Original Research Article

To evaluate efficacy of local Amikacin therapy as an adjuvant to parenteral antibiotics in control of surgical site infection compared to parenteral antibiotic alone in a tertiary care centre

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International Archives of Integrated Medicine, Vol. 5, Issue 2, February, 2018.

Available online at http://iaimjournal.com/
ISSN: 2394-0026 (P) **ISSN: 2394-0034 (O)**
Received on: 25-01-2018 **Accepted on:** 31-01-2018
Source of support: Nil **Conflict of interest:** None declared.
How to cite this article: A.K. Rajendran, C. Arun Babu, Gnana Sezhian. To evaluate efficacy of local Amikacin therapy as an adjuvant to parenteral antibiotics in control of surgical site infection compared to parenteral antibiotic alone in a tertiary care centre. IAIM, 2018; 5(2): 64-71.

Abstract

Background: Surgical site infection is a common cause of morbidity for the operated patients. Hence a cost effective and simple method was formulated and studied on cases of laparotomy and appendicectomy patients which can be categorized as dirty and contaminated wounds.

Materials and methods: 25 cases and adequately matched controls were selected from patients who underwent laparotomy or appendicectomy which can be categorized as dirty or contaminated wounds. Cases were given local application Inj. Amikacin over the subcutaneous plane preoperatively and for the subsequent three post-operative days through a subcutaneously placed feeding tube along with systemic iv antibiotics. The control patients only received systemic IV antibiotics. ASEPSIS scoring was used to grade the post-operative surgical site infection in the cases and the corresponding controls, at the end of the first and second week after surgery. Various criterions were specifically evaluated such as the isolation of microbe from the wound site or the requirement of change of antibiotic at the end of the 1st or 2nd week and the tendency of prolonged stay in the hospital for more than 2 weeks.

Results: It was observed that the cases that received the local Amikacin application as an adjuvant to systemic antibiotic showed significantly lesser incidence and/ or grading of SSIs in the first week and also lesser, but not statistically significant reduction of SSIs in the second week. The incidence of antibiotic change, hospital stay and isolation of microbe from the wound site was statistically found be to lesser in the study group compared to their controls.

Conclusion: It is observed that the local therapy as an adjuvant is cost effective and without any significant local or systemic adverse effects in the prevention of SSIs in dirty and contaminated patients. But it was also observed that it did not have sustained effect for prolonged period beyond its time of administration (as evidenced by its lesser effect in the second week after surgery). It may be suggested that a further combination of suction drainage of the subcutaneous DT along with local antibiotic treatment may have added advantage in further preventing SSIs.

Key words

Surgical site infection, Dirty wound, Contaminated wound, Topical antibiotic, Local application antibiotic, Inj. Amikacin, Laparotomy, Appendicectomy, SSI prevention, Tertiary care centre, Seroma, Wound gapping, Surgical site microbial colonisation.

Introduction

Infections that occur in the wound created by an invasive surgical procedure are generally referred to as surgical site infections (SSIs). SSIs are one of the most important causes of healthcare-associated infections (HCAIs). A prevalence survey undertaken in 2006 suggested that approximately 8% of patients in hospital in the UK have an HCAI. SSIs accounted for 14% of these infections and nearly 5% of patients who had undergone a surgical procedure were found to have developed an SSI [1, 2].

However, prevalence studies tend to underestimate SSI because many of these infections occur after the patient has been discharged from hospital. SSIs are associated with considerable morbidity and it has been reported that over one-third of postoperative deaths are related, at least in part, to SSI [3]. In patients undergoing laparotomy with contaminated and dirty wounds the infection rate is 20% to 30% and 30% to 40% respectively [4, 5].

SSIs leads to severe morbidity in the operated patient in the form of costs of treatment and prolonged hospital stay and the need for redo surgery in some cases. Most infection occurs from the skin and superficial microbes [6] and various methods can be used to tackle this condition by using this matter of fact. Several preventive steps are followed and recommended by most of the surgical research teams and the use of local antibiotic over the wound site as an attempt to prevent the surgical site infection is one of them [7]. A cost effective and adequately sufficient method is being studied to prevent surgical site infection through this method.

