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A Comparative Study between Conservative Treatment and Appendicectomy in Cases of Uncomplicated Acute Appendicitis

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ABSTRACT:*Acute appendicitis is the most common cause of acute abdomen requiring surgery, with a lifetime risk of developing about 7%. The decision whether to operate or not, is key in the management of acute appendicitis.*
With this study, we intend to provide some insight on the questions arising nowadays when dealing with uncomplicated acute appendicitis.
Objective: *To evaluate the feasibility and safety of non-surgical treatment in patient with uncomplicated acute appendicitis. And to compare conservative treatment with appendectomy in the management of uncomplicated acute appendicitis.*
Methods:*Over 2 years, we enrolled 74 patients with diagnosis of uncomplicated acute appendicitis, after randomization patients were divided into conservative group and surgical group. The failure of antibiotic therapy was defined as the need for appendicectomy. We evaluated the rates of treatment failure, complications, duration of hospital stay, cost expenditure and recurrence.*
Outcome measures*:The primary end point for patients in the antibiotic group was resolution of acute appendicitis, resulting in discharge from the hospital without the need for surgical intervention and no recurrent appendicitis during a minimum follow-up of 1 year (treatment efficacy). Treatment success in the appendicectomy group was defined as a patient successfully undergoing an appendicectomy.*
Results*: In appendicectomy group post-op complications was seen in 8 patients (21%). In conservative group complications was seen in 5 patients (13.1%). Duration of hospital stay was significantly more in conservative group, and the cost expenditure was significantly higher in the appendicectomy group.*
Conclusions*:We recommended conservative treatment for selective uncomplicated appendicitis especially in the setting of developing countries like India where majority of the population consist of middle or low socioeconomic group. We also recommend larger series studies to collaborate our finding for application to general population.*
Keywords:*uncomplicatedappendicitis,appendicectomy,surgery,conservative,management*

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I. Introduction

Acute appendicitis is the most common cause of an acute abdomen requiring surgery, with a lifetime risk of around 7%.Appendicitis is common in less than 50 years old, with a peak incidence in the second and third decades.[1]Symptoms of appendicitis overlap with a number of other conditions making diagnosis a challenge, particularly at an early stage of presentation.Appendicectomy is the most frequently performed emergency abdominal operation and is often the first major procedure performed by a surgeon in training.Most common symptoms of appendicitis are right lower abdominal pain, vomiting & fever but symptoms may vary with the position of appendix.[2]

The decision whether to operate or not, is key in the management of acute appendicitis. Historically, appendicectomy has been the gold-standard for the treatment of acute appendicitis, either via an open or a laparoscopic approach. However, this strategy has been challenged in recent years with the advent of antibiotic therapy and studies documenting less morbidity with nonoperative strategy.[3]

Even though appendectomy has been the mainstay treatment for appendicitis, relatively soon after antibiotics were available, Coldrey reported treating 471 patients with acute appendicitis with antibiotic therapy in 1956. Mortality was low (0.2%) and recurrent appendicitis occurred in only 14.4% of patients.[4]

The main aim during management is to decrease the negative appendicectomy at the same time keeping the appendiceal rupture rates low. A decrease in unnecessary appendicectomies should not cause an increase in perforation rates.[5]

Common terms used in appendicitis
Simple appendicitis: - inflammation of appendix without gangrene, perforation or abscess.
Complicated appendicitis: - inflammation of appendix with gangrene, perforation or abscess.
Negative appendicectomy: - term used for an operation done for suspected appendicitis, in which appendix is found to be normal on histopathological evaluation.

II. Methods

The present study was based on a primary sample of 76 patients who presented to surgery OPD/ casualty of RIMS with a clinical suspicion of acute appendicitis and finally confirmed by USG / CT scan as applicable. As the type of the study was Randomized Control Trial (RCT), the sample was divided into two groups viz., Conservative and Appendicectomy with 38 cases each. The study was carried out in Department of Surgery, Regional Institute of Medical Sciences (RIMS) Imphal, Manipur during two years period with effect from August 2018 to July 2020.

Inclusion criteria

- Patients attending surgery OPD or emergency in RIMS Hospital who are clinically/USG/CT diagnosed cases of uncomplicated acute appendicitis.
- Age between 18 to 60 years.

Exclusion criteria

- Complicated acute appendicitis in USG/CT scan:

Appendicolith
Appendicular perforation,
Appendicular abscess,
Appendicular peritonitis,
Suspicion of tumour.

- Patient previously treated conservatively for appendicitis.
- Pregnant women.
- Patients recognised to have any co-morbidity like heart disease, psychiatric illness and diabetic.
- Patient who refuse to give consent.

