### **Original Research Article**

DOI: http://dx.doi.org/10.18203/2349-2902.isj20201386

## A comparative study of surgical site infection after single dose of preoperative antimicrobial prophylaxis versus multiple doses of antimicrobials in clean and clean contaminated abdominal surgeries

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Received: 01 January 2020 Revised: 09 February 2020 Accepted: 11 February 2020

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#### ABSTRACT

**Background:** The advent of antimicrobial therapy has offered an important adjuvant to the prevention of surgical infection. In spite of vast accumulation of research and review published there are still conflicting views. Some study shows multiple doses require for the eradication of microorganisms in the wound. While numerous authors have reported that single dose of an appropriate antibiotic is effective, but there has been no direct comparison of one dose against three doses regimens. Objective was to study about effect and safety of single dose of antibiotic against routine multiple dose regimens in clean and clean-contaminated abdominal surgeries.

**Methods:** Patients recruited in the study according to specific inclusion and exclusion criteria. The participants were divided in two groups: group I and group II. Group I was given single dose of injection cefotaxime. While another group was given 5 days course of injection cefotaxime and injection amikacin or injection ciprofloxacin and injection metronidazole. Postoperative wound was assessed by Southampton wound grading system.

**Results:** The rate of wound infection on 3rd day was for 16.30% for group I and 13.82% for group II. The infection rate decrease on 7th post-operative day and it was 13.04% for group I and 11.7% for group II.

**Conclusions:** Long course of antibiotic as prophylaxis has no added advantage. Good operative technique plays a major role in preventing infections. Single dose antibiotic regimen has comparable infection rate for clean surgical cases and it saves lot of money in this era of cost containment.

Keywords: Long course antimicrobial prophylaxis, Surgical site infection, Single dose antimicrobial prophylaxis

#### **INTRODUCTION**

Infection of the operative wound is as old as problem as surgery is an art and surely older than surgery is a science. Antimicrobial agents were once hailed as magic Bullets that promised to eradicate infection. Unfortunately this promise has not been fulfilled. The use of antimicrobial agents to prevent surgical infection has become a subject of controversy and disappointment in clinical practice. An advance in the approach to surgical infection over the past 100 years has been the concept and practice of prophylaxis. The basic surgical skills of post-operative precaution, pre-operative preparation, excellent surgical technique, fastidious wound care and post-operative management are corner stones of infection prophylaxis. The advent of antimicrobial therapy has offered an important adjuvant to the prevention of surgical infection.<sup>1</sup> Prophylaxis in surgery means the prevention of Postoperative infections. It must be distinguished clearly from the therapy of established infections. Operative wound infection is examined through classification based on estimation of frequency, severity and source of infection.<sup>2</sup>

In spite of vast accumulation of research and review published there are still conflicting views. Polk and Lopez Mayer showed that most bacteria are killed by antibiotics and phagocytes within four hours, but remainder proliferate and require a second or third dose for their eradication.<sup>3</sup> Since then numerous authors have reported that single dose of an appropriate antibiotic is effective, but there has been no direct comparison of one dose against three doses regimens. There is however, no justification for continuing prophylactic antibiotics beyond the day of operation. While Pollock emphasis that the danger of primary antimicrobial contamination ceases at the end of the operation and there is no justification for more than one or occasionally 2 or 3 dosage of antibiotics.<sup>4</sup>

So the objective was to study about effect and safety of single dose of antibiotic against routine multiple dose regimens in clean and clean-contaminated abdominal surgeries.

#### **METHODS**

This was a prospective observational study conducted at SSG Hospital, Vadodara over a period of twenty months from September 2007 to February 2009. Human research ethics committee permission was taken prior to starting the study.

All patients between 5-65 years of age who were undergoing planned clean or clean-contaminated abdominal surgeries were included in the study. Patient exclusion criteria were patients of age <5 years or >65 years, patient with history of hypersensitivity to cephalosporin, pregnant or nursing women, patients with renal impairment, severe hepatic diseases, patients with immune-compromised status, steroid therapy, obese, diabetes mellitus, tuberculosis, patient in septicemia defined by systemic inflammatory response syndrome (SIRS), patient with contaminated and dirty abdominal surgeries and duration of surgery >3 hours.

