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Original Research Article

Intra-incisional versus intravenous route of antibiotic administration in preventing surgical site infections: a randomized controlled trial

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ABSTRACT

Background: Surgical site infection (SSI) is one of the most common postoperative complications following abdominal surgeries. Whilst the use of prophylactic antibiotics has been shown to reduce postoperative wound infection, controversy still remains as to the optimum route of administration and the duration of treatment. This study aims to compare the efficacy of a preoperative single dose of a cephalosporin antibiotic (cefotaxime) administered intraincisionally versus that administered intravenously, in preventing postoperative surgical site infections following appendicectomy.
Methods: Sixty consecutive cases diagnosed as uncomplicated appendicitis who consented for open appendicectomy at a tertiary care institute were included in the study. Cases were randomized to 2 comparable groups of 30 patients each. Preoperatively, patients in Group A received a single dose of Inj. Cefotaxime 1g intraincisionally while those in Group B received the same intravenously. Incision sites were examined every alternative day starting on postoperative day 3 until removal of sutures. Signs of surgical site infection, if any, were recorded and outcomes were statistically tested for significance.
Results: One patient in Group A (3.3%) and 4 patients in Group B (13.3%) showed signs of postoperative surgical site infection ($p > 0.05$) during the follow up period which prolonged their hospital stay.
Conclusions: This study showed that a single dose preoperative intraincisional administration of cefotaxime was as effective as intravenous administration for prevention of postoperative surgical site infection after open appendicectomy. Although the difference was not statistically significant, there was a reduced incidence of SSI in individuals who received intraincisional antibiotic. These results are encouraging for a way forward in reducing unnecessary burdening of systemic antibiotics in patients undergoing abdominal surgeries.

Keywords: Appendicectomy, Antibiotics, Intraincisional, Intravenous, Surgical site infection

INTRODUCTION

Since the evolution of medicine, great strides have been taken in the field of advanced and minimal access surgeries. The focus is gradually shifting to day-care surgeries and surgeries with more cosmetically acceptable scars. However, despite the recent advances, one of the most commonly observed postoperative complication is surgical site infection (SSI). According to the National Nosocomial Infection Study (NNIS) report of the Centre for Disease Control (CDC), the prevalence rate of SSI, though preventable, is high.[1]

Surgical site infections are one of the most common nosocomial infections and constitute almost 38% of all infections in surgical patients.[2] Postoperative wound infection is a reason for pain, anxiety, loss of function, scar contractions, and possible mortality secondary to

sepsis. It also leads to increased hospital stay which further adds to the worry of both patient and the treating surgeon. With the fear of a patient developing wound infection, surgeons, even today, burden the patient with higher antibiotics, even in clean and uncontaminated surgeries which is certainly not justifiable especially in the wake of new drug resistant microorganisms. Prolonged use of antibiotics also adds to the cost incurred by the patient and various side effects such as nausea, vomiting, metallic taste, loose stools, etc.

Hence, the timing, route and duration of antibiotic prophylaxis in surgery assume significant importance in that they should ensure that as high a concentration as possible reaches the wound before contamination as the most important factor in the pathogenesis of wound sepsis is the presence of bacteria in the incision at the time of closure. Local intraincisional administration of antibiotics is sensible, practical, and in this era of cost containment and increasing drug resistance, it is responsible.

The present study was undertaken to compare and evaluate the efficacy of single dose of preoperative intraincisional administration of cefotaxime with intravenous administration in preventing postoperative surgical site infections after open appendicectomies.

METHODS

The study design was one year randomized clinical trial conducted during the year 2012 at a tertiary care hospital. The study was approved by the institutional Ethical and Research Committee. Sixty consecutive patients who were clinically diagnosed to have appendicitis and consenting for surgery were admitted and considered eligible for the study. Patients aged less than 18 years, those undergoing laparoscopic surgery, and those with a history of Diabetes mellitus or immunodeficiency were excluded. Also excluded were patients with a history of receiving systemic antibiotics within 2 weeks of proposed surgery, a history of ongoing/ recent systemic corticosteroid therapy, presence of pre-existing systemic/ local infection, presence of associated complications - appendicular abscess/ gangrenous appendicitis/ appendicular mass, gastrointestinal perforation, peritonitis and/or other apparent foci of active abdominal infection.