Aim and objective

- To analyse the effects of local antibiotic (Amikacin) therapy at the surgical site along with systemic antibiotic therapy in an attempt to prevent surgical site infections in contaminated and dirty surgical wounds as compared to that of systemic antibiotics alone.
- Grading the SSIs in both the groups and study the effects of local antibiotic in reducing the incidence/ severity of SSIs at the end of first and second week of the post-operative period.

Materials and methods

Type of study: Prospective and Observational Study.

Study approval: Prior to commencement of this study - Thesis and Ethical Committee of Stanley Medical College and Hospital, Chennai had approved the thesis protocol.

Place of study: Stanley Medical College and Hospital.
Period of study: 10 months, November 2016 to August 2017.
Source of data: All cases of abdominal surgeries which falls under contaminated (class III) and dirty (class IV) wounds like emergency laparotomies, open appendicectomies, etc.
Sample size: A total of 25 cases and 25 control.

Study group (A): All elective and emergency surgeries of the abdomen in which local antibiotic therapy was given preoperatively and postoperatively along with systemic antibiotic

Control group (B): All cases of contaminated and dirty wounds which are matched with the cases, who received only systemic antibiotics

Selection of patients: All patients operated for abdominal surgeries, both elective and emergency surgeries, which falls under class III (clean contaminated) and class IV (dirty).
Sampling method - Purposive**.**

Inclusion criteria
All cases of abdominal surgeries which falls under contaminated (class III) and dirty (class IV) wounds like emergency laparotomies, open appendicectomies, etc.
Exclusion criteria
- Extremes of age <18 years >70 years
- Patients on immunosuppressants, chemo/radiotherapy, steroids other serious pre-existing cardiovascular, pulmonary and immunological disease.
- Uncontrolled diabetic patients
- Clean (Class I) and Clean contaminated (Class II) surgical wounds

Study procedure
Method of sampling was non-random, purposive. Ethical clearance was obtained from the institute ethical committee Written informed consent was obtained from all patients before subjecting them for the study. All patients planned for abdominal surgeries were counselled and the procedure explained in their local language. All patients in the group were assigned as study and corresponding matched control were selected. The following parameters were taken and observations were recorded and tabulated and analyzed to achieve the objective. The study group patients which included cases of abdominal surgeries with class III and class IV type of wounds, preoperatively a single adult dose of Inj. Amikacin was applied over the 'subcutaneous cavity' of the incision site prior to skin closure. A Subcutaneous DT was kept (8 or 10 size feeding tube) (**Figure – 1**). Subsequently patient received a single daily adult dose (as per body weight) of Inj. Amikacin on the first 3 post-operative days (POD 1 to POD 3). The Subcutaneous DT was intentionally closed without any suction drainage, to avoid confounding effecting of keeping a subcutaneous suction DT [8].

Figure - 1: Subcutaneous DT kept in the laparotomy wound site.

Parameters to be assessed
- Indication for surgery
- Surgical procedure done
- Type of Surgical Wound: contaminated/ dirty
- Systemic antibiotic used preoperatively and during immediate post-operative period
- Incidence of Surgical site infection: Yes/ No
- If Yes - Grading of Surgical site infection as per ASEPSIS scoring as per below table.

ASESPIS scoring

Wound characteristics	0	<20	20-39	40-59	60-79	>80
Serous Discharge	0	1	2	3	4	5
Erythema	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissues	0	2	4	6	8	10

Antibiotic change - 10
Drainage of pus - 5
Wound debridement - 10
Isolation of Bacteria - 10
Stay as inpatient prolonged >14 days - 5

Highest total scoring in the first week
Highest total scoring in the second week

Data Analysis

Statistical methods: Diagnosis, total asepsis scoring, antibiotic changes at 1 week, stays as Prolonged >14 days, Systemic Antibiotic used were considered as outcome variables. Case and control group were considering as primary explanatory variable. Demographic age and gender were considered as other explanatory variable.

Descriptive analysis: Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

Quantitative outcome: The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. The mean differences along with their 95% CI were presented. Independent sample t-test.Association between quantitative explanatory and outcome variables was assessed by calculating person correlation coefficient and the data was represented in a scatter diagram.

