

## Original Research Article

# A comparative study between preoperative intraincisional coamoxiclav infiltration and intravenous coamoxiclav injection for prevention of surgical site infection

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## ABSTRACT

**Introduction:** Infection remained a great problem in surgical practice. Infection is encountered by all surgeons by the nature of their craft; they invariably impair the first line of host defense. It happens to be one of the major causes of post-operative morbidity and mortality. Intraincisional antibiotic injection should be beneficial in two ways; very high wound levels will prevent wound sepsis, and good serum levels will minimize systemic complications.

**Methods:** This is a prospective randomized controlled study comprising of 200 patients divided in to two groups i.e. 100 in each group. Group A-Preoperative intraincisional infiltration of 1.2g Coamoxiclav dissolved in 20 ml of 0.9% saline solution will be infiltrated along the skin and the subcutaneous tissue in the proposed line of incision, 20 minutes before surgical incision. Group B-Preoperative administered a single dose of 1.2 g Coamoxiclav intravenously just before the induction of anaesthesia.

**Result:** Overall incidence of SSI in Group A was 1% and in Group B 6%. Overall average time for complete healing in group A less than group B. Frequency of infection due to gram negative bacteria was more as compared to gram negative in the cases that developed SSI.

**Conclusion:** The incidence of SSI was lower in the group of patients who were subjected to preoperative intraincisional Coamoxiclav infiltration as compared to the group who received preoperative intravenous Coamoxiclav. There was statistically significant relation between the types of wounds, duration of surgery to the development of SSI in this study.

**Keywords:** Antibiotic prophylaxis, Wound infection, Preoperative, Coamoxiclav, Surgical site infection

## INTRODUCTION

Surgical site infection remained a great problem in all surgically operated practice. Infection is encountered during and after surgery almost surgeons by the nature of their craft; they invariably damage the first line of host defense mechanism of infection control in body.<sup>1</sup> Bacteria and there infective material may enter the wound

during or after the operation and they may be endogenous origin and/or exogenous origin.<sup>2</sup> Endogenous source can be come from mouth, skin, respiratory tract, gastrointestinal tract, biliary tract, anal tract, perineum or genitourinary tract of the patient own. Exogenous organisms came from operating surgeons, assistant surgeon, attending nursing staff, and breach in asepsis mechanism in operation theatre or in wards. Infection of

the operating incised skin or soft tissues is a common but potentially avoidable complication of any surgical procedure. Some bacterial contamination of surgical site is inevitable, either from the patient's own bacterial flora or from the environment source. The concept of "Preincisional-intracincisional" injection of antibiotics first introduced by Taylor et al.<sup>2</sup> This technique achieves high local concentrations of antibiotic at injectable site combined with adequate blood serum levels. Preoperative intracincisional antibiotic injection should be beneficial in two ways; very high wound (incision site) levels will prevent wound infection, and good blood serum levels will minimize systemic inflammatory complications like systemic sepsis, SIRS.

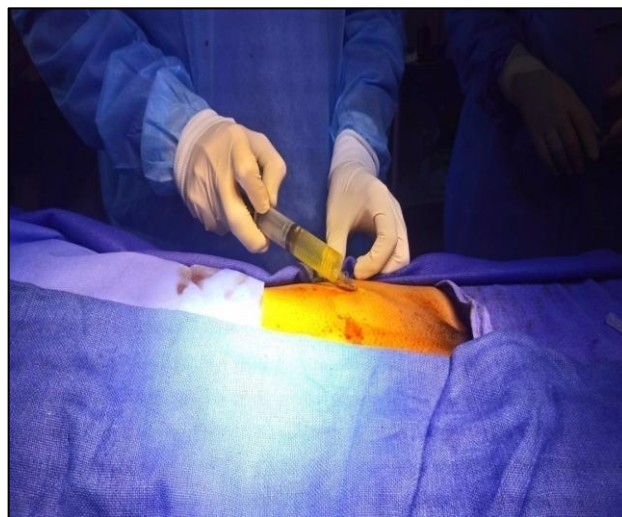
Amoxicillin and clavulanic acid (Coamoxiclav) combination have highest susceptibility to gram positive bacilli, gram negative bacilli and some other non-fermenting organisms and suitable and useful for subcutaneous and intramuscular, causing no or little reported local adverse side effects. Intracincisional antibiotic amoxicillin and clavulanic acid (Coamoxiclav) should be given to cover decisive period and that they could be decisive at the time in preventing of infection developing. This study is done to evaluate the preoperative intracincisional antibiotic infiltration in prevention of surgical site infection as compare with intravenous antibiotic given.

