IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 20, Issue 8 Ser.7 (August. 2021), PP 06-12
www.iosrjournals.org

Defining the role of single-dose systemic antibiotic prophylaxis in clean surgical cases in a tertiary care centre; a prospective comparative study

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Abstract: *this prospective study was done to compare the effect of single dose prophylactic intravenous antibiotic versus conventional triple antibiotic therapy in preventing surgical site infection in clean surgical cases operated in ssims&rc. A total of 200 cases were studied, male to female ratio in study was 3:2, with mean age of 42.7 years, among the clean surgery cases operated, lichtenstein mesh repair done for inguinal hernia is being highest, 31%.in group-ii 6% of and 2% case in group-i had postoperative infection, with staphylococcus aureus being most common organism isolated. This study highlights the rational use of antibiotic as injudicious use can adversely affect the patient, cause emergence of antibiotic resistance and increase the cost of health care*

Date of Submission: 01-08-2021 Date of Acceptance: 15-08-2021

I. Introduction

surgical site infections (ssis) are infections of the tissues, organs, or spaces exposed by surgeons during performance of an invasive procedure. Ssis are classified into incisional and organ/space infections, and the former are further subclassified into superficial (limited to skin and subcutaneous tissue) and deep incisional categories [1],[2]

By definition, an incisional ssi has occurred if a surgical wound drains purulent material or if the surgeon judges it to be infected and opens it.

The overall incidence of surgical site infection (ssi) has been estimated to be 2.8% in the united states, according to the u.s. Centers for disease control and prevention, although the data may underrepresent the true incidence of such infections owing to inherent problems with voluntary self-reporting by surgeons of infections that occur in the ambulatory surgical setting. [3]

Surgical site infections are recognized as a common surgical complication, occurring in about 3% of all surgical procedures and in up to 20% of patients undergoing emergency intra-abdominal procedures.[4]

Surgical wounds are classified based on the presumed magnitude of the bacterial load at the time of surgery clean wounds (class i) include those in which no infection is present; only skin microflora potentially contaminate the wound, and no hollow viscus that contains microbes is entered. Class i d wounds are similar except that a prosthetic device (e.g., mesh or valve) is inserted. Clean/contaminated wounds (class ii) include those in which a hollow viscus such as the respiratory, alimentary, or genitourinary tracts with indigenous bacterial flora is opened under controlled circumstances without significant spillage of contents.[5]

More than 70% of surgical procedures are now performed on an outpatient basis, which poses major problems for surveillance of ssi [6]. Although many ssis will develop in the first 5 to 10 days after surgery, an ssi may develop as long as 30 days after surgery. Estimates of the incidence of ssi thus depend upon voluntary self-reporting by surgeons, which is unreliable. Therefore, estimates of the incidence of ssi in nnis are probably underestimates, although the data are the best that are available. Host-derived factors may contribute to the risk of ssi. Factors of importance include advanced age [7], obesity, malnutrition, diabetes mellitus [8],[9] hypocholesterolemia [10] and numerous other factors that are not accounted for specifically by the nnis system.

Public reporting of process, outcome, and other quality improvement measures is now required, and reimbursements for treating ssis are being reduced or denied. It has been estimated that approximately half of ssis are preventable by application of evidence-based strategies

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 .also ssi can double the length of time a patient stays in hospital and thereby increase the costs of health care. Additional costs are related to re-operation, extra nursing care and interventions, and drug treatment costs.

Accurate surveillance can only be achieved using trained, unbiased and blinded assessors. Most include surveillance for a 30-day postoperative period. The us centers for disease control (cdc) definition insists on a 30-day follow-up period for non-prosthetic surgery and 1 year after implanted hip and knee surgery.

Maneuvers to diminish the presence of exogenous (surgeon and operating room environment) and endogenous (patient) microbes are termed *prophylaxis*, and consist of the use of mechanical, chemical, and antimicrobial modalities, or a combination of these methods.

Patients with ssis are more likely to require readmission to hospital or intensive care unit (icu) treatment, and are at higher risk of death, than those without such infections hence continuing vigilance is therefore required to minimise the incidence of such infections. This requires a systematic approach, with attention to multiple risk factors related to the patient, the procedure, and the hospital environment.

Objective

To determine the efficacy of single-dose prophylactic iv antibiotic versus conventional triple antibiotic therapy in clean surgical cases.

Results: study included 200 patients (mean age:42.7 years), 2% was incidence of ssi in group i and 6% in group ii, staphylococcus aureus was most commonest organism isolated, duration of stay, treatment cost are significantly increased for the control group patient on 3 days conventional antibiotics.

