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" Prophylactic Antibiotics Versus Empirical Antibiotics In Clean And Clean-Contaminated General Surgical Cases-A Comparative Study In A Tertiary Care Hospital"

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ABSTRACT

Background:
The role of prophylactic antibiotic alone to prevent surgical site infection (SSI) in clean and clean contaminated cases has been recognized. Inappropriate use of antibiotics as empiric therapy does not give any added advantage.

Objective:
To compare the efficacy of prophylactic antibiotics with empirical antibiotic usage in clean and clean contaminated general surgical procedures.

Methods:
Pre-operative single dose of antibiotic in 52 patients who underwent class I procedures were compared with 52 patients who received empiric therapy after the procedure.
Pre-operative single dose of antibiotic in 52 patients who underwent class II procedures were compared with 52 patients who received empiric therapy after the procedure.

Results:
4 of the 52 study cases of class I surgeries developed SSI, and 2 of the 52 control cases of class I surgeries had significant SSI.
Among the clean-contaminated group, 8 of the 52 study cases and 6 of the 52 control cases developed significant post-operative SSI.
The over all p value when prophylactic group was compared to empiric group was found to be 0.271.
There is no significant difference between the two groups.

Conclusion:
The use of antibiotic prophylaxis alone is as effective as that of empiric antibiotics in clean and clean contaminated cases. This prevents inadvertent use of antibiotics, multi-drug resistance and drug toxicity

Key words: Prophylactic antibiotic therapy, single dose prophylaxis

I. INTRODUCTION

Although treatment of infection has been an integral part of the surgeon's practice since the dawn of time, the body of knowledge that led to the present field of surgical infectious disease was derived from the evolution of germ theory and antisepsis. Application of the latter to clinical practice, concurrent with the development of anesthesia, was pivotal in allowing surgeons to expand their repertoire to encompass complex procedures that previously were associated with extremely high rates of morbidity and mortality due to postoperative infections. However, occurrence of infection related to the surgical wound was the rule rather than the exception. In fact, the development of modalities to effectively prevent and treat infection has occurred only within the last several decades.

However, it was not until the late 1860s after Joseph Lister introduced the principles of antisepsis that postoperative infections morbidity decreased substantially. Lister's work radically changed surgery from an activity associated with infection and death to a discipline that could eliminate suffering and prolong life.

The work of Holmes, Pasteur and Koch in infectious diseases as well as operating room environment and discipline established by Halsted continued to prove the "aseptic and antiseptic" theory to be the first effective measure in preventing infection in surgical patients.

Post operative wound infection remains one of the most common, of all post operative complications, and its diagnosis, treatment and prevention are matters of singular importance in pre-operative and post-operative care of all surgical patients Based on NNIS system reports, SSIs (surgical site infections) are the

third most frequently reported nosocomial infection, accounting for 14% to 16% of all nosocomial infections among hospitalized

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patients[1].

Among surgical patients, SSIs (previously known as surgical wound infections) were the most common nosocomial infection, accounting for 38% of all such infections. Of these SSIs, two thirds were confined to the incision and one third involved organs or spaces accessed during operation.

The surveillance of SSIs brings about the awareness to the present day modern surgeon the need of having the knowledge of the appropriate use of aseptic and antiseptic technique, proper use of prophylactic and therapeutic antibiotics and adequate monitoring and support with novel surgical and pharmacological as well as non-pharmacological aids.

Prophylactic antibiotic therapy is clearly more effective when begun pre- operatively and continued though intra-operative period, with the aim of achieving therapeutic blood levels throughout the operative period

A single dose, depending on the drug used and length of the procedure, is often sufficient. Prophylactic antibiotic coverage for more than 12 hours for a planned operation is never indicated

II. AIMS AND OBJECTIVE

To compare the efficacy of prophylactic antibiotics with empirical antibiotic usage in clean and clean contaminated elective gene.