## METHODS

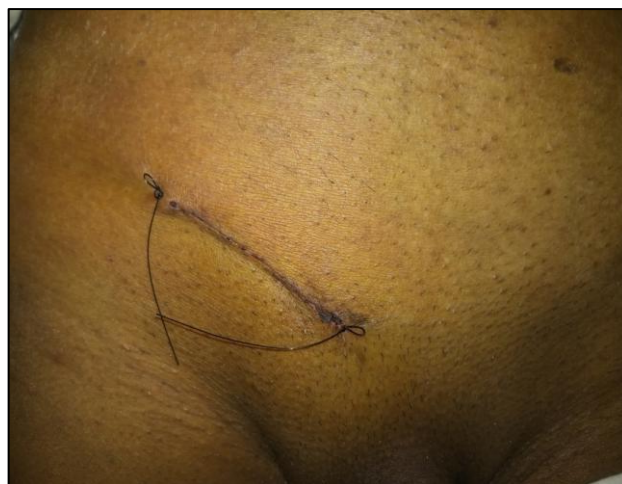
This is a prospective randomised controlled study conduct in Department of general surgery in M.B.S. hospital and GOVT. medical college KOTA from May 2015 to November 2017. Comprising of 200 patients divided in to two groups i.e. 100 in each group. Group A-Preoperative intracincisional infiltration of 1.2g Coamoxiclav dissolved in 20 ml of 0.9% saline solution will be infiltrated along the skin and the sub cutaneous tissue in the proposed line of incision, 20 minutes before surgical incision. Group B-Preoperative administered a single dose of 1.2 g Coamoxiclav intravenously just before the induction of anaesthesia. Inclusion criteria were patients in age group of 16-60 years clean and clean contaminated surgical procedures, operative procedure that lasted for less than 3hours. Exclusion criteria were patients with diabetes mellitus, immunodeficiency, on chemotherapeutic drug, tuberculosis, on steroid therapy and those not given informed consent and those loss of follow up. The study was conducted in adherence to the ethical guidelines of declaration of Helsinki and its amendments.

Patients fulfilling the selection criteria were randomized into two groups of 100 each by picking slip from a box. Group A was offered to intracincisional antibiotic and group B for single intravenous antibiotic. All patients were tested with test dose of Coamoxiclav (0.5 cc into intradermal) for any reaction pre-operatively. An informed consent was taken from all the patients. The

preoperative intracincisional infiltration was done at proposed site of incision and care was taken that infiltration is bigger than the incision area after anaesthetizing the patient. Infiltration was done by 20/22 G needle in subcutaneous tissue plane (Figure 1). Incision was given 20 minutes later. Operation site was covered by occlusive dressings for two days, when first inspection of the suture site was carried out (Figure 2).



**Figure 1: Age distribution of patients.**



**Figure 2: Day 2 wound status right mesh hernioplasty.**

The patients were seen on a daily basis till the day of discharge from the hospital for any wound complications were documented as per Centers for Disease Control and Prevention (CDC) guidelines, and followed up as outpatient basis once a week for 30 days (Figure 3). Incidence of SSI, time for complete healing and type of organisms cultured in case of infection were studied. Statistical analysis was performed using the Chi-square test or student's t-test as applicable. Analysis was done with the help of IBM SPSS Statistics version 17/GeNIe/Open Bug. Statistical significance was defined if the p value was <0.05.

