

Original Research Article

Randomized controlled trial comparing clinical outcome and cost analysis between laparoscopic and open appendectomy for acute appendicitis at Dharan, Sunsari, Nepal

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ABSTRACT

Background: Acute appendicitis is the most common etiology of acute abdomen, generally requiring urgent surgical intervention, with a lifetime incidence between 7 and 9%. With the experience in minimal invasive surgery, laparoscopy has advantage of being both diagnostic and therapeutic. In developing country like Nepal, with limited health resources, the trend of laparoscopic appendectomy (LA) is emerging. This study was conducted to determine difference in clinical outcome and cost analysis between laparoscopic (LA) and open appendectomy (OA).

Methods: This study was Randomized Controlled Trial conducted in the Department of Surgery, B.P. Koirala Institute of Health Sciences (BPKIHS), a tertiary care hospital in Eastern Nepal, over a period of twelve months from January 2017 to December 2017. Ethical clearance was obtained from Institutional Review Committee (IRC). The study population were adults with clinical diagnosis of acute appendicitis fulfilling inclusion and exclusion criteria.

Results: In this study, 47% patients were male and 53% were female in LA and 58.8% patients were male and 41.2% were female in OA ; the mean age was 24.6 years in LA and 27.7 years in OA ; mean operation time was more in LA than in OA i.e. 70 minutes and 57 minutes respectively (p value 0.001); mean hospital stay was more for OA (3.6 days) as compared to LA (3.06 days), (p value 0.125) ; The number of analgesic injections during postoperative period in two groups was 5.52±0.99 for LA, 5.62±1.02 for OA (p value 0.626); infection rate was 1% in LA, 6% in OA; The cost of surgery was higher in case of LA (NRs 15067.04) than in OA (NRs. 12524).

Conclusions: OA had statistically significant lower pain in 1st three postoperative periods, and a shorter hospital stay, early postoperative recovery but a slightly higher cost per discharge than OA.

Keywords: Appendectomy, Cost, Laparoscopic, Open, Outcome

INTRODUCTION

It has been 125 years since Reginald Heber Fitz coined the term 'appendicitis' to describe the inflammation of the vermiform appendix, which he correctly identified as the underlying cause for what has been called 'inflammation in the connective tissue about the caecum'.¹ Acute appendicitis is the most common etiology of acute abdomen, generally requiring urgent surgical

intervention, with a lifetime incidence between 7 and 9%.² The vermiform appendix is considered by most to be a vestigial organ, its importance in surgery is due to its propensity for inflammation, which results in the clinical syndrome known as acute appendicitis. Acute appendicitis is the most common cause of an "acute abdomen in young adults. Appendicitis is sufficiently common that appendectomy is the most frequently performed urgent abdominal operation. Despite

extraordinary advances in modern radiographic imaging and diagnostic laboratory investigations, the diagnosis of appendicitis remains essentially a clinical diagnosis.³ Numerous studies have compared OA with LA, but the role of laparoscopy is still a controversial issue. Some studies have showed better clinical results for LA, while some others fail to prove a significant advantage or demonstrated disadvantages such as higher cost or intra-abdominal abscess.⁴ The overall mortality of open appendicectomy is around 0.3%; and morbidity, about 11%.⁵ USA report shows approximately 300,000 cases/year, with the greatest incidence falling in the 2nd and 3rd life decade and with a rate of 3-4:1 among men and women during puberty.⁶

It is the second most common general surgical procedure performed in the United States, after laparoscopic cholecystectomy, and the most common intraabdominal surgical emergency, with a lifetime risk of 6%.⁷ Appendicectomy, being the most common surgical procedure performed in general surgery, is still being performed by both open and laparoscopic methods due to lack of consensus as to which is the most appropriate method. Because further trials are necessary, and few such studies have been performed in developing countries, we decided to evaluate the outcomes of the two procedures to share our experience with the international community.⁴ Appendicectomy is the most common emergency surgery being performed at our institute. With the experience in minimal invasive surgery, laparoscopy has advantage of being both diagnostic and therapeutic. In developing country like Nepal, with limited health resources, the trend of LA is emerging. Hence, this study was conducted to determine difference in clinical outcome and cost analysis between LA and OA.