The study objective was to evaluate the single dose I.V. administration of injection cefotaxime sodium with the conventional prophylactic 3 to 5 day course of antimicrobial agents. All participants were divided in two groups, group I and group II. In Group I, patients were given single dose of inj. cefotaxime <sup>1</sup>/<sub>2</sub> hour before skin incision and Group II, were given 5 days course of Inj. Cefotaxime and inj. amikacin or inj. ciprofloxacin and inj. metronidazole (or tablets).

All patients selected for study were admitted two days prior to operation and were investigated for routine preoperative assessment. The shaving was done one day prior to operation. The operative site was painted before operation by cetavolon and spirit. Operative field was draped with autoclave gowns and operative field was isolated. In operation theatre strict aseptic precautions were taken. All patients of group I in study received injection cefotaxime 1 gm I.V. at the time of induction of anesthesia. While patients of group II received inj. cefotaxime and inj. amikacin or inj. ciprofloxacin and inj. metronidazole at the time of anesthesia.

Intra-operatively adequate painting and draping, excellent haemostatic, gentle handling of tissues was carried out. Post-operatively after returning patients to ward, all patients of group I were given no antibiotics and group II patient were given total 5 days of antibiotics (Parenteral and/or oral). Those patients in group I, who develop any two of following signs were excluded from study and evaluated for cause of systemic inflammatory response syndrome.

- Temperature  $>100^{\circ}$  F or  $<96^{\circ}$  F
- Heart rate >100/min or respiratory rate >20/min
- Total WBC count >12,000/mm or 4000 mm

Dressings were changed on second post-operative day, fifth post-operative day. Stitches were removed either on 7th or 8th post-operative day. Condition of the wound was noted in following grades and associated complain noted.

Postoperative wound was assessed by Southampton wound grading system.<sup>5</sup>

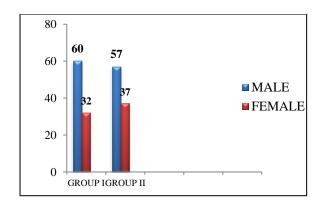
- Grade 0- No infection
- Grade 1- Erythema
- Grade 2- Edema and wound tenderness
- Grade 3- Serosanguinous discharge
- Grade 4- Discharge of pus from wound

In addition to monitoring wound infection was also followed for urinary tract and pulmonary infections. Patients who were discharged earlier were called for dressing on 5th post-operative day and for stitch removal on 7th post-operative day. All patients were called after one month for follow up and to see the condition of the wound. For discharge of pus from wound, swab was taken and sent for culture and sensitivity. Till the report comes in case of grade IV infection, broad spectrum antibiotic was started.

#### RESULTS

Over a period of twenty months' time total 194 participants were included in the study according to inclusion and exclusion criteria. However, total 186 participants could be included during the statistical analysis. Patients from all age groups and both gender were included in the study with mean age was around 35 years. 'F test' applied for statistical analysis. Combined p value for all age group is 0.95 which is suggestive of no significant difference of age between two groups (Table 1).

The p value show no significant difference of age and sex between two groups as p value is >0.05 (Figure 1).



#### Figure 1: Gender wise distribution of all participants.

Table 2 shows the type of surgeries included in both the groups in present study. All surgeries were either clean or clean-contaminated abdominal planned surgeries. The average duration of surgery was 30 minutes to 150 minutes with mean duration of 75 minutes. Two patients one in each group was having retroperitoneal drain who were operated for lumbar sympathectomy up to 3rd post-operative day. No patient was having intra-peritoneal free fluid or collection. And intra-peritoneal drain was not contraindication to include patient in study.

Table 1: Age wise distribution of all participants.

Age	Group I	Group II	Total
(yrs)	N (%)	N (%)	N (%)
5-25	21 (11.29)	20 (10.75)	41 (22.04)
26-45	36 (19.35)	34 (18.28)	70 (37.63)
46-65	35 (18.81)	40 (21.51)	75 (40.32)
Total	92 (49.46)	94 (50.54)	186 (100)

Assessment was done according to Southampton wound grading system.<sup>5</sup> The wound was assessed according the grading system on 3rd and 7th post-operative day. The rate of wound infection on 3rd day was for 16.30% for group I and 13.82% for group II. According to grading system both groups had infection of grade II and III on 3rd postoperative day. Grade II infection was seen in 6 participants each among the group I and II. While grade III infection was seen in 7 participants of group I and 6 participants of group II. The infection rate decrease on 7th post-operative day and it was 13.04% for group I and 11.7% for group II. On 7th post-operative day grade 3 infection decrease in both the Groups (Table 3). One participant in whom colon resection was done had grade 4 infection on 3rd postoperative day, which converted to grade 3 on 7th postoperative day.