Categorical outcome: The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance.P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

Results and Discussion

The study group received Inj. Amikacin over the wound site before skin closure and on 3 consecutive days after surgery. This was in addition to the usual Intravenous antibiotic given for all cases of laparotomy surgery. The subsequent development of surgical site infection in this study group was compared to the control group which did not receive the additional local wound site Inj. Amikacin.

The incidence of surgical site infection and the grading (based on ASEPSIS grading [9]) was done for the both groups for 2 weeks post operatively. The second week monitoring was to assess if there was any residual effect of adding Amikacin or any adverse effect due to its addition to the treatment regimen.

Among the study population, 50% people were in case group and 50% people were in control group (**Table – 1**).

Table - 1: Descriptive analysis of group in study population (N=50).

Group	Frequency	Percentage
Case	25	50.00%
Control	25	50.00%

The mean age of case group was 39.28 ± 14.32 and of the control group was 40.16 ± 13.42. The difference between two groups was statistically not significant (p value 0.824) (**Table - 2**).

Among the case group 21 (84%) were male and 4 (16%) were female. The number of male and female participants was 20 (80%) and 5 (20%) in control group. The differences gender proportion between the two groups was statistically not significant (P value 0.713) (**Table - 3**).

The mean total asepsis scoring at 1 week of case group was 16.32 ± 16.67 and the control group was 25.84 ± 15.64. The difference between two groups was statistically significant (p value 0.043) (**Table - 4**).

Table - 2: Comparison of mean age between the study groups (N=50).

Group	**Age Mean± STD**	**Mean difference**	**95% CI**		**P value**
			Lower	**Upper**	
Case	39.28 ± 14.32	-0.88	-8.77	7.01	0.824
Control	40.16 ± 13.42				

Table - 3: Association of group with gender of study population (N=50).

Gender	**Group**		**Chi square**	**P-value**
	Case (N=25)	**Control(N=25)**		
Male	21 (84%)	20 (80%)	0.136	0.713
Female	4 (16%)	5 (20%)		

Table - 4: Comparison of mean total asepsis scoring at 1 week between study groups (N=50).

Group	**Total ASEPSIS Scoring at 1 week (Mean± STD)**	**Mean difference**	**95% CI**		**P value**
			Lower	**Upper**	
Case	16.32 ± 16.67	-9.52	-18.71	-0.33	0.043
Control	25.84 ± 15.64				

Table - 5: Comparison of mean total ASEPSIS scoring at 2 week across the two groups (N=50).

Group	**Total ASEPSIS Scoring at 2 week (Mean± STD)**	**Mean difference**	**95% CI**		**P value**
			Lower	**Upper**	
Case	19.76 ± 22.38	-5.68	-18.15	6.79	0.365
Control	25.44 ± 21.48				

Table - 6: Association of group with Diagnosis of study population (N= 50).

Diagnosis	**Group**	
	Case (N=25)	**Control (N=25)**
Penetrating injury abdomen	2 (8%)	2 (8%)
Complicated appendicitis- ileostomy	1 (4%)	1 (4%)
Complicated appendicitis- appendectomy	6 (24%)	6 (24%)
Duodenal perforation	4 (16%)	4 (16%)
Gastric perforation	2 (8%)	2 (8%)
Intestinal obstruction	0 (0%)	1 (4%)
Intestinal obstruction - ileostomy	2 (8%)	1 (4%)
Meckel's diverticulitis – resection anastomosis	2 (8%)	2 (8%)
Blunt injury abdomen –exploratory laparotomy	3 (12%)	2 (8%)
Blunt injury abdomen – resection anastomosis	1 (4%)	1 (4%)
Sigmoid volvulus – resection colostomy	1 (4%)	1 (4%)
Small bowel gangrene	1 (4%)	1 (4%)
Splenic cyst rupture - Splenectomy	0 (0%)	1 (4%)

Table - 7: Association of group with antibiotic changes at 1 week of study population (N=50).

Antibiotic Changes at 1 Week	Group		Chi square	P-value
	Case (N=25)	Control (N=25)		
Yes	4 (16%)	13 (52%)	7.219	0.007
No	21 (84%)	12 (48%)		

Table - 8: Association of group with Staying >14 days of study population (N=50).

