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Study of Efficacy of Prophylactic Antibiotics in Post Operative Wound Infections

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Abstract

Surgical site infections (SSIs) are the leading type of infection among hospitalized patients.Careful handling of the surgical equipments reduces the chances of surgical site infections,& those who incorporate best practice standards can reduce the morbidity & mortality associated with SSIs.The purpose of the research was to find out the efficacy of prophylactic antibiotics & how surgical site infections arise. Postoperative surgical site infections (SSIs) remain a major source of illness & morbidity in surgical patients. These infections number approximately 500000 per year, among an estimated 27 million surgical procedures, & account for approximately one quarter of the estimated 2 million nosocomial infections each year. This study focuses on the prophylactic antibiotics given before surgery, and also compares it with conventional post operative antibiotic treatment. Study would also consider,if one can dispense the use of conventional post operative antibiotics, if the efficacy of prophylactic antibiotics is significant.

Keywords: Prophykactic Antibiotics and Surgical Site Infection.

Introduction

Surgical site infections (SSIs) are the leading type of infection among hospitalized patients. Careful handling of the surgical equipments reduces the chances of surgical site infections, & those who incorporate best practice standards can reduce the morbidity & mortality associated with SSIs.The purpose of the research was to find out the efficacy of prophylactic antibiotics & how surgical site infections arise. Postoperative surgical site infections (SSIs) remain a major source of illness & morbidity in surgical patients. These infections number approximately 500000 per year, among an estimated 27 million surgical procedures, & account for approximately one quarter of the estimated 2 million nosocomial infections each year. This study focuses on the prophylactic antibiotics given before surgery, and also compares it with conventional post operative antibiotic treatment. Study would also consider, if one can dispense the use of conventional post operative antibiotics, if the efficacy of prophylactic antibiotics is significant.

Approximately 1 million patients have wound infection each year in the United States, extending the average hospital stay by one week and increasing the cost of hospitalization by 20 percent. This translates to en additional $1.5 billion in health care costs annually.

In the interest of promoting cost-effective surgical practice as well as reducing the development of bacterial resistance to antimicrobial agents, several surgical centres in many countries have adopted this practice of using a "single dose pre-operative prophylactic antibiotic (s)" to prevent surgical site infections in suitable surgical patients. However at our hospital & many other health instituitions in India, most of patients undergoing elective major surgery are still being subjected to prolonged "post-operative prophylactic antibiotics". This probably increases not only the expenditure for purchase of antibiotics, but also the emergence of bacterial resistance strains to antimicrobials. The purpose of this study was to compare the rate of surgical site

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infection in patients receiving a single dose pre-operative prophylactic antibiotic with that in patients receiving prolonged post-operative prophylactic antibiotics as per current practice.

The occurrence of wound infection requires a local inoculum sufficient to overcome host defenses and establish growth. The process is complex and depends on the interaction of various host, local tissue and microbial virulence factors. Measures intended to prevent wound infection typically attempt to modify the host and local tissue factors and include, for example, preoperative optimization of comorbid illness, control of the operative environment, proper cleansing of the skin and use of aseptic surgical technique.

Antibiotic prophylaxis is only one relatively minor effort among numerous preventive measures, but the efficacy and impact of antimicrobial prophylaxis has clearly been demonstrated to be significant. The argument against prophylaxis for clean procedures, based on the intrinsically low are of infection without antibiotic treatment, is overly simplistic for several reasons. For specific clean procedure, infection may be unlikely, but the morbidity and cost of even infrequent infection can justify the use of prophylaxis.

An example is the insertion of prosthetic devices, such as heart valves or joints. Also, clean procedures constitute approximately 60 percent of all surgical procedures and account for approximately 40 percent of all wound infection.

It is estimated that prophylaxis for clean procedure wound reduce the overall incidence of wound infection by 17 percent.

A survey of antibiotic control measures published by the British Society for Antimicrobial Chemotherapy in 1994 found that policies for surgical prophylaxis existed in only 51% of the hospital surveyed and compliance was monitored in only half of these.

