

COMPARISON OF NEEDLE ASSISTED LAPAROSCOPIC REPAIR AND OPEN REPAIR OF INGUINAL HERNIA IN PAEDIATRIC POPULATION: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

OBJECTIVE: To compare needle assisted laparoscopic repair (NALR) of inguinal hernia in children with open hernia repair (OHR).

METHODS: This randomized controlled trial was conducted at the Paediatric Surgery Unit of Khyber Teaching Hospital, Peshawar, Pakistan from February 2017 to September 2018. Children aged upto 16 years and diagnosed with reducible inguinal hernia were randomized into two-groups; NALR and OHR. Obstructed inguinal hernia and cases which presented with recurrence were excluded from this study. Demographic and clinical data was collected and analysed using SPSS 20.

RESULTS: One hundred and fifteen patient were included in the study with NALR (n=50) and OHR group (n=65). NALR group included unilateral (n=35), bilateral hernia (n=5), patent processus vaginalis (n=10). OHR group included unilateral (n=55), bilateral (n=10). The mean age for NALR was 2.96 ± 2.5 years and OHR was 4.17 ± 3.62 years. Mean weight for NALR group was 11 ± 6 kg and OHR was 7.6 ± 3.7 kg. Operating time for unilateral NALR was 12 ± 2.4 minutes and OHR was 24 ± 3.8 minutes while bilateral NALR was 18.3 ± 3.1 minutes and OHR was 32 ± 6.3 minutes. Hospital stay for NALR group was 40 ± 6.8 hours and OHR was 30 ± 7.7 hours. Analgesia doses for unilateral NALR (4.5 ± 1.2) were less than OHR (6.96 ± 1.8) ($p=0.02$) and same is the case for bilateral repair ($p=0.03$). OHR had a high rate of postoperative complications; surgical site edema (14%), wound infection (4%) and recurrence (2.8%).

CONCLUSION: NALR is a safe and reliable substitute to OHR in terms of less operating time, minimum hospital stay, less doses of analgesia required and low rate of postoperative complications.

KEY WORDS: Hernia (MeSH); Hernia, Inguinal (MeSH); Needle assisted repair (Non-MeSH); Post operative complications (Non-MeSH); Processus vaginalis (Non-MeSH); Herniotomy (Non-MeSH); Herniorrhaphy (MeSH).

THIS ARTICLE MAY BE CITED AS: Rahman FU, Abdullah F, Rehman IU, Ali S. Comparison of needle assisted laparoscopic repair and open repair of inguinal hernia in paediatric population: a randomized controlled trial. Khyber Med Univ J 2019; 11(4):209-13. DOI: 10.35845/kmuj.2019.19351

INTRODUCTION

Inguinal hernia (IH) is a common surgery performed by pediatric surgeon on elective list.¹ IH has reported incidence of 4.4%.² The basic cause behind the development of inguinal hernia repair in children is persistence of processus vaginalis which has to be obliterated by the gestational

age of 36 week.³ Unilateral hernia is more common with reported incidence of 85%.⁴ Initially open repair by high ligation was the standard procedure, but trends have changed with the introduction of minimal invasive surgery.⁵ Certain risks has been found to be related to open repair, like vas injury, vessel injury, hematoma formation in wound, infection and recurrence.^{6,7} First

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Date Submitted: March 14, 2019

Date Revised: October 10, 2019

Date Accepted: October 15, 2019

laparoscopic inguinal hernia has been reported to be successfully repaired in 1990.⁸ Current research is focused to know the impact and superiority of laparoscopic surgery. Laparoscopy has been adapted well for repairing pediatric inguinal hernia and even now different techniques have been published. The persistent upgrading in surgical instrumentation have cultivated a fashion toward the use of minimal invasive technique in paediatric inguinal hernia repair. Advantages of laparoscopic repair of inguinal hernia include reduced pain, improved cosmesis, decrease in hospital stay, minimal dissection, reduced surgery time, improved visualisation of structures, detection of patent processus vaginalis on opposite side (PPV), speedy recovery and high parents satisfaction.⁷ Researchers have reported two types of inguinal hernia repair in children, intraperitoneal and extraperitoneal.⁹ Intraperitoneal repair was done through purse string technique at the level of deep ring and require high level of skills related to intracorporeal knotting. Reported operative time and recurrence is high with this technique. Extraperitoneal repair can be done by using spinal needle, epidural needle and some special needles. Learning curve for this technique is low and reported complication rate minimal with this technique.³