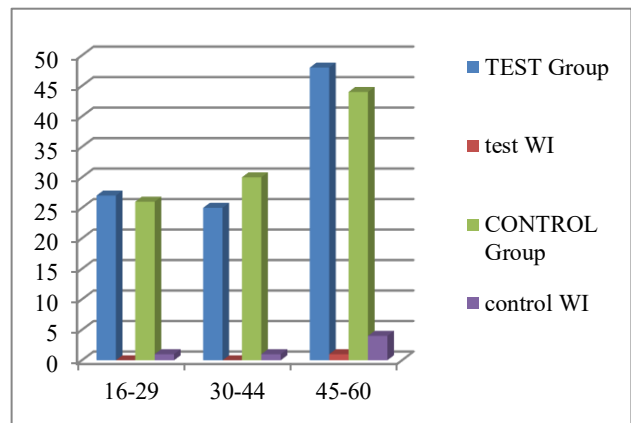


**Figure 3: Day 30 wound status open cholecystectomy.**

## RESULTS

The age of the patients ranged between 16 to 60 years with a mean age of 40.63years. The mean age for males and female was 42.27years and 39.01years respectively. Total number of male patients was 49.5% and the total female patients were 50.5%. The rate of wound infection in male patients was 4.04% as compared to 2.97% wound infection in females (Table 1). The overall rate of wound infection rate was 3.5% and in test (A) and control group (B) was 1% and 6% respectively (Figure 4). This was

statistically significant. There was no infection in clean cases in test group, while in clean contaminated cases in test group about 2.5% wound infection, while in control group for clean and clean contaminated cases wound infection 3.44% and 9.52% respectively (Table 2). Of the total patients the largest percentage of patients were those undergoing Hernia surgeries (34.5%), followed by Gall bladder surgeries (29.5%), Breast surgeries (14.5%), Hydatid cyst of liver surgeries (4.5%), appendix surgeries (3.5%), Thyroid surgeries (2.5%), Intestinal surgeries (2%) (Which included feeding jejunostomy, loop colostomy, hemicolectomy), varicose vein surgeries (1.5%), Nephrectomy for nonfunctioning kidney (1%).



**Figure 4: Age and wound infection.**

**Table 1: Sex and wound infection.**

Sex	Test group	WI	Control group	WI	Total in both group	WI%
Male	50	0	49	4	99 (49.5%)	4.04
Female	50	1	51	2	101 (50.5%)	2.97
<b>Total</b>	<b>100</b>	<b>1</b>	<b>100</b>	<b>6</b>		

P value >0.05

**Table 2: Overall rates of wound infection in test and control group.**

	Test	WI	Control	WI
Clean	60	0	58	2 (3.44%)
Clean contaminated	40	1 (2.5%)	42	4 (9.52%)
<b>Total</b>	<b>100</b>	<b>1 (1%)</b>	<b>100</b>	<b>6 (6%)</b>
<b>P value</b>	0.038		0.028	

**Table 3: Distribution of wound infection according to type of surgery.**

S. no.	Type of surgery	Test group	WI	Control group	WI
1	Hernia surgeries	40	0	29	2 (6.89%)
2	Gall bladder surgeries	31	1 (3.22%)	28	3 (10.71%)
3	Breast surgeries	13	0	16	0
4	Hydatid cyst of liver surgeries	4	0	5	0
5	Appendix surgeries	3	0	4	1 (25%)
6	Thyroid surgeries	2	0	3	0
7	Intestinal surgeries	2	0	2	0
8	Others	5	0	13	0
<b>Total</b>		<b>100</b>	<b>1 (1%)</b>	<b>100</b>	<b>6 (6%)</b>
<b>P value</b>		0.033		0.009	

**Table 4: Duration of surgery and no of wound infection.**

Type of cases	group	Duration < 1 hrs		Duration 1-2 hrs		Duration 2-3 hrs	
		No. of cases	No. of WI	No. of cases	No. of WI	No. of cases	No. of WI
<b>Clean</b>	Test	41	0	16	0	3	0
	Control	49	1	9	1	0	0
<b>Clean contaminated</b>	Test	21	0	17	0	2	1
	Control	26	2	16	2	0	0
<b>Total</b>		137	3 (2.18%)	58	3 (5.17%)	5	1 (20%)
<b>P value</b>		0.0021		0.004		0.25	

**Table 5: Time for complete wound healing.**

Status of operation	Time of complete healing	
	Test (days)	Control (days)
<b>Clean</b>	8.53	9.60
<b>Clean contaminated</b>	8.50	10.19
<b>Total mean</b>	8.52	9.85
<b>P value</b>	0.0429	

