A PROSPECTIVE LONGITUDINAL STUDY ON THE EFFECTS OF FIRST DOSE ANTIBIOTIC PROPHYLAXIS GIVEN IN CLEAN CONTAMINATED CASES ADMINISTERED HALF AN HOUR BEFORE SKIN INCISION VS ADMINISTERED INTRAOPERATIVELY ON POSTOPERATIVE INFECTIONS

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Submitted by

PRATHIBA. I	**(38181024)**
RITU YADAV. R	**(3818102)**
SELSHICA. J	**(3818102)**
SHUBHAJIT PAUL	**(3818104)**

Under the Guidance of

Dr. Krishna Kumar D, M. Pharm, Ph.D., Professor &
Head of Department of Pharmacy Practice

THE ERODE COLLEGE OF PHARMACY, PERUNDURAI MAIN ROAD, VEPPAMPALAYAM, ERODE – 638112

ABSTRACT

Abstract

Surgical site infections are infections are commonest among all healthcare-associated infections and particularly following clean-contaminated surgeries. Surgical site infections impact changes in patient outcome, high healthcare cost, and increased duration of hospital stay. Therefore, prophylactic antibiotic redosing is an important strategy suggested for reducing the rates of surgical site infections in surgical patients. This study is about evaluating the effectiveness of redosing antibiotics compared with a single preoperative dose and redosing in clean-contaminated surgeries in the prevention of SSIs.

Methods: A prospective observational study was carried out over six months in Tirupur Government, Medical College Hospital. Total of 110 patients aged between 15 and 80 years undergoing clean-contaminated surgeries were included. Data were collected on demographic details of patients who underwent clean contaminated surgery, and antibiotic administration (single dose versus redosing). Statistical analyses were carried out to compare the SSI rates between the two groups.

Results: The overall SSI rate was 7.2%. Patients receiving a single preoperative dose had a higher SSI rate (5.9%) compared to those who received redosing (0.9%) ($p = 0.0396$). The results showed a significant reduction in SSIs with antibiotic redosing was observed.

Conclusion: Redosing antibiotics during clean-contaminated surgeries did significantly reduce SSI rates compared to a single preoperative dose yet further investigation is needed. These findings do support to some extent the implementation of redosing strategies in surgical antibiotic prophylaxis to improve patient outcomes and reduce SSIs. Further research into optimal redosing protocols is recommended.

Keywords: Surgical site infections (SSIs), antibiotic prophylaxis, clean-contaminated surgeries, redosing, infection prevention, healthcare-associated infections (HAIs).

CERTIFICATES

EVALUATION CERTIFICATE

This is to certify that the dissertation entitled **A PROSPECTIVE LONGITUDINAL STUDY ON THE EFFECTS OF FIRST DOSE ANTIBIOTIC PROPHYLAXIS GIVEN IN CLEAN CONTAMINATED CASES ADMINISTERED HALF AN HOUR BEFORE SKIN INCISION VS ADMINISTERED INTRAOPERATIVELY ON POSTOPERATIVEINFECTIONS** was carried out truly by the fifth year Pharm. D students **PRATHIBA. I (381810264), RITU YADAV. R (381810269), SELSHICA. J (381810273), SHUBHAJIT PAUL (381810274)**, in the Department of Pharmacy Practice, The Erode College of Pharmacy, Erode which is affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, under the direct supervision and guidance of **Dr. D. KRISHNA KUMAR, M. Pharm., Ph.D.,** Professor and Head**,** Department of Pharmacy Practice, The Erode College of Pharmacy, Erode.

CENTRE FOR EXAMINATION: The Erode College of Pharmacy, Erode

Internal Examiner

External Examiner

The Erode College of Pharmacy

Perundurai Main Road
Veppampalayam
Vallipurathanapalayam (PO),
Erode- 638112, Tamil Nadu, India

Phone : 0424 – 2339929
Telafax : 420 – 2339539
E- Mail : ecperode@gmail.com
Website : www.ecp.ac.in

Dr.D. Krishna Kumar, M.Pharm., Ph.D.,

Professor and Head, Department of Pharmacy Practice

This is to certify that the dissertation entitled **A PROSPECTIVE LONGITUDINAL STUDY ON THE EFFECTS OF FIRST DOSE ANTIBIOTIC PROPHYLAXIS GIVEN IN CLEAN CONTAMINATED CASES ADMINISTERED HALF AN HOUR BEFORE SKIN INCISION VS ADMINISTERED INTRAOPERATIVELY ON POST OPERATIVE INFECTIONS** was carried out precisely by the fifth year Pharm. D students **PRATHIBA. I (381810264), RITU YADAV. R (381810269), SELSHICA. J (381810273), SHUBHAJIT PAUL (381810274),** in the Department of Pharmacy Practice, The Erode College of Pharmacy, Erode, which is affiliated to The Tamil Nadu Dr. M.G.R Medical University, Chennai, under the guidance **of Dr. KRISHNA KUMAR D M. Pharm., PhD.,** The Erode College of Pharmacy, Erode.

Place:

Date:

Dr. KRISHNA KUMAR D M. Pharm., PhD.,
Professor and Head,
Department of pharmacy Practice,
The Erode College of Pharmacy
Erode – 638 11

The Erode College of Pharmacy

Perundurai Main Road
Veppampalayam
Vallipurathanapalayam (PO),
Erode- 638112, Tamil Nadu, India

Phone : 0424 – 2339929
Telafax : 420 – 2339539
E- Mail : ecperode@gmail.com
Website : www.ecp.ac.in

Dr.SAMPATHKUMAR M.Pharm.,Ph.D

Professor and Head, Department of Pharmacy Practice

A PROSPECTIVE LONGITUDINAL STUDY ON THE EFFECTS OF FIRST DOSE ANTIBIOTIC PROPHYLAXIS GIVEN IN CLEAN CONTAMINATED CASES ADMINISTERED HALF AN HOUR BEFORE SKIN INCISION VS ADMINISTERED INTRAOPERATIVELY ON POST OPERATIVE INFECTIONS was carried out meticulously by the fifth year Pharm. D **PRATHIBA. I (381810264), RITU YADAV. R (381810269), SELSHICA. J (381810273), SHUBHAJIT PAUL (381810274)** in the Department of Pharmacy Practice, The Erode College of Pharmacy, Erode, which is affiliated to The Tamil Nadu Dr. M.G.R. Medical university, Chennai, under the direct supervision and guidance of **Dr. D. KRISHNA KUMAR, M. Pharm., Ph.D.,** Professor and Head, The Erode College of Pharmacy, Erode- 638 112.

Place:

Date:

Dr.SAMPATHKUMAR M.Pharm.,Ph.D.,
Principal,
The Erode College of
Pharmacy, Erode- 638 112

DECLARATION

DECLARATION

We hereby declare that the **A PROSPECTIVE LONGITUDINAL STUDY ON THE EFFECTS OF FIRST DOSE ANTIBIOTIC PROPHYLAXIS GIVEN IN CLEAN CONTAMINATED CASES ADMINISTERED HALF AN HOUR BEFORE SKIN INCISION VS ADMINISTERED INTRAOPERATIVELY ON POSTOPERATIVE INFECTIONS** was carried out in the Department of Pharmacy Practice, The Erode College of Pharmacy, Erode, which is affiliated to The Tamil Nadu Dr.M.G.R Medical University, Chennai, under the guidance and supervision of **Dr.D.KRISHNA KUMAR, M.Pharm., Ph.D.,** Professor and Head, Department of Pharmacy Practice, The Erode College of Pharmacy, Erode.