METHODS

Randomized controlled trial was conducted in the Department of Surgery, B.P. Koirala Institute of Health Sciences, a tertiary care hospital in Eastern Nepal, over a period of one year. Ethical clearance was obtained from Institutional Review Committee (IRC).

The study population were all adult clinically diagnosed cases of acute appendicitis fulfilling inclusion and exclusion criteria.

Inclusion criteria

- All clinically diagnosed case of acute appendicitis and/or
- Mantrel's score >7

Exclusion criteria

- Appendicular lump, abscess, perforation/ generalized peritonitis
- Pregnancy
- Age <10 or >50

- Patients not giving informed consent

Sample size

This study considered 95% confidence interval and 80% power to estimate sample size. For this purpose, this study considered a complication proportion of LA and OA as 0.029 and 0.132 respectively as per the study by Minutolo V et al "outcomes and cost analysis of laparoscopic versus open appendectomy for treatment of acute appendicitis: 4-years' experience in a district hospital".

Now using the difference between two proportion formula for a RCT study as below

$$n = [(Z\alpha/2) / (\sqrt{2pq}) + Z\beta \sqrt{(p_1q_1 + p_2q_2)}]^2 / (p_1 - p_2)$$

Where, n = number of sample; $Z\alpha/2 = 1.96$ at 95% confidence interval (C.I); $Z\beta = 0.842$ at 80% power (P)

According to literature review, 95% CI and 80% P has been used for sample size estimation.

$p = 1/2(p_1 + p_2)$; $q = 1 - p$; $p_1 =$ the complication rate of LA; $p_2 =$ complication rate of OA; $q_1 = 1 - p_1$; $q_2 = 1 - p_2$.

Then the sample size becomes 109 in each surgery. The total sample is 218. According to previous record, it was found that only 100 OA was done last year. Therefore, possible number of open surgery for this year was 80.

Using the corrected sample size formula which is recommended by WHO, CDC Atlanta (EPI info 2007 software).

Corrected sample size = (Calculated sample size) / [1 + (Calculated sample size) / (Estimated population)]

$$\text{Corrected sample size} = 218 / [1 + 218 / (160)] = 96$$

Considering 10% lost to follow up in each group, 51 sample sizes were taken in each group and total of 102 was taken.

Data collection procedure

Allocation

Concealment permuted block design of randomization was utilized with allocation ratio 1:1 and a block size of 4 was created using www.randomization.com. A sequentially generated number with the treatment group was written in sealed envelope.

Each patients was assigned a patient identity number and allocated to undergo LA and OA depending upon the treatment specified in sealed envelope.

- Group A: Patient treated with LA.
- Group B: Patient treated with OA.

Intervention

All adult patients admitted and presenting in emergency with pain abdomen were assessed thoroughly by clinical examination and investigations. The diagnosis of appendicitis was made on the following criteria (Table 1).

Table 1: MANTRELS score used for diagnosis of acute appendicitis.

Symptom	Score
Migratory RIF pain	1
Anorexia	1
Nausea and vomiting	1
Signs	
Tenderness (RIF)	2
Rebound tenderness	1
Elevated temperature	1
Laboratory	
Leucocytosis	2
Shift to left	1
Total	10

Score: 1 to 4-discharge/watchful waiting; 5 to 6-observation/waiting; 7 to 10-surgery

The qualifying patients were informed of the risk and benefits of each operation and asked to sign a detailed informed consent in their respective native language. Patient were administered 1gm of ceftriaxone IV from the time of diagnosis until surgery. Operation procedure was done by consultant and senior resident on duty.

Laparoscopic appendicectomy



Figure 1: Port creation and telescope insertion to view the abdominal contents.

Umbilical port was made by open Hassen's method, allowed insufflation of the peritoneal cavity with carbon dioxide gas, following which a 10mm port and telescope was inserted to view the abdominal contents (Figure 1).

