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A CLINICAL STUDY OF EFFICACY OF PROPHYLACTIC V/S EMPIRICAL ANTIBIOTIC USAGE IN CLEAN AND CLEAN CONTAMINATED GENERAL SURGICAL PROCEDURES

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ABSTRACT: It is a prospective study carried out on patients who underwent clean and clean contaminated elective general surgical procedures from June 2012 to May 2014 at Govt. General Hospital, Kakinada, East Godavari District of Andhra Pradesh. Patients with diabetes mellitus, Patients on steroids, chemotherapy, and immunosuppression are excluded. Total of 100 cases were studied. 50 cases of clean and 50 cases of clean contaminated procedures were selected. Out of 50 cases of clean procedures 25 were given prophylactic and 25 were given empirical antibiotics. Out of 50 cases of clean contaminated cases 25 were given prophylactic and 25 were given empirical antibiotic. Data analysis was done with SPSS software. To present the results mean+SD was used and a 'P' value of < 0.05 was considered statistically significant. **RESULTS:** Our study shows that 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 >0.05, which was not significant. **CONCLUSION:** 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, financial burden on the hospital can be decreased, work load on junior doctors can be reduced.

KEYWORDS: prophylactic antibiotic, empirical antibiotic, clean surgery, clean contaminated surgery.

INTRODUCTION: Although treatment of infection has been an integral part of the surgeon's practice since the dawn of time, the knowledge that led to the present field of surgical infectious diseases was derived from the evolution of germ theory and antisepsis.¹ Application of the later to clinical practice, concurrent with the development of anaesthesia, was pivotal in allowing surgeons to expand their expertise to encompass complex procedures that previously were associated with extremely high rates of morbidity and mortality due to postoperative infection. Lister's work radically changed the face of surgery. The scientific basis for the use of prophylactic antibiotics in surgery was laid by Miles and Burke in the late 1950s. They demonstrated that infections could be prevented only when AMAs (anti-microbial agents) were given prior to or at the time of infectious challenge. Strachan and his colleagues performed the first prospective controlled trial, which investigated the proper post-operative duration of administration of AMA in 1977.^{2,4}

SURGICAL WOUND CLASSIFICATION: 1,2,3,5,6,7

CLASS I/CLEAN: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. In addition, clean wounds

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are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow non-penetrating (blunt) trauma should be included in this category if they meet the criteria.

CLASS II/CLEAN-CONTAMINATED: An operative wound in which the respiratory, alimentary, genital or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.

CLASS III/CONTAMINATED: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered are included in this category.

CLASS IV/DIRTY-INFECTED: Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

Fig. 1: CDC's CRITERIA FOR DEFINING SURGICAL SITE INFECTION (SSI)⁴

SUPERFICIAL INCISIONAL SSI: Infection occurs within 30 days after the operation involving only skin or subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat.

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DEEP INCISIONAL SSI: Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision and at least one of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever ($>38^{\circ}\text{C}$), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

ORGAN/SPACE SSI: Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following:

1. Purulent drainage from a drain that is placed through a stab wound into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

There are three main aspects in prevention of infection.

1. Careful, gentle and neat surgery.
2. Reduction of contamination during and after surgery.
3. Support of the patient's defenses, including use of prophylactic antibiotics wherever necessary.

CHOOSING THE AMA: Not many AMAs are ideal choices for AMP but the front runners, as the AMAs of choice for AMP are the cephalosporins. Cefazolin, a first generation cephalosporin, which adequately covers gram-positive and gram-negative organism, has been considered an adequate and safe AMA for prophylaxis in all "clean" and many "clean contaminated" procedures.

However, second generation cephalosporins like the cefoxitin or cefotetan, which have an additional activity against anaerobes, may be needed to be employed in clean contaminated surgeries of the colorectum or gynaecological procedures.

If the patient is allergic to penicillins or cephalosporins, aztreonam clubbed with clindamycin or metronidazole for coverage against anaerobic bacteria seems to be a safe alternative.^{8,9,10,11,12,13,14}

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

MATERIALS AND METHODS: The study is carried out in 3rd unit of General Surgery department, Government General Hospital, Rangaraya Medical College, Kakinada from June 2012 to September 2014. The study is done on 50 clean surgical procedures and 50 clean contaminated procedures. All the patients were explained about the procedure and consent obtained.