PRATHIBA I
(381810264)

RITU YADAV R
(381810269)

SELSHICA J
(381810273)

SHUBHAJIT PAUL
(381810274)

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The secret of success is motivation, dedication, confidence on self and above all the blessing of God. Success doesn't lie in "results"; but in "efforts". Success is an outcome of collaborated efforts aimed at achieving different goals. Being the best is not so important; doing the best is all that matters.

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PRATHIBA I

(381810264)

RITU YADAV R

(381810269)

SELSHICA J

(381810273)

SHUBHAJIT PAUL

(381810274)

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ABBREVIATIONS

ABBREVIATIONS	FULL FORM
HCAI	Hospital associated infection
SSI	Surgical site infection
LOS	Length of stay
SAP	Surgical antibiotic prophylaxis
IDSA	Infectious disease society of America
ASHP	American society of health system pharmacist
WHO	World health organization
LMIC	Low- and middle-income countries
NNIS	National Nosocomial Infection Surveillance Program
NHS	National health service
MIC	Minimum inhibitory concentration
ASA	American society of Anesthesiologist
CDC	Centre for disease control and prevention

INTRODUCTION:

Hospital associated infections (HCAIs) are one of the major health burdens to the society that not only disrespect geopolitical and social limitations but also incurs considerable losses in quality of life of an individual as a whole. Of such HCAIs, SSIs or surgical site infections are most frequently encountered in the operative field, following a surgical intervention [1], precisely a 19.6% statistic wise hardship on healthcare [2,3], which under plain sight houses a complex transaction of biological and molecular machinery held accountable for dictating the pathogenetic influence upon the body. This, but also reflects forth the clinical judgment, adherence to medical codes and understanding of the physicians in their interprofessional discipline towards management and conduct of such conditions [4]. An SSI, defined as a distinct resulting infectious activity commencing from a simple superficial tissue infestation till convoluted deep organ site contamination, achieved subsequent post successful breakdown of the systemic host defense[4,5,6,7,8,9,10,11,12,13]. This not only helps reduce hospital cost, but also shorten hospital stay or Length of stay (LOS) and other related burdens [14,3,15,12]. While it is important to note that infection is just a form of inflammatory response not to be confused with sepsis whose definition confines to dysregulated immune response [16]. Surgical antibiotic prophylaxis or SAP is a brief course of antibiotics initiated closely prior to commencement of procedure begins with selection of precise drugs to provide optimal benefit and maintenance of sufficient concentration in tissues [6,10]. Guidelines towards such are stated in the IDSA respectively for peri and post operative ventures within the state [5]. ASHP norms are supervised and adopted by nations under supervision of WHO [17]. Even though guidelines for non surgical procedures currently do not exist or are rather empirical in an institution wise settings, a panel of experts convened by the WHO outsourced 29 guidelines to prevent SSI some of which state; antibiotic prophylaxis initiation average 60-120 minutes (precisely 30 min prior skin incision to maintain adequate concentration in tissue – Cyssens 1999, within 120 min for Vancomycin and Fluoroquinolones) before surgery, no post-operative prolongation after any type of surgery or cessation within 24 hrs. surgical end time etc.[2,7,17,15]. Prolonged Surgical approaches need to acknowledge tissue Minimum inhibitory concentration, drug interaction, t½ intraoperative redosing, scoping availability of antibiotics post 2-3 half

lives of initial prophylactic agent, excessive blood loss etc.[18,8,10]. Although the redundancy of such redosing is limited by the timely preoperative administration and length of surgery, incidence of an SSI can still not entirely be ignored [10]. 2 million nosocomial infections arise in the US every year. While internationally, figuratively speaking incidences of such are likely to be restricted to the Low and middle income countries (LMIC), owing to resource limitations. Every 1 out of 10 patients in LMIC who underwent surgery incur an SSI. But lack of adequate research on such incidence studies inadvertently fails to bolster such intuitive claims [5,15,11]. SSIs' contribution extends to as much as 20% of all hospital acquired infections, averaging 14-18% of which potentially 60% are liable to mitigation by current and emergent evidence based practices of Preventive antibiotic prophylaxis [14,19,8,20,11]. Mismanagement is a case of prophylactic routines probably emerged as a byproduct of industrialization virtue irrational indication, excessive duration of antimicrobial prescription, increased workload, crowded hospital environment, understaffed, staff with inadequate skills [7,12,21]. Thereby, an effort to discern relevant information and produce substantial evidence based data to highlight the importance of good clinical practice, adherence to guidelines in hospital settings and reduction in the negative effects of SSI acting as a hurdle to optimal treatment which our attempted study ultimately aims at will hopefully address the scientific community and the healthcare system as a whole.

CLASSIFICATION:

A wound qualifies as an SSI when certain established rules of thumb are followed.

1. Incidence 30 days post surgery, up to a year after implants.
2. Only skin, subcutaneous tissues, deep layers or distant organs.
3. Purulent discharge or presence of organism in skin isolates [4,12,21].

According to the National Nosocomial Infection Surveillance Program (NNIS) surgical wound can be classified as

- **Superficial:** - involves skin and subcutaneous tissue.

  Criterions to be abided (any one): purulent discharge from wound, aseptic isolation of organ organisms from the superficial site, a final diagnosis established by the attending physician or surgeon.

  - ❖ An abscess at point of suture infiltration is not diagnosed as SSI
- **Deep incisions:** - involves deep soft tissue (fascia and muscle layers).

  Criterions to be abided (any one): purulent discharge from deep incisions wound, spontaneous dehiscence or deliberate reopening of incision by surgeon on suspicion of infection, a histopathological or radiological exam that annotates abscess formation or other deep incisional infection, or a diagnosis established by the attending physician or surgeon.
- **Organ/ systemic:** - involves any part of the body, excluding the skin incision, fascia, or muscle layers, prone to manipulation or environmental exposure amidst procedure: examples: - intra-abdominal infection, endocarditis/pericarditis, mediastinitis, intracranial infection, osteomyelitis, sinusitis, mastitis, vascular infections.

  Criterions to be abided (any one): purulent discharge from the stab site, organisms isolated and detected, followed by abscess or analogous infections [4,1,22,12,33].

Operative wounds and risk of infection can be classified into :-

Table 1: Classification of Operative wounds and risk of infection

Wound classification	**Criteria**
Class I or Clean	Elective, not emergency, non traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered

Class II or Clean contaminated	Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g., appendectomy) not encountering infected urine or bile; minor technique break
Class III or Contaminated	Nonpurulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma < 4 hours old; chronic open wounds to be grafted or covered
Class IV or Dirty contaminated	Purulent inflammation(e.g., abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma > 4 hours old

According to Cruse PJ, Foord R 1980

INCIDENCE AND PREVALENCE:

1 in every 10 patients in LMICs fall prey to surgery attributed to nosocomial infection, and this statistic is just an educated guess, of maybe something comparable to the top of an iceberg, and this is said to be 2-3 times higher than developed countries [11]. Targeted SSI incidence surveillance and Point prevalence surveys highlight the highest odds of recorded infection after prophylaxis was 2.6% [7]. 10-30% of infective shortcomings are a contribution of elective colorectal surgery [3]. While, Gastrointestinal surgeries (especially large bowel surgery) tenanted 9% of all HCAIs in the NHS hospital, England in 2018/19 [32], 3% - 12% incidence rates prevailed within the boundaries of the Indian clinical setting [35]. When analyzed by surgery type, the prevalence of SSI in neurosurgery, cardiovascular (central and peripheral) surgery, orthopedic surgery, abdominal wall surgery, and others surgeries was 5% (95% CI 3–7%), 4% (95% CI 3–6%), 4% (95%

CI 3–5%), 4% (95% CI 1–7%), and 6% (95% CI 3–10%), respectively. The prevalence of SSI in elective clean and clean-contaminated surgeries post discharge was 15% (95% CI 6–27%), as compared to only 5% for those with no post-discharge surveillance [33].