Conclusion:

Prophylactic single-dose antibiotic is sufficient in preventing surgical site infection and is cost-effective in clean surgical cases, especially lichtenstein tension free mesh repair.

Keywords: prophylactic antibiotics, surgical site infection, clean surgical cases, cost-effective

Materials & methods: this is a randomized case-control prospective study conducted in the department of general surgery ssims&rc hospital davangere from 2019 january to 2021 june. 200 patients admitted electively for clean surgery without any underlying co-morbidities were included in this study.

Inclusion criteria:

- Patients undergoing elective clean procedures such as thyroid surgeries , hernia repair , varicose vein surgeries, soft tissue cysts excision, hydrocele surgeries ,circumcision etc

Exclusion criteria:

- Patients age less than 18 and more than 65 years
- All emergency surgeries
- Coexisting diabetes mellitus, hypertension , pulmonary kochs and immune-compromised conditions, pregnancy and lactating mothers
- Contaminated surgeries
- Refusal to give consent.

Ethical clearance was obtained from ethical committee, ssims &rc , davangere. Patients undergoing elective clean surgical cases were randomly allocated a group into random number table using computer generated software into two groups.

Study group(i) :single of 1 g injection ceftriaxone iv after test dose at the time of incision. No antibiotics were further given during postoperative period.

Control group(ii) : pre-operative antibiotic is not given. During post-operative period iv antibiotics were given for the first 3 days as follows:

Inj ciprofloxacin 200 mg iv bd

Inj metronidazole 500 mg iv tid

Inj amikacin 500 mg iv bd.

All the patients posted for these elective surgeries were admitted on the day prior to surgery and necessary investigations were done, on table clipping of hair at operative site was done under aseptic precaution. All the instruments were counter checked for sterility.

The operative site was prepared with povidone-iodine and spirit. Under all aseptic precautions and strict vigilance the surgery is conducted in patients of both groups with no differences in surgical technique. Principles of surgery, especially minimal tissue handling, adequate haemostasis were followed. Patients undergoing elective lichtenstein tension free mesh repair, monofilament polypropylene mesh of 6*11cm with minimal handling was used.

On demand analgesia is administered postoperatively.
For the day care surgeries done under outpatient basis, oral analgesic tablet tramadol 50 mg twice a day basis is prescribed as a routine hospital practice.

Apart from daily routine examination an attention towards the surgical wound infection is given. Surgical wound is examined on post-operative day on 2,3,5,7, 30, 60 under aseptic precautions, to check for erythema, raised temperature, discharge, suggestive of acute inflammation confirming surgical site infection. After day 2 wound examination, wounds are kept open to air with no dressing pad on the surgical wound.

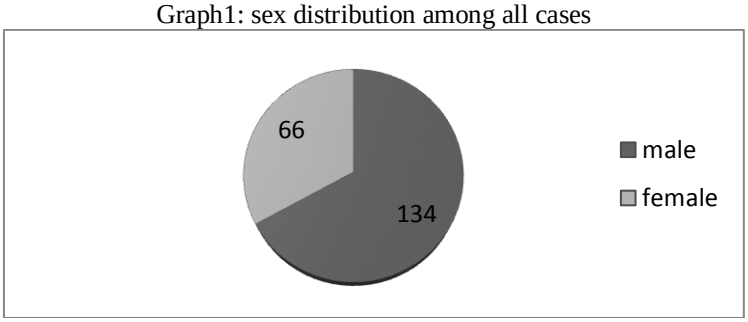
Suture removal is done on day 8 under aseptic precautions after confirming no infection is present. Discharge was sent for bacterial culture sensitivity in case of ssi.

Immediately, empirically antibiotics are started with injection ceftriaxone 1 gram intravenously twice a day till the report of culture and sensitivity is obtained followed by sensitive antibiotic to the organism cultured .

II. Observation & Results

Infection grading
Southampton wound scoring system was applied during post-operative period on the 3rd, 5th, and 7th day and the wound infection were graded.
200 patients undergoing clean surgery in ssims&rc divided into two groups. Results obtained after the completion of study under various parameters are analysed.

Graph1: sex distribution among all cases



Among 200 cases, 134 were males and remaining 66 were females. In study male to female ratio was 3:2

Table 1: age wise distribution in both groups.

