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ORIGINAL RESEARCH

Transumbilical laparoscopic-assisted appendectomy as a safe procedure for pediatric uncomplicated appendicitis: a comparison with laparoscopic and open appendectomy in a randomized clinical trial

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Abstract

Purpose Deemed as a safe and easily performed procedure in children, transumbilical laparoscopic-assisted appendectomy (TULA) also offers several other advantages: reduced costs, a lower wound infection rate, fewer postoperative complications, and better cosmetic outcomes. The present investigation compares the results of three methods of appendectomies: 1-conventional, 2- laparoscopic, and 3- transumbilical laparoscopic-assisted.

Methods The current study enrolled 210 patients and divided them into three groups of 70 each. Each group underwent one of the three methods of appendectomy. In TULA, the appendix exteriorized from the umbilicus laparoscopically, and then an extra-corporeal appendectomy was performed. The surgical approaches for the other two patient groups were standard techniques normally utilized in laparoscopic (LA) and open appendectomy (OA).

Results In TULA, the mean operation length was significantly shorter than that in LA. Regarding scar size, the smallest were from the TULA group, with a significant difference in surgical wound size when compared with those of the other two groups. The length of the hospital stay was significantly shorter for TULA and LA patients than for OA patients. In addition, there was a lower wound infection rate associated with TULA than with LA and OA.

Conclusions TULA is an alternative method of appendectomy in uncomplicated pediatric acute appendicitis. Compared to other approaches, TULA is technically easier, has a shorter operation time, offers better surgical outcomes, involves less surgical site infections, and results in excellent cosmetic results.

Trial registration The trial is registered in the Iranian Registry of Clinical Trials (IRCT id: IRCT201703088375N12).

Keywords Acute appendicitis · Transumbilical · Laparoscopic-assisted · Open appendectomy · Laparoscopic appendectomy

Abbreviations

TULA	Trans-umbilical laparoscopic-assisted appendectomy
OA	Open appendectomy
LA	Laparoscopic appendectomy
SILA	Single incision laparoscopic appendectomy

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Introduction

Acute appendicitis is considered the most common cause of acute abdomen in children. The treatment of choice is appendectomy and, for years, the conventional surgical procedure was open appendectomy (OA) [1]. Introduced in 1983, laparoscopic appendectomy (LA) [1] provides many advantages over OA, such as better pain management, shorter hospital stays, and lower overall complication rates [2–6]. LA can cause less surgical wound contamination by infected tissues and fluids, which in turn leads to less surgical site

infection [2, 3]. This is clinically important for this age group, in which a high rate of perforated appendicitis is typically observed [7]. Certain disadvantages of LA have been reported as well, including a tendency of incurring higher medical charges and/or hospitalization costs [9–12] and prolonged operative times compared to OA [11, 13–15]. Each method presents its own benefits and drawbacks. In OA, large surgical wounds, high contamination risks, and related elevated costs are potentially related issues [8].

In the early 1990s, a new technique of appendectomy was introduced called transumbilical laparoscopic assisted appendectomy (TULA). This technique uses a single incision that exteriorizes the appendix through the umbilicus [16]. Both satisfactory laparoscopic visualization and the safety and quickness of open appendectomy are considered as the advantages of this technique. Moreover, compared to adults, TULA is particularly beneficial in children because the distance between the umbilicus and the cecum is shorter in children and their abdominal wall is more flexible than that of adults, thus enabling easier exteriorization of the appendix through the umbilicus [17, 18]. Recent studies have shown the feasibility, efficacy, and cost-effectiveness of TULA compared to conventional three-port laparoscopic appendectomy [17–20]. However, no study has compared the outcomes of TULA, OA, and LA. Therefore, the aim of the present study is to compare the surgical outcomes of TULA with those of OA and LA in the management of pediatric acute appendicitis.

Materials and methods

Study design

The current research is a randomized clinical trial [balance block randomization (1:1:1) in parallel groups] and was conducted from November 2017 to March 2019. The study took place in Birjand, Iran at the general surgery ward of Imam Reza Hospital, with which Birjand University of Medical Sciences is affiliated. The trial is approved by Ethics Committee of the university (Reference number: Ir.bums.REC.1395.264) and also registered in the Iranian Registry of Clinical Trials (IRCT id: IRCT201703088375N12), as well. The participants were selected from among pediatric patients (ages 8–14) suffering from acute uncomplicated appendicitis, the diagnosis of which was based on patient history and physical examination findings and confirmed by radiologic and laboratory evaluations.