	Microbes[#]	**Quantity**
Skin (all areas)	Acinetobacter Brevibacterium Corynebacterium[*] Micrococcus Pityrosporum Propionibacterium[*] Staphylococcus aureus and Epidermidis[*] Streptococcus (non-enterococcal)	10^2 - 10^3
Skin (infraumbilical)	Candida Streptococcus fecalis, Escherichia coli	10^2 – 10^5
# Potential pathogenic organisms * These organisms are also found in infra-umbilical region		

Factors for Development of Surgical Site Infections

Patient factors
Older age
Immuno-suppression
Obesity
Diabetes mellitus
Chronic inflammatory process

Malnutrition
Peripheral vascular disease
Anemia
Radiation
Chronic skin disease
Carrier state (e.g., chronic Staphylococcus carriage)
Recent operation

Local factors
Poor skin preparation
Contamination of instruments
Inadequate antibiotic prophylaxis
Prolonged procedure
Local tissue necrosis
Hypoxia, hypothermia
Microbial factors
Prolonged hospitalization (leading to nosocomial organisms)
Toxin secretion
Resistance to clearance (., capsule formation)

Source of data

III. METHODOLOGY

Patients admitted as inpatients in Hi-tech Medical College Hospital for Class I (clean) and Class II (clean contaminated) elective general surgeries between September 2018 and May 2020

Calculated sample size: 208 Clean surgeries – 104 Clean contaminated surgeries – 104

Inclusion criteria

Patients who underwent Class I (clean) and Class II (clean contaminated) elective general surgeries in Hi-Tech Medical College Hospital bhubaneswar

Exclusion criteria

- Patients with implants or prosthetic material
- Patients with Diabetes mellitus
- Patients on steroids, chemotherapy or immuno-suppression

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Method of collection of data:

- Details of cases were recorded including history and clinical examination.
- Routine pre-operative investigations performed in both the groups.
- The study group received one dose of prophylactic antibiotic, Ceftriaxone one hour before or at the time of induction of anesthesia followed by a second dose within 12 hours when the surgery was prolonged for more than 2 hours. In cases where anaerobic organisms are likely to be encountered pre-operative dose of Metronidazole was added. While the control group received antibiotics post-operatively for 72 hours or more.
- Operative wound was examined on the second, fifth and eighth post-operative day for signs of surgical site infection.
- Patients from both the study and control groups were compared for final analyses.

Statistical analysis

The data was analyzed by Z test. P value of <0.05 was considered statistically significant.

IV. RESULTS

The study was conducted on a total of 208 patients aged between 2-80, of which 104 underwent clean general surgical procedures and 104 underwent clean contaminated general surgical procedures in Hi-tech medical college and hospital from September 2018to May 2020

Among the 104 clean surgical cases, 52 received single pre-operative dose of antibiotic and 52 received post-operative empiric antibiotics for 3 or more days.

Among the 104 clean-contaminated surgical cases, 52 received single pre- operative dose of antibiotic and 52 received post-operative empiric antibiotics for 3 or more days.

SEX DISTRIBUTION

Table no-1a Sex distribution in prophylactic group

Sex	Number	Percentage (%)
Male	65	62.5%
Female	39	37.5%

Of the 104 cases who received single dose prophylactic antibiotic pre-operatively 62.5% were males and 37.5% were females.

Graph – 1a

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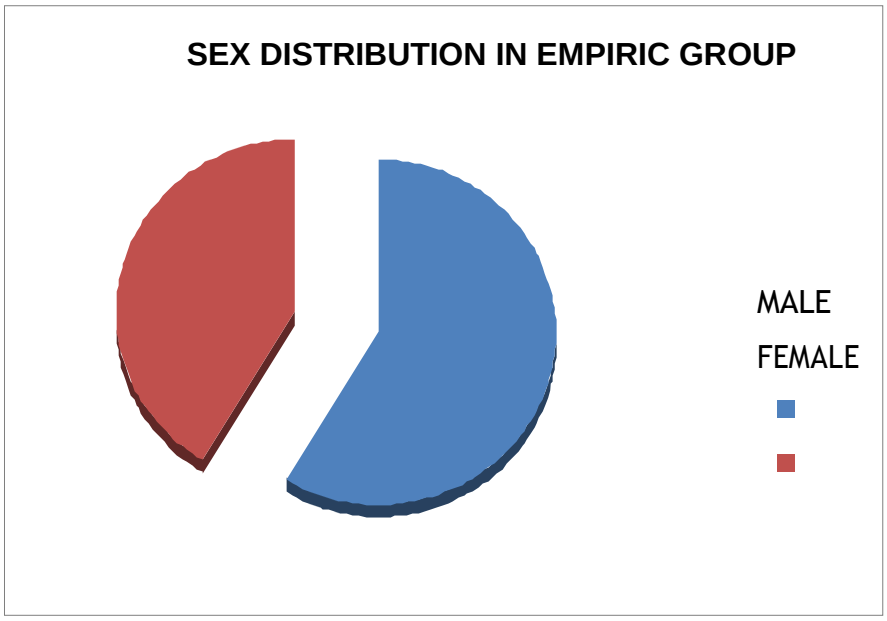
Table no-1b