The telescope was connected via a video camera to a monitor. With the Trendelenburg manoeuvre and left rotation of the table the appendix was brought into view. Acute appendicitis was confirmed at this stage and other pathologies were excluded. A second port, 10mm, was inserted into the left iliac fossa lateral to the inferior epigastric artery under direct vision. A third port, 5mm was inserted in the midline suprapubic area, again under direct visual control. Through the second port some atraumatic forceps was inserted to enable manipulation of the appendix (Figure 2).



Figure 2: Forceps inserted to enable manipulation of the appendix.



Figure 3: Mesoappendix being separated by diathermy until the base of the appendix was cleared of mesentery.

The third port was used variously for the diathermy hook, the laparoscopic scissors, the Roeder-loop suture, extraction of the appendix and suction/irrigation. With the appendix under traction, the appendicular artery was identified and its branches to the appendix was carefully coagulated and divided using a diathermy hook.

The mesoappendix was then separated by diathermy until the base of the appendix was cleared of mesentery (Figure 3). A pre-tied Maxon Roeder-loop suture was inserted through the suprapubic port and secured around the base of the appendix (Figure 4). The appendix was then transected distal to the tie and retrieved through the umbilical port. The appendix site and inflamed areas was cleaned by laparoscopic suction/ irrigation with saline. After desufflation of the peritoneal cavity, the port sites were sutured/stapled.



Figure 4: A pre-tied Maxon Roeder-loop suture inserted through the suprapubic port and secured around the base of the appendix.

Open appendicectomy



Figure 5: The base of the appendix being ligated using Vicryl 2-0.

The open approach was done by traditional Grid- Iron or Lanz incision over McBurney's point. The arteries in the mesentery and the base of the appendix was simply ligated and divided. The base of the appendix was ligated using Vicryl 2-0 (Figure 5). The appendix was divided 1 cm distally to the ligature without invagination of the

appendicular stump. All the resected specimens were submitted for histopathologic examination (Figure 6).



Figure 6: Resected specimen for histopathologic examination.

All patients received preoperative antibiotics, third generation Cephalosporin and Metronidazole. Postoperative antibiotics administration varied and was determined by the surgeon according to the surgical findings. The operating time, hospital stay, and perioperative complications was recorded. The patients was given narcotic analgesia as the first medication for postoperative pain control for 24 hours.

They were given oral liquids next day after the surgery, gradually the diet was progressed as tolerated. Patients was discharged once they were afebrile, had good pain control and tolerated soft diet.

No urinary catheter was used. Nasogastric tubes were inserted in patients suspected to have to have a significant postoperative ileus. The right lower quadrant, the right paracolic gutter and sub-hepatic space was irrigated at the end of the procedure if pus is found.

The skin incisions were closed in every case using 3-0 nylon/stapled. Bowel sounds was checked regularly, once present, the patients were started on clear liquid diet and advanced to regular diet when the liquid diet was tolerated. Patients was discharged once regular diet was tolerated and afebrile for 24 hours.

Postoperative pain was assessed in 2 ways; 1) Quantitatively by daily tabulation of medication requirements (shots of *i.m.* diclofenac and tramadol as needed). 2) Qualitatively by visual analog scale (VAS). The item was scaled from 0 to10, with 0 being no pain and 10 being the most intense pain imaginable.

Mean operative time, intraoperative and post-operative complications, mean duration of postoperative ileus and average length of hospital stay was recorded for each

group. The total hospital cost was calculated as a mean for each group. After discharging the patient, the patient followed up in OPD after 1 week and was checked for complications (wound infection, intraabdominal abscess formation etc.) then in 2 weeks with histopathological examination (HPE) report. Cases of conversion from LA to OA was included in the LA group.

Cost analysis

The cost for each patient was assessed taking into account the cost of material used during surgery, the cost of hospital stays, *i.v* fluids, analgesics, antibiotics.

Statistical analysis

All encoded data was treated using proper statistical measures. In this case, the program SPSS version 19 was used. A p-value of <0.05 was considered statistically significant. Descriptive statistics specifically frequency distribution and percentage were used to determine the socio-demographic factors. While t-test for independent samples (normally distributed data) or Mann Whitney U test (non-normally distributed data) was used.