After considering the inclusion criteria, the current study assessed 257 (Fig. 1) patients for eligibility. 26 patients with the following conditions were excluded: gangrenous appendicitis (9 patients), appendicular abscess in 7 patients, which diagnosed preoperatively by abdominal sonography, perforation, and peritonitis (10 patients). Of the remaining, 21 patients declined to participate in the study. Finally, 210 patients were enrolled into the study and divided into three groups of 70 each and each group underwent one of the three methods of appendectomy: 1—open appendectomy (OA), 2—laparoscopic appendectomy (LA), or 3—transumbilical laparoscopic-assisted appendectomy (TULA).

Exclusion criteria were: seriously compromised general condition, generalized peritonitis, a palpable right lower quadrant mass, an appendicular phlegmon or abscess, immunosuppression, diabetes, and history of corticosteroid prescription.

Open appendectomy (OA)

In the OA group, appendectomies were performed under general anesthesia through a McBurney incision. The base and meso-appendix were ligated using silk (3–0) sutures and the appendix was removed from the incision.

Laparoscopic appendectomy (LA)

In an operating room equipped for children laparoscopic surgeries, patients received general anesthesia for the LA. Three trocars were placed and the video monitor was positioned on the patient's right side with the surgeon and surgical assistant on the left side. A 10-mm laparoscopic camera port was inserted through the umbilicus by an open technique and then CO_2 pneumoperitoneum was established. The two other ports were then inserted in the supra-pubic (5-mm) and right upper quadrant (5-mm) under direct laparoscopic vision. After dissection, the meso-appendix was ligated by Ligasure and the appendix base by hemo-lock. A retrieval bag was used to remove the inflamed appendix through the umbilical port.

Transumbilical laparoscopic-assisted appendectomy (TULA)

The preparation of the TULA operation settings was the same as that of the LA group. The current study specifically invented a new double-channel port for TULA. This port contains one 2-mm camera port and a 5-mm working channel for a Maryland insertion (Fig. 2). In the TULA technique, the double channel port was inserted into the abdomen through the umbilicus via an open-technique port insertion. Insufflation was performed through this port followed by a camera (30°) insertion by which visualization of the right lower quadrant was achieved. A Maryland was then inserted into the abdomen. After locating the inflamed appendix, the surgeon grasped its tip and carefully pulled the appendix completely out of the abdomen through the