Even in the era of laparoscopy, some centers favours open repair of inguinal hernia and have reported extremely less complications in expert hands. It is utmost important to critically evaluate the outcome of different techniques of

TABLE I: DEMOGRAPHIC DATA AND LATERALITY OF THE STUDY SUBJECTS

| Variables | | NALR (n=50) | OHR (n=65) | P Value |
|----------------------------|------------|-------------|------------|---------|
| Weight (kg) | < 5 | 12 (24%) | 20 (31%) | 0.007 |
| | ≥ 5 – 10 | 16 (32%) | 30 (46%) | |
| | > 10 | 22 (44%) | 15 (23%) | |
| Age (years) | ≤ 1 | 17 (34%) | 18 (28%) | 0.19 |
| | ≤ 5 | 23 (46%) | 27 (41%) | |
| | > 5 | 10 (20%) | 20 (31%) | |
| Gender | Male | 42 (84%) | 55 (85%) | 0.84 |
| | Female | 08 (16%) | 10 (15%) | |
| Laterality (pre-operative) | Unilateral | 45 (90%) | 55 (84.6%) | 0.285 |
| | Bilateral | 05 (10%) | 10 (15.4%) | |

NALR = Needle Assisted Laparoscopic Repair; OHR = Open Hernia Repair

TABLE II: OPERATION TIME, HOSPITAL STAY, ANALGESIA DOSES IN STUDY

| Variables | | NALR (n=50) | OHR (n=65) | P Value |
|--------------------------|------------|-------------|------------|---------|
| Operative time (minutes) | Unilateral | 12 ± 2.41 | 24 ± 3.83 | 0.001 |
| | Bilateral | 18.3 ± 3.19 | 32 ± 6.39 | 0.03 |
| Hospital Stay (hours) | | 40 ± 6.87 | 30 ± 7.7 | 0.55 |
| Analgesia Doses (doses) | Unilateral | 4.5 ± 1.2 | 6.96 ± 1.8 | 0.02 |
| | Bilateral | 7.0 ± 1.3 | 10.6 ± 2.8 | 0.01 |

NALR = Needle Assisted Laparoscopic Repair; OHR = Open Hernia Repair

TABLE III: POSTOPERATIVE COMPLICATIONS OF THE STUDY GROUPS

| Postoperative complications | NALR (n=65) | | OHR (n=75) | | P Value |
|-----------------------------|-------------|------------|------------|------------|---------|
| | Frequency | Percentage | Frequency | Percentage | |
| Surgical site edema | 00 | 00 | 10 | 14 | 0.001 |
| Wound infection | 00 | 00 | 03 | 4 | 0.001 |
| Recurrence | 02 | 03 | 02 | 2.8 | 0.963 |
| Hydrocele | 01 | 02 | 00 | 0 | 0.001 |

NALR = Needle Assisted Laparoscopic Repair; OHR = Open Hernia Repair

inguinal hernia repair. The importance of this study lies in the fact that it was conducted to compare needle assisted laparoscopic repair with open repair of inguinal hernia, to highlight dominance of one repair over the other.

METHODS

This prospective randomized control trial was conducted in Paediatric Surgery Unit, Khyber Teaching Hospital, Peshawar, Pakistan after the approval from institutional research and ethical review board (IREB) of Khyber Medical College, Peshawar. Study duration was from February 2017 to September 2018. Patients with reducible inguinal hernia and age up to 16 years were included in the study after taking informed consent from the patient / patients' guardian. Obstructed inguinal hernia and cases

which presented with recurrence were excluded from this study. Remaining 115 patients were randomized into two groups, needle assisted laparoscopic repair (NALR) group (n=50) and open hernia repair (OHR) group (n=65). Two similar cards were made having the procedure name (either NALR or OHR) on it and sealed in opaque envelopes. The patient / patients' guardian was requested to choose one envelope and the subject is enrolled in the either group (NALR or OHR). The demographic data and pre operative laterality were compared among the two groups. Outcome measures included operative time, hospital stay and analgesia requirement. Analgesia requirement and operative time were recorded separately for unilateral and bilateral hernia repair.

