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Laparoscopic Inguinal Hernia Repair

Long-term outcomes of pediatric laparoscopic needled-assisted inguinal hernia repair: A 10-year experience☆,☆☆

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ABSTRACT

Purpose: Laparoscopic inguinal hernia repair (LIHR) has gained wide acceptance over the past decade, although studies with longer term follow-up are lacking. We present one of the largest cohorts of children undergoing laparoscopic needle-assisted repair (LNAR) with long-term follow-up.
Methods: A clinical quality database was maintained for children ≤14 years of age who underwent laparoscopic needle-assisted repair between 2009 and 2017 with review of follow-up through 2019. De-identified data was reviewed.
Results: 1023 patients with 1457 LNAR were included during the 10-year period. Mean age at surgery was 2.56 years (2 days to14 years). The overall hernia recurrence rate was 0.75% (11/1457). A total of four postoperative hydroceles required intervention. Preterm infant repair done <60w post conceptional age had a significantly lower recurrence rate (0.63%) than other patients (0.82%) ($p < 0.01$). 64.2% of patients had clinical follow-up over a period of 11 years with a mean follow-up of 5.97 years.
Conclusion: We present a large cohort study of consecutive pediatric laparoscopic hernia repairs followed over an 11-year period. LNAR is safe and effective for term and preterm patients with similar complication rates to other techniques, including open repair. Additionally, our results suggest that preterm infants may have superior outcomes with this method.
Level of Evidence: Level III – Retrospective Comparative Study.

Over the last 2 decades, laparoscopic inguinal hernia repair (LIHR) has gained wide acceptance after multiple studies demonstrated the safety and efficacy of the laparoscopic method [1–3]. The benefits of laparoscopy include excellent visual exposure, visualization of the contralateral side, reduced operative time, excellent cosmetic results, and comparable recurrence and complication rates [1].

Despite numerous reports demonstrating the efficacy of LIHR, these studies have been lacking in long-term outcomes data that extend beyond the 1–2 years after surgery. Our initial report of 710 hernias in 495 patients demonstrated favorable recurrence and cosmetic outcomes for the laparoscopic approach, and had a mean follow-up time of 10.7 months [3]. Currently, the longest follow-up times in the literature come from a retrospective study of 541 patients followed up for 2.6 years [4] and another retrospective analysis of 1033 laparoscopic hernia repairs with a mean follow-up time of 2.4 years [5]. Because hernia repairs should be durable, studies with longitudinal follow-up are needed to fully evaluate new techniques.

At our institution we achieved early consensus on a surgical technique called laparoscopic needle-assisted assisted repair (LNAR), which was originally described by Takehara et al. [6], and modified by Hebra et al. to include use of the Tuohy spinal needle [3]. This technique was adopted early by all surgeons in the pediatric surgery department, and has demonstrated low rates of minor complications and low recurrence in an earlier study at our institution [3].

There has been strong evidence supporting the effectiveness of LIHR in children, but few studies have demonstrated a benefit in the infant population [7]. Furthermore, there is a paucity of literature on LIHR in preterm infants. While some published studies suggest that LIHR in preterm infants is feasible and safe, these have small sample sizes with only short-term follow-up [8,9]. The purpose of this clinical quality database study of pediatric patients undergoing LNAR was to further define the benefits of utilizing pediatric laparoscopic hernia repair, including a subset analysis of LNAR repair in preterm infants. We hypothesized LNAR

Abbreviations: LNAR, laparoscopic needle-assisted repair; LIHR, laparoscopic inguinal hernia repair; PCA, post-conceptual age; IIR, internal inguinal ring.

☆ Declarations of Interest: None.

☆☆ *How this study should change care: This large cohort study follows consecutive pediatric laparoscopic hernia repairs over an 11-year period. The findings of this study support LNAR as a safe and effective method of hernia repair in pediatric patients and should be considered in preterm infants.*

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would demonstrate similar outcomes between the pediatric population and preterm infants. The authors maintained a clinical quality database to monitor these patients for adverse outcomes, particularly recurrence. This analysis represents the longest follow-up of a large cohort of children undergoing a single laparoscopic hernia repair technique.

