in adolescent patients represents a viable and safe therapeutic option, consistently yielding superior perioperative measures and favourable long-term outcomes.

Keywords: Adolescent inguinal hernia; Short-term and long-term surgical outcomes; Propensity score matching; minimally invasive repair; Conventional surgical repair.

Introduction

Each year, an estimated 20 million individuals worldwide seek surgical intervention for inguinal hernias [1]. Historically, the open Lichtenstein approach served as the primary method for unilateral cases, with laparoscopic techniques reserved mainly for recurrent or bilateral presentations [2]. However, burgeoning evidence from US-based studies, highlighting diminished morbidity, has increasingly positioned laparoscopic repair as the preferred option for all inguinal hernias [3]. Over the past decades, laparoscopic inguinal hernia repair (LHR) has undergone significant evolution, establishing itself as a widely adopted and mature alternative to open hernia repair (OHR) among surgical practitioners. A notable shift towards minimally invasive techniques has occurred, with general surgeons increasingly favouring LHR for its reduced invasiveness and accelerated postoperative recovery [4]. Previous research consistently demonstrates that LHR, in comparison to OHR, leads to less pain, improved patient quality of life, and a lower incidence of common postoperative complications such as wound breakdown, infections, pulmonary dysfunction, and haemorrhage [5]. Furthermore, within the broader

context of minimally invasive ventral hernia repair, benefits like shorter hospital stays, reduced operative times, fewer wound-related complications, and lower overall complication rates have been documented. While there is a prevailing consensus regarding LHR's superior perioperative and short-term postoperative outcomes compared to OHR, the literature presents conflicting findings on recurrence rates—some studies reporting higher, others lower, and still others no significant difference between laparoscopic and open methods [6]. This variability underscores the absence of a definitive recommendation for an optimal surgical approach to inguinal hernia treatment. Inguinal hernias manifest across a broad spectrum of age groups, with their incidence notably escalating with advancing age [7]. Consequently, presentations in elderly and middle-aged patients are frequently documented, whereas cases in paediatric populations are less common. Of particular note, current literature contains limited reports concerning hernias in adolescents. A critical knowledge gap persists regarding whether significant distinctions exist in the perioperative outcomes and long-term prognoses of laparoscopic versus open hernia repair within this specific younger demographic [8–13]. To address this crucial gap, the present study was designed to meticulously analyse and compare the short-term surgical outcomes and protracted prognoses for adolescents diagnosed with inguinal hernia who underwent either laparoscopic or open repair. By employing propensity score matching (PSM) analysis, this research aims to furnish a higher calibre of clinical evidence on this overlooked patient cohort.

Methodology

Patient Cohort Selection: This investigation involved a consecutive series of adolescent individuals diagnosed with inguinal hernias who underwent either laparoscopic (LHR) or open (OHR) hernia repair at VIMSAR Burla between March 2018 and February 2024. The patient records were accessed retrospectively from electronic medical systems and prospectively compiled into a centralized repository. The study received clearance from the Clinical Research Ethics Committees. Inclusion in this study was limited to patients who underwent surgical correction for inguinal hernias.

The specific criteria for inclusion were: (I) individuals aged between 13 and 18 years; (II) diagnosed with indirect inguinal hernias; (III) absence of prior major abdominal surgical history or significant underlying health conditions. These excluded conditions encompassed, but were not limited to, poorly managed cardiovascular issues (such as hypertension or coronary artery disease), respiratory ailments (like COPD or severe asthma), bleeding disorders, compromised liver or kidney function, or advanced cancers with peritoneal spread. (IV) Furthermore, patients must not have received any prior treatment for their inguinal hernia before the surgical intervention.

The selected patients were subsequently categorized into two groups based on their surgical approach: those undergoing laparoscopic inguinal hernia repair and those undergoing open inguinal hernia repair. The determination of the surgical technique was a collaborative decision, made after thorough discussion between the patient and the attending surgeon, respecting the patient's preferences. All laparoscopic procedures were executed by surgeons who had demonstrably mastered the technique, having progressed beyond the initial learning curve for LHR.