Summeries	Group I	Group II	Total
Surgeries	N (%)	N (%)	N (%)
Laparoscopic cholecystectomy	26 (13.98)	29 (15.59)	55 (29.57)
Laparoscopic appendicectomy	18 (9.68)	15 (8.06)	33 (17.74)
Open appendicectomy	1 (0.54)	2 (1.08)	3 (1.61)
Laparoscopic TEP	18 (9.68)	17 (9.14)	35 (18.82)
Inguinal hernioplasty	14 (7.53)	20 (10.75)	34 (18.28)
Inguinal herniotomy	9 (4.84)	5 (2.69)	14 (7.53)
Epigastric and umbilical hernia repair	3 (1.61)	4 (2.15)	7 (3.76)
Lumbar sympathectomy	1 (0.54)	1 (0.54)	2 (1.08)
Colon resection	2 (1.08)	1 (0.54)	3 (1.61)
Total	92 (49.46)	94 (50.54)	186 (100)

Table 3: Post-operative assessment of wound infection according to Southampton wound grading system.

Cuedes of mound	3 <sup>rd</sup> post-operative day			7 <sup>th</sup> post-oper:	7 <sup>th</sup> post-operative day		
Grades of wound infection	Group I	Group II	P value	Group I	Group II	P value	
	N (%)	N (%)		N (%)	N (%)		
0	77 (83.70)	81 (86.17)	0.78	80 (86.96)	83 (90.1)	0.79	
1	1 (1.08)	1 (1.06)	0.82	0	1 (1.06)	-	
2	6 (6.52)	6 (6.38)	0.89	6 (6.52)	5 (5.34)	0.82	
3	7 (7.60)	6 (6.38)	0.71	6 (6.52)	5 (5.34)	0.82	
4	1 (0.08)	0	-	0	0	-	
Total	92	94	-	92	94	-	

Table 4 shows the surgery wise distribution of all participants with post-operative wound infections on 7th

day of the surgery. The table shows that 4 participants of group I and 5 from group II operated for inguinal hernia

had wound infection. While in clean-contaminated surgeries like laparoscopic cholecystectomy and laparoscopic appendicectomy shows that 4 and 3 participants respectively got wound infection in Group I and 2 participant in each surgery from Group II had infection. In group I patient with colon resection got grade 4 infection.

# Table 4: Wound infection according to surgeries on7th post-operative day.

	Group I	Group II		
Clean surgeries				
Inguinal hernioplasty	4	5		
Lumbar sympathectomy	0	1		
Clean-contaminated surgeries				
Laparoscopic cholecystectomy	4	2		
Laparoscopic appendicectomy	3	2		
Colon resection	1			

Six patients in group I and two patients from group II, who were included into study but excluded from the statistical analysis. Among them, three patients were operated for laparoscopic cholecystectomy developed consolidation and for that injectable cefotaxime were started. Two patients, one operated for laparoscopic and one for open appendicectomy and had urinary tract infection and for that injectable ciprofloxacin was started. There was one patient operated for laparoscopic appendicectomy in group I who was detected hyperthyroidism postoperatively and for that oral anti-thyroid drugs were started and was having no wound infection. Two patients with had to admitted in the intensive care unit for post anesthetic complication.