The deciding factors for antibiotic prophylaxis include :

A. Patient risk of Surgical Site Infection (SSI).

B. Potential severity of SSI consequences.

C. Effectiveness of Surgical Prophylaxis.

D. Consequences of Prophylaxis.

The principles of Prophylaxis include the following:

1. There is probable risk of infection in the absence of a prophylactic agent at the operative wound or organ site.
2. The activity of the chosen prophylaxis agent should encompass the majority of pathogens likely to contaminate the wound or operative site.
3. When more than one choice is given as a prophylaxis agent, the agents or agents. There is a knowledge of the probable contaminating flora associated with the selected should be based on the most likely contaminating organisms.
4. The prophylactic agent must be administered in a dose which provides an effective tissue concentration prior to intra operative bacterial contamination. Administration must occur 30-45 minutes prior to incision (usually with the induction of anesthesia).
5. The effective doses should be governed by the patient's weight.
6. In procedures lasting 3 hours or less, a single prophylactic dose is usually sufficient. Procedures lasting greater than three hours require an additional effective dose.

The benefits of Prophylaxis such as reduced hospital stay, short and long term morbidity and mortality vs. the drawbacks of increased resistance, enterocolitis, increase and standard definitions of Surgical Site Infection considered for the above comparisons.

An effective and thoughtful prophylaxis regimen is however no substitute for exquisite surgical technique and competent post surgical management.

Aims and Objectives

1. To determine the efficacy of the prophylactic antibiotics preoperatively in preventing the surgical site infections.
2. To find out epidemiology of wound infections for quality assurance in the surgical department.
3. To know antibiotic susceptibility of isolated bacteria.
4. To compare prophylactic antibiotics to routine therapeutic dose antibiotics in clean surgeries.
5. To achieve cost effectiveness by:

a. Establishing a protocol by standardizing the time of administration, dosage and choice of drug.

b. Using on-schedule drugs.

c. Improving patient compliance by the subsequent dose reduction.

d. Reducing antibiotic resistance.

6. Minimize effect of antibiotics on patient's normal flora.
7. Minimize adverse effects.
8. Eventually statistically reduce the incidence of

Surgiccal Site Infections, compared to routinely practiced regimes.

It is important to emphasize that surgical antibiotic prophylaxis is an adjunt to not a substitute for good surgical technique. Antibiotic prophylaxis should be regarded as one component of an effective policy for the control of hospital – acquired infection.

Materials and Methods

1. Study will be conducted on all inpatients who will be admitted & operated in all units of the Department of General Surgery in Annasaheb Chudaman Patil Medical college & Hospital (ACPMMCH), Sakri road, Dhule.
2. The patients to be studied would be randomly divided into 2 groups of 30 each. One group will receive injectable prophylactic antibiotics & other will receive no prophylactic antibiotics but conventional post operative antibiotics. Both groups will identically matched regarding the surgical conditions.
3. All patients showing signs of post operative infections will be subjected to routine investigations & also swab will be sent for culture & sensitivity.

Blinding: This is a open randomized comparative prospective study.

Inclusion Criteria

a. All inpatients undergoing surgery.
b. Clean surgery
c. Haemoglobin > 10gm%
d. ASA Grade I, II (including controlled diabetes)
e. All superficial surgical site infections (Skin & subcutaneous layer only)developing within a 30 day period post surgery, as per traditional definition.
f. Patients willing to give informed consent.

Exclusion Criteria

a. Localized infection at operative site prior to surgery.
b. Allergy to the chosen antibiotic.
c. Haemoglobin <10gm%.
e. Patients having history of hypersensitivity reactions to any antibiotics.
f. Deep or Organ/Space surgical site infection.
g. Wound infections occurring beyond a 30 days time period post surgery.
h. ASA Grade III, IV & V.
i. Trauma and Emergency Surgery.
j. Patients not willing to give informed consent.

Approval of the Ethics Committee and appropriate consent from the patients inducted into the study were obtained.