Data concerning demography, history of the illness and details of thorough clinical examination were recorded onto a predesigned proforma. Routine investigations in the form of complete blood count, blood urea, serum creatinine and special investigations such as ultrasound of abdomen were done as required. The 60 patients were randomized into 2 groups by 'Opaque Envelope Method'. Group A would receive single dose of preoperative intraincisional cefotaxime while Group B would receive the same intravenously.

For intraincisional administration, antibiotic was infiltrated at the proposed site of incision in the subcutaneous tissue and intramuscular plane after induction of anesthesia and 10 minutes prior to the incision. The dose of antibiotic was approximately 1 ml per cm of incision (which corresponded to 100 mg of antibiotic per cm). A 22G spinal needle was used to inject the antibiotic with a single-entry point.

No other antibiotic was given by any route preoperatively or postoperatively other than that followed in the study protocol. Analgesics, intravenous fluids and other supportive treatments were given as required. Beginning on postoperative day 3, the surgical wound was examined every alternate day until removal of sutures. Findings at each dressing were charted in a pre-formed table to assess wound infection. The wound was labelled as 'infected' if it fulfilled the CDC criteria for Surgical Site Infection.

Statistical analysis

The analysis of data was done using SPSS version 13.0 (SPSS Inc, Chicago, IL). Statistical evaluation of the collected data was carried out using mean, frequency, percentage, chi square test and Fisher's exact test. The difference between wound infection rates in two groups was analysed using Fischer's exact test. Fischer's exact p value <0.01= highly significant, <0.05= significant, >0.05= not significant.

RESULTS

A total of 60 patients (30 in each group) were enrolled for the study with ages that ranged from 18 to 64 years (mean 30.8±12.62 years in Group A and 30.3±10.29 years in Group B). A total of 33 (55%) male patients and 27 (45%) female patients participated in the study. Group A had 9 (30%) males and 21 (70%) females. Group B had 18 (60%) males and 12 (40%) females. Patients presented with multiple symptoms and signs, a summary of which is depicted in Table 1. Pain and tenderness in RIF, and fever were present in all the patients in both groups.

Table 1: Presenting symptoms and signs.

Symptom/sign	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Pain in RIF	30	100	30	100	60	100
Fever	30	100	30	100	60	100
Anorexia	10	33.3	9	30	19	31.7
Nausea	17	56.7	13	43.3	30	50
Vomiting	6	20	3	10	9	15
RIF tenderness	30	100	30	100	60	100
Rebound tenderness	4	13.3	7	23.3	11	18.3
Elevated body temperature	18	60	24	80	42	70
Leucocytosis	14	46.7	16	53.3	30	50

Out of the 60 study patients, 43 (71.7%) had features of acute appendicitis for the first time whereas 17 (28.3%) of them had past history suggestive of recurrent episodes of appendicitis. Group A had a higher number (22/30) of patients with acute appendicitis compared to Group B (21/30). Overall, appendicectomy was performed as an elective surgery in 24 patients (80%) of Group A and 20 (66.7%). The rest underwent elective appendicectomy.

No patients from Group A and B developed signs of infection on postoperative day 3. By the end of postoperative follow up, 1 patient (3.3%) from Group A and 4 (13.3%) patients from Group B were documented as having developed superficial surgical site infection. (Table 2). Figures 1 and 2 show examples of SSI noted in the study.

Table 2: Overall post-operative surgical wound assessment.

Wound infection	Absent		Present		Total
	Frequency	%	Frequency	%	
Group A	29	96.7	1	3.3	30
Group B	26	86.7	4	13.3	30
Total	55	91.7	5	8.3	60

p=0.350

Figure 1: Example of SSI in Group A.

Figure 2: Example of SSI in Group B.