Bilateral hernia and contralateral PPV were repaired in same anaesthesia. Sixty

five (65) NALR were performed on 50 patients, which included 5 bilateral herniae and 10 PPVs. Out of 65 cases of OHR group, 10 cases had bilateral hernia, so a total of 75 hernia repairs were done in open group. Due to limited working space in laparoscopic repair, nasogastric tube and urinary catheter was passed to all patient undergoing NALR.

NALR was performed using a single 3mm umbilical port and internal deep ring was encircled with a non absorbable suture using spinal needle of 22G. Ring closed with ligating the suture extraperitoneally in the subcutaneous plane. Contralateral detected PPV was operated during same anaesthesia in order to prevent metachronous hernia. OHR performed through the skin crease incision. Herniotomy was performed in a conventional way.

The discharge medication included oral acetaminophen, with a calculated dose of 15mg/kg. Parents were given instructions to give analgesia when the patient felt pain and record doses of analgesia. All patients were sent home on the same day after recovery. Follow up plan was made for 6 months, having 4 visits, 1st visit after 2 weeks, 2nd visit after one month, 3rd visit after 3 months and 4th visit after 6 months of surgery. Post operative complications were recorded during follow up period and included surgical site edema, wound infection, recurrence, hydrocele. Reappearance of inguinal swelling was regarded as recurrence and recorded in the follow up period through clinical examination.

Data was collected on pre designed proforma. Collected data was coded and calculations made on SPSS-20. Value of 0.05 was set as level of significance statistically. Numerical data was presented by mean and SD while categorical data by frequency and percentage. Chi-square (χ^2) and student's t-test were used for categorical and numerical data respectively.

RESULTS

This study enrolled 115 patients, who were randomized into two groups of repair, NALR group (n=50) and OHR group (n=65).

Sixty five NALR were performed on 50 patients as 10 bilateral herniae and 5 PPVs were repaired in same anaesthesia. Seventy five (75) OHR were performed

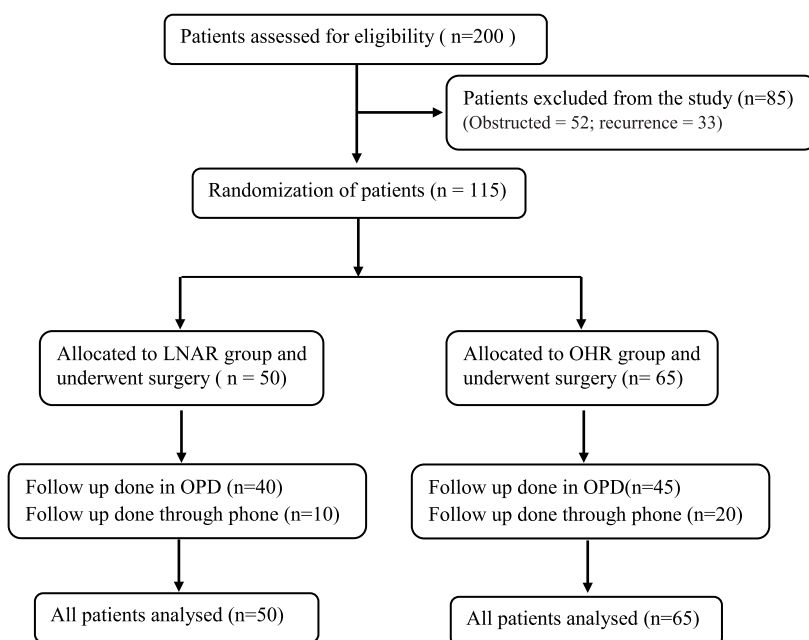


Figure 1: Methodology Flow Chart

on 65 patients as this group had 10 bilateral herniae. Mean age for NALR was 2.96 ± 2.5 years and OHR was 4.17 ± 3.6 years. The age, gender and weight distribution and pre operative laterality is shown in Table I.