EPIDEMIOLOGY:

Even preventive measures sometimes cannot mitigate infection and may lead to unforeseen circumstances, an SSI, leading to surgical revision, rehabilitation, prolonged treatment, lost work and productivity, substantial outcome burden. Every affected individual on an global estimate squanders $15,800-$43,900 in financial resources [33]. An approximation affirms 157,000 patient morbidity, with an estimated mortality of 8,205, 11% of all deaths in intensive care units associated to SSI. Furthermore, contributing to about 3.3 $ billion to nations GDP in the US [1,23]. 14-16% of patient bed occupancy in secondary and tertiary care hospitals are as a direct consequence of HCAI, of which 38% begins following skin perforation for ensuing surgical mechanics, 2nd most prevalent cause of hospitalization. In the European Union, an annual expedite of 19 $ million is spent treating SSIs [26,28].

ETIOLOGY AND RISK FACTORS:

Platter of risk factors that a patient ought to experience first hand categorized either as patient related or procedural related. The heterogeneity of the clinical pathogenesis of these infections vary from geographical limitations till genetic susceptibility and everything between. Patient related factors simmers down to Advancing age, nutritional status, coexisting infection at a remote site, colonization with a pathogenic microorganism, wound classification, comorbidities (Diabetes; especially when not under robust surveillance, obesity), jeopardized immune status, alcohol and substance abuse, Cigarette smoking. Procedural factors have in their arsenal, Duration of surgery, formation of a hematoma, the use of foreign material as drains, leaving dead space, prior infection, surgical paraphernalia as duration of surgical scrub, poor skin preparation, skin preparation timing, poor choice of surgical approach and execution of surgical skills,

hypothermia, contamination from the operating room, prolonged perioperative care and stay in hospital, ASA classification [1,4,12,19,17,27,28,32,35]. As aforementioned relation between risk evaluation and wound standard/ description has been established, as such in a numerical data presented as

Table 2: Risk of SSI according to wound category

Wound category	Risk of SSI (%)
Clean	1.3-2.9
Clean contaminated	2 .4-7.7
Contaminated	6.4-15.2
Dirty contaminated	7.1-40

(27

PATHOPHYSIOLOGY:

The preliminary criterion for an SSI to be diagnostically accurate is the presence of an invading microorganism that has to either be of Endogenous or exogenous origin. The patient's skin, mucous membranes (eg:- nasal reservoir) and viscous organs of the hollow viscera are the principal agents in context to Endogenous flora. The most common culpable organisms include: - *S. aureus*, coagulase-negative staphylococci, *Enterococcus*, and *Escherichia coli*. However, these claims are procedure dependent. In cardiac, breast, ophthalmic, orthopedic, and vascular surgeries, frequently *S. aureus* and coagulase-negative staphylococci, while Gram-negative bacilli and anaerobes are more likely to prevail in given instances of exposed colon or rectal surgical manipulations (constitute Clean- contaminated cases – no precipitous preexisting abdominal infection).Exogenous flora, residential organisms of otherwise everyday

microbiome but have latent pathogenetic traits, staphylococci and streptococci are some common examples. Although the spectrum of microorganisms wreaking havoc has more or less stayed stagnant throughout decades, increase in their resistance to antibiotics is more of a reason for the shifting concerns. Example Methicillin resistant staphylococcus aureus (MRSA) and some opportunistic fungi [1,10,19].

PREVENTION AND MANAGEMENT:

Measures that stall the progress of the infection are always first sought after. Prevention strategies need to be multimodal and compliant to standard guidelines. SSI related mortality and morbidity consumes an awful lot of resources that may have had potential utility elsewhere medically, but also has a negative impact on patient‘s financial and socio-economic attribute; Hindrance to general well being and health, loss of productiveness, decreased morale, towering expenditure on medical bills to name a few.

Some pre-established methods of preoperative approach to manipulate the standard course of microbial action to a safer endpoint includes Skin preparation, theater sterility rules, perioperative antibiotic-prophylaxis and dressings [1,13]. Essentially the role of antibiotics on prophylactic occasions is to supplement the host defenses, help reduce the bacterial load, maintain fairly toxic levels of MIC in tissue of interest (15,17). CDC guidelines highlight the use of narrow coverage antibiotics that too for the shortest of the effective therapeutic time slots possible, to be administered somewhere between 30-60 min prior the exposure of visceral contents via skin incision thereby giving a greater allowance on tissue distribution [1,19]. Clean-contaminated and contaminated cases are liable to prophylactic routines, but not so true in case of dirty cases since the influence of antibiotics is just but therapeutic [19,21].

For clean-contaminated procedures, coverage for Staphylococci in addition to the surgery and geography prophylaxis is necessitated. Cefazolin 2g - 2nd Gen. Cephalosporin (weight-adjusted) or Vancomycin 15 mg/kg plus metronidazole, Cefoxitin, or ertapenem forms the 1st line of defense protocol wise. The success of such procedures depends on the wise selection, timing, quality of dosing. Wide spectrum drugs generally are reserved as plan b considering the probability of developing microbial resistance. Furthermore, it is mandated to provide an optimal tissue concentration that neither leads to sub-

therapeutic response nor elevates the chances of resistance. Finally, prophylactic measures are not supposed to substitute a proper aseptic technique disposal but an additional line of reinforcement to alleviate the risk of infection [19,21,26].

Prescribed antibiotics for surgical prophylactic care

Table 3: Antibiotics prescribed for surgical prophylaxis

Type of procedure	**Recommended agents**	**Recommended agents in case of β-lactam allergy**
Gastroduodenal (either involving entry into lumen of gastrointestinal tract or not)	Cefazolin	Clindamycin or vancomycin + gentamicin or aztreonam or levofloxacin
Small intestine Non-obstructed Obstructed	Cefazolin Cefazolin + metronidazole Cefoxitin Cefotetan	Clindamycin + gentamicin or aztreonam or levofloxacin Metronidazole + gentamicin or levofloxacin
Appendectomy for uncomplicated appendicitis	Cefoxitin/ Cefotetan/Cefazolin + metronidazole	Clindamycin + gentamicin or aztreonam or levofloxacin Metronidazole + gentamicin or levofloxacin
Colorectal †	Cefazolin + metronidazole Cefoxitin Cefotetan Ampicillin/sulbactam, Ceftriaxone + metronidazole Ertapenem	Clindamycin + gentamicin or aztreonam or levofloxacin, Metronidazole + gentamicin or levofloxacin