All adult patients (aged 18-60 years old) admitted with clinical diagnosis of "Acute Appendicitis" consist of patients presenting with migratory pain in right iliac fossa, associated with anorexia/ nausea/vomiting/fever and tenderness in right iliac fossa $\pm$ rebound tenderness/ Rovsing sign/Cope's psoas/Cope's obturator sign. under Surgery department in Regional Institute of Medical Sciences, Imphal, Manipur, was taken for this study.

Primary test like complete blood count, random blood sugar, urine analysis, ECG and Chest X-ray were done.
After diagnosis of uncomplicated AA, patients satisfying both inclusion and exclusion criteria were invited to participate. After taking the proposed Informed Consent, data was collected using the pre designed pro forma.

- **Outcome measures**:

The primary end point for patients in the antibiotic group was resolution of acute appendicitis, resulting in discharge from the hospital without the need for surgical intervention and no recurrent appendicitis during a minimum follow-up of 1 year (treatment efficacy).

Treatment success in the appendicectomy group was defined as a patient successfully undergoing an appendectomy.

Secondary end points included overall post-intervention complications, late recurrence (after 1 year) of acute appendicitis after conservative treatment, length of hospital stay.

Post intervention complications included clinical wound infection (surgical site infection) occurring within 30 days after the operative procedure as diagnosed by a surgeon or with a positive bacterial culture, other general postoperative complications (eg, pneumonia), adverse effects of the antibiotic treatment (eg, diarrhea), incisional hernia, possible adhesion-related problems (eg, bowel obstruction), and persistent abdominal or incisional pain.

Recurrent acute appendicitis was diagnosed on a clinical basis. Patients treated with antibiotics who had a suspected recurrence of appendicitis always underwent appendectomy.
The diagnosis of recurrent appendicitis was confirmed by surgical and histopathological examination of the resected specimen.
Total cost of treatment was calculated in a pragmatic way.

Procedure:
A total of 76 consecutive patients satisfying both inclusion and exclusion criteria diagnosed with acute appendicitis clinically and appendix visualized in ultrasound/CT scan without any sign of complications were recruited for this study. Clinical history, physical examinations and laboratory results were recorded for all patients.

- **Randomization:**

Patients were randomized by a closed envelope method either to undergo open appendectomy or to receive antibiotic therapy. The randomization was performed with a 1:1 equal allocation ratio and a sequentially numbered random code (A= conservative treatment; and B= Appendicectomy) was used for each group . There was 76 opaque, sealed, and sequentially numbered randomization envelopes. The envelopes were shuffled every time and then sister/Doctor on duty was asked to choose one envelope from box.

- **Conservative treatment:**

After randomization to receive conservative treatment, intravenous broad spectrum Antibiotic (Injection ceftriaxone + sulbactum 1.5gm IV BD and Inj Metronidazole 500mg IV TDS) was administered for three days with the first dose given in the emergency room. Patient was kept nil per oral forfirst 24hours, intravenous fluid and adequate analgesic was given. The clinical status of the antibiotic group patients was re-evaluated within 12 – 24 hours after admission and monitored during the whole stay. once the patient become clinically well and started tolerating oral intake, the treatment was changed to oral antibiotic (Tab ofloxacin + ornidazole 1 tab BD) therapy for 5 days.

- **Surgical treatment**

After randomization to undergo operative treatment, open appendicectomy was performed by standard technique using a McBurney`s right lower quadrant muscle splitting incision.Intra operative findings were recorded in the pro forma, and appendicectomy specimen was sent for HPE, diagnosis of acute appendicitis requires involvement of the muscularis of the appendix (transmuralneutophil invasion) Post operative complications are recorded and treated in routine manner.

- **Follow up**

Patient outcomes were assessed during their hospital stay (days 0, 1, 2) and then OPD basis at 1week, 2 months, and 1 year after the intervention. At both 1week and 2 months following randomization, presence of wound infections, any other sign of complication and recurrent appendicitis was determined.

Ethical Issues:
The study was carried out only after obtaining approval from the Research Ethics Board (REB), Regional Institute of Medical Sciences, Imphal.**No-A/206/REB-comm/SP/RIMS/2015/478/96/2018.**

III. Results

It is observed from the table-1 that irrespective of groups, the sample consists of more number of male 48 (63.2%) than that of female 28 (36.8%). There were three types of socio-economic status considered. They are high, middle, and low classes. Irrespective of groups, highest percentage of case belongs to middle class and next to it are low class and high class respectively. This is also true in both the groups. Further insignificant test value (P=.309) highlights that structure of socio-economic status in both the groups are almost similar and thus it would not make any change in the finding.