Operative time recorded for unilateral NALR and OHR is 12 ± 2.41 and 24 ± 3.83 minutes respectively ($P=0.001$). Hospital stay comparison showed no statistically significant difference between the two groups (NALR and OHR) which is 40 ± 6.87 hours in NALR group. Analgesia doses given in bilateral NALR and OHR are 7.0 ± 1.3 and 10.6 ± 2.8 doses respectively (Table II).

Surgical site edema and wound infection were more common in OHR group while hydrocele is more common in NALR group. Recurrence is comparable in both groups having no statistical significance (Table III).

DISCUSSION

Open inguinal hernia repair has been practiced for decades and considered excellent for hernia repair. However the open method has a high risk of cord injury and post operative complications. Laparoscopic inguinal hernia repair has gained popularity^{10,11} and many techniques

for it has been adopted but still it is debatable to be considered over open technique.¹² Different techniques were adopted for laparoscopic hernia repair; extraperitoneal and transperitoneal. Laparoscopic repair can be performed with different ports; single, two or three ports.¹³ We preferred NALR over other laparoscopic technique which is also single incision laparoscopic repair. One main advantage of laparoscopic hernia repair is to detect contralateral PPV which is helpful in preventing the metachronous hernia.¹⁴ We have conducted this study to make clear the advantages of laparoscopic repair over the open technique in our transition from open to laparoscopic technique.

The current study shows significant shorter operative time for laparoscopic repair. Initially in the learning curve there was increased operative time and with experience, time for procedure became short.¹⁵ Laparoscopic repair has a shorter learning curve than open technique. In open technique, there is difficulty in identifying structures and dissection requires time. No skin stitches applied after laparoscopic repair, which further add to cosmesis.

The literature shows almost same hospital stay for both procedures. However, our

study show increased hospital stay for the laparoscopic group. This increased stay in the hospital is surgeon's choice as we transition from open to laparoscopic technique and not due to complications of the procedure.

Recurrence in inguinal hernia is a rare complication. Reported recurrence rate is 1% to 5% in elective hernia repair while this percentage increases for strangulated hernia.^{16,17} Older children have a high recurrence rate as compared to younger. Current study has a recurrence rate of 3% recurrence in NALR group for age 16 months and 18 months while 1.42% in open group for 5 months age. The recurrence rate in laparoscopic group was highly high which can be attributed to the initial learning curve. High rate of recurrence is reported for cases where absorbable suture was used.¹⁶

Reported incidence of contralateral PPV detected in laparoscopic repair is 23%.¹⁴ Physical examination is not helpful in diagnosis of PPV. During laparoscopic repair of hernia contralateral ring is inspected and opportunity is provided to repair it in same anaesthesia. In our study, we detected contralateral PPV in 20% of cases. Laparoscopic repair done in same setting to prevent metachronous hernia.⁶

Post operative pain is an important indicator of the outcome of surgery. Minimal invasive surgery has been reputed for mild pain and low analgesia requirement.^{18,19} Mild pain is attributed to less surgical trauma single port NALR has been distinguished as extremely minimal invasive compared to OHR. NALR has low analgesia requirement which has been approved by current study as well.²⁰

Post operative complications are more common in open surgery. Recurrence, hematoma, wound infection, testicular atrophy and hydrocele are some alarming complications of inguinal hernia surgery. Open surgery has a high incidence of swelling of the wound which added to the parents anxiety. With a large hematoma, even parents assume that surgery is not successful and leads to multiple clinic visits. Laparoscopic surgery has the advantage of no such complications.²¹ Current study reports surgical site edema in 14% OHR cases. It was treated conservatively and took 3-4 weeks to resolve.