The collected clinical and pathological data points included patient age, sex, body mass index (BMI), American Society of Anaesthesiologists (ASA) score [14], hernia dimensions [15], affected side, operative duration, length of hospitalization, estimated blood loss, instances of hernia recurrence, development of chronic pain, and the occurrence of general postoperative complications. These complications encompassed bleeding, hematoma formation in the wound, seroma accumulation, wound infections, and difficulties with urinary retention.

Surgical Methodology: Open hernia repair (OHR) in our institution closely followed the classic method first described by Potts et al. [16]. Once anaesthesia was administered, the patient was positioned supine and a small oblique incision—usually 2 to 4 cm—was made over the groin on the affected side. The layers beneath the skin were gently opened one by one until the hernia sac was identified. The sac was carefully mobilised up to the level of the internal ring, after which it was tied off securely using a non-absorbable suture. The distal segment of the sac was removed, followed by mesh hernioplasty, and closure was completed in the usual step-wise fashion following meticulous hemostasis and electrocoagulation.

The laparoscopic hernia repair (LHR) performed in adolescents was based on the technique proposed by Takehara et a. [17]. Most adolescent hernias arise from a persistent patent processus vaginalis rather than a defect in the abdominal wall, meaning that the primary goal is to achieve a high ligation of the sac.

The procedure began The procedure began with the creation of pneumoperitoneum, followed by the introduction of a laparoscope through an umbilical

port, with two additional 5-mm ports placed under direct vision to allow smooth instrument maneuverability. A generous peritoneal incision was then made 2–3 cm above the internal ring, and the pre-peritoneal plane was gradually and meticulously developed to expose the entire myopectineal orifice, along with the inferior epigastric vessels, Cooper's ligament and the spermatic cord elements in clear detail. The hernia sac was carefully dissected free and reduced; in indirect cases, its separation from the cord was performed with delicate precision to avoid trauma. A 10 × 12 cm mesh was introduced and unfolded to lie broad and flat, ensuring complete coverage of the direct, indirect and femoral spaces without tension. Fixation was done with tacks or adhesive as required, and the peritoneal flap was re-approximated securely to isolate the mesh from bowel. Pneumoperitoneum was then released, ports were withdrawn under vision followed by port closure

Follow-up Protocol: Patients were monitored at two-month intervals for the first year post-discharge. Commencing from the second year, follow-up appointments were scheduled every four months. If no recurrence was evident after five years, regular check-ups were conducted every six months, beginning from the sixth year. The primary method of follow-up for all patients was physical examination. For individuals suspected of recurrence, abdominal ultrasound (US) and computed tomography (CT) scans were performed. The diagnosis of inguinal hernia recurrence was established based on the findings from these imaging modalities.

Study Outcomes: The primary endpoint for this study was the assessment of long-term outcomes, specifically focusing on recurrence-free survival (RFS). RFS was calculated from the date of surgery until the occurrence of inguinal hernia recurrence or the date of the last recorded follow-up. Secondary outcomes included intraoperative metrics, such as blood loss and operative duration, as well as short-term postoperative results, including the length of hospital stay and the overall incidence of postoperative complications. Chronic pain was defined as discomfort persisting for three months or longer following surgery.

The intensity of this pain was evaluated during follow-up visits using a Visual Analog Scale (VAS), with scores exceeding 3 considered indicative of clinically significant chronic pain. Statistical comparisons between groups for normally distributed continuous variables were performed using the Student's t-test, with data presented as mean ± standard deviation (SD). For continuous variables that did not follow a normal distribution, the Mann-Whitney U test was employed, with data expressed as median and interquartile range (IQR). Categorical data, presented as frequencies and percentages, were analysed using the Chi-square test or Fisher's exact probability test. To mitigate potential confounding factors and selection bias, Propensity Score Matching (PSM) analysis was utilized to balance baseline characteristics between the study groups. Employing a nearest-neighbour matching technique without replacement, a multivariate logistic regression model was constructed to estimate the propensity score for each patient. The matching variables included age, sex, BMI, ASA classification, hernia size, and hernia location (whether unilateral or bilateral). A caliper width of 0.2 standard deviations was applied to ensure the quality of the matches. Survival analysis was conducted using the Kaplan-Meier method, with differences between the groups assessed via the log-rank test. Potential factors influencing RFS were explored through univariate regression analysis. Variables that demonstrated statistical significance in the univariate analysis were subsequently incorporated into a multivariate analysis. A backward stepwise selection process, utilizing likelihood ratios (LR), was employed to identify independent prognostic factors within the Cox proportional hazards regression model. A p-value less than 0.05 was considered statistically significant for all analyses. A power calculation was performed to determine the necessary sample size to detect a difference in recurrence-free survival between the LHR and OHR groups. With a two-sided log-rank test, an alpha level of 0.05, 80% power, and an anticipated recurrence rate of 10% in the OHR group versus 3% in the LHR group.