#### DISCUSSION

In this era of development of strains of organism resistant against antimicrobials leads to need of more and more newer and costly antimicrobials to fight against those resistant strains of organism. In such instances one should use antimicrobial agents where they are not needed or needed for limited duration. This study was develop to check judicious use of precious antimicrobials and analyzes the results in form of surgical site wound infection. In this study all the clean and cleancontaminated abdominal surgeries routinely performed by the surgery department were included, like laparoscopic cholecystectomy, laparoscopic and open appendicectomy, laparoscopic and open inguinal hernioplasty, epigastric and umbilical hernias, lumbar sympathectomy. According to the inclusion and exclusion criteria total 194 patients were included in the study, but during statistical analysis 8 patients were excluded as describe in the result part. The age distribution in present study was almost identical with no significant difference between two groups with p value >0.05. Extremes of age increase the chances of infections among the post-operative wound. But in present study variation in age distribution was not much among the group I and II, so that bias due to variation in age group

could be prevented in this study. The duration of surgeries included in study was ranged from 30 minutes to 150 minutes with average duration of 75 minutes. The effect of single dose of antibiotic lasts for 3 hours, and we need to administer another dose if surgery lasts longer than 3 hours. There was no need of administration of another dose of antibiotics in group I of the study as no surgery was longer than 2 hours.

In present study the wound infection on 3rd post-operative day, was 16.30% in group I and 13.82% in group II. Which was nearly same and there was no significant difference of surgical site wound infection between clean and cleancontaminated surgeries in group I as 4 patients in each class surgeries were having wound infection with p value >0.05. The percentage of surgical site wound infection on 7th postoperative day in group I was 13.04% and in group II was 11.70%. There was no statistically significant difference between two groups with p value >0.05. As due to presence of surgical site wound infection there was delayed skin suture removal in those patients. Another study by Likman et al had done on 175 patients in two groups for SSI and concluded that there was 6.5% infection rate in single dose antimicrobial administration group verses 3.6% in conventional group with no significant difference by statistical analysis with p value > 0.6. As compared to that study, rate of SSI in present study was higher in both groups but the p value was almost same.<sup>6</sup> Jones et al had done study on 907 patients for SSI after single shot of antibiotic administration in class 2 abdominal surgeries and concluded that there was 7.3% rate of SSI in study group compared to 7.1% in conventional group which was similar incidence of SSI in both the groups with p value >0.05. As compared to this study, rate of SSI in present study was slightly higher.<sup>7</sup> Zelenisky et al had done study on 146 patients for SSI in Class 2 surgeries and found 8.1% rate of infection in study group compared to 6.9% in conventional group with no significant difference between two groups with p value >0.05.<sup>8</sup> As compared to this study, rate of SSI in present study was slightly higher. It had shown that the rate of wound infection in the study is somewhat higher than other studies but there is no significant difference of wound infection statistically in two groups of the study. There are some factors like lack in chain of sterilization or ventilation or postoperative wound care which are responsible for overall higher rate of SSI in the institute compared to other study which requires further evaluation.9,10

On the average the post-operative hospital stays for patients who develop wound infections is 1-2 weeks longer than that of patients whose wound heals without infection. However there were no fixed criteria for discharge of patient from hospital so it was not taken into consideration in present study.

The antimicrobial drugs used in present study were of government supply. However for the study minimum cost of the generic drug was search in the market and calculated the cost of the prophylactic dose. And the cost of single dose of injection cefotaxime was 12 rupees. While injection cefotaxime and amikacin 5 days treatment was 290 rupees. Also, oral 5 days therapy of ciprofloxacin and metronidazole costs 170 rupees. There was significant difference between costs of antimicrobial agents required for both group with p value <0.05. This clearly shows that mere economical burden on health care facility of unnecessary administration of antimicrobial in those patients who do not need it actually. As SSI occurs in both the groups irrespective of use of prolonged postoperative antimicrobial prophylaxis. The use of prophylaxis to decrease a wound infection rate from 2% to 1% using even one day of prophylactic regime, would cost about 100 patient day of antibiotic and thousands of rupees per wound infection prevented.

It can be concluded from the study that long course of antibiotic as prophylaxis has no added advantage. Good operative technique plays a major role in preventing infections. Single dose antibiotic regimen has comparable infection rate for clean surgical cases and it saves lot of money in this era of cost containment.

Funding: No funding sources Conflict of interest: None declared

*Ethical approval: The study was approved by the Institutional Ethics Committee* 

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**Cite this article as:** Vala H, Vaja MA, Gohil AB. A comparative study of surgical site infection after single dose of preoperative antimicrobial prophylaxis versus multiple doses of antimicrobials in clean and clean contaminated abdominal surgeries. Int Surg J 2020;7:1143-7.