Wound infection rates in laparoscopic group is reportedly very low as compared to open repair. There is reported

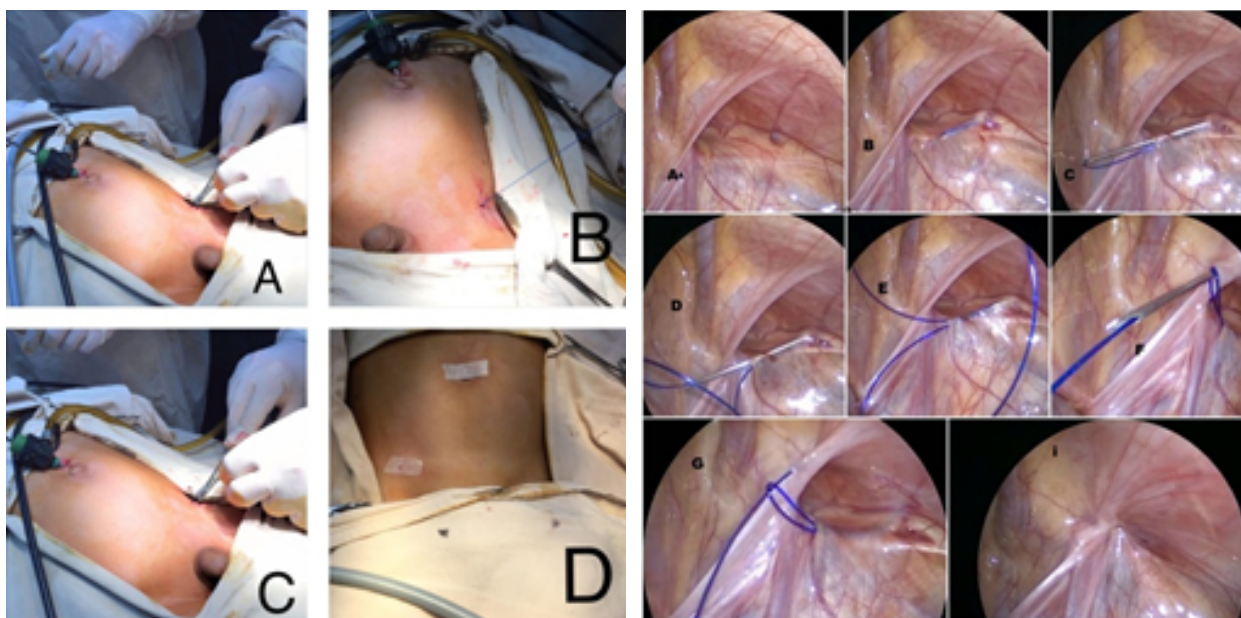


Figure 2: External and Internal view of LNAR



Figure 3: Postoperative edema after open surgery

incidence of 1.5% wound infection in laparoscopic repair. In our study wound infection in laparoscopic group is 0%, while in open group it is 4%.

Hydrocele is reported to occur is 0.6% after laparoscopic surgery and always resolves conservatively within 3 weeks. The current study shows the hydrocele incidence of 1.5%, while no hydrocele in open technique. Laparoscopic repair has virtually no scar and has excellent cosmetic effects as compared to open repair.

CONCLUSION

NALR is a safe and reliable substitute to OHR in terms of less operating time, minimum hospital stay, less doses of

analgesia required and low rate of postoperative complications.

LIMITATIONS

Small sample size, short duration of study and our early experience with needle assisted repair of inguinal hernia can affect the result of this study. Follow up period was short.

RECOMMENDATIONS

We recommend NALR as procedure of choice over conventional open technique. NALR can be regarded as extremely minimal invasive, safe and effective technique for all pediatric age group. Multi-centre study with a large sample size and a follow up period of 2 years is our recommendation for future study to be conducted.

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AUTHORS' CONTRIBUTIONS

Following authors have made substantial contributions to the manuscript as under:

FUR: Conception, interpretation of data, drafting the manuscript, critical review, final approval of the version to be published

FA: Study design, acquisition, analysis and interpretation of data, drafting the manuscript, final approval of the version to be published

IUR: Analysis of data, critical review, final approval of the version to be published

SA: Acquisition of data, drafting the manuscript, final approval of the version to be published

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST

Authors declared no conflict of interest

GRANT SUPPORT AND FINANCIAL DISCLOSURE

NIL



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