CASES SELECTED ARE:**A. CLEAN CASES:**

1. Uncomplicated inguinal hernia- hernioplasty.
2. Fatty hernia of linea alba-hernioplasty.
3. Hydrocele-jabouleys procedure.
4. Carcinoma breast-MRM with suction drain.
5. Adenoma thyroid-hemithyroidectomy with closed drain.
6. MNG –subtotal thyroidectomy with closed drain.

B. CLEAN CONTAMINATED CASES:

1. Cholelithiasis-open cholecystectomy with closed drain.
2. Lap cholecystectomy with closed drain.
3. Appendicitis without perforation –open appendicectomy.
4. Lap appendectomy.
5. Choledocholithiasis-CBD exploration with closed drain and T- tube.

AMA selected is ceftriaxone. Ceftriaxone is useful for treatment of number of bacterial infections. It is a third generation cephalosporin having broad spectrum of activity against gram positive bacteria and expanded gram negative coverage. It is on the “WORLD HEALTH ORGANISATION LIST OF ESSENTIAL MEDICINES”-a list of most important medicines needed in basic health system. If anaerobes are suspected metronidazole is added.

THE REGIMENS ARE:

1. Inj ceftriaxone 1 gm iv- single dose.
2. inj ceftriaxone 1 gm iv bd and inj.metronidazole 500mg iv tid for 3-5 days.

CALCULATED SAMPLE SIZE: 100

Clean surgeries – 50

Clean contaminated surgeries – 50

EXCLUSION CRITERIA:

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

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 prophylactic group received inj. Ceftriaxone 1gm iv one hour before or at the time of induction of anaesthesia followed by a second dose within 12 hours if the surgery was prolonged for more than 2 hours. In cases where anaerobic organisms are likely to be encountered inj. Metronidazole 500mg was added.
- While the empirical group received the same antibiotics post-operatively (after completion of surgery) for 72 hours or more.

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- Operative wound was examined on the second, fifth and eighth post-operative day for signs and symptoms of surgical site infection.
- All the cases are followed for one month.
- 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.

RESULTS: The study was conducted on a total of 100 patients aged between 18 to 80.

	Total	SSI	NO SSI	PERCENTAGE
Prophylactic	25	2	23	8
Empiric	25	3	22	12

Table 1: Results in class I group

- Of the 50 patients who underwent class I surgeries, 25 patients received only one dose of pre-operative prophylactic antibiotic. 2 of these patients developed features of SSI (8%).
- seroma collection with tenderness – 1.
- erythema and tenderness around incision site – 1.
- Of the 25 class I surgery group who received empiric therapy for 3 days or more post-operatively, 3 developed features of SSI.
- edema and erythema – 1.
- seroma collection with tenderness – 2.

The p value in class I surgeries, when the prophylactic group was compared with that of the empiric group, was found to be 0.63 (>0.05). Thus there was no statistically significant difference between the two groups.

Fig. 2

	Total	SSI	NO SSI	PERCENTAGE
Prophylactic	25	2	23	8
Empiric	25	4	21	16

Table 2: Results in class II group

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- Of the 50 who underwent class II general surgical procedures, 25 patients received only one dose of pre-operative prophylactic antibiotic. 2 of these patients developed features of SSI (8%).
- Sero-purulent discharge – 1.
- Seroma collection at the incisional site – 1.
- Of the 25 patients who received empiric therapy for 3 days or more postoperatively,
- 4 developed features of SSI (16%).
- Erythema and tenderness – 1.
- Edema, erythema and tenderness with seroma – 2.
- Frank purulent discharge – 1.

The p value in class II surgeries, when the prophylactic group was compared with that of the empiric group, was found to be 0.384 (>0.05). Thus there was no statistically significant difference between the two groups.

Fig. 3

DISCUSSION: The present study had infection rates of 4% in both class I and class II procedures 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 12% and 16% in class I, 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 0.337 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 14% Prophylactic 8%	>0.05

Table 3 Comparison with other studies

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CONCLUSION: 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.

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 0.337 (>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 procedures thus preventing multi drug resistance and drug toxicity. It is also cost effective. Workload on junior doctors can be reduced. Now based on this study, treatment protocols are being prepared for general surgical procedures in Govt. General Hospital, Kakinada.

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