Table-1
Group-wise comparison of distribution of caseswith respect sex and socio-economic profile

Parameters		Group			P -value
		Conservative 38 (50.0%)	Appendicectomy 38 (50.0%)	Total 76 (100.0%)	
Sex	Male	23(47.9%)	25(52.1%)	48(100.0%)	.634
	Female	15(53.6%)	13(46.4%)	28(100.0%)	
Socio-economic status	High class	4(33.3%)	8(66.7%)	12(100.0%)	.309
	Middle class	25(56.8%)	19(43.2%)	44(100.0%)	
	Low class	9(45.0%)	11(55.0%)	20(100.0%)	

The mean age of those patients who were administered conservative treatment is found to be 38.39 years as against the mean age (31.36 years) of those who were performedappendicectomy (Table 2). The variation of means is tested by t-test and found to be significant at 5% probability level statistically, and it proves that in the sample, those who were performedappendicectomy are certainly younger than that of those who were administered conservative treatment. In other words, age structure is varied between the groups.

Table-2
Group-wise comparison of demographic profile

Parameters	Mean±SD		P-value
	Conservative	Appendicectomy	
Age (yr)	38.39± 13.09	31.36± 11.97	.017

There are six symptoms considered in the present study. They are shifting of pain, anorexia, nausea, vomiting, fever, and Mc Burney's point tenderness. Irrespective of the groups, nausea was present in 65.8% of patients and absent in 34.2% of patients in the present sample. The pattern is found existed in both the groups in the sense that the pattern of the present of nausea in conservative group is almost similar with the pattern of the present of nausea in appendicitis group. This assertion is supported by P= .147. There is no difference of either present or absent of vomiting in the one group to another group as highlighted by P=.087. This is true in both the groups, considered. In case of the fever, higher number of cases is found absent in comparison to present. This nature is persisted in both the groups. However, the insignificant test value suggests that there is no variation of fever pattern between the groups (P=.574). All the patients, in both the groups, are found to have Mc Burney's point tenderness. In brief, the pattern of symptoms, considered, over the groups is almost alike and no significant difference persisted.

During the study period, out of the 76 patients irrespective of their type of treatments, 7 patients (9.2%) have complications aroused while remaining 69 (90.8%) have no complications at all (Table 3). The same pattern is seen in both groups. Again, insignificant P=.692 indicates that the nature of complications arises in both the groups is almost same.

Table-3
Group-wise comparison of distribution of caseswith respect to complications

Complications		Group			P -value
		Conservative 38 (50.0%)	Appendicectomy 38 (50.0%)	Total 76 (100.0%)	
Complication	Present	4(57.1%)	3(42.9%)	7(100.0%)	.692
	Absent	34(49.3%)	35(50.7%)	69(100.0%)	

It is quite interesting to note that the duration of hospital stay for conservation treatment is very highly significantly longer than that of appendicectomy. The corresponding figures are 4.58 days and 3.05 days. This statement is in conformity with P<.001 which is a very highly significant even at .01 probability level. On the contrary, appendicectomy needs more amounts to expend while administering than that of the amount expend on conservation treatment. The former has mean total expenditure of Rs. 5442.11 as against Rs. 2923.68 for the latter(Table 4). The variation of amount of expenditure is very highly significant P<.001. From this interpretative analysis, one may infer that conservation treatment has more duration in hospital stay but less amount of expenditure than that of appendicectomy.

Table-4
Group-wise comparison of hospitalstay & expenditure

Parameters	Mean±SD		P-value
	Conservative 38 (50.0%)	Appendicectomy 38 (50.0%)	
Duration of hospital stay (day)	4.58±1.13 4 4.58±1.13	3.05±.95	<.001
Total expenditure (Rs)	2923.68±919.29	5442.11±1380.29	<.001

IV. Discussion

Appendicitis may present in different ways. It can present as uncomplicated acute appendicitis as was the case for the patients enrolled in this study. Appendicitis may also present with complicated disease such as perforation, intra-abdominal abscess, or with appendicoliths. Consequently, acute appendicitis treatment should be individualized based on which form of the disease is present. The most severe complications of appendicitis are diffuse peritonitis from a perforated appendix and intra-abdominal abscess. In our study, none of the antibiotic-treated patients experienced these complications.

The decision whether to operate or not, is key in the management of acute appendicitis. Historically appendectomy has been the gold-standard for the treatment of acute appendicitis, either via an open or a laparoscopic approach. However, this strategy has been challenged in recent years with the advent of effective antibiotic therapy and studies documenting less morbidity with this nonoperative strategy.[3]

Antibiotic therapy is commonly used in the treatment of uncomplicated appendicitis, and it may be associated with few complications, in addition to allowing patients to avoid unnecessary operative risks. Antibiotic treatment of patients with uncomplicated acute appendicitis was not shown to be noninferior to appendectomy for uncomplicated appendicitis within the first year of observation following initial presentation of appendicitis. Nevertheless, the majority (86.8%) of patients with uncomplicated acute appendicitis were successfully treated with antibiotics. These results suggest that patients with uncomplicated acute appendicitis should be able to make an informed decision between antibiotic treatment and appendectomy. Future studies should focus both on early identification of complicated acute appendicitis patients needing surgery and to prospectively evaluate the optimal use of antibiotic treatment in patients with uncomplicated acute appendicitis.