1. Methods

1.1. Study design

We performed a single-center cohort study utilizing a clinical outcomes database kept for longitudinal follow-up of pediatric patients who underwent LNAR at our institution between January 2009 and December 2017. This database was maintained as a quality improvement project over the study duration. De-identified study data was extracted in aggregate from the designated "owner" of the quality improvement database and given to the research team with no personal health identifying factors. Since identifying information was removed for research analysis, this study did not meet the qualifications for human subject research as determined by the Institutional Review Board and was exempted from review. Board certified pediatric surgeons at MUSC, with experience in advanced laparoscopic techniques, completed all procedures using the LNAR technique. We concluded our entry of LNAR surgeries in 2017 and then continued EMR follow-up to ensure that all patients had a minimum of two-years of follow-up. All further maintenance of the quality database occurred for clinical follow-up purposes after December 2017.

1.2. Inclusion criteria

All pediatric patients age 14 years and younger who underwent LNAR with our specific surgical technique as outlined in our previous publication [3], were included in this study. Excluded from this study were palliative cases, open repairs, and any deviations from surgical protocol including 24 patients and 44 hernias that were not repaired with Prolene® suture.

1.3. Surgical technique

The laparoscopic needle-assisted inguinal hernia repair (LNAR) technique involves one trocar placed through the umbilical skin, with a stab incision overlying the internal inguinal ring (IIR). Using a Tuohy spinal needle, a 2–0 Prolene suture is guided around the IIR in the preperitoneal space, carefully dissecting the vas deferens and gonadal vessels away from the peritoneum. An intracorporeal loop is then introduced through the peritoneum while the needle is retracted. The free needle is the guided in the preperitoneal on the opposite side of the IIR and guided through the intraperitoneal loop, which is then used as a snare and the two ends of the suture are brought up to the surface. This suture is tied down, completing the high ligation of the sac at the IIR. The suture knot is then buried in the subcutaneous tissue.

1.4. Data collection

Study data were collected and managed using REDCap electronic data capture tools hosted at the Medical University of South Carolina [10,11]. Datapoints were obtained using a combination of surgeon-reported questionnaires and chart review of all patients at our institution that underwent LNAR over the time-period between January 8, 2009 and December 21, 2017. Data variables included age, gestation, surgical estimated gestational age (EGA), gender, laterality of repair, operative details, concurrent procedures, follow-up data, and complications. Both pre-operative and post-operative diagnoses were recorded and any contralateral defect noted on surgical evaluation was documented as a bilateral inguinal hernia and repaired laparoscopically. Recorded complications included recurrence, contralateral hernia, wound infection, hydrocele, and suture granuloma. Once collected, this data was transferred into a de-identified dataset for analysis.

1.5. Data analysis

The study population was analyzed for number of hernia repairs, laterality, age and gender distribution, weight at operation, operative time, and complications as listed above. A subset analysis of preterm patients was performed and compared to the rest of the population. We defined the preterm population as any patient born at an EGA of <37 weeks who underwent LNAR prior to 60 weeks post-conceptional-age (PCA). All remaining patients operated on at >60 weeks PCA regardless of EGA at birth were aggregated into one group that contained both term patients and patients born at <37 weeks EGA.

Complications were divided into those occurring early (<30 days) or late (>30 days). Complications such as hydrocele, wound infection, and suture granulomas were categorized into two groups: those that resolved with medical management or those that required surgical intervention. Self-resolving hydroceles were observed but were not included in the calculation of the surgical complication rate. All complications were assessed for co-occurrence to remove redundancy. Mean operative time was calculated for all patients, with notation of unilateral *versus* bilateral repair. Cases with combined procedures were excluded from operative time analysis, including Nissen fundoplication, gastrostomy tube, circumcision, urologic procedures, bowel resections, adhesiolysis, and pyloromyotomy.