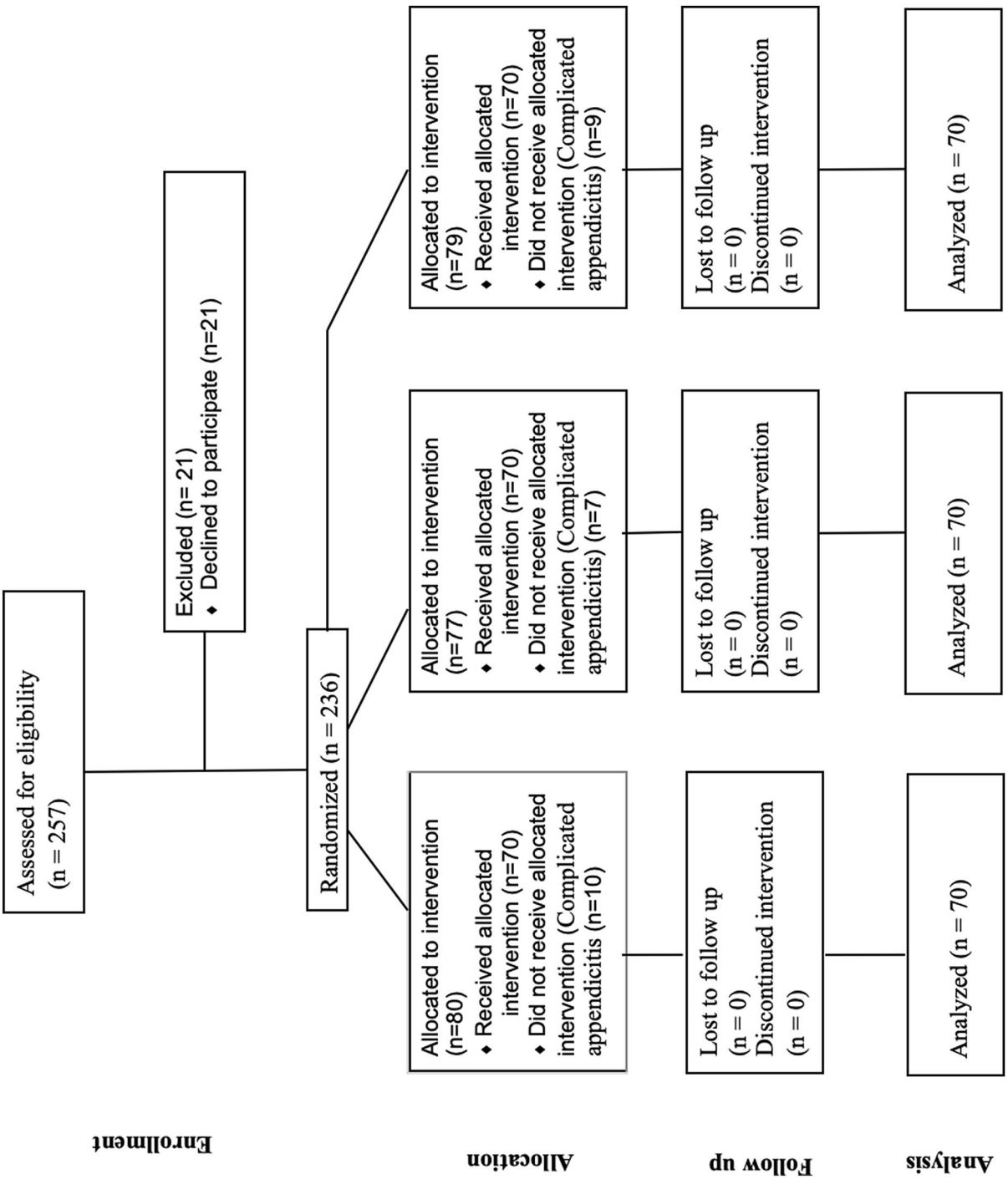

Fig. 1 Consort diagram for the study

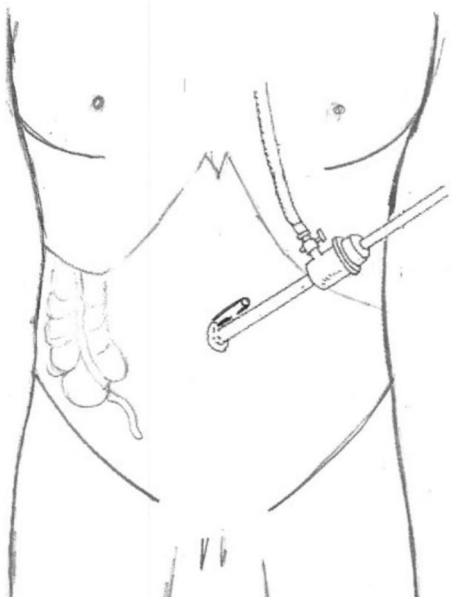

Fig. 2 Special port inserted in the umbilicus

umbilicus port (Fig. 3a). A conventional appendectomy (Fig. 3b) was performed extra-corporeally after which the appendix base was pushed back into the abdomen without any resulting wound contamination.

For all of the patients in our study, a single dose of prophylactic IV antibiotics is given 30 min before the operation to cover gram-negative and anaerobic bacteria (metronidazole and ceftriaxone). Antibiotics were not administered after the operation nor prescribed after discharge from the hospital. However, for severe and complicated appendicitis, antibiotics continued for 10 days.

All of the appendectomy samples in three groups were evaluated by pathologic examination. There was no statistically difference ($P < 0.001$) between normal appendectomy of the three groups was seen. The number of normal appendectomies was 6,7 and 9 in OA, TULA, and LA, respectively.

In all three groups, a low volume liquid diet began 4–6 h postoperatively and upon full awakening; if tolerated, a normal diet was prescribed. On the first day after the operation, patients were visited again and discharged if stable and not presenting any special problems. Two days after surgery, discharged patients went to the surgery clinic for the examination of any surgical complications as well as the condition of the surgical wound. Patients' sutures were removed 7–10 days after the operation and the size and shape of scars were evaluated in this time.