A potential benefit of non-operative treatment is the avoidance of an appendectomy (and associated spinal anesthesia). For this benefit to be realized, the recurrent appendicitis rate must below and acceptable to both surgeons and patients. In this study, there were two cases (5.26%) of histologically proven recurrent appendicitis during the follow-up period which was quite acceptable.

When the trial was designed we assumed that there would be sufficient benefits from avoiding surgery and that a 24% failure rate in the antibiotic group would be acceptable. Instead, we found a failure rate of13.15% only and it prove the non-inferiority of antibiotic treatment for appendicitis. We found that 33 of 38 patients with uncomplicated acute appendicitis were successfully treated with antibiotic therapy alone. This compares favorably with the results from previous randomized trials[6-8] and a recent population-based prospective study.

Similar to Paajanen Het al[9], we minimized the diagnostic uncertainty of appendicitis compared with when the diagnosis is made on clinical grounds by only enrolling patients into the trial who had a diagnosis of uncomplicated acute appendicitis confirmed by a USG/CT .We excluded patients from enrollment if they had an appendicolith identified on a USG/CT scan. Intraluminal appendicoliths can predict failure of non-operative management for appendicitis and the development of complicated acute appendicitis.

A limitation of prior antibiotic trials for treating appendicitis was the selection of the antibiotic. To succeed, the antibiotic must provide broad-spectrum coverage for all the pathogens that might cause appendicitis. To avoid this limitation, we used 3rd generation cephalosporin in our study because it provides broad-spectrum coverage.

The mean length of hospital stay was longer in the antibiotic group; however, it was predefined in the protocol for the monitoring of patients in the antibiotic group to ensure patient safety in the trial. In our study the length of hospital stay (primary hospitalization) was statistically significantly shorter ($P < .001$) in the surgical group (Mean $\pm$ SD= 3.05 $\pm$ 0.95 days) than in the antibiotic-treated group (Mean $\pm$ SD =4.58 $\pm$ 1.1 days). For non-operative treatment to be considered equivalent to appendectomy, some may believe that the length of hospitalization should be similar. In this study, the post randomization length of stay was longer for non-operative treatment group than for those who underwent appendectomy. A possible explanation for this is that we stipulated a minimum of 72 hours of intravenous antibiotics in our protocol for patients safety.

Because none of the patients initially treated with antibiotics and later having appendectomy had major complications, the length of hospital stay related to antibiotic therapy may possibly be shortened in practice. One drawback of antibiotic treatment for acute appendicitis is the possible bias due to spontaneously resolving appendicitis. A double-blind, placebo-controlled RCT is needed to differentiate these effects.

This study had several important limitations. Because appendectomy is considered the standard treatment for appendicitis, we had difficulty enrolling patients into the study. Another limitation is that most of the appendectomies were performed using the open operative approach. Open appendectomy was chosen as the protocol operative intervention based on both (1) the standardization of the procedure regarding the large group of surgeons most familiar with the open technique and (2) the global generalization of the study results because the equipment for laparoscopic appendectomy and surgical experience are not available throughout the world. However, laparoscopic appendectomy is commonly performed and is associated with less pain, shortened hospital stay, faster return to normal activity, and fewer wound infections. The most common cause of morbidity in the surgical group of our studies related to wound infection, the complication rate might have been less had the operations been performed laparoscopically.

Although the number of patients treated non-operatively was small, there were no safety issues either during the acute admission or during the follow-up period and so this trial provides no evidence that nonoperative treatment of acute appendicitis is unsafe.

In our study the cost expenditure was significantly higher in the surgery group (P value= 0.001) and it was almost double as compared to conservative group. In appendicectomy group (Mean $\pm$ SD = 5442 $\pm$ 1380 rupees) as compared to (Mean $\pm$ SD = 2923 $\pm$ 919 rupees) in the conservative group. A cost-effectiveness analysis should be performed as part of any future study.

V. Conclusion

Antibiotic therapy without surgery may be a safe treatment for uncomplicated appendicitis in selected patients. Removing of the normal appendix will cause them extra financial burden, and avoidable complications associated with appendicectomy. In conclusion we recommended conservative treatment for selective uncomplicated appendicitis especially in the setting of developing countries like India where majority of the population consist of middle or low socioeconomic group. We also recommend larger series studies to collaborate our finding for application to general population.

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