Sex distribution in empiric group

Sex	Number	Percentage (%)
Male	61	58.6%
Female	43	41.4%

Graph – 1b



AGE DISTRIBUTION

Table no-2a
Age distribution in prophylactic group

Age(yrs)	<10	11-20	21-30	31-40	41-50	51-60	61-70	>70
Total no.	10	14	30	20	12	9	7	2

Graph – 2a

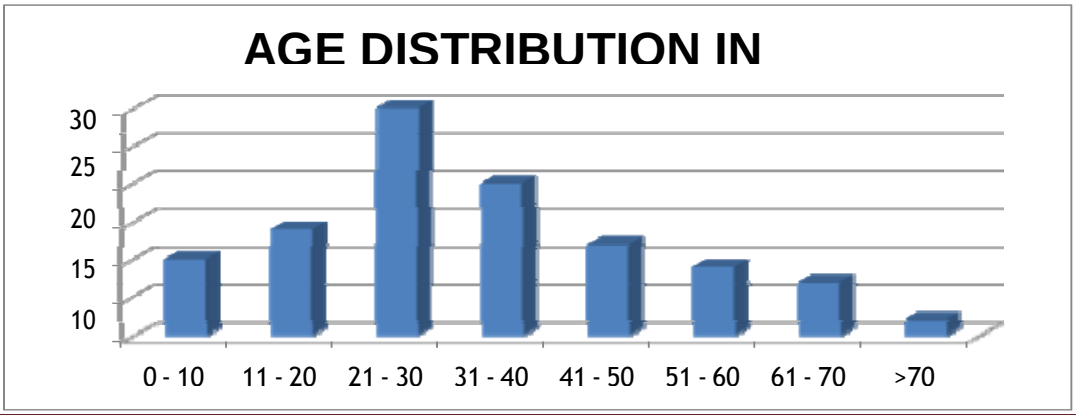


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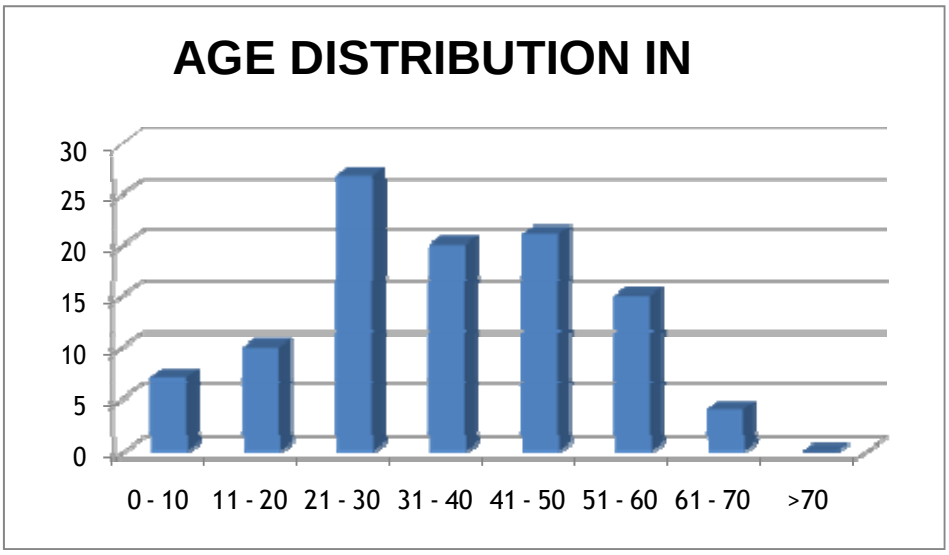
Table -2b Age distribution in empiric group

Age(yrs)	<10	11-20	21-30	31-40	41-50	51-60	61-70	>70
Total no.	7	10	27	20	21	15	4	0

Graph – 2b



Among the patients who received single dose pre-operative prophylaxis, the age varied from 1-80 years. The number of patients in the 21-30 years group was highest. Among the patients who received multiple dose antibiotics post-operatively, the age varied from 1-70 years. The number of patients in the 21-30 years group was the highest.