The following variables were studied and analyzed

1. Age
2. Sex
3. Preoperative stay.
4. Preoperative depilation timing.
5. Timing of administration of the first antibiotic dose.
6. Route of administration.
7. Diabetes Mellitus
8. ASA Grade.
9. Type of skin preparation
10. Operation
11. Time of Surgery
12. Operating Surgeon
13. Use of foreign material
14. Use of drains
15. Wound assessment
16. Post-operative stay

In the Test Group, patients received a single dose of antibiotic at the time of induction and two doses post-operatively within 24 hours. In the Control Group, the patients received the same antibiotic for 5 days. Our study included patients with ages ranging from 1 years to 74 years. There were 23 females and 37 males. All the patients were admitted a day prior to the surgery. Hair removal at the operative site was done by depilation of the night prior to the surgery. All the patients were requested to take bath on the morning of surgery with medicated soap. The operative site was scrubbed with 10% povidone-iodine scrub for 5 minutes. The surgeon scrubs his / her hands with povidone-iodine scrub for 5 minutes.

Prior to induction, all patients received the first dose of intravenous antibiotics si.e. Injection Ampicillin (40 mg/kg) + Injection Gentamycin (3mg/kg). All the patients were draped & incision made & actual procedure done.The surgeon was not controlled: the operation was done according to the surgeons usual technical routine without altering anything.The total blood loss & duration of the

operation were recorded. All the wounds were closed primarily.

Post-operatively, patients of either group had their body temperature monitored on 6 hourly basis. Operation wounds were exposed between 24-48 hours post-operatively in both study & control group patients.The cleaning was done on daily basis using an antibacterial soap & clean water. Each patient, regardless of the group he/she belong to,was seen & examined daily in order to elicit any symptoms & signs of wound infection. Grades of infection noted. For those who showed signs of wound infection,pus swab was collected for microbiological analysis (microscopy, culture & sensitivity) & were be offered treatment. Wound stitches were removed not later than day 10 post-operative in those who developed no surgical site infection. After discharge wounds were reexamined weekly for further three weeks.

Table 1: Groupwise comparison of Age in yrs

Age in yrs		Group		Total
		Case	Control	
<10	No.	1	0	1
	%	3.33	0	1.67
11-20	No.	5	3	8
	%	16.67	10	13.33
21-30	No.	11	9	20
	%	36.67	30	33.33
31-40	No.	9	12	21
	%	30	40	35
41-50	No.	3	4	7
	%	10	13.33	11.67
>50	No.	1	2	3
	%	3.33	6.67	5
Total	No.	30	30	60
	%	100	100	100

Chi-Square Tests	Value	DF	p-value	Significance
Pearson Chi-Square	2.605	5	0.761	Not significant
Likelihood Ratio	3.005	5	0.699	Not significant

Table 2: Groupwise comparison of ASA grade

ASA grade		Group		Total
		Case	Control	
I	No.	22	26	48
	%	73.33	86.67	80
II	No.	8	4	12
	%	26.67	13.33	20
Total	No.	30	30	60
	%	100	100	100

Chi-Square Tests	Value	DF	p-value	Significance
Pearson Chi-Square	1.666667	1	0.197	Not significant
Continuity Correction	0.9375	1	0.333	Not significant
Likelihood Ratio	1.692913	1	0.193	Not significant

Table 3: Groupwise comparison of Diabetes Mellitus

Diabetes Mellitus		Group		Total
		Case	Control	
No	No.	22	23	45
	%	73.33	76.67	75
Yes	No.	8	7	15
	%	26.67	23.33	25
Total	No.	30	30	60
	%	100	100	100

Chi-Square Tests	Value	DF	p-value	Significance
Pearson Chi-Square	0.089	1	0.766	Not significant
Continuity Correction	0	1	1	Not significant
Likelihood Ratio	0.089	1	0.766	Not significant

Table 4: Groupwise comparison of Foreign material

Foreign material		Group		Total
		Case	Control	
No	No.	9	13	22
	%	30	43.33	36.67
Yes	No.	21	17	38
	%	70	56.67	63.33
Total	No.	30	30	60
	%	100	100	100

Chi-Square Tests	Value	DF	p-value	Significance
Pearson Chi-Square	1.148	1	0.284	Not significant
Continuity Correction	0.646	1	0.422	Not significant
Likelihood Ratio	1.153	1	0.283	Not significant

Table 5: Group wise comparison of Grade of infection

Grade of Infection		Group		Total
		Case	Control	
I	No.	2	2	4
	%	6.67	6.67	6.67
II	No.	0	1	1
	%	0	3.33	1.67
Nil	No.	28	27	55
	%	93.33	90	91.66
Total	No.	30	30	60
	%	100	100	100