1.6. Follow-up

Follow-up was divided into short-term follow-up in the immediate 30 days post-operative period and long-term follow-up. Long-term follow-up was defined as any documented encounter in the institutional electronic medical record with a genitourinary examination by a healthcare professional, including nurse practitioners, physician assistants, or physicians that occurred after the 30-day postoperative period. The database was maintained until 2 years after the last patient from December 2017 was entered.

1.7. Statistical analysis

All means, medians, standard deviations and standard error of the mean were calculated in Microsoft Excel. A student's t-test or Fisher's exact test was used for statistical analysis of data sets as appropriate to determine significant differences in patient demographics, operative time, and complication rates between different subsets. Significance level was set at a p-value of <0.05.

2. Results

2.1. Study population

1023 patients with 1457 hernias underwent LNAR at our institution between January 8, 2009 and December 21, 2017. Bilateral repair occurred in 42.8% of patients, right-only in 37.5%, and left-only in 19.8% (Table 1). Post-operative diagnosis was changed on 355 (34.7%) patients. A majority of these (320/355) were changed from a single side diagnosis to bilateral after surgical evaluation discovered a contralateral patent processus vaginalis, which was then repaired. Mean operative time in minutes of all patients was 24.8 min ± 0.28 with a range from 8 min to 66 min (Table 1). Mean operative time of total unilateral hernias was 23.1 min $\pm$ 0.4, while bilateral hernia mean operative time was 28.6 min $\pm$ 0.39 ($p < 0.0001$).

Mean patient age at surgery was 2.56 years ± 0.095 with a range of 2 days to 14 years. 34.9% of the study population (358/1023) included patients born prematurely (<37 weeks gestational age). A subset analysis of these patients identified 247 preterm patients that were operated

Table 1
Demographics of LNAR population. Preterm is defined as EGA or <37 weeks and <60 weeks post-conceptional age at time of surgery. Term patients represent those operated on at >60 weeks PCA. *p < 0.05.

	Total	Term (PCA >60 weeks)	Pre-term (PCA <60 weeks)	p-Value
# of patients	1023	776 (75.8%)	247 (24.1%)	-
# of hernias	1457	980 (67.3%)	477 (32.7%)	-
Age	(Years)	(Years)	(Weeks)	
Mean	2.56 ± 0.1	3.45 ± 0.12	45.7 ± 0.36	-
Range	0.005–14	0.03–14.8	28–60	
Median	1.22	2.36	45	
Gender				
Male	831 (81.2%)	621 (74.7%)	210 (85.0%)*	p = 0.016
Female	192 (18.8%)	155 (18.6%)	37 (15.0%)	
Weight (kg)				
Mean	12.9 ± 0.33	15.6 ± 0.34	4.33 ± 0.08*	p < 0.0001
Range	2–83	2.3–83	2–8.9	
Median	10.2	12.8	4.2	
Laterality				
Right	545 (37.4%)	489 (49.9%)	56 (18.8%)	
Left	288 (19.8%)	227 (23.2%)	61 (20.6%)	
Bilateral	312(2) (42.8%)	132(2) (26.9%)	180(2) (60.6%)*	p < 0.0001
Operative time				
(minutes)	24.8 ± 0.28	24.3 ± 0.32	26.7 ± 0.55*	p = 0.001
Unilateral	23.2 ± 0.4	22.7 ± 0.47	24.3 ± 1.36	
Bilateral	28.6 ± 0.39	28.3 ± 0.68	29.3 ± 0.65	
Recurrence	11 (0.75%)	8 (.82%)	3 (0.63%)*	p = 0.025

on prior to PCA of 60 weeks and compared to the rest of the patient population (Table 1).

2.2. Follow-up

Of the 1023 patients that underwent LNAR, 657 (64.3%) had long-term follow-up, as previously defined. The mean follow-up time for these patients was 5.97 years; 366 patients (35.7%) did not receive follow-up beyond the 30-day post-operative period. Of these patients, 318 (86.9%) had short-term follow-up with a mean follow-up time of 19 days; 48 patients (13.1%) were lost to follow-up entirely despite phone calls and scheduled appointments. The mean and median ages of the short-term and long-term follow-up cohorts were calculated in order to determine if age was a determinant of loss of follow-up. The mean ages in the analysis of term patients were 3.74 ± 0.19 years in the short-term follow-up cohort (median 2.92 years) and in the long-term follow-up cohort 3.34 ± 0.15 years (median 2.13 years) (p = 0.11).