Table no-3a
Results in class I group

	SSI	NO SSI	PERCENTAGE (%)
Prophylactic	4	48	7.6%
Empiric	2	50	3.8%

Of the 104 patients who underwent class I surgeries, 52 patients received only one dose of pre-operative prophylactic antibiotic. 4 of these patients developed features of SSI (7.6%)
2 (seroma collection with tenderness)

1 (erythema and tenderness around incision site) 1 (frank purulent discharge)
Of the 52 class I surgery group who received empiric therapy for 3 days or more post-operatively, 2 developed features of SSI
1 (edema and erythema)
1 (seroma collection with tenderness)

The p value in class I surgeries, when the prophylactic group was compared with that of the empiric group, was found to be 0.68 (>0.05). Thus there was no statistically significant difference between the two groups

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Table no-3b
Results in class II group

	SSI	NO SSI	PERCENTAGE (%)
Prophylactic	8	44	15.3%
Empiric	6	46	11.5%

Of the 104 who underwent class II general surgical procedures, 52 patients received only one dose of pre-operative prophylactic antibiotic. 8 of these patients developed features of SSI (15.3%)
2 (sero-purulent discharge)
3 (seroma collection at the incisional site) 1 (erythema and tenderness)
2 (frank purulent discharge) Of the 52 patients who received empiric therapy 3 days or more post-operatively, 6 developed features of SSI (11.5%)
4 (edema and erythema and tenderness with seroma) 2 (frank purulent discharge) The p value in class II surgeries, when the prophylactic group was compared with that of the empiric group, was found to be 0.271 (>0.05). Thus there was no statistically significant difference between the two groups

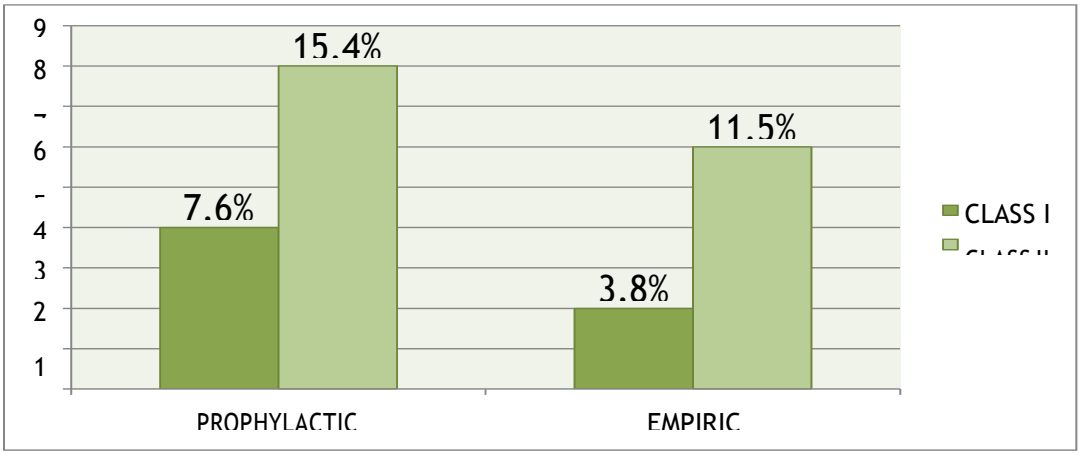
Table no-4 Overall results

	SSI	NO SSI	PERCENTAGE (%)
Prophylactic	12	92	11.5%
Empiric	8	96	7.6%

Thus it was seen that the 12 out of the 104 patients who received a single dose of antibiotic pre-operatively developed surgical site infections.
8 of the 104 patients who received multiple doses of antibiotics post-operatively developed surgical site infections

The p value between these two groups was found to be 0.29 (>0.05). Hence there was no statistical difference between the two groups

Graph no-3



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V. DISCUSSION

Perioperative anti-microbial prophylaxis is widely used, and probably overused, for the prevention of SSI. The general principles regarding anti-microbial prophylaxis include

- Selection of anti-microbial agents based on the likely pathogens responsible for a SSI with a particular operation
- Administration of antibiotics shortly before the commencement of that operation such that serum and tissue levels are high at the time of incision and during the course of operation

To achieve high concentrations of antibiotic in the tissues during an operative procedure, the timing of prophylactic antibiotics is critical. A study conducted by Classen et al[20] showed that subjects who received antibiotics within a two hour period before the incision was made had the lowest incidence of SSI. Several studies conducted by Mangram et al, Bratzler and Hunt, Springer et al and Classen et al[14, 15] showed that use of antibiotics appropriate for the potential pathogen and administration of prophylactic antibiotics within 1 hour before incision reduced the incidence of surgical site infections.