Outcomes

The primary outcome of this study is operation time, which we calculate the sample size based on it. Measured outcomes consisted of the patient's demographic data (age, gender, and BMI), length of the operation time, size of the scar, length of hospital stay, and the rate of wound infection.

According to a study conducted in South Korea by Jin et al. [37], the average operation time of MLA and TULAA was 44.8 ± 16.8 min and 37.2 ± 11.3 min, respectively. Based on the formula for "the comparison of the two means in interventional studies," the type 1 error (α) equaled 0.05 and

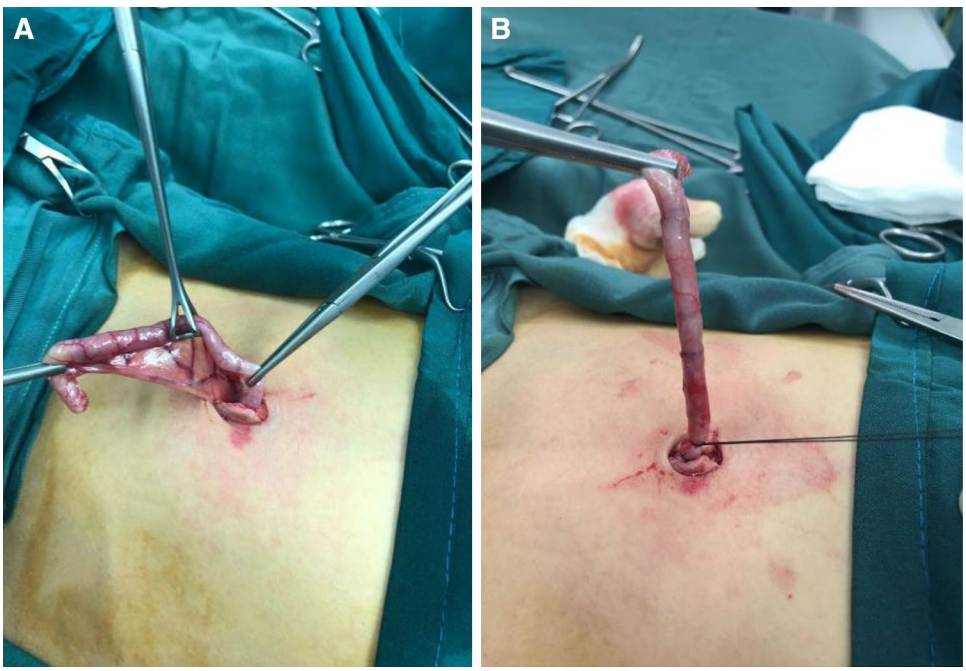

Fig. 3 **a** Exteriorizing the appendix, **b** extra-corporeal appendectomy

the type 2 error (β) equaled 0.02. The sample size in each category was 56 patients and, considering the 25% bias, the study enrolled 70 patients in each group.

According to a computer-generated randomization list, all of the patients in three randomized groups, operated by the same surgeon. A randomization sequence was created by employing balanced block randomization with a 1:1:1 allocation with random block sizes of 6. After the assignment of a subject to one of the three study groups, demographic data (Table 1), operation length of time, size of the scar, length of hospital stay in days, and the rate of wound infection were obtained and recorded by a questionnaire administered by a researcher. In the present study, concealment and blinding were not essential for each patient as the evaluation did not concern the consequences of a specific therapy method and the main variables were clear. Among the three groups, no similarity in interventions was found.

Statistical analyses

All statistical analyses were performed with SPSS version 16 (Chicago, USA). The level of significance was set to $P < 0.05$ and all hypothesis tests were two-sided. The difference in operation length of time, size of the scar, and admission time were compared by k-independent samples and two independent sample tests. Wound infection was analyzed by employing the chi-square test and Fisher's exact test.

Results

The current study involved 210 pediatric patients (117 males and 93 females) with a mean age of 11.58 who underwent an appendectomy by one of three different methods. In both the TULA and LA groups, there was no need for conversion to open appendectomy. Among the three groups, no significant difference in age, gender, and BMI was observed (Table 1).

The mean operation time was significantly shorter in the TULA group than in the LA group (18.93 vs. 39.19 min, $P < 0.0001$). However, no statistically significant difference in operation time was reported between the TULA and the OA groups ($P < 0.747$). TULA was performed in a significantly shorter length of time than was LA ($P < 0.0001$).