2.3. Overall complication rate

Overall there were 40 total complications with the 1457 hernia repairs which is a 2.7% complication rate. A total of 30 complications (2.1%) required surgical intervention. The complications observed in this study were recurrence (n = 11), contralateral metachronous hernia (n = 4), wound infection (n = 9), hydrocele requiring intervention (n = 4), and suture granuloma (n = 12). The overall recurrence rate was 0.75% with 11 hernias recurring out of 1457 repairs. The mean time to recurrence of 1.52 years ±0.5. Although recurrent hernias ranged from less than a month from initial LNAR surgery to over 5 years after surgery, 82% were identified within 3 years of the index procedure.

A total of 4 patients (0.27%) were found to have contralateral metachronous hernias on the unrepaired side on follow-up. Nine patients (0.61%) were found to have wound infections. One third of these wound infections required drainage, while the majority of infections (6/9) were treated successfully on antibiotics alone. Post-operative hydroceles were observed in 61 (4.2%) of patients with 4 (0.27%) requiring surgical drainage. Suture granulomas occurred post-operatively in 12 hernia repairs (0.82%) with 9 requiring surgical excision. There were no reports of testicular atrophy or testicular ascent in the database.

Any patient who underwent an operation that had LNAR repair with polydiaoxanone (PDS) rather than Prolene® was excluded after a subset analysis revealed a significant increase in recurrence in this group. Four of the 44 hernias repaired with PDS (9.1%) recurred. This was a statistically significant difference compared to the prolene repairs (p < 0.001). One of these hernias recurred within 30 days and the remaining 3 PDS repairs recurred >30 days post-operatively.

2.4. Preterm patients operated on <60 weeks PCA) versus all others

Of the 358 patients born less than 37 weeks EGA, 247 (69%) underwent repair at a PCA of <60 weeks are described as 'preterm' for this analysis. The mean age of these preterm patients at surgery was 45.7 weeks ± 0.35 weeks PCA ranging from 28 to 59 weeks (Table 1). The preterm cohort mean weight was 4.33 kg (2–8.9 kg). Comparatively, the remaining patient population had a mean age of 3.45 years and weight of 15.6 kg (p < 0.0001). There was a significantly higher proportion of females in the term group (18.8%) compared to the preterm group (15.0%) (p < 0.0001).

The mean operative time of the preterm cohort was 26.7 min which was found to be slightly longer than the mean operative time of term patients (24.3 min) (p < 0.001). Preterm patients had a statistically significant higher proportion of bilateral hernia repairs (60.6%) compared to the rest of the cohort (26.9%) (p < 0.001). The cohort including term and premature operated on at greater than 60w PCA had a larger proportion of unilateral hernias (73.3%) than the preterm patients (39.4%) (p < 0.0001). When further stratified into bilateral and unilateral times we found that the difference in procedure length lost significance (p = 0.27, p = 0.28) signifying that this difference was related to the higher number of bilateral hernia repairs in the preterm group.

Additionally, the preterm cohort was found to have a lower recurrence rate (0.63%) compared to rest of the patient population (0.82%) that was statistically significant (p < 0.01). Occurrences of hydroceles requiring operative intervention was significantly higher in the preterm patients (p < 0.01) (Table 1). There were no significant differences between wound infections and suture granulomas. When all complications requiring surgical intervention were examined together, the preterm interventional complication rate was 1.47% while the remaining population had a rate of 2.45% but this difference did not reach significance.

2.5. Timing of complications

All complications were defined as occurring within 30 days of the index operation (early) or after 30 days (late). Twenty-four out of 40 complications occurred in the late postoperative period. Only 1/11 recurrences were observed in the early post-operative period (p < 0.05). Half of the four contralateral hernias found on post-operative follow-up were within the early complication group and half were observed in the late post-operative period. A majority of wound infections (8/9) occurred during the early post-operative period (p < 0.05). All of the wound infections requiring drainage occurred within 30 days following surgery.