Observation

Patient Demographics and Enrolment Process: Our investigation commenced with an initial cohort of 495 adolescent inguinal hernia patients. This group was naturally divided into two arms: 122 participants in the laparoscopic hernia repair (LHR) group and 126 in the open hernia repair (OHR) group. To ensure comparability between treatment approaches, propensity score matching (PSM) was subsequently applied, resulting in a balanced cohort of 188 patients, with precisely 94 individuals allocated to each surgical group, as also represented in Figure 1.

Baseline Clinical Characteristics: Table 1 provides a comprehensive overview of the patients' initial clinicopathological characteristics before PSM. Prior to matching, discernible differences existed between the LHR and OHR groups. The LHR cohort exhibited a significantly higher proportion of adolescent patients aged between 13 and 15 years (58% vs. 38.1%, $p<0.001$). Conversely, the LHR group registered a lower incidence of patients with a BMI ≥ 28 kg/m2 (24.7% vs. 35.7%, $p=0.01$) and a greater percentage

of individuals with an ASA score of 1-2, indicating lower surgical risk (81.1% vs. 70.2%, p=0.007). Furthermore, laparoscopic repair patients had a smaller percentage of hernias exceeding 4 cm in diameter (16% vs. 24.2%, p=0.032), as enumerated in Table 1. Critically, after the application of PSM, all these baseline demographic and clinical features were effectively harmonized, rendering them well-balanced and statistically comparable across both groups, with all p-values exceeding 0.05, as also presented in Table 1.

Table 1: Participant characteristics before and after PSM

Characteristics	Before PSM LHR (n=240)	OHR (n=255)	P-value	After PSM LHR (n=200)	OHR (n=200)	P-value
Age (13–15 yr)	145 (60.4%)	108 (42.3%)	<0.001	118 (59.0%)	115 (57.5%)	0.74
Age (15–18 yr)	95 (39.6%)	147 (57.7%)	<0.001	82 (41.0%)	85 (42.5%)	0.74
Sex Male	196 (81.6%)	214 (83.9%)	0.49	162 (81.0%)	165 (82.5%)	0.69
Sex Female	44 (18.3%)	41 (16.0%)	0.49	38 (19.0%)	35 (17.5%)	0.69
BMI ≥ 28 kg/m²	58 (24.1%)	92 (36.1%)	0.004	50 (25.0%)	56 (28.0%)	0.48
ASA classification (1–2)	196 (81.6%)	176 (69.0%)	0.002	164 (82.0%)	160 (80.0%)	0.62
ASA classification (3–4)	44 (18.3%)	79 (30.9%)	0.002	36 (18.0%)	40 (20.0%)	0.62
Hernia diameter ≤4 cm	185 (77.0%)	166 (65.0%)	0.005	152 (76.0%)	150 (75.0%)	0.83
Hernia diameter >4 cm	55 (22.9%)	89 (34.9%)	0.005	48 (24.0%)	50 (25.0%)	0.83
Side unilateral	188 (78.3%)	202 (79.2%)	0.81	160 (80.0%)	155 (77.5%)	0.57
Side bilateral	52 (21.6%)	53 (20.7%)	0.81	40 (20.0%)	45 (22.5%)	0.57

Recurrence-Free Survival Outcomes

An analysis of recurrence-free survival (RFS) trajectories within the adolescent inguinal hernia population yielded important insights. Before the application of PSM, Kaplan-Meier survival curves distinctly indicated that patients in the LHR group experienced significantly superior RFS compared to those in the OHR group (p=0.001), a finding visually communicated in Figure 2.