Regarding scar size, the surgical wound size was smaller in the TULA group, with a significant difference in scar size between TULA and the two other groups ($P < 0.0001$). The use of post-operative analgesics was less frequent among TULA patients (6 cases vs. 19 LA cases $P = 0.0011$ and 24 OA cases $P = 0.0001$). The starting of a regular diet was earlier in the TULA group ($P = 0.0069$). The length of hospital stay was significantly shorter for TULA and LA patients than for OA patients ($P < 0.005$). TULA was associated with a lower wound infection rate (1 patient = 1.5%) than was LA (3 patients = 5.2%) and OA (7 patients = 9.8%) ($P = 0.0035$) (Table 2).

Discussion

Open appendectomy was a standard operation for decades. However, in the early 1990s, LA steadily emerged as an

Table 1 Patients' demographic and clinical characteristics

Demographic and clinical characteristics	TULA ($n = 70$)	LA ($n = 70$)	OA ($n = 70$)	*P* value
Age	12.32 ± 2.14	11.43.32 ± 2.76	11.01 ± 3.12	0.1714
Sex				
Female	32	35	26	0.3714
Male	38	35	44	0.4382
BMI	17.35 ± 3.12	17.92 ± 2.43	18.11 ± 2.46	0.3512

TULA transumbilical laparoscopic-assisted appendectomy, *LA* laparoscopic appendectomy, *OA* Open appendectomy, *BMI* Body mass index

Table 2 Comparisons of perioperative outcomes

	TULA ($n = 70$)	LA ($n = 70$)	OA ($n = 70$)	*P* value
Operation time (min)	18.93	39.19	17.14	< 0.0001
Wound infection rate	1.5%	%5.2	9.8%	0.0035
Size of scar (mm)	7–10	20–30	30 and more	< 0.0001
Hospital discharge	Same day	Day 1 post op	Day 2 post op	

TULA transumbilical laparoscopic-assisted appendectomy, *LA* laparoscopic appendectomy, *OA* open appendectomy

attractive alternative option for an appendectomy. Resulting in reduced abdominal scarring, less postoperative pain, and speedier recovery, laparoscopic appendectomy has practically replaced open appendectomy [35].

In recent years, with the advancement in medical technology, the trend is toward a decrease in the size and number of laparoscopic ports. Attempts to further reduce the number of incisions have resulted in the development of single-incision appendectomy techniques [17, 36]. As a modified type of the single incision laparoscopic appendectomy (SILA), TULA offers some advantages over SILA, such as costs.

The current clinical trial compares the results of three different appendectomy methods. One of the significant objectives of the study is to compare conventional laparoscopic appendectomy with hand-assisted laparoscopic appendectomy. In contrast to the open approach, laparoscopic techniques produce less surgical trauma, better postoperative recovery, improved exploration of the entire abdominal cavity (especially in obese patients and women), superior management of unexpected findings, and better cosmetic outcomes [21]. As opposed to conventional appendectomies, laparoscopic appendectomy offers several significant advantages, such as less postoperative disability, reduced hospital length of stay, lower medical costs, and an earlier return to normal life [23, 24]. In the present research, the overall rate of complications was significantly lower in the TULA group than in the LA and OA groups.

Operation duration

The reduced operation time in TULA is mainly due to the use of one suture for the facial closure in the umbilicus, which eliminates manual suturing for skin closure and appendectomy. In TULA, the surgeon approaches the appendix only by the means of one port and performs the appendectomy outside of the cavity. The operation is thus very easy, fast, and safe to perform in a short amount of time. Concerning the operation's duration, however, it should be noted that the preparation of operation settings for laparoscopic surgeries (LA and TULA) requires more time than for OA preparation. On the other hand, the opening and closing of multiple abdominal layers in OA is time-consuming. Once surgeons pass the laparoscopic surgery learning curve, LA reports a comparable operation time, a decreased postoperative hospital stay, and a faster return to normal bowel function in comparison with OA for children with acute nongangrenous, non-perforated appendicitis [22].