Staying >14 days	Group		Chi square	P-value
	Case (N=25)	Control (N=25)		
Yes	6 (24%)	8 (32%)	0.397	0.529
No	19 (76%)	17 (68%)		

Table - 9: Association of group with systemic antibiotic used of study population (N=50).

Systemic Antibiotic used	Group		Chi square	P-value
	Case (N=25)	Control (N=25)		
Carbapenems	7 (28%)	7 (28%)	0.114	0.944
Cephalosporins	10 (40%)	11 (44%)		
Piperacillin+Tazobactum	8 (32%)	7 (28%)		

The mean total asepsis scoring at 2 week of case group was 19.76 ± 22.38 and the control group was 25.44 ± 21.48. The difference between two groups was statistically not significant (p value 0.365) (**Table - 5**).

Among the case group, 2 (8%) had Penetrating injury abdomen. The proportion Complicated appendicitis- ileostomy, Complicated appendicitis- appendectomy and Duodenal perforation was 1 (4%), 6 (24%) and 4 (16%) respectively. The number of Penetrating injury abdomen, Complicated appendicitis- ileostomy, Complicated appendicitis- appendectomy and Duodenal perforation was 2 (8%), 1 (4%), 6 (24%) and 4 (16%) in control group (**Table - 6**).

In the case group, in 4 (16%) people antibiotic was changed at 1 week. In the control group, 13 (52%) people antibiotic was changed at 1 week. The differences antibiotic changes at 1 week proportion between the two groups was statistically significant (P value 0.007) (**Table - 7**).

In the case group 6 (24%) patient were in hospital staying>14days. In the control group, 8 (32%) patient were in hospital staying >14days. The differences hospital staying >14 days proportion between the two groups was statistically not significant (P value 0.529) (**Table - 8**).

Among the case group was 7 (28%) people were using Carbapenems. The proportion Systemic Antibiotic using, Cephalosporins and Piperacillin Tazobactum was 10 (40%) and 8 (32%) respectively. The number of Systemic Antibiotic using, Carbapenems, Cephalosporins and Piperacillin + Tazobactum was 7 (28%), 11 (44%) and 7 (28%) in control group. The differences Systemic Antibiotic used proportion with two groups was statically not significant (P value 0.944) (**Table - 9**).

Conclusion

This prospective, interventional and comparative study was conducted among 50 purposively selected patients who underwent abdominal surgeries categorized as dirty and contaminated wounds in the department of General Surgery, Stanley Medical College and Hospital from November 2016 to August 2017.

The study was conducted to analyse the effectiveness of using local antibiotic over the wound site to prevent surgical site infections. The SSIs were graded using one of the standard methods of grading ASEPSIS scoring system, which grades the SSIs from 0 to 70 assessing various parameters. The scoring was done for 1st and 2nd week after surgery.

The cases and controls were sufficiently matched against age, sex, age, antibiotics used, the type of surgical diagnosis and treatment given, the type of surgical wound. Differences found to be statistically insignificant.

Subsequently the ASEPSIS scores at the end of 1st week of surgery showed that the study group patients who received the Inj. Amikacin in the local wound site showed significantly lesser grade of SSIs compared to that of the control group. The ASEPSIS score at the end of 2nd week of surgery showed lesser grade of SSIs in the study group compared to the control though it was statistically insignificant.

The probability of antibiotic change and duration of stay in the patient was lesser in the study group though the later parameter was not statistically significant [10].

Hence, overall conclusion is that the patients who received local wound site antibiotic (Inj. Amikacin) showed lesser grades of SSIs, more so in the 1st week of surgery and lesser need for antibiotic change and lesser duration of stay in hospital during the postoperative period compared to the control group which only received the systemic antibiotics.

Limitations of the study

- Very short duration of study.
- Lesser number of cases (due to unavailability during the study period).
- Other associated parameters like the general condition of the patient and co-morbidities were not thoroughly matched.
- The use of Subcutaneous DT (in spite of not being functional) may have some positive or negative effect on the outcome.

Recommendations

Based on this prospective study, it can be proposed that use of Local application of Inj. Amikacin is a cost effective and effective method with less adverse effects in preventing surgical site infection in the immediate post-operative period.

It is also recommended to combine the use of a subcutaneous suction DT along with the once daily dose of Amikacin, for enhancing the preventive ability.

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