Most of the suture granulomas requiring surgical excision (7/9) occurred in this later post-operative period. Of note, one patient developed a suture granuloma that was excised which lead to a hernia recurrence on that side a few months later. A significant majority of the hydroceles observed (51/61) were during the early post-operative period (p < 0.0001) but were not calculated in the complication rate as no intervention was necessary. However, the late post-operative group required operative intervention of their hydroceles significantly more than the early post-operative group (p < 0.05) (Table 2).

3. Discussion

This study represents one of the largest reported cohorts of pediatric patients undergoing laparoscopic hernia repair with long-term follow-up. This study of children who underwent LNAR inguinal hernia repair, demonstrates that the technique is effective, with a recurrence rate of 0.82%, which is comparable or lower than that reported for open repair [2,8,9,12]. Additionally, complications related to this technique have a relatively low surgical intervention rate of 2.1%. Furthermore, the lower complication rates in the preterm cohort supports LNAR repair as a favorable technique in this patient population.

Despite widespread acceptance of minimally invasive techniques among pediatric surgeons, adoption of laparoscopic inguinal hernia repair in practice has been relatively slow. Open inguinal hernia repair in children has historically excellent results and is considered to be the gold standard. Despite this, a meta-analysis of recent studies comparing laparoscopic *versus* open approaches have shown that operative time is shorter in laparoscopic extraperitoneal repair compared to open [13], which leads to decrease healthcare utilization and shorter anesthetic time. Additionally, studies have shown that laparoscopic approaches had less post-operative complications in patients. Complications evaluated in these studies included intraoperative complications, recurrence, return to normal activity, hydrocele, testicular atrophy, and metachronous contralateral hernia [13–16]. A recent meta-analysis comparing laparoscopic and open approaches showed no statistically significant difference in recurrence rates between laparoscopic and open approaches [2]. The randomized, controlled study by Shalaby et al. also reported lower recurrence rate in the laparoscopic group (0.8%) compared to the open repair (2.4%). [14]. Despite these encouraging studies, the lack of comparable long-term follow-up of LNAR patients is a limitation when comparing laparoscopic to the open repair method that has been noted in the literature [2]. This is an issue that could be contributing to delays in the adoption of laparoscopic repair as recurrences can occur several years after surgery.

One important finding in this study was that the preterm population repaired before 60 weeks PCA had a lower recurrence rate compared to term patients and premature babies repaired later. This is particularly impactful as there has been controversy about the safety and timing of hernia repair, especially open repair in the preterm population [17–19]. Several studies report increased instances of incarceration with delayed open repair in premature infants and try to find the balance of increased risk of injury and reoperation in early open repair with the increased risk of incarceration with delayed repair in premature infants [20,21]. Although our study is with LNAR rather than open repair, our results also support that earlier intervention is safe and demonstrates lower recurrence and interventional complication rates when compared to the literature on open repair [14,22]. While this study does not answer the age-old question of timing of inguinal hernia repair in premature infants, we found that LNAR may be advantageous in preterm infants in terms of hernia recurrence alone.

Short operative time with this technique corroborated our previous report of LNAR in 495 children [3]. We did additionally find that operative time was longer for the preterm cohort by an average of 2.4 min. This is likely due to the higher rate of bilateral inguinal hernias in this population. Compared with other recent reports of laparoscopic inguinal repair on preterm patients operative times in this study are similar [8,9,23,24]. Each surgeon in our group had significant laparoscopic experience prior to starting LNAR. We excluded the first 10 cases of each new surgeon from the database to adequately reflect the proctoring and learning time. After 10 cases, each case was consecutively tracked. Yoshizawa et al. found a similar learning curve with their laparoscopic technique, finding that 12 cases were needed to become proficient [25].