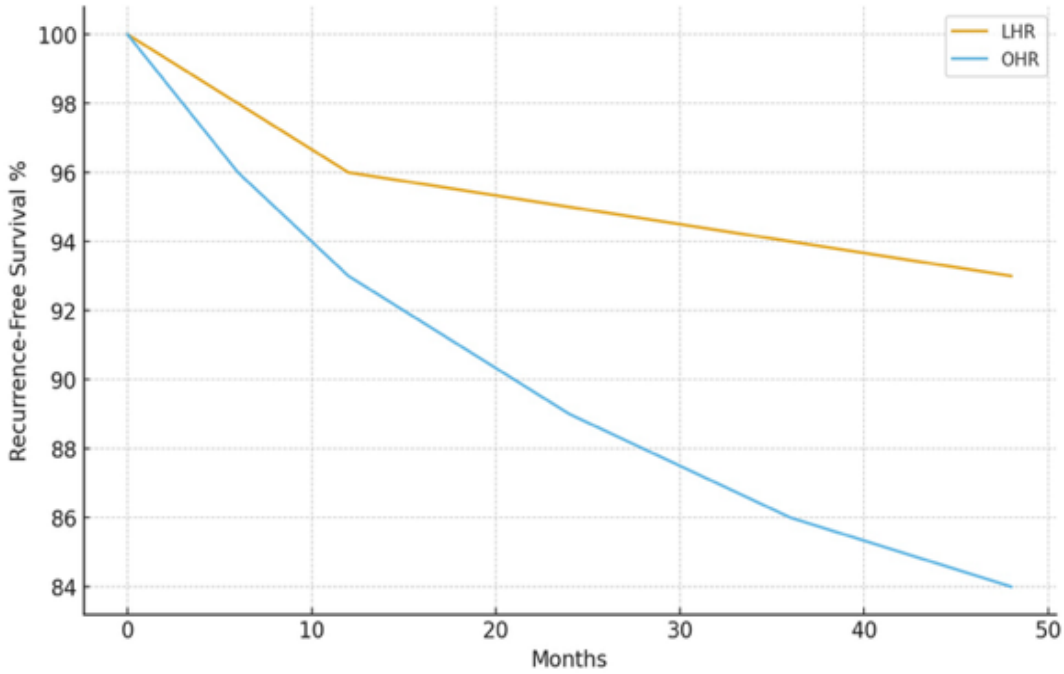

Figure 1: Kaplan-Meier curves for hernia recurrence of LHR or OHR before PSM

Remarkably, even after the rigorous balancing achieved through PSM, Kaplan-Meier curves continued to demonstrate a more favourable RFS for the LHR cohort when juxtaposed with the OHR cohort (p=0.011), as illustrated in Figure 3.