RESULTS

A total of 305 patients of Acute Appendicitis presented to Emergency Room at BPKIHS over a period of 1 year. Out of these patients 102 of these patients fulfilled the inclusion criteria and were taken as the study population, of which 51 were randomized into group A in which patients underwent LA and 51 in group B in which patients underwent OA (Figure 7).

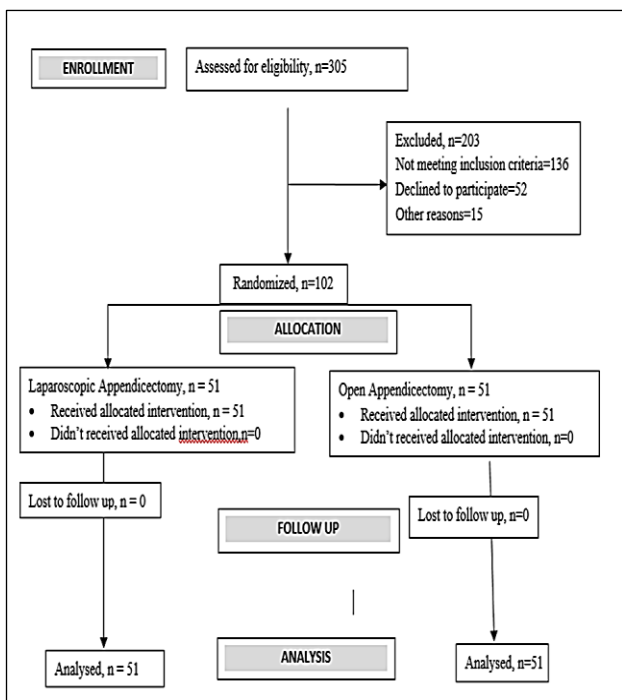


Figure 7: Consort chart.

In the present study, 47% patients were male and 53% were female in LA and 58.8% patients were male and 41.2% were female in OA.

Table 2: Comparing sociodemographic and clinical parameter in two groups.

Characteristic	Group		P-value
	Laparoscopic	Open	
Age (yrs.) (Mean±SD)	24.629.68	27.74±7.88	0.13
Sex	Male	30	0.16
	Female	21	
Symptom to arrival time (hrs.) (Mean±SD)	85.41±85.91	84±50.98	0.922
Fever	Present	22	0.427
	Absent	29	
Alvarado score (Mean±SD)	8.45±0.50	8.43±0.50	0.844
Operation time (hrs.) (Mean±SD)	1.17±0.30	0.95±0.35	0.001
Hospital stay (days)(Mean±SD)	3.06±1.41	3.62±1.20	0.105
Time to ambulation (hrs.) (Mean±SD)	8.17±1.65	13.02±1.97	0.096
Resumption of diet (hrs.) (Mean±SD)	16.75±5.21	20.35±4.80	0.535

The mean age was 24.6 years for the LA and 27.7 years for the OA. Mean operative time was more in LA then in OA i.e. 70 minutes and 57 minutes respectively (statistically significant, p=0.001). Mean hospital stay was more for OA (3.6 days) as compared to LA (3.06 days) (p value =0.125).

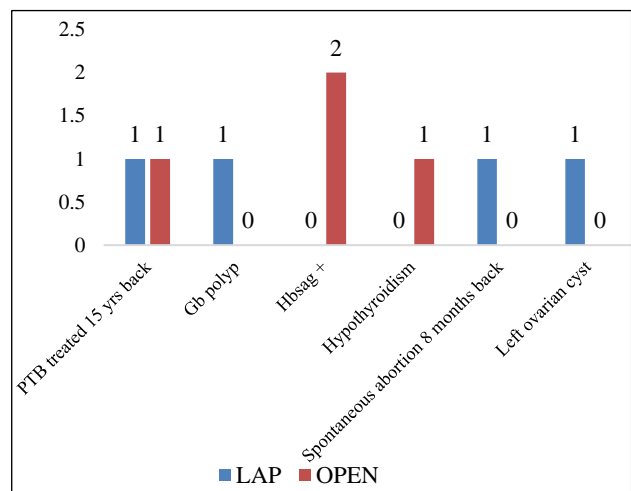


Figure 8: Associated medical problems between the two groups.