Table 6: Groupwise comparison of SCAST

Scast		Group		Total
		Case	Control	
No growth	No.	29	29	58
	%	96.67	96.67	96.67
Staph Aureus	No.	1	1	2
	%	3.33	3.33	3.33
Total	No.	30	30	60
	%	100	100	100

Chi-Square Tests	Value	DF	p-value	Significance
Pearson Chi-Square	0	1	1	Not significant
Continuity Correctionb	0	1	1	Not significant
Likelihood Ratio	0	1	1	Not significant

Table 7: Groupwise comparison of Age distribution and Incidence of infection

Age of pt in yrs		Group					
		Case			Control		
		Infection	No infection	Total	Infection	No infection	Total
<10	No.	0	1	1	0	0	0
	%	0	100	100	0	0	0
11_20	No.	0	5	5	0	3	3
	%	0	100	100	0	100	100
21-30	No.	0	11	11	1	8	9
	%	0	100	100	11.11	88.89	100

31-40	No.	0	9	9	1	11	12
	%	0	100	100	8.33	91.67	100
41-50	No.	1	2	3	0	4	4
	%	33.33	66.67	100	0	100	100
>50	No.	1	0	1	1	1	2
	%	100	0	100	50	50	100
Total	No.	2	28	30	3	27	30
	%	6.67	93.33	100	10	90	100

Group	Chi-Square Tests	Value	DF	p-value	Significance
Case	Pearson Chi-Square	12.285	5	0.073	Not significant
	Likelihood Ratio	10.876	5	0.54	Not significant
Control	Pearson Chi-Square	4.382	4	0.357	Not significant
	Likelihood Ratio	3.569	4	0.467	Not significant
Only 'Infection' frequency					
Case v/s Control	Pearson Chi-Square	2.917	3	0.425	Not significant

Table 8: Groupwise comparison of ASA grade and Incidence of infection

ASA grade		Case			Control		
		Infection	No infection	Total	Infection	No infection	Total
I	No.	0	22	22	2	24	26
	%	0	100	100	7.69	92.31	100
II	No.	2	6	8	1	3	4
	%	25	75	100	25	75	100
Total	No.	2	28	30	3	27	30
	%	6.67	93.33	100	10	90	100

Group	Chi-Square Tests	Value	DF	p-value	Significance
Case	Pearson Chi-Square	5.892	1	0.015	Significant
	Continuity Correction	4.559	1	0.019	Significant
	Likelihood Ratio	5.698	1	0.016	Significant
Control	Pearson Chi-Square	1.153	1	0.282	Not significant
	Continuity Correction	0.032	1	0.857	Not significant
	Likelihood Ratio	0.904	1	0.341	Not significant

Only 'Infection' frequency	Chi-Square Tests	Value	DF	p-value	Significance
Case v/s Control	Pearson Chi-Square	2.222	1	0.136	Not significant

Table 9: Groupwise comparison of Diabetes Mellitus and Incidence of infection

Diabetes		Group					
		Case			Control		
		Infection	No infection	Total	Infection	No infection	Total
No	No.	0	22	22	3	20	23
	%	0	100	100	13.04	86.96	100
Yes	No.	2	6	8	0	7	7
	%	25	75	100	0	100	100
Total	No.	2	28	30	3	27	30
	%	6.67	93.33	100	10	90	100

Group	Chi-Square Tests	Value	DF	p-value	Significance
Case	Pearson Chi-Square	5.893	1	0.015	Significant
	Continuity Correction	4.559	1	0.019	Significant
	Likelihood Ratio	5.698	1	0.016	Significant
Control	Pearson Chi-Square	1.014	1	0.314	Not significant
	Continuity Correction	0.082	1	0.773	Not significant
	Likelihood Ratio	1.693	1	0.193	Not significant

Only 'Infection' frequency	Chi-Square Tests	Value	DF	p-value	Significance
Case v/s Control	Pearson Chi-Square	5	1	0.025	Significant

Table 10: Groupwise comparison of Use of Foreign material and incidence of infection