LITERATURE REVIEW

Sl.No	Authors name	Year	Study title	Findings of the study
1	Musmar SM et al	2014	Adherence to guidelines of antibiotic prophylactic use in surgery: a prospective cohort study in North West Bank, Palestine. BMC surgery.	carried forward a prospective cohort of 400 abdominal, orthopedic and OB GYN patients, of a tertiary care hospital in Palestine and established a result of low compliance (2%); 59.8% appropriate first dose timing, 18.5% had appropriate antibiotic selection, and 31.8% appropriate duration. Male patients consequently faced less adherence to timing but better selection compared to females.
2	Bocard E et al	2023	Antibiotic prophylaxis for surgical procedures: A scoping review. Revista Panamericana de Salud Pública.	evidently supports the role of preoperative prophylaxis in preventing SSI, while attributing no credit whatsoever to antibiotics after surgery.
3	Sun H et al	2023	Analysis of risk factors for surgical site	E. coli was discovered to be the dominating

			infection after colorectal surgery: a cross-sectional study in the east of China pre-COVID-19. Frontiers in Public Health.	organism causing SSI in Colorectal surgery. Incidence trend follows 13.3% to 3.56% from 2010 to 2019, with rise in resistance strains noted
4	Zabaglo M et al	2022	Postoperative wound infection.	disclosed emergent information on postoperative wound infection, etiopathophysiology, prevention and management.
5	Anand S et al	2019	Antibiotic prescription practices for surgical prophylaxis in India: An observational study.	a retrospective basis of around 1012 patients (2019), at a three-point study in India, reporting injudicious use and poor adherence to IDSA norms

6	Alemkere G et al	2018	Antibiotic usage in surgical prophylaxis: A prospective observational study in the surgical ward of Nekemte referral hospital.	The use of compliant antimicrobial strategies by physicians in up to 10.6% of cases and almost 53.2% were continued for >24hrs. Also, male patients were more likely to be exposed to irrational treatment and timing.
7	Stefánsdóttir A et al	2009	Inadequate timing of prophylactic antibiotics in orthopedic surgery. We can do better. Acta orthopaedica	how a simple checklist can do as much as bar the falling standards of aseptic and septic techniques with respect to prophylactic antibiotics in knee arthroplasties, conducted over at Lund University, Sweden currently stating an average of 15-45 min prep time.
8	Baseel D et al	2022	The Ideal Time to Administer Preoperative Antibiotics: Current and Future Practices. Cureus.	Pinpointing an ideal time to administration of antibiotics, context to MIC, peak serum levels, appropriate redosing of Cefazolin and clindamycin was addressed to be 40 min and 45 min respectively

9	Poggio JL et al	2013	Perioperative strategies to prevent surgical-site infection. Clinics in colon and rectal surgery	an evidence-based review and compliance study on SCIP (Surgical care improvement program).
10	Wolfhagen N et al	2022	Intraoperative redosing of surgical antibiotic prophylaxis in addition to preoperative prophylaxis versus single-dose prophylaxis for the prevention of surgical site infection: A meta-analysis and GRADE recommendation. Annals of Surgery.	pooled odds ratio with 0.47 (95% CI) for 2 RCTs and 0.55% (95% CI) for 8 cohorts comparing redosing to single dose.
11	Ratnesh K et al	2022	Incidence of Surgical Site Infections and Surgical Antimicrobial Prophylaxis in	a cross-sectional study outcome attributed a 2.6 times higher SI rate in emergency

			JNMC, Bhagalpur, India.	surgeries and 2.6 times higher SSI rates in absence of any prophylaxis.
12	Freitas AC et al	2023	ANTIBIOTIC PROPHYLAXIS FOR ABDOMINAL SURGERY: WHEN TO RECOMMEND? BRAZILIAN COLLEGE OF DIGESTIVE SURGERY POSITION PAPER. ABCD. Arquivos Brasileiros de Cirurgia Digestiva (São Paulo).	ÀMP is necessary especially in clean contaminated and contaminated cases, whereas they exhibit a rather therapeutic credit than prophylaxis in dirty cases. Also, to keep in mind patient and prodigal risk factors.
13	Kumar A et al	2017	Prevalence of surgical site infection in general surgery in a tertiary care center in India.	retrospective analysis allocated 17.7% of SSI to emergency surgeries as compared to 12.5% of elective surgeries from data outcome from RIMS, Ranchi. Also, SSI chronology rate wound wise superficial>Deep organ>Organ space.
14	Tolba YY et al	2018	An observational study of perioperative antibiotic-prophylaxis use at a major quaternary care and referral hospital in Saudi Arabia. Saudi Journal of Anesthesia.	Identified a gap between the international guidelines and the recommended prescribing patterns in their retrospective database retrieved from a tertiary/quaternary care hospital in Saudi Arabia.

15	Bhangu A et al	2018	Surgical site infection after gastrointestinal surgery in high-income, middle-income, and low-income countries: a prospective, international, multicentre cohort study. The Lancet Infectious Diseases.	collaborative data (2018) from 66 countries found LMIC's showcasing highest incidents and resistance reinfections of 23.2% and 35.9% respectively amongst Higher and Middle-income countries.
16	Alemu ET et al	2021	Perioperative management of adult surgical patients with septic shock in resource limiting setting, systematic review.	systematic review data utilizing PRISMA protocol to state that septic shock is a factor to multitude of organ dysfunction, especially in low socioeconomic settings, but planned perioperative management has the potential to reduce health care burden.
17	Haidar YM	2018	Antibiotic prophylaxis in clean-contaminated head and neck cases with microvascular free flap reconstruction: a systematic review and meta-analysis. Head & neck.	timing of antibiotic prophylaxis less than or equal to 24 hrs. had no landslide of a significance if the choice was right, further clindamycin prophylaxis was associated with increased RR of 2.85 compared to Ampicillin-sulbactam.
18	Jacques PS et al	2005	Improving timely surgical antibiotic	The utility of a computerized reminder system

			prophylaxis redosing administration using computerized record prompts. Surgical infections.	in connection to Anesthesia chatting system to prevent omitting unintentional redosing in lengthy cases of cardiac surgeries
19	Enzler MJ et al	2011	Antimicrobial prophylaxis in adults. InMayo Clinic Proceedings	Perioperative antimicrobial prophylaxis on various diseases, rheumatic fever, recurrent cellulitis, in women, bacterial peritonitis in patients with pertussis to name a few and comprehensive details on optimal timing, duration to provide required therapy which is cost efficient.
20	Hou Y et al	2023	Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surgery Open Science.	A retrospective analysis to calculate propensity score and incremental LOS linking financial expenditure averaged between $18626 to $20,979 respectively for Medicare and Premier Open surgeries
21	Habteweld HA et al	2023	Surgical site infection and antimicrobial prophylaxis prescribing profile, and its determinants among hospitalized patients in Northeast Ethiopia: a hospital based cross-	Multivariate regression model to estimate a frequency of about 62.2% inappropriate antibiotic selection and a 3.39 times higher probability of catching an SSI in procedures

			sectional study. Scientific Reports.	lasting more than an hour.
22	Takesue Y et al	2008	Guidelines for implementation of clinical studies on surgical antimicrobial prophylaxis (2007)	Comprehensive guidelines and regulations concerning surgical antimicrobial prophylaxis (SAP), classification and management of SSI
23	Mohan N et al	2023	Prevalence and Risk Factors of Surgical Site Infections in a Teaching Medical College in the Trichy District of India	5.6% prevalence rate predominantly abdominal (61.2%), age group at 16-24 following emergency cases serving more as a threat compared to elective procedures.
24	Hassan RS et al	2020	Incidence and root causes of surgical site infections after gastrointestinal surgery at a public teaching hospital in Sudan. Patient Safety in Surgery	A high prevalence of SSI was justified by an outcome of 27.5% out of 80 patients, microorganism isolated typically were *E coli* (47.8%), followed by *Enterococcus faecalis* (13.0%) and combined *Pseudomonas aeruginosa* + *E coli* infection (13.0%).
25	Curcio D et al	2019	Surgical site infection in elective clean and clean-contaminated surgeries in developing countries.	Funnel plot test aggregated a prevalence rate of 10% (95% CI 6–15%), 7% (95% CI 5–10%), 4% (95% CI 4–5%), and 4% (95% CI 2–6%), respectively in Africa/Middle East, Latin America, Asia, and China