The mean time for ambulation was less for LA (8.17hours), than for OA (13.02 hours). Resumption of

normal diet was in 16.75±5.21 hours in LA and 20.35±4.80 hours in OA. Preoperative fever was present in 50.98 % patient who underwent LA, while 43 % of OA had fever. In the present study, mean ALVARADO scoring was almost similar in both group, i.e. 8.45/10 for LA and 8.43/10 for OA. Most of the patients were operated within 12 hours of arrival to the emergency i.e. 92.15% in LA and 98.04 % in OA (Table 2).

There were total nine patients who had medical problems, 2 of them had a history of pulmonary tuberculosis treated 15 years back, 1 patient had GB Polyp, 2 with HBsAg positive status, 1 patient each with hypothyroidism, ovarian cyst and spontaneous abortion 8 months back (Figure 8).

In this study, pain was evaluated using VAS score. It gradually decreased over a passage of time after operation. There was significant difference in pain in both the groups at 1st three postoperative days i.e. LA had less pain than OA but there was no significant difference in VAS score at any other stage of follow up, although it was slightly more in the OA at different stages of follow-up. The number of analgesic injections during postoperative period in two groups was, 5.52±0.99 for laparoscopic group, and 5.62±1.02 for open group, slightly higher in open group but statistically not significant (p value 0.626) (Table 3).

Table 3: Pain between the two groups at 3 consecutive post-operative day.

VAS score post –op (mean±SD)	Lap	Open	P value
Day 1	7.47±0.57	8.27±0.56	0.001
Day 2	6.16±0.42	6.61±0.67	0.001
Day 3	4.69±0.62	5.14±0.78	0.002
Mean±SD no. of inj.	5.52±0.99	5.62±1.02	0.626

There were no intraoperative complications. Intraoperatively, findings were 4 appendicular perforations in LA as well as OA, while 2 appendicular abscesses in LA only.

There was 1 case of surgical site infection in LA while 6 cases in OA. All were superficial infections, treated with regular dressing and antibiotic coverage for 2 weeks.

There was 1 case of abdominal distension in LA. There was 1 case of post-operative ileus in LA, while 3 cases of post-operative ileus in OA. Though more complication were seen in early postoperative period in OA, it was not statistically significant. There were 2 cases of SAIO (sub-acute intestinal obstruction) and 3 cases of infection in 1st week follow up in OA, while no complication in LA.

All cases of infection were superficial, who underwent regular dressing under antibiotic coverage and got healed. No debridement or re-exploration were done (Table 4).

Table 4: Postoperative complications in the two groups (early and 1st week).

Complication (early)	Lap	Open	P-value
None	49	45	0.093
Surgical site infection	1	6	
Abd. Distension	1	0	
Post op. Ileus	1	3	
1 st wk complication			0.08
None	51	46	
Sub-acute intestinal obstruction	0	2	
Infection	0	3	
Others	0	0	

In HPE report, 1 case in LA showed normal appendix, while all other cases showed findings of acute appendicitis. In this study, the cost of surgery was higher in case of LA (NRs 15067.04) than in OA (NRs. 12524) (Table 5).

Table 5: Mean cost of surgery, consumable item and total cost of operation in two groups.

Mean-cost (NRs)	Lap	Open	P-value
Cost of surgery	13000±0.0	10000±0.0	-
Cost of consumable item	2577.45±201.08	2524.80±199.78	0.188
Total cost	15577.04±201.08	12524.80±199.77	0.001

DISCUSSION

The purpose of this study was to compare LA with OA regarding clinical outcomes and cost analysis. The LA and OA were similar with respect to age, sex, associated medical problems, arrival to surgery interval, which indicated that the randomization is effective.