Prosthesis		Group					
		Case			Control		
		Infection	No infection	Total	Infection	No infection	Total
No	No.	0	9	9	1	12	13
	%	0	100	100	7.69	92.31	100
Yes	No.	2	19	21	2	15	17
	%	9.52	90.48	100	11.76	88.24	100
Total	No.	2	28	30	3	27	30
	%	6.67	93.33	100	10	90	100

Group	Chi-Square Tests	Value	DF	p-value	Significance
Case	Pearson Chi-Square	0.918	1	0.338	Not significant
	Continuity Correction	0.025	1	0.873	Not significant
	Likelihood Ratio	1.487	1	0.223	Not significant
Control	Pearson Chi-Square	0.136	1	0.713	Not significant
	Continuity Correction	0	1	1	Not significant
	Likelihood Ratio	0.139	1	0.709	Not significant

Only 'Infection' frequency	Chi-Square Tests	Value	DF	p-value	Significance
Case v/s Control	Pearson Chi-Square	0.833	1	0.361	Not significant

Table 11: Groupwise comparison of Duration of surgery and Incidence of infection

Duration of surgery in hrs		Case			Control		
		Infection	No infection	Total	Infection	No infection	Total
0.2	No.	0	2	2	0	0	0
	%	0	100	100	0	0	0
0.3	No.	0	8	8	1	7	8
	%	0	100	100	12.5	87.5	100
1	No.	0	18	18	1	17	10
	%	0	100	100	5.56	94.44	100
1.5	No.	2	2	4	1	1	2
	%	50	50	100	50	50	100
Total	No.	2	28	30	3	27	30
	%	6.67	93.33	100	10	90	100

Group	Chi-Square Tests	Value	DF	p-value	Significance
Case	Pearson Chi-Square	13.928	2	0.001	Significant
	Likelihood Ratio	9.15	2	0.01	Significant
Control	Pearson Chi-Square	4.228	3	0.238	Not significant
	Likelihood Ratio	2.979	3	0.395	Not significant

Only 'Infection' frequency	Chi-Square Tests	Value	DF	p-value	Significance
Case v/s Control	Pearson Chi-Square	2.22	1	0.136	Not significant

Discussion

Between 2015 and 2017, 60 patients from ages 1-75 years entering a tertiary center for health in ACPM Medical college 20 for the purpose of elective surgical procedure requiring an incision were included in our study. Irrespective of age & sex, these were randomized prospectively into two groups namely Case (Test) and Control. We included foreign maaterial mainly as a Mesh & drain. Suture materials were not included in foreign material.

The prevalence of nosocomial infections varying from 3 to 21 percent,with surgical wound infections accounting for 5 to 34 percent of the total. Emori calculated the rate of SSIs to be 14-16 percent, while others estimate that upto 2 to 5 percent of patients undergoing intr-abdominal operations develop an SSI.

Large number of factors can contribute to the development of SSIs. Appropriately administered antibiotic prophylaxis reduces the incidence of SSIs. Antibiotic prophylaxis is only one relatively minor effort among numerous preventive measures,but the efficacy & impact of antimicrobial prophylaxis has cleary been demonstrated to be very significant. In developed countries, single dose antibiotic has proven to be an effective prophylaxis in abdominal surgery. Antibiotic prophylaxis as a preventive measure for SSIs is best given pre-operatively & intravenously. Administering parenteral antibiotics prior to the surgical incision ensures that adequate tissue & serum antimicrobial levels are the time of contamination,that is, for the duration of the operation, serum & tissue drug levels that exceed the Minimum inhibitory concentrations for the organisms likely to be encountered during the operation.

In our series, the maximum incidence of infection was found in patients between 20-40 years of age. While the lowest rate was found in patients less than 10 years of age. The numbers of patients above 50 years of age were just 3, However in younger patients where numbers were much higher.Proportion of patients beyond 40 years of age was relatively more among controls (20%) as compared to cases (13.33%).

In one study, SSI rates were 5.6% in patient who had hair removed by razor compared to 0.6% (P< 0.02) in patients who had hair removed by depilatory or who had no hair removed. Shaving immediately before the operation compared to shaving within 24 hours preoperatively was associated with decreased SSI rates (3.1% vs 7.1%). It increased to 20% when shaving was done more than 24 hours.