The proper duration of antimicrobial use for the prevention of postoperative surgical infection has been a subject of controversy. Currently, more than 40 published clinical trials are available in which the efficacy of single dose surgical prophylaxis with parenteral antimicrobials has been studied. These studies have compared single doses versus multiple doses of the same agent, single doses of antimicrobial versus placebo, single doses of various antimicrobials, and a single dose of one agent versus multiple doses of another agent. Dipro JT et al[14, 15, 23] in his study proved that the single dose regimens resulted in a similar frequency of postoperative wound infections.

McDonald et al[24] in his study of single versus multiple dose microbial prophylaxis for major surgery, observed that combined odds ratio by both fixed (1.06, 95% CI, 0.89-1.25) and random effects (1.04, 95% CI, 0.86-1.25) models indicated no clear advantage of either single or multiple-dose regimens in preventing SSI.

Mohri Y et al[25] conducted a study in Mie University Graduate School of Medicine, Japan comparing a single dose with a multiple dose regimen of anti- microbial prophylaxis for prevention of surgical site infection between May 2001 and December 2004. It was found that surgical site infection was seen in 9.5 per cent in the first group and in 8.6 per cent in the second group. Thus they concluded that incidence of surgical site infection in elective gastric cancer surgery was similar with both antibiotic prophylaxis regimens.

Fonseca SN et al[26] conducted a study in Brazil from February 2002 to August 2003 by replacing a 24-hour regimen with a single antibiotic prophylaxis for elective surgery. 12299 patients were followed up during their hospital stay. They found that the rate of surgical site infection did not change. Thus they concluded that one-dose antibiotic prophylaxis did not lead to an increase in rates of surgical site infection.

Oostvogel HJ et al[28] conducted a prospective, randomized double-blind trials to investigate the effectiveness of a single dose antibiotic regimen for preventing post-operative wound infection at St Elisabeth Hospital in Netherlands. Patients undergoing "clean-contaminated", "contaminated" or "clean" surgeries were included. Single-dose (pre-operative) prophylaxis was compared with short-term prophylaxis (1 dose pre-operatively and 2 doses post-operatively). They found that the incidence of wound infection was 1.8 % in the short-term group and 3.1% in the single-dose group. The difference was not statistically significant. Thus they concluded that single-dose of antibiotic prophylaxis lowered the rates of post-operative wound infection, even in "clean-contaminated" or "contaminated" cases.

The present study had infection rates of 7.6% and 15.4% in class I and class II respectively among those who received only pre-operative antibiotic prophylaxis. Whereas in those that received post-operative empiric therapy the infection rates were found to be 3.8% and 11.5% in class I and class II respectively.

On comparing the single dose prophylaxis group with that of the group which received multiple post-operative doses of antibiotics, the p value was found to be 0.49 and thus it was concluded that there was no statistical significance between the two groups.

STUDY	PERCENTAGE OF SSI	P VALUE
MOHRI ET AL	EMPIRIC – 8.6% PROPHYLACTIC – 9.5%	**<0.05**
OSSTOVOGEL ET AL	EMPIRIC – 1.8% PROPHYLACTIC – 3.1%	**<0.05**
FONSECA ET AL	-	**<0.05**
PRESENT STUDY	EMPIRIC – 3.8% AND 11.5% PROPHYLACTIC - 7.6%, 15.4%	**<0.05**

VI. CONCLUSION

Our study shows that a single dose of antibiotic given prior to surgery in clean and clean contaminated surgeries is effective in preventing post-operative surgical site infection.

The rate of surgical site infections was similar in patients who received a single pre-operative dose of antibiotic in comparison to those who received multiple doses of antibiotics post-operatively. The p value was found to be 0.29 (>0.05), which was not significant.

Thus it can be concluded from this study that a single dose antibiotic prophylaxis prior to surgery is sufficient to prevent post-operative surgical site infections in clean and clean contaminated surgeries thus preventing adverse outcomes of inadvertent antibiotic usage, such as multi-drug resistance and drug toxicity.

SUMMARY

The study was conducted on 208 patients who underwent either clean or clean contaminated elective general surgical procedures at Hitech Medical College Hospital, bhubaneswarbetween September 2018 to May 2020.

104 of whom received a single dose of antibiotic prior to surgery and 104 received multiple doses of antibiotics post-operatively

Occurrence of post-operative wound infection was noted among those who received only prophylactic antibiotics and those who received post-operative empiric therapy.

Statistical analysis was done accordingly, P-value less than 0.05 was considered significant.

On analysis there was no statistically significant difference between the prophylactic group and empiric group in both clean and clean contaminated surgeries.

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