DISCUSSION

Wound infection remains an important postoperative complication with significant clinical and economic consequences.[3] Moylan estimated that in the United States, 7-8% of all operations are complicated by wound infection.[4] From the study of 1000 general surgical operations, Davidson et al clearly showed that the most important factor in the pathogenesis of wound sepsis was the presence of bacteria at the time of wound closure.[5]

The goal of surgical prophylaxis is to achieve and maintain a satisfactory tissue concentration of a drug with a reasonable spectrum of activity against expected organisms during the period of potential bacterial contamination of the wound, so that organisms introduced into the wound during the operation would be immediately destroyed. Failure to maintain adequate serum and tissue levels throughout the surgical procedure increases the likelihood of infection.[6] It has also been emphasized that wound levels, not blood or serum levels, appear to determine the efficacy of agents for prophylaxis of operative wound infection. These very high tissue levels can only be achieved by a preoperative intraincisional injection. Prophylactic antibiotics are generally administered systemically prior to operation. The concentration of an appropriate antibiotic in the wound itself, rather than in the serum, is the critical factor in determining the efficacy of agents used for the prophylaxis of surgical wound infections.[7]

Appendicitis is one of the most common causes of an abdominal emergency.[8] Appendicectomy is considered the treatment of choice in acute and recurrent appendicitis and remains one of the most commonly performed surgical procedures with SSI complicating 1–5% of all cases.[9-12] The pathologic state of the appendix is the most important determinant of postoperative infection.[13-14] Wound infection after appendicectomy, for perforative or gangrenous appendicitis is four to five times higher than for early disease. Because the pathologic state of the appendix often cannot be determined before or during operation, a parenteral antibiotic agent is recommended as prophylaxis in all patients. The present study was undertaken to compare and evaluate the efficacy of single dose of preoperative intraincisional administration of cefotaxime with intravenous administration in preventing postoperative surgical site infections after open appendicectomies.

Several similar studies have been done to establish the efficacy of intraincisional administration of antibiotics. Shubing et al studied preoperative intraincisional metronidazole in preventing postoperative surgical site infection in patients undergoing appendicectomies compared to a control group in which no antibiotic was administered.[15] The infection rate was considerably low in the intraincisional group (0.8%) compared to intravenous group (11.6%). Similar results were reported by Taylor et al who demonstrated a statistically

significant difference in the incidence of postoperative surgical site infection as well as in the duration of hospital stay when Cefamandole was used intraincisionally in the study group versus the control group which did not receive any antibiotics.[16]

Pollock et al showed a similar trend when they compared intraincisional administration of Amoxycillin plus clavulanic acid to intravenous administration of the same in patients undergoing abdominal surgeries.[17] In this study, however, metronidazole was added to select group of patients depending on anticipated complications.

Griego et al studied the effect of intraincisional nafcillin in 790 patients with 908 wounds undergoing clean surgeries viz reconstruction following Moh's micrographic surgery.[18] The control group did not receive any antibiotic. The study concluded that nafcillin was statistically significant in preventing postoperative infection (0.2%) versus 2.5% in control group.

As evident, the results obtained in our study are comparable to and concur with the other studies (3.3% versus 13.3%) indicating that intraincisional administration of antibiotic is as effective as intravenous administration of the same. However, despite the above conclusion, the importance of good surgical technique, maintenance of asepsis and good postoperative care cannot be undermined to reduce the incidence of postoperative surgical site infection and thereby reduce significant morbidity and mortality.

Overall, the results of this study suggest that the use of single dose of intraincisional cefotaxime is as effective as intravenous administration of the same and resulted a clinically noticeable reduction in the rate of postoperative surgical site infection.

However, the difference was not found to be statistically significant. This may be attributed to the smaller sample size of the study. Further studies on larger sample size could focus the beneficial effect of intraincisional antibiotics.

CONCLUSION

The results of the present study show that a single dose preoperative intraincisional administration of cefotaxime is as effective as intravenous administration of cefotaxime for prevention of postoperative surgical site infection after open appendicectomies.

Although not statistically significant, there was clinically a lesser incidence of SSI in individuals who received intraincisional antibiotic.

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