In most circumstances, prophylaxis should be started preoperatively, ideally within 30 minutes of the induction of anaesthesia. The consensus among authorities is that p In our study, the infection rate was 6.67% among the case group as compared to 10% among the control Group. Even though the difference was not statistically significant, this proved that use of prophylactic antibiotic in clean surgeries decrease the incidence of surgical site infection.

Novelli et al studied the importance of pharmacokinetics in antibiotic prophylaxis. From pharmacological point of view, the key factor for the efficacy of antibiotic prophylaxis is to attain bactericidal levels of antibiotic in serum and tissues (target site) during the intraoperative period and carry through to the postoperative period.

An appropriately timed single shot antibiotic prophylaxis is as effective as multiple dose prophylaxis. Antimicrobial prophylaxis that provides coverage throughout the "period of rise" will not only reduce the risk of wound infections but also other infections complication. In our series, the incidence of infection among diabetics cases & controls were 25% & 0% respectively. And among non-diabetic cases & controls were 0% & 13.04% respectively and this was proved to be statistically significant ($P < 0.05$).

The American Society of Anaestheriologists (ASA) has devised a preoperative risk score based on the presence of co-morbidities at the time of surgery An ASA score > 2 is associated with increased risk of wound infection and this risk is additional to that of classification of operation and duration of surgery.

We used foreign material in our study mainly as a drain & mesh. Suture materials were not included as a foreign material because each & every patient we used suture material. In our study, the rate of infection among the cases was less as compared to those among control group in which foreign material was used (9.52% vs 11.76%), even though the difference was not statistically significant it proves that antibiotic prophylaxis helped to decreased the incidence of SSI in clean surgeries even when foreign materials were were used.

Conclusion

1. Antibiotic prophylaxis is only one relatively minor effect among. Numerous preventive measure, but the efficacy and impact of antimicrobial prophylaxis has been demonstrated to be significant in various studies including ours.
2. The single dose pre-operative prophylactic antibiotic is more cost effective.
3. The argument against prophylaxis for clean procedures, based on the intrinsically low rate of infection without antibiotic treatment is overly simplistic for several reasons. For specific clean procedures, infection may be unlikely, but the mortality and cost of even infrequent infection can justify the use of prophylaxis.
4. This was an open randomized comparative prospective study comprising of 60 patients irrespective of age and sex.

5. As the average age increases, the propensity for infection was found to be increased. However the percentage in the Case group (6.67%) still remained lower than Control group (10%).
6. Twenty two patients in the Case group were ASA Grade 1 and there was no infection in any of them as compared to 2 of 26 patients in the control group which had infection. However in the patients belonging to ASA Grade 2 category there was much higher incidence of infection i.e. 2 of 8 patients (25%) in the case group & 1 of 4 (25%) infection rate in the Control group. The above result indicates that antibiotic prophylaxis should be carried out with caution if at all in the high risk categories including Diabetes Mellitus.
7. As seen, the use of foreign material was significantly more among the cases (70%) as compared to controls (56.67%), the difference being statistically not significant. Inspite of increased use of foreign material in the Case group (21 of 30) as compared to Control (17 of 30), the overall infection rate for the Case group was 6.67% as compared to 10% in Control group. This further propagates the use of antibiotic prophylaxis in this particular high risk category.
8. In our study group, infection rate increased as the duration of surgery increased. There was no infection when duration of surgery was less than 30 minutes among cases and among controls it was 12.5%. As duration of surgery increased rate of infection increased too, showing results which are statistically significant. However this could be because of other high risk factors also involved such as the timing of the surgery increased, chances of infection are increased. The rate of infection amongst the cases was still lower (6.67%) as compared to controls (10%).
9. In almost all patients in the low risk category the use of antibiotic showed decreased or similar rate of infection as compared to therapeutic doses (6% vs 8%).
10. In the high risk case it should be viewed with caution as there was a significant higher rate of infection in the Test group.
11. Antibiotic prophylactic cases showed better results than the controls. (6.67% in the case group vs 10% in the control group).

Antibiotic prophylaxis can be a safe alternative to therapeutic antibiotic in all low risk patients undergoing clean surgical procedures and at the same time also prove to be cost effective in the long run.

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