26	Epstein NE et al	2018	Preoperative measures to prevent/minimize risk of surgical site infection in spinal surgery.	While, the importance of preoperative and intraoperative maneuvers was elucidated by Nancy E Epstein in her review article on elective spinal surgeries (2018).
27	Bratzler DW et al	2013	American Society of Health-System Pharmacists; Infectious Disease Society of America; Surgical Infection Society; Society for Healthcare Epidemiology of America. Clinical practice guidelines for antimicrobial prophylaxis in surgery	The functionality of automated computerized reminders to anesthesiologists for timely IP redosing amidst various antibiotic regimens.
28	Phillips M et al	2014	Preventing surgical site infections: a randomized, open-label trial of nasal Mupirocin ointment and nasal povidone-iodine solution. Infection Control & Hospital Epidemiology.	A multifaceted open label RCT to compare action of Mupirocin vs nasal providing iodine solution at restricting S. aureus proliferation to deep organ SSI, deemed successful at 5 in 763 vs 1 in 776 arthroplasties respectively
29	Abe T et al	2019	Implementation of earlier antibiotic administration in patients with severe sepsis and septic shock in Japan: a descriptive analysis of a prospective observational study. Critical Care	highlighted a significance between hospital mortality and earlier administration of antibiotics, 30-60 min vs 60-120 min had an infection rate of 28% and 20.2% respectively.

30	Ahmed N et al	2022	Antibiotic usage in surgical prophylaxis: A retrospective study in the surgical ward of a governmental hospital in Riyadh region.	discrepancy amongst recommended guidelines and medical prescribing practices in the Riyadh region of Saudi Arabia, thus raising a question upon medical judgment and rational drug use.
31	Zanetti G et al	2001	Intraoperative redosing of cefazolin and risk for surgical site infection in cardiac surgery.	A retrospective outcome of 16% reduction in SSIs Cefazolin (2nd generation cephalosporin) for surgeries lasting >400 min.
32	Holtom PD et al	2006	Antibiotic prophylaxis: current recommendations.	60 min prior skin incision dispension, its continuation post 24 hr. duration. Addressed the conflicting ideologies in surgical gunshot wound SAP for 48-72 hrs.
33	Holzheimer RG et al	2001	Antibiotic prophylaxis	Individually set the medical map of AMP in context to different SSI procedures.
34	Crader MF et al	2022	Preoperative antibiotic prophylaxis	etiopathophysiology, risk factors, treatment etc.
35	Meijs AP et al	2019	Prevalence and incidence of surgical site infections in the European Union/European Economic Area: how do these measures	applied the concept of point prevalence survey (PPS) to measure HCAIs in national and multi-country settings using Rhame and

			relate?	Sudderth (R&S) formula, found reliable only if population size was large, incidence surveillance data unavailable or specialty specific data needed.
36	R. Gupta et al	2000	Antibiotic prophylaxis for post-operative wound infection in clean elective breast surgery.	Septic cases are guided through the lane of regulations laid by SOFA/ Sequential organ failure assessment, as defined in the Sepsis 3 provided by the SCC infections, 2016. Sepsis followed by septic shock contributes to about 40% mortality rates in hospitals in Europe and the USA. Ideally, an antibiotic regimen needs to be initiated within an hour before surgery to avoid debilitating and potentially detrimental consequences.
37	Shridhar D. Baliga et al	2014	The Evaluation of Efficacy of Post-Operative Antibiotics in the Open Reduction of the Zygomatic and Mandibular Fracture: A Prospective Trial,	Randomized controlled trial in antibiotic prophylaxis of clean, elective Breast surgery via simulated analysis of 340 eligible patients, found minimal difference in control as opposed to placebo group rendering a statistical significance of no paramount

				significance of 17.7% to 18.8% respectively.
38	Siddharth Dugar et al	2020	Sepsis and septic shock:Guideline-based management.	In a prospective randomized trial of 300 patients undergoing clean-contaminated surgery, highlighted a trivial significance in SSI rates between preoperative and intraoperative antibiotic administration. But rather a notable ordeal of reduction in the incidence of wound complications in the intraoperative group was demonstrated.

39	Claudia C Orelio et al	2020	Antibiotic prophylaxis for prevention of postoperative wound infection in adults undergoing open elective inguinal or femoral hernia repair.	Compared preoperative and intraoperative antibiotic prophylaxis in 334 patients undergoing dental implant. But managing to correlate the incidence of SSIs or wound complications opposed to the two groups. Yet still managing to associate lower risk of adverse events to intraoperative prophylaxis.
40	Wolfhagen et al	2022	Intraoperative Redosing of Surgical Antibiotic Prophylaxis in Addition to Preoperative Prophylaxis Versus Single-dose Prophylaxis for the Prevention of Surgical Site Infection : A Meta-analysis and GRADE Recommendation,	A Japanese study on implementation of earlier preoperative antibiotics substantiated on a median value of 102 min. (IQR 55-89), but no relation in earlier administration as opposed to reduction in hospital mortality in severe sepsis was established.

AIM AND OBJECTIVES

AIM AND OBJECTIVES

AIM:

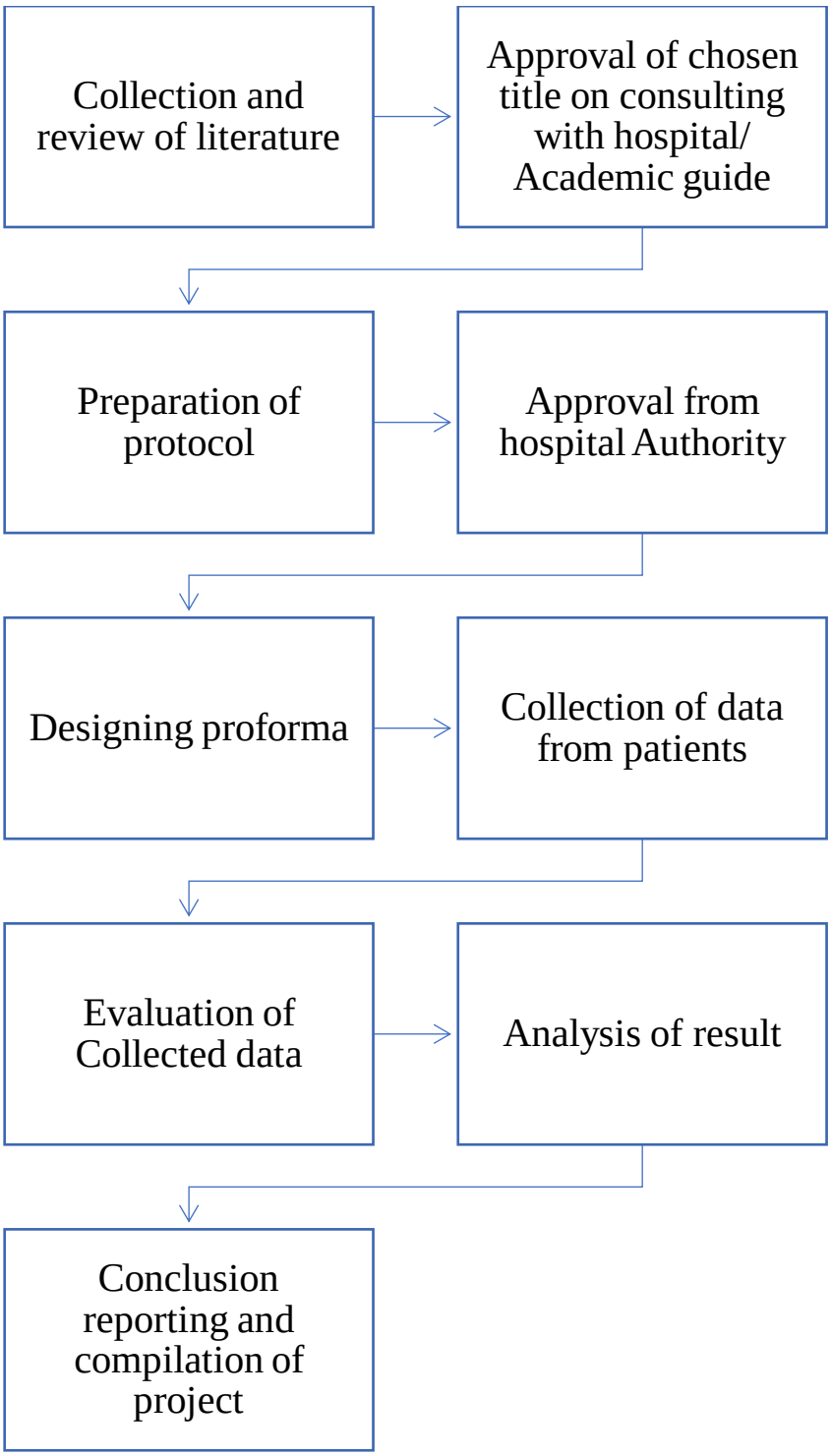
To evaluate the effects of First dose antibiotic prophylaxis on clean contaminated septic patients upon incidence of Postoperative infections when given enroute Skin incision vs intraoperatively.