Age	Group I N	Group ii N	Total N
<20	4	8	12
21-30	14	16	30
31-40	22	34	56
41-50	18	14	32
51-60	34	14	48
61-65	8	14	22

Maximum number of patients belonged to age group 31-40 years with 56 cases and least in <20 years with only 12 cases.
In group i , majority of the patients belonged to 51-60 years age group accouting for 34% and least in <20 years age group with 4%. Mean age was 42.7 years.
In group ii the mean age was 42.47. Maximum patients were of age group of 31-40 years accounting for 34% and least in <20 years age group with 8% .

Table 2: disease wise distribution of the cases:

Diseases	Group i	Group ii	Total
Hernia(ventral, groin)	32	30	62
Varicose veins	08	10	18
Genitalia	14	12	26
Breast(fibroadenoma , malignancy)	16	10	26

Thyroid and parathyroid	00	04	04
Benign lesions	30	34	64
Total	100	100	200

In the study majority of patients underwent elective surgery for excision of benign lesions such as lipoma, lymphnode, corn and ectopic salivary gland excision. A total of 64 patients were operated of which 30 cases were operated under group i and remaining 34 cases under group ii.

Hernioplasties form the second highest number elective surgeries performed under this study as an individual disease. Total number of 62 patients were taken into study,of which 32 in group i and 30 in group ii.
31patients with uncomplicated inguinal hernia were chosen and 31 patients with ventral hernia were chosen.
Varicose veins of lowerlimb undergoing trendelenberg surgery with perforator ligation were also operated and considered for study with total number of 09 cases with 04 in group i and 05 in group ii.

Total of 13 patients with diseases pertaining to external genitalia were operated and taken into study with 07 under group i and 06 cases under group ii. Surgeries include excision of ependymal cyst, jabouleys operation for hydrocele, circumcision for phimosis.

A total of 13 patients with breast diseases were operated, 08 cases in group i and other 05 cases falling in group ii. Fibroadenoma excision of the breast was commonly done followed by mrm for carcinoma breast.

2 cases of solitary thyroid nodule was taken into study with both cases falling into group ii

Table 3: distribution of benign lesions

Disease	Number
Lipoma	28
Sebaceous cyst	24
Lymphadenopathy	4
Ectopic salivary gland	2
Corn	6

Benign lesions formed the major part of the study with 64 cases. Majority being lipoma including fibrolipoma and axillary lipoma accounting to 28 cases followed by 24 cases as sebaceous cyst, 6 corn excisions, 4 lymph node excision biopsies and 2 ectopic salivary gland excisions.

Table 4:laterality of inguinal hernia in the study.

Inguinal hernia	Right	Left	Bilateral
Group i	18	12	02
Group ii	20	10	00

Right sided inguinal hernia formed the highest number with 18 cases in group i followed by 12 cases on the left side and 2 cases of bilateral inguinal hernia.

In group ii also right sided were more common accounting for 20 cases followed by the left sided inguinal hernia with 10 cases.

Table 5: varicose veins of lower limb cases distribution

Varicose veins	Right	Left
Group i	6	2
Group ii	4	6

Patients with varicose veins of lowerlimb with sapheno-femoral incompetence with multiple perforators without complications such as dvt, thrombophlebitis were considered for study and performed trendenlenberg procedure with vein stripping and perforator ligation .
Of 18 cases, 8 cases were under group i with 6 having right lowerlimb involved and 2 cases on the left lowerlimb.

In the group ii, 4 were operated for right sided disease and 6 on the left side with similar techniques.

Table 6: distribution of diseases related to genitalia

Disease	Group i	Group ii	Total
Hydrocele	8	6	8
Phimosis	2	2	4
Epididymal cyst	2	0	2

8 patients with hydrocele , 4 patients phimosis and 2 patients with epididymal cyst were operated under group i. Under group ii , 6 patients with hydrocele and 2 patients with phimosis were operated.
None of the procedures extended beyond 120 minutes. Maximum number of cases had a duration of surgery ranging in

- Less than 30 minutes group were 41%
- Group of 30 to 60 minutes were 52%
- 60 to 120 minutes group were 7%.

Table 7: incidence of post-operative wound infections.

Infection	Present N(%)	Absent N(%)	Total
Group i	2(2%)	98(98%)	100
Group ii	6(6%)	94(94%)	100

As per the study design regular wound examination was done after postoperative day 2 for signs of ssi. In group i , 2 patients (2%) in group i had ssi and in 6 patients (6%) in group ii had developed ssi.

Table 8 : organisms isolated from wound infection.

Organism	Number	Percentage
Staphylococcus aureus	6	75
Pseudomonas	2	25

Wound discharge was sent for culture and sensitivity in all the 8 patients who had wound infection.