**Table 6: Condition of wound in test and control group.**

Condition of wound	Number of patients in test group	Number of patients in control group	Total no of patients in both groups	P value
<b>Healthy wound</b>	92	83	175 (87.5%)	
<b>Redness/edema of wound</b>	2	4	6 (3%)	<0.05
<b>Serous discharge</b>	5	7	12 (6%)	<0.05
<b>Wound infection</b>	1 (1%)	6 (6%)	7 (3.5%)	<0.05
<b>Total</b>	100	100	200	

For other surgeries it was 13.5% (Which included Scalp and limbs swellings, cysts, lumbar sympathectomy, bladder calculus, and hydrocele). In hernia surgeries no wound infection in test group, and 6.89% in control group. In gall bladder surgeries wound infection 3.22% in test group and 10.71% in control group. In appendix surgeries no wound infection in test group while 25% wound infection in control group. No other infected case was reported (Table 3). This was statistically significant in both groups. When procedure lasted for less than one hour there was 2.18% wound infection, when it lasted between 1 to 2 hours infection was 5.17% and between 2 to 3 hours it was 20% (Table 4). The wound infection was statistically significant in both group in <1 hr and 1–2-hour surgery but statistically insignificant in 2–3-hour surgery in two group.

Average post operative stay for the test group was 4.61 days and for control group was 4.56 days. This was statistically significant. In test group, clean and clean contaminated surgery, time of complete healing was 8.53 days and 8.50 days respectively. The overall rate of complete healing in clean and clean contaminated surgery in control group was 9.60 days and 10.19 days respectively. Average time of complete healing for the

test group was 8.52 days and for control group was 9.85 days (Table 5).

This was statistically significant. One patient developed wound infection on fifth postoperative day in test group. Patient was obese and previously history of multiple acute cholecystitis attack. During operation dense adhesion and mucocoele of gall bladder was found. Pus was evacuated and sent for culture and sensitivity. Patient was received antibiotic as per culture and sensitivity report for 8 days and wound was treated with povidone ointment dressing. Wound healed on 16th postoperative day.

In control group three patients developed wound infection on 5th to 7th postoperative day and remaining three were initially serosanguinous discharge 3rd to 4th postoperative day later found bacterial organism in culture and sensitivity report so these patients include in wound infection group in control group. All patients were treated with antibiotic for 5 to 9 days as per culture and sensitivity report and wound treated with povidone ointment/saline dressing. Pus gradually decreased and it takes wound to healed around 12th to 18th days except one patient needed to secondarily intention in 26th day (Table 6).



All seven patients were healthy at time of their subsequent follow up. This was statistically significant. Among the organisms cultured from postoperative wound, *E. coli* was commonest organism, i.e. total 3 cases (42.85%), followed by one case of staph Coagulase positive (14.84%), one case of pseudomonas (14.84%), one case of *Citrobacter diversus* (14.84%) and one case of enterobacter (14.84%). Among the organisms cultured from postoperative wound there was predominance of gram-negative organism (85.71%) as compared to gram positive organism (14.28%). Bleeding per rectum 80%, weight loss 60%, anemia 60% and altered bowel habits 77.13 % were the presenting symptoms. All patients were subjected to biopsy or fine needle aspiration cytology and the diagnosis confirmed. Other investigations done are ultrasonography, barium enema, CT scan, CEA etc. Figure 1 represents the various surgical management.

## DISCUSSION

With the advent of antibiotics and their widespread use, the incidence of wound infection has come down remarkably. Perioperative administration of antibiotics to prevent post-operative infection represents a cornerstone in modern medicine. An effective prophylactic regimen should be directed against the most likely infecting organisms. Infections can be prevented when effective concentrations of the drug are present in the tissue and the blood during and shortly after the procedure. Therefore, antibiotic prophylaxis should begin just before the operation.

The use of pre incisional intraparietal infiltration of antibiotic is a new and original concept that has been developed in university department of clinical surgery, Edinburgh. Extremely high concentration of antibiotic is present in the wound throughout the operation in pre incisional intraparietal infiltration of an antibiotic. The minimum inhibitory concentration is also sustained sometime after the operation. The serum level of antibiotic is also comparable with IM and IV routes, thus minimizing systemic septic complication. No increase preoperative problems resulted from this route.