OBJECTIVES:

- To evaluate the effects and responses of First dose antibiotic prophylaxis, primarily on the incidence of postoperative infections, the length of hospital stays, and the overall recovery time.
- To rule out valuable insights concerning the effectiveness of antibiotic prophylaxis in preventing postoperative infections thereby helping clinicians make graduated decisions while opting for the route of administration.
- To help develop evidence-based recommendations for the optimal use of antibiotics in preoperative care.

PLAN OF WORK

PLAN OF WORK


Collection and review of literature
Approval of chosen title on consulting with hospital/ Academic guide
Preparation of protocol
Approval from hospital Authority
Designing proforma
Collection of data from patients
Evaluation of Collected data
Analysis of result
Conclusion reporting and compilation of project

MATERIALS AND METHODS

MATERIALS AND METHODS:

STUDY SITE: The proposed study proceeded with all regards to respective community guidelines in the Tiruppur Government Medical College.

DEPARTMENTS: Department of General Surgery
STUDY DESIGN: Prospective longitudinal study
STUDY DURATION: The study followed a 6-month timeline (with 3 months for interim analysis).

SAMPLE SIZE :110

Study criteria:

Inclusion Criteria:

1. Patient age group 15 - 80 years
2. Both genders.
3. Surgical post-operative patients prophylactically treated to subdue infection.
4. Clean contaminated surgical cases.
5. Patients who require follow up until 1st week of duration post operatively.
6. Patients with controlled hypertension/Diabetes mellitus.

Exclusion criteria:

1. Pregnant and lactating mothers.
2. Pediatric patients.
3. Patients with immuno-compromising status.
4. Patients discharged before or not reporting for follow until 1st week of duration.

STUDY PROCEDURE:

The chronological order that alleviates the flow of information was organized and stated below: -

- Potential list of patients' due surgery was collected and listed via prior permission from the Surgical asst. stationed on duty.
- Patients or their respective guardians are met in person and the study, its purpose explained.
- Adequate data was collected following the patient's valuable consent on the grounds of surety that it will not be misused, as required.
- Answers to questionnaires curated to the needs of the study and patient's convenience were collected via mentioned in the pro- forma.
- Whilst this process patients are also entitled to skip the study on their independent will.
- The information had been collected every 3 weekdays preceding surgery.
- This trend had continued until procurement of said number of pre calculated individual case sheets.
- Responses generated have been noted and carefully applied, evaluated and tabulated.
- Tabulated dataset was statistically analyzed using Fisher's test and comparison of results has been established.

SEARCH STRATEGY:

We searched the PubMed, Elsevier and Google scholar database from inception until 10th of September, 2023, using the keyword "Surgical site infection" combined to the following

"clean contaminated cases", "preoperative antibiotic prophylaxis", "intraoperative redosing", "SSI incidence and prevalence", "risk factors", "wound classification", "Skin incision". There was no restriction on selection of study type, language and date published. A total of 160 articles were analyzed, of which 50 were comprehensively reviewed all sourced from aforementioned databases.

DATA COLLECTION AND ANALYSIS:

The 6 surgical wards of the GMCH, Tiruppur were screened for clean contaminated cases in the postoperative section both male and female. A total of n=110 cases of surgery were collected, Elective and emergency cases were both sought after. Respective patient consent to data collection, manipulation, calculation and publication was also acquired. For the next 6 months, post ethical committee allowance procurement the mentioned routine was followed. The collected dataset was then double checked for duplication of data. Then, it was accordingly arranged in context to gender and age wise population distribution, mean age, SSI frequency distribution, antibiotic selection, rate of redosing, disease wise and prophylactic procedure wise SSI frequency distribution. This information was compiled onto a category wise distributed spreadsheet.

RESULTS

RESULTS:

The Tirupur Government Medical College and Hospital served as the site of the investigation. One hundred ten patients in total participated in the trial and gave their written authorization. They were chosen depending on the surgical wound categorization, which only comprised clean contaminated cases. Prior to and following surgical procedures, the patients were observed. Every patient was followed for at least a week subsequent surgery. Male and female patients above the age of 18 were considered. Comorbid illnesses in patients were not included.

The Beta-lactam antibiotics were most frequently used for prophylaxis, with cefotaxime accounting for 75% of all usage. The incidence of surgical site infections was lower in our observational study when preoperative antibiotics were used in combination with redosing administration than when preoperative antibiotics were solely administered for thirty minutes prior to the skin incision.We discovered that 73.6% of the 110 patients in our study were men and 26.4% were women. In the gender-based classification indicated above, SSI affected 4.2% of male patients and 2.5% of female patients. The comparison showed that men were more likely than women to receive an SSI diagnosis.

According to our findings, surgical procedures involving adults over the age of 50 comprised a higher percentage than those involving people in other age categories. Age classification indicates that 50% of persons who have reached the age of 50 or older are more likely to have SSI than people in other age groups.When antibiotics were just administered as a preoperative dose for prophylaxis, the SSI was found to be 5.9%, in contrast to redosing, when the SSI was found to be 0.9%, showing the lowered rate of SSI in patients.