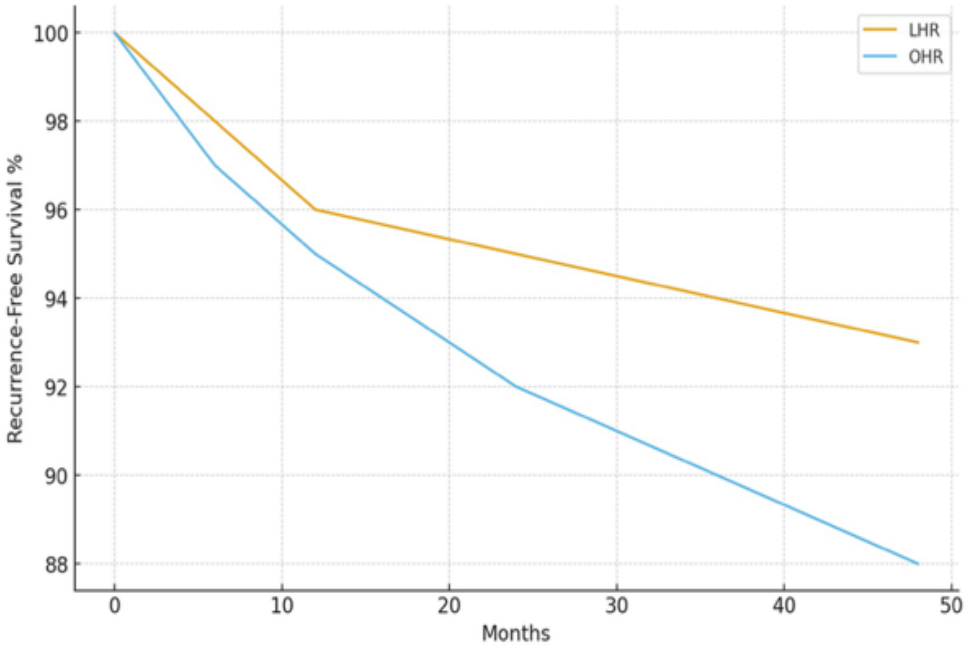

Figure 2: Kaplan-Meier curves for hernia recurrence of LHR or OHR after PSM

Intraoperative and Postoperative Performance Metrics: Evaluations of intraoperative and postoperative outcomes, performed after PSM and summarized in Table 2, revealed several distinct advantages for the LHR group. Patients undergoing laparoscopic repair experienced notably shorter hospital stays, less intraoperative blood loss, and a reduced incidence of overall postoperative complications compared to those who underwent open repair. Additionally, the rates of both hernia recurrence and the development of chronic pain were observed to be lower in the LHR group.

The overall duration of the surgical procedure, however, was found to be comparable between the two treatment groups subsequent to PSM.

Table 2: Intraoperative and postoperative outcomes before and after PSM

Characteristics	Before PSM LHR (n=240)	OHR (n=255)	P-value	After PSM LHR (n=200)	OHR (n=200)	P-value
Operation time (min)	63 (50–94)	81 (60–120)	0.001	66 (52–99)	72 (54–106)	0.258
Hospitalization (days)	2 (1–4)	4 (3–7)	<0.001	2 (1–4)	3 (2–6)	0.004
Blood loss (ml)	20 (10–40)	44 (25–76)	<0.001	22 (11–40)	38 (22–70)	<0.001
Overall postoperative complications (%)	20 (8.3%)	42 (16.4%)	0.006	13 (6.5%)	29 (14.5%)	0.007
Bleeding	3	7	—	2	6	—
Hematoma	4	11	—	3	9	—
Wound seroma	5	8	—	4	7	—
Wound infection	4	9	—	2	5	—
Urinary retention	4	7	—	2	2	—
Recurrence (%)	9 (3.7%)	18 (7.0%)	0.046	4 (2.0%)	11 (5.5%)	0.032
Chronic pain (%)	14 (5.8%)	26 (10.1%)	0.041	7 (3.5%)	17 (8.5%)	0.021

Identification of Independent Risk Factors for Recurrence-Free Survival: A thorough investigation into independent prognostic factors influencing RFS was conducted both before and after PSM. Initial univariate and multivariate analyses carried out before PSM identified several distinct factors impacting recurrence-free survival, as detailed in Table 3. These early findings served to underscore the inherent heterogeneity present within the unmatched patient sample and highlighted the crucial necessity of implementing PSM. Following PSM, subsequent univariate and multivariate analyses, presented in Table 4, pinpointed several key independent predictors of RFS. These included an age range of 13 to 15 years, a body mass index (BMI) of ≥ 28 kg/m2, a hernia diameter exceeding 4 cm, prolonged operational times, the occurrence of overall postoperative complications, and the choice of the open inguinal hernia repair approach (Table 4).