The overall rate of wound infection in present study was 3.5%. In control group it was 6% and in test group it was 1%. There was no infection in test group in clean cases, clean contaminated cases wound infection was 2.5% in test group. In control group wound infection in clean and clean contaminated cases was 3.44% and 9.52% respectively. When compared with Dongra et al study, wound infection in intraincisional and intravenous group were 10% and 18% respectively.<sup>3</sup> In Pollock et al study, overall rate of wound infection was nearly twice as great as in the intravenous group (15.9%) as in the intraparietal group (8.4%).<sup>4</sup>

In this study when prophylactic antibiotic was given in clean cases between test and control group, wound infection in intravenous group were 3.44% and 0% in

intraincisional (test) group. In clean contaminated case wound infection were 2.5% in test group and 9.52% in control group. In compare with cephamandole, (Dixon and Armstrong) two hundred and five patients and amoxicillin/Clavulanic acid combination (Pollock) on 624 patients for the prophylaxis of wound infection showed that intraincisional infiltration were more efficacious than intravenous administration.<sup>4,5</sup> In this study, distribution of wound infection according to type of surgery as mention in Table 2 was statistically significant. It compares to Pollock et al, study, out of total 624 patients, 296 patients received intraincisional Augmentin and 328 patients received intravenous Augmentin. Major wound infection in both groups were 8 and 16 patients present respectively, which included cases like appendix surgery, colon surgery, breast surgery, and other clean cases. In context to our study, both studies were statistically significant for wound infection in overall different surgical cases. In this study, duration of surgery and number of wound infections as mention in Table 3 compared to study done by Bhasker et al where wound infection was 3.6% when procedure lasted for less than one or equal to one hour. And when surgery lasted for between one to two hours it was 17% and between when two to three hours it was 37.5%.<sup>6</sup>

Time for complete healing among control group in clean and clean contaminated cases was statistically significant. There was no standard protocol to define exact time for complete wound healing, but most of the times complete wound healing was assumed on the day of stitch removal. When wound was infected, seroma formation present, redness over suture line present, time for complete healing was delayed and needed addition procedure for healing aid.

In our study, organism cultured from wound swabs or collections were predominantly gram negative (85.71%) as compared to gram positive (14.29%). *E. coli* was the commonest organism cultured followed by *Staph Coagulase positive*, *Pseudomonas*, *Citrobacter*, and *Enterobacter*. It compares, by Kamat et al, in India where 79.33% of isolates were gram negative bacteria; pseudomonas being the commonest one followed by staphylococcus pyogenes. In another study by Khan et al *Escherichia coli* was the commonest pathogen found (25%) followed by *Pseudomonas aeruginosa* (20.83%) and coagulase positive staphylococci (19.04%) in general surgical setup. Compare with Akalin et al found near same results.<sup>7-9</sup> So prophylactic antibiotic to be given should cover gram negative organism and gram-positive organism, thus extended spectrum penicillin drug having similar spectrum should be an ideal choice as used amoxicillin and Clavulanic acid for this study. Results of our study were comparable to the study done by Bhasker et al, Barnard et al, and Sainio et al also when he used third generation cephalosporin for prophylaxis.<sup>6,10-12</sup>

Although mostly patient in our study belong mainly clean group and clean contaminated group, so result is

favourable in that patient for single dose of preoperative intraincisional coamoxyclov to prevent surgical site infection as compare to prophylactically given longer duration intravenous antibiotics. But this study needs to compare in large number of patient groups, so we found exact data for patients' safety in postoperative period to prevent post operative complication and also prevent unnecessary given empirical injectable antibiotics in those types of surgical patients, also help to reduce antibiotics associated drug resistance. Limitations of this study also that a smaller number of contaminated group and dirty groups of patients.

## CONCLUSION

We concluded that single-dose of preoperative intraincisional antibiotics are sufficient in preventing wound infection. Prolonged administration of antibiotics is unnecessary and costlier. Prolonged use of antibiotics is associated with emergence of resistant strains and super infections, which can be prevented by cost-effective short-term antibiotic prophylaxis. Preoperative intraincisional infiltration of Coamoxiclav reduces the postoperative hospital stay and time for complete healing as compared to intravenous antibiotics. Preoperative intraincisional infiltration of Coamoxiclav was found to be convenient as well as effective and also doesn't have complication such as thrombophlebitis, rigor, pain etc. which are very common when intravenous route is used.

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

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