Table 4: SSI Frequency and Percentage rate in various parameter:

PARAMETERS		n= 110	Frequency (in %)	SSI Frequency	Infection %
Gender	Male	81	73.6	5	62.5
	Female	29	26.4	3	37.5
Age (in years)	<20	8	7.3	1	12.5
	21 - 30	25	22.7	1	12.5
	31 - 40	27	24.5	2	20.0
	41 - 50	23	20.9	Nil	Nil
	>50	27	24.5	4	50.0
Type of antibiotic	Cefotaxime	89	80.9	6	75.0
	Ceftriaxone	21	19.1	2	25.0
Prophylactic procedure	Preoperative	70	63.64	7	87.5
	Redosing	40	36.36	1	12.5
Type of surgery	Elective	20	18.18	1	12.5
	Emergency	90	81.81	7	87.5

Gender - wise distribution:

Figure 1: the ratio of genders who underwent clean contaminated surgical procedure

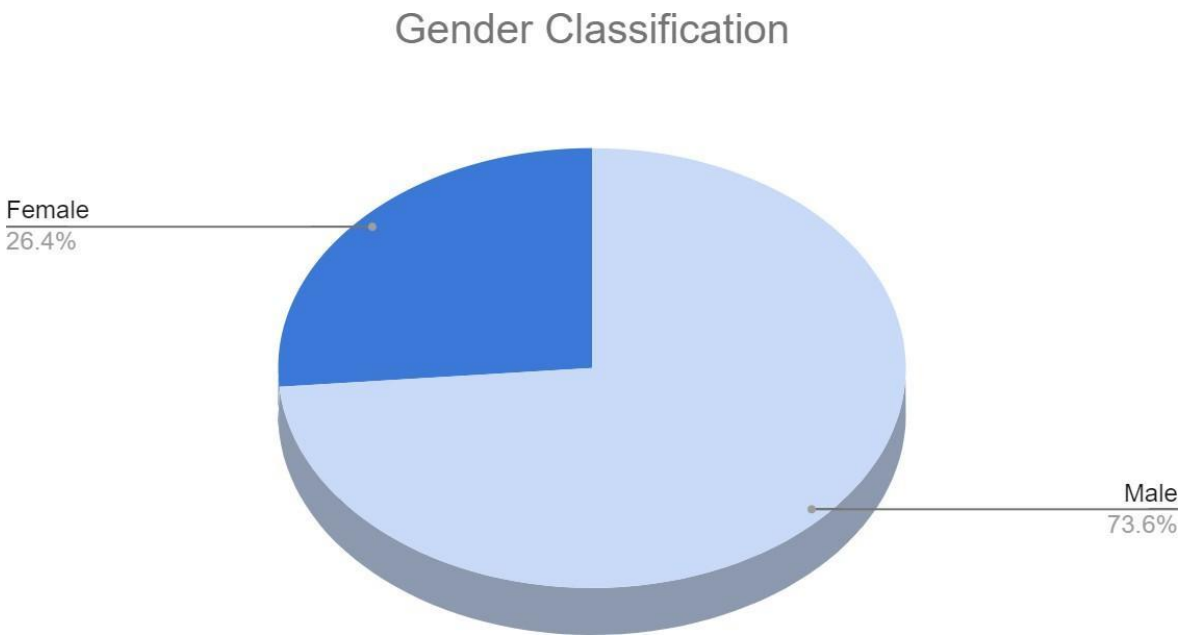
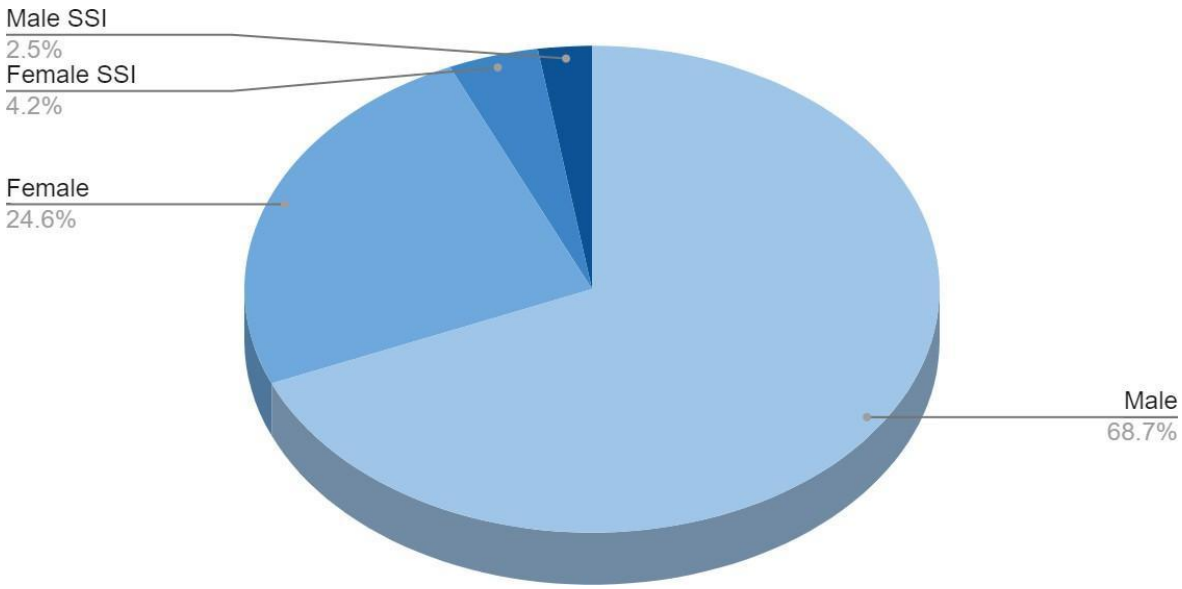


Table 5: SSI based on gender

Gender	*Presence of SSI*	Total Population
Female	No	26
	Yes	3
Female Total		29
Male	No	76
	Yes	5
Male Total		81
Grand Total		**110**

Figure 2: SSI incidence in both the male and female demographic



Out of 110 patients in our study, we found that 73.6% were men and 26.4% were women. In the previously mentioned gender-based classification, SSI impacted 4.2% of male patients and 2.5% of female patients. According to the comparison, men were more likely than women to be diagnosed with SSI.

Age wise distribution:

Table 6.1 and 6.2: Ratio of SSIs in the different age groups and respective mean

Table 6.1

Age	**n=110**	**Mean age**
<20	8	18.375
21 - 30	25	25.44
31 - 40	27	34.88
41 - 50	23	46.347
>50	27	61.74

Total mean = 40.52

Table 6.2

Age(in years)	Frequency of SSI	Percentage (%)	Mean age
<20	1	12.5	18.375
21 - 30	1	12.5	25.44
31 - 40	2	25.0	34.888
41 - 50	0	0	46.347
>50	4	50.0	61.74

Figure 3: shows the histogram frequency of clean contaminated surgery performed on different age groups

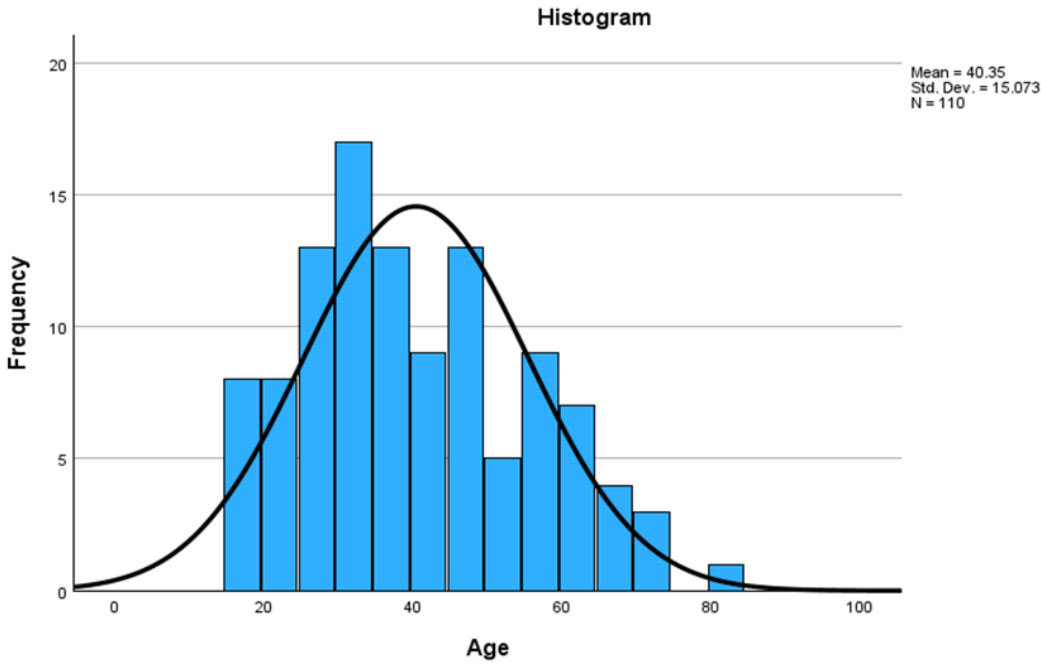


Figure 4: shows the age wise distribution frequency for clean contaminated surgical procedures