Staphylococcus aureus was isolated in 6 patients(75%) and pseudomonas aeruginosa was isolated in other 2 patients(25%). All patients were further treated with sensitive antibiotics.

III. Discussion

This is a institute basesd prospective study of 200 cases of clean surgical cases undergoing elective surgeries ssims&rc hospital davangere. Clean surgery is where there is no break in the aseptic techniques and there is no entry into the gastrointestinal tract , respiratory or the genitor-urinary tract strictly.

The use of prophylactic antibiotic in all surgical cases are advocated ever since, the concept of use of antibiotic pre-operatively to curtain and prevent wound infection was postulated by bernard and cole in 1964[11].

The recommendations of the Surgical Infection Society (SIS) include single-dose prophylaxis with a first-generation cephalosporin (cefazolin) for most procedures (including orthopedic, non-cardiac thoracic, and gastroduo- denal)[12]. A single dose of a second-generation cephalosporin was recommended for abdominal trauma, appendectomy, and colorectal surgery. The Medical Letter on Drugs and Therapeutics recommended that multiple doses may be inappropriate for any surgical prophylaxis [13]

Chalkiadakis in their study recommended that inj ceftriaxone can be used as prophylactic antibiotics for the prophylaxis to prevent surgical wound infection [14].in our study also inj ceftriaxone is preferred prophylactic antibiotic due to its availability.

Proper usage of antibiotics in patients undergoing surgery is necessary , otherwise misuse of potent antimicrobials lead to drug toxicity , super infections , colonization of wards by highly resistant microbes and healthcare cost.

Three uncontrolled observational studies showed that when antibiotics were given for surgical prophylaxis , there was an increased risk of the patients treated acquiring antibiotic resistant strains following treatment [15],[16],[17]

Many studies have recommended the first dose of antibiotic to be given 30- 60 min prior to surgery or at the time of induction of anesthesia and antibiotic with prolonged half life must be selected. Administration of prophylaxis more than 120minutes after start of the operation significantly reduces its effectiveness [18].

A study by SP Lilani et al showed that staphylococcus aureus was the most common isolate followed by pseudomonas [19] which is in consistent with our study too as the organisms isolated are s.aureus followed by pseudomonas.

Wound infection reported in literature for clean wound is between 1.5% and 4% [20],[21] .Our study shows a wound infection rate of 6% with conventional antibiotics and 2% with prophylactic antibiotics.

Fernandez et al conducted a study of 5260 patients to find out the economical saving achieved with the right prophylaxis to prevent surgical wound infections operated during 1990-1993. He calculated the percentage of infections prevented by a right prophylaxis, and the cost was calculated starting from the number of extra days of infection. The number of infections prevented during the four years was 310, saving a total of 194 million pesetas (1.5 million dollars), due to right prophylaxis. Cost-benefice ratio = 1/17. We consider of special importance to control this manipulable risk factor, in order to avoid the development of infections [22].

Arjona F et al had conducted a study to find out the economic advantages following use of prophylactic antibiotic rather than traditional 7 days antibiotics, using 5260 patients in a medical Centre in Southern Taiwan and stated that use of prophylactic antibiotic alone for the surgical patients had resulted in gain of 1.5 million dollars for the public [23]

In our study patients in group II had prolonged hospital stay and incurred high cost for antibiotics compared to patients in group I

Prophylaxis is limited to a single dose administered immediately prior to creating the incision. Empiric therapy should be limited to 3 to 5 days or less, and should be curtailed if the presence of a local site or systemic infection is not revealed. In fact, prolonged use of empirical antibiotic therapy in culture-negative critically ill patients is associated with increased mortality, highlighting the need to discontinue therapy when there is no proven evidence of infection. [24]

Prophylactic antibiotics are no substitute for good surgical practice .Along with prophylactic antibiotics, clean surgical environment, adequate hand washing, adequate preoperative preparation of patients, minimal tissue handling with tissue respect and following universal precautions will improve the wound healing and prevent wound infection.

IV. Conclusion

Single dose prophylactic antibiotic is sufficient in preventing wound infection in clean surgical cases. Appropriate use of antibiotics in surgical patients includes timely and appropriate use of prophylaxis ,prospective determinations of the duration and endpoint of antibiotic therapy. Short courses of antibiotics are equally effective, and minimize the chance of superinfection, adverse drug interactions, and the development of antibiotic resistance, also their judicious reduces the economic burden to patient.

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Dr Deepak Gopalreddy, et. al. "Defining the role of single-dose systemic antibiotic prophylaxis in clean surgical cases in a tertiary care centre; a prospective comparative study." *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 20(08), 2021, pp. 06-12.