Table 3: Univariate & Multivariate predictors before PSM

Characteristics	Univariate analysis HR	95%CI	P-value	Multivariate analysis HR	95%CI	P-value
Age (13–15 vs 15–18)	1.52	1.12–2.18	0.014	1.40	1.05–2.03	0.029
Sex (male vs female)	0.88	0.61–1.29	0.51	0.94	0.62–1.44	0.78
BMI ≥28 kg/m²	1.75	1.18–2.61	0.006	1.62	1.10–2.44	0.018
ASA (3–4 vs 1–2)	1.39	0.99–2.01	0.06	1.28	0.88–1.91	0.19
Hernia >4 cm	1.48	1.03–2.14	0.034	1.36	0.95–1.99	0.086
Operation time (>90 min)	1.61	1.08–2.38	0.021	1.45	1.00–2.16	0.049
Blood loss >50 ml	1.55	1.04–2.30	0.030	1.41	0.96–2.12	0.071
Overall postop complications	2.20	1.50–3.22	<0.001	1.88	1.28–2.82	0.002
Surgical approach (LHR vs OHR)	0.63	0.42–0.94	0.024	0.71	0.49–1.05	0.083

Table 4: Univariate & Multivariate predictors after PSM

Characteristics	Univariate analysis HR	95%CI	P-value	Multivariate analysis HR	95%CI	P-value
Age (13–15 vs 15–18)	1.48	1.07–2.26	0.021	1.36	1.01–2.14	0.046
BMI ≥28	1.88	1.29–2.98	0.003	1.70	1.14–2.70	0.011
Hernia >4 cm	1.54	1.06–2.30	0.029	1.42	0.97–2.16	0.067
Operation time >90 min	1.63	1.08–2.49	0.020	1.51	1.00–2.39	0.047
Blood loss >50 ml	1.56	1.03–2.41	0.034	1.44	0.95–2.34	0.081
Overall complications	2.15	1.45–3.35	<0.001	1.92	1.26–3.20	0.005
Surgical approach (LHR vs OHR)	0.69	0.48–0.99	0.049	0.77	0.52–1.17	0.224

Discussion

This comparative analysis, conducted through a retrospective cohort approach, examined the clinical trajectory of adolescent patients with inguinal hernias treated either by the minimally invasive laparoscopic method (LHR) or traditional open hernia repair (OHR). The investigation uncovered several paramount findings supporting the application of LHR. The central discovery was the notably superior long-term performance of the laparoscopic approach, demonstrating a significantly higher rate of recurrence-free survival (RFS) when compared to the open technique. This advantage persisted even after meticulous statistical adjustment using propensity score matching (PSM) to equalize baseline patient characteristics. Furthermore, the LHR group experienced substantial clinical benefits in the short-term recovery period: patients had shorter durations of hospital admittance, minimized operative blood loss, and a markedly reduced frequency of immediate postoperative complications, including lower rates of chronic pain and subsequent recurrence. These results strongly suggest that LHR may constitute a safer, more efficacious procedure for repairing adolescent inguinal hernias, particularly when performed at high-volume surgical centres. Surgical intervention is requisite upon diagnosis of an inguinal hernia in an adolescent, a condition reported to affect between 0.5% and 14% of this age demographic. For decades, conventional open inguinal hernioplasty was maintained as the established standard of care, reliably achieving low complication and recurrence rates. Nevertheless, the recent decades have witnessed an exponential surge in the use of minimally invasive surgical modalities worldwide. Innovations in technological equipment and enhanced surgeon proficiency in laparoscopic operations have rendered LHR both safer and more frequently viable, establishing both laparoscopic and open methods as widely accepted, co-existing "gold standard" treatments for inguinal hernia repair among general surgeons.

While the relative merits of LHR and OHR have been extensively documented and debated in the general surgical literature, there remains a critical dearth of studies specifically comparing the perioperative and enduring outcomes in the adolescent patient population. Although prospective randomized controlled trials (RCTs) represent the highest standard for evaluating treatment efficacy, their execution in real-world clinical practice is often complicated or ethically prohibitive. Observational studies are inherently susceptible to selection bias, where subjects' baseline features influence treatment assignment. Therefore, rigorous statistical control to mitigate these baseline differences is essential, a goal we achieved through the specialized application of PSM. We utilized the PSM method, including all pertinent covariates that might affect group allocation, to derive robust and trustworthy conclusions. In contrast to older meta-analyses concerning the general population, which suggested comparable long-term outcomes between the two