In the present study, the duration of the operation was longer in the LA group than in the TULA and OA groups. Excluding patients with perforated appendicitis, Jonathan et al. [33] observed a shorter operative time in TULA than in LA. Reports in the literature have varied with regard to the effect of TULA on operation duration. In a small case series by a single surgeon, Visjnic reported a shorter operative time, while two prospective studies by Frutos et al. and St. Peter et al. demonstrated longer operation lengths with the TULA technique [25, 26]. The longer operations in LA may be related to the placement of two more trocars, the interchange of instruments multiple times (graspers, vascular sealer, stapler, and endoscopic bag), and the closure of three incisions instead of one [27].

Wound infection

Wound infection and intra-abdominal abscess are frequent complications of appendectomy. In some studies, TULA had a significantly lower wound infection rate than that of LA and no observed intra-abdominal abscesses [28, 29]. In the present study, the rate of infection-related complications was significantly lower in TULA than in OA and LA; however, there was no statistical difference between OA and LA. According to the current study, the main reasons for the reduced infection rate in TULA are: 1—shorter operation length, 2—less trauma to the surgery site because of the extracorporeal appendectomy, and 3—the umbilicus' negligible subcutaneous fat, which is the main tissue feeding wound infections. Kim et al. reported a higher rate of surgical site infection (SSI) in open surgery than in conventional laparoscopic appendectomy [29]. LA may involve a shorter hospital stay and present a lower risk of superficial incisional surgical site infection than OA [20]. With the increasing application of laparoscopic procedures, the incidence of SSI after appendectomy has declined accordingly. Compared with OA, LA was independently associated with a significantly lower incidence of SSI, but both shared a similar incidence of organ/space SSI [30].

Scar

The best cosmetic results are achieved in TULA as its 7-mm incision scar inside the umbilicus eventually disappears. Although the overall size of the three incisions in laparoscopic surgery is almost equal to the one OA incision, the LA scars are generally more cosmetically appealing than that of OA. In TULA, there is a single delayed absorbable suture in the umbilicus defect and so there is no need to close the skin. In OA, the wound must be washed and closed in multiple layers and the skin is mostly closed with a nylon subcuticular suture. OA and LA scars are visible. The mean scar size in LA is 15 mm and the OA scar size reaches 3 cm in most cases.

Pain

Although the present study did not analyze the factor of pain nor compare the severity of pain among the three study groups, the requests for analgesics and their administration were significantly lower in the TULA group than in the other groups. For single incision laparoscopic surgery, several studies and reviews have reported equivalent or improved patient outcomes in terms of less postoperative pain, shorter hospitalization, and fewer complications [31]. Blinman showed that [32] laparotomy incisions cause more aggravation and pain when compared to a combination of small incisions. Less pain and better cosmetic outcomes were found in single incision laparoscopic appendectomy than in conventional open appendectomy [29]. In single incision laparoscopic surgery, patients report experiencing less pain, a faster recovery, and better long term cosmetic results than those undergoing multi-port laparoscopy [33]. Most patients in the current research's TULA group were discharged after 12 h on the same day of the operation. In LA, most cases are discharged the following day, while most OA cases are discharged on the second post-operation day. Later hospital discharge can significantly increase medical costs.

Some investigations do not support the present study's findings. For example, Katkhouda et al. reported that laparoscopic appendectomy, unlike other minimally invasive procedures, did not offer a significant advantage over open appendectomy in their studied parameters, with the exception of the quality of life scores at 2 weeks. The study also noted the longer time needed to perform LA [34].

Limitations

Even though we had randomized the trials, are lack of blinding the follow up the cases might have introduced some biases.

Conclusion

In conclusion, the current study promotes TULA as an alternative method of appendectomy in pediatric un-complicated acute appendicitis. TULA is technically easy, takes less operating time, provides better surgical outcomes, results in reduced surgical site infections, and produces excellent cosmetic results. Unfortunately, TULA does not treat gangrenous or complicated appendicitis and adult patients. For more reliable findings, the present work proposes that another investigation be performed within multi-Centre groups of patients.

Acknowledgements This investigation has been done in Imam Reza hospital, department of general surgery at Birjand University of medical sciences. It is approved by Ethics Committee of Birjand University of Medical Sciences, Reference number: Ir.bums.REC.1395.264. This manuscript is in Clinical trial category.

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Compliance with ethical standards

Conflict of interest This clinical trial doesn't have any conflict of interest.

Ethical approval In this investigation, all of the private patient's information are blinded and there is nothing as potentially identifiable patient information.

Informed consent Consent form is consisting of, detail of benefits and risks of three methods of surgeries and signed by all of the patients.

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