A strength of this study was consistency in the surgical repair technique. The only other study with longer-term outcomes is a report of multiple different laparoscopic techniques over a 15-year period [16]. In general, the pediatric surgical community has failed to achieve consensus in laparoscopic inguinal hernia surgical technique, resulting in a diminished capacity to draw strong conclusions on outcomes. The LNAR technique in this study was uniform across all surgeons. Each surgeon was trained in the same way by the same mentor. Several other studies report this as an important variable to consider in reporting their results [16,26]. Importantly, consistent surgical technique led to the discovery that minor inconsistencies may affect outcomes. One such inconsistency was the use of PDS suture rather than Prolene®. This change was temporarily made due to several early suture granulomas seen in patients. These 24 patients within the PDS-repaired population that had a 10-fold higher recurrence rate were excluded as they were deviations from the standard technique. As a result of this observation this method was discontinued at our institution and should be taken into consideration when performing this repair.

There are several limitations to this study. Firstly, we were unable to ascertain if patients had recurrences outside of our institution with using our method of longitudinal institutional EMR to track follow-up. Secondly, a patient may be examined by a medical professional at our institution following surgery with no documentation of recurrence, but unless the visit was with a surgeon, a recurrence or complication could go undetected. Even though a documented genitourinary examination was required to be considered as a documented follow-up encounter, a limitation of chart review follow-up is that there is no way to ascertain the thoroughness of the documented exam. Thirdly, 35.7% of patients were lost to follow-up after 30 days. However, another study evaluating laparoscopic inguinal hernia repair in infants <1 year had a long-term follow-up by phone of only 42% with a mean follow-up time of 4 years [7]. Of note, there was a significant age difference between the short-term and long-term follow-up groups on initial analysis. However, this was likely a biased analysis with the inclusion of preterm infants which require more rigorous and specialized follow-up for other co-morbidities. When only term patients were included in the analysis, the significance in age difference was lost.

Future plans are to expand on this study with an active form of follow-up *via* phone survey to will ascertain more data about potential undocumented recurrences. Addition of this follow-up will also expand on the complications tracked including testicular atrophy. Although, testicular atrophy, a known reported complication in all types of inguinal hernia repairs, was not tracked in this study, in a 15-year study by Shalaby et al., there were no reports of testicular ascent or atrophy [16]. Further, another study specifically following testicular vascularity following laparoscopic inguinal hernia repair, cited no changes in pre- and post-operative resistive indices [27]. Based on these findings we hypothesize that the incidence of testicular complications in our study population are low.

Despite the limitations of using chart review for long-term follow-up, our study, which has a mean-time follow-up of almost 6 years, reports similar rates of complications from laparoscopic repair in both the preterm and term populations. This study also has a longer mean follow-up time, to our knowledge, than any reported study thus far.

Table 2
Early (<30 days) *versus* late complications of LNAR. *p < 0.05, ** p < 0.0001.

Complications:	Early (<30 days)	Late (>30 days)
Recurrence	2	9*
Contralateral Hernia	2	2
Wound Infection	8*	1
• Antibiotics only	5	1
• Drainage	3	0
Hydrocele	51	10
• No intervention	50	7
• operative	1	3*
Suture Granuloma	4	8
• Excision	2	7

This is extremely important for reporting recurrences especially since, in our study, 90.9% occurred in the late complication group with mean time to recurrence spanning from 45 days to more than 5 years. Furthermore, the length of follow-up of this study increases the validity of the low recurrence rate observed.

4. Conclusions

The LNAR technique is an effective method for minimally invasive inguinal hernia repair in children. This is the largest prospective series of patients in the American surgical literature using this one-trocar technique. This single-center database analysis of outcomes of LNAR on pediatric patients further demonstrates the safety and efficacy of the laparoscopic technique. Furthermore, the uniform surgical technique minimizes confounding factors to allow for a clear assessment of surgical outcomes. Most importantly, this study supports using laparoscopic inguinal hernia repair in preterm patients <60 weeks PCA as a safe and effective method with acceptably low recurrence and complication rates.

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Appendix A. Supplementary data

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