procedural types, our large cohort study—sourced from three medical facilities in China—clearly established a superior recurrence-free survival profile for the laparoscopic cohort, both pre- and post-PSM. This observed advantage is likely attributable to a confluence of factors. First, all laparoscopic procedures were conducted by highly seasoned surgeons who had definitively overcome the associated learning curve, thereby guaranteeing procedural meticulousness, maturity, and safety. Second, the magnified visual field intrinsic to laparoscopy, occasionally bolstered by intraoperative ultrasound guidance, enables heightened surgical accuracy and manipulation. Third, scientific literature posits that laparoscopic surgery induces less suppression of the body's immune response relative to traditional open surgery, a factor that could potentially influence recurrence probability. A detailed concurrent comparison of short-term intraoperative and postoperative metrics further supported the laparoscopic approach. Our data confirmed that the LHR group benefitted from a reduced duration of hospital stay, decreased blood loss, and lower incidence of various postoperative complications, including recurrence, chronic pain, bleeding, hematoma, seroma, wound infection, and urinary retention. In the context of Chinese healthcare, where parents often prefer extended hospitalization for closer adolescent monitoring, the brevity of the LHR stay reflects its status as a less invasive procedure that promotes faster convalescence. Although statistically negligible, the laparoscopic procedure evidenced a trend toward shorter operating times, likely due to enhanced operative efficiency, reduced surgical trauma, and smaller incisions.

The reduction in specific complications, such as wound issues and bleeding, following LHR is associated with its lower degree of invasiveness. Traditional open surgery mandates dissection of the inguinal region and meticulous freeing of the hernia sac up to the internal ring for high ligation, a process that carries a substantial intrinsic risk of iatrogenic injury to vital structures, including the vas deferens and spermatic vessels.

This trauma contributes directly to the increased rates of haemorrhage and hematoma formation observed in the open cohort. Nonetheless, the operative duration and complication rates associated with these two techniques remain topics of controversy in the broader literature. Our analysis pinpointed several factors that acted as independent prognostic predictors of RFS failure. These adverse prognostic indicators included specific age ranges (13 to 15 years), elevated body mass index (BMI $\geq$ 28 kg/m^2), large hernia diameter (exceeding 4 cm), protracted surgical time, the occurrence of overall postoperative complications, and, notably, the choice of the open inguinal hernia repair method. The heightened recurrence rate within the OHR group may be linked to its higher associated complication burden, as complications themselves can predispose the patient to subsequent hernia recurrence. We therefore suggest that surgical strategies relying solely on high hernia sac ligation may be better suited for older teenagers who present with smaller BMIs and minor hernia defects. Despite yielding meaningful comparative data, this study is subject to several inherent limitations. Firstly, the study's non-randomized, retrospective design introduces unavoidable selection bias. While rigorous 1:1 propensity score matching was applied to minimize baseline disparities, the possibility of residual unmeasured confounders influencing the results cannot be entirely dismissed.

Consequently, future research must involve dedicated prospective studies. Secondly, institutional variability in surgeon expertise, procedural nuances, and perioperative management across the participating centres may affect outcome consistency. Thirdly, notwithstanding a relatively large regional sample size, the overall patient count is insufficient to mandate universal pronouncements regarding LHR's definitive superiority for all adolescent inguinal hernia cases. Finally, the cohort was restricted to adolescents aged 13 to 18 and predominantly drawn from Eastern China, meaning the generalizability of these findings to other geographical populations or distinct age brackets remains unascertained. A multi-centre, prospective, randomized controlled approach, utilizing a larger and more geographically diverse population, is essential to furnish conclusive evidence on the long-term advantages and overall merits of laparoscopic repair in this specific demographic.

Conclusion

The evidence synthesized from our research indicates that, when considering the long-term clinical prognosis for adolescent patients affected by an indirect inguinal hernia, the outcomes achieved through laparoscopic correction are demonstrably non-inferior to results obtained using the traditional open surgical method. Consequently, laparoscopic inguinal hernia repair represents a secure and practical alternative to conventional open surgery for this patient demographic—a paradigm that is already widely validated and integrated into accepted medical practice.

Ethical approval: The study was approved by the institutional ethics committee.

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