In the present study, 47% patients were male and 53% were female in LA while 58.8% patients were male and 41.2% were female in OA. Several studies reported male preponderance for appendicectomies.⁷⁻⁹

In the present study, the mean age was 24.6 years for the LA and 27.7 years for the OA. Several previous studies have shown highest incidence in 2nd and 3rd decade as in our study.^{5,7,9,10}

In the present study, mean operation time was more in LA then in OA i.e. 70 minutes and 57 minutes respectively (statistically significant, p=0.001). In several previous studies, operative time are variable, some had more operative time for OA.^{5,7,9,10,12} While some had similar operative time between two groups.^{11,13}

In the present study, mean hospital stay was more for OA (3.6 days) as compared to LA (3.06 days). However, the difference was not significant, (p value =0.125). Most of the studies has shown significantly shorter hospital stay in LA.^{4,10-14} In some of the studies, the difference in length of stay between OA and LA was only 1 day.^{7,8} One study has also shown difference in length of stay of 2 days.⁵ One study has shown difference in length of stay of 3 days.⁹ So, it is quite clear from many studies that length of hospital stay is less in LA .

In the present study, pain was evaluated using VAS score. It gradually decreased over a passage of time after operation. There was significant difference in pain in both the groups at 1st three postoperative days i.e. LA patient had less pain than OA, but there was no significance difference in VAS score at any other stage of follow up, although it was slightly more in OA at different stages of follow-up. In the present study, the number of analgesic injections during postoperative period in two groups was, 5.52±0.99 for LA, and 5.62±1.02 for OA, i.e. slightly higher in OA but statistically not significant (p value 0.626). Some studies has reported similar analgesia requirement in the two groups.¹¹ Some studies has shown that there was significantly less need for analgesia in LA (1.0 in LA and 1.5 doses in OA).⁵ Some studies has shown pain after LA on the first postoperative day to be significantly less (p =0.008).¹²

In the present study, the mean time for ambulation was less for LA (8.17hours) than for OA (13.02 hours). Early mobilization has been seen in one of the study where patient of LA was mobilized after 12 hrs and OA after 36-48 hrs.⁹

In the present study, infection rate was 1% in LA, 6% in OA, all of which were superficial infection and got healed with regular dressing and antibiotics. There was no need of debridement or re-exploration. LA was associated with statistically significant lower rate of infections in most of the previous studies.^{11,12,14} The lower complication rate in LA technique can be explained by the advantage of minimally invasive surgery and reduced damage to viscera and intestinal serous membrane compared to open approach.¹⁶

In the present study, resumption of normal diet was in 16.75±5.21 hours in LA and 20.35±4.80 hours in OA. In one of the study, Oral feeds were allowed after 24 hrs and 48 hrs of LA and OA respectively.⁹ In some of previous studies, the LA group took less time to return to a regular diet.^{5,12}

In the present study, the cost of surgery was higher for LA (NRs 15067.04) than OA (NRs. 12524). In a study by Wang CC et al, in a study at Taiwan, higher cost per discharge (NT \$40,554 versus NT \$38,509, p, 0.001. in 2007, the average exchange rate was US\$1=NT\$31.0) was found for LA.¹⁵ In a study by Minutolo et al, the

mean total cost was 2282 Euro in LA and 2337 Euro in OA (p = 0.812).¹⁰ In a study by Kurtz et al, the hospital cost of LA was greater than that for OA but the extra expenditure in the operating room was offset by the longer length of stay of the patients having open surgery.⁸ In a study by Kehagias et al, the cost of treatment was higher by 370 € in LA.¹¹ In a study by Nakhmiyayev V et al, the mean total cost was \$5,663 in the LA and \$6,031 in the OA (non-significant difference of -\$368; 95% CI, -\$926-\$190; p = 0.19).¹³ Most of the studies has shown higher cost for LA than OA, which was similar to our study.

CONCLUSION

The present study concludes that, LA has statistically significant lower pain in 1st three postoperative periods, and a shorter hospital stay, early postoperative recovery but a slightly higher cost per discharge than OA.

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