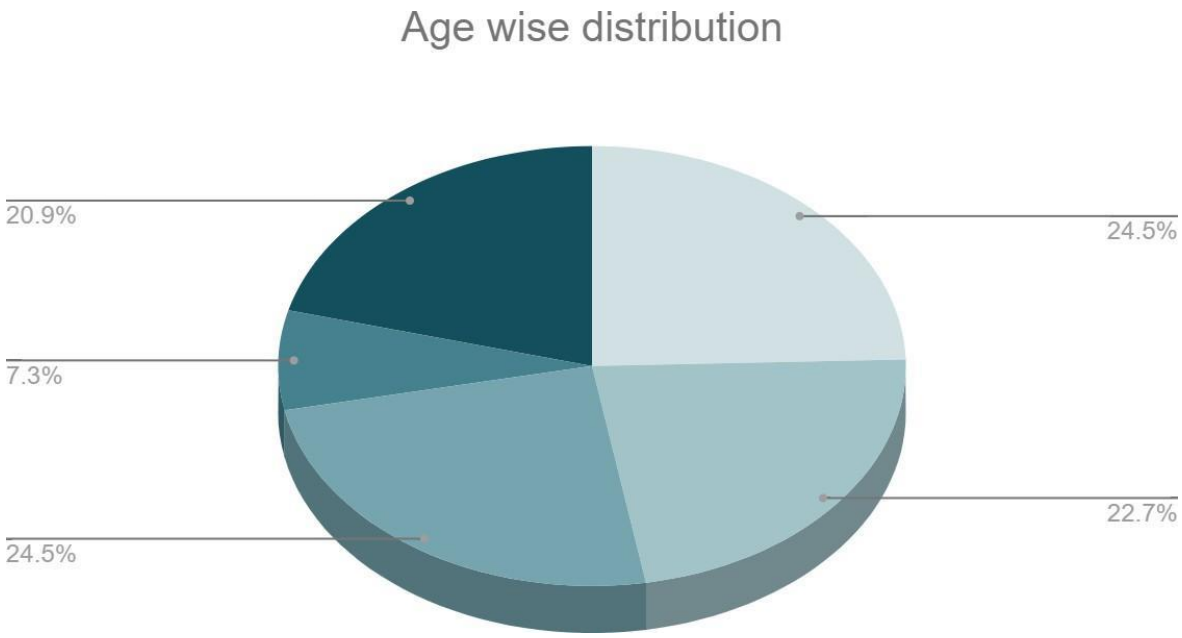
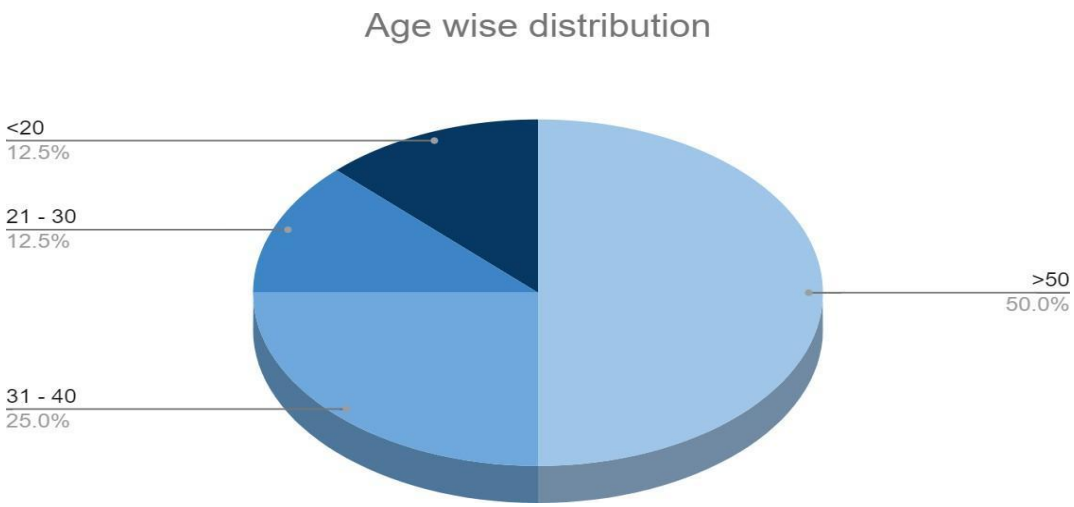


Figure 5: shows the ratio of SSI observed in different age



In accordance to our observations, compared to other age groups, people over the age of 50 formed a greater percentage of surgical procedures. According to age classification, 50% of people who have reached over 50 years old are more likely to have SSI than individuals of other age groupings

BMI:

Figure 6: shows the BMI

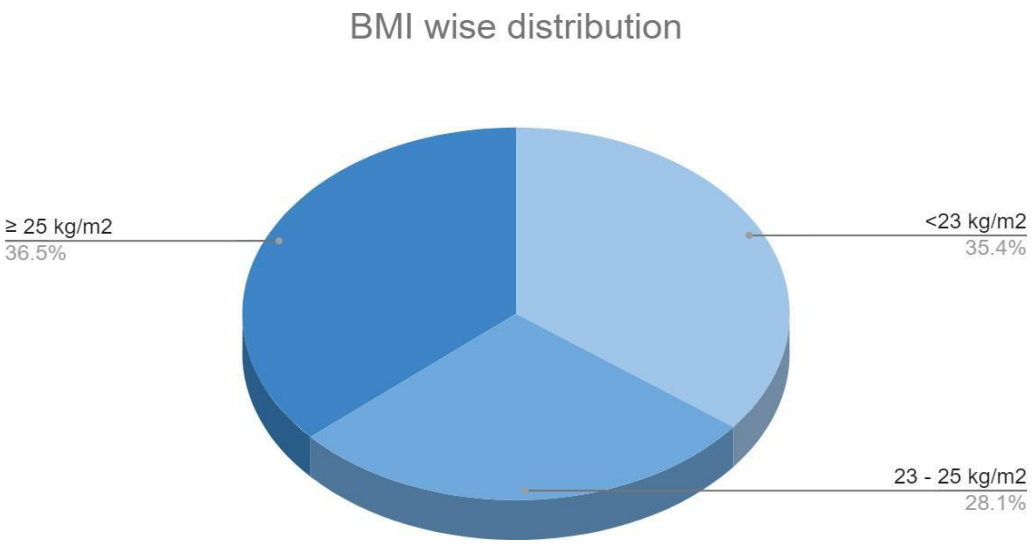


Table 7: shows the BMI mean value with its frequency

BMI	n=110	Mean
<23	39	21.225
23 - 25	31	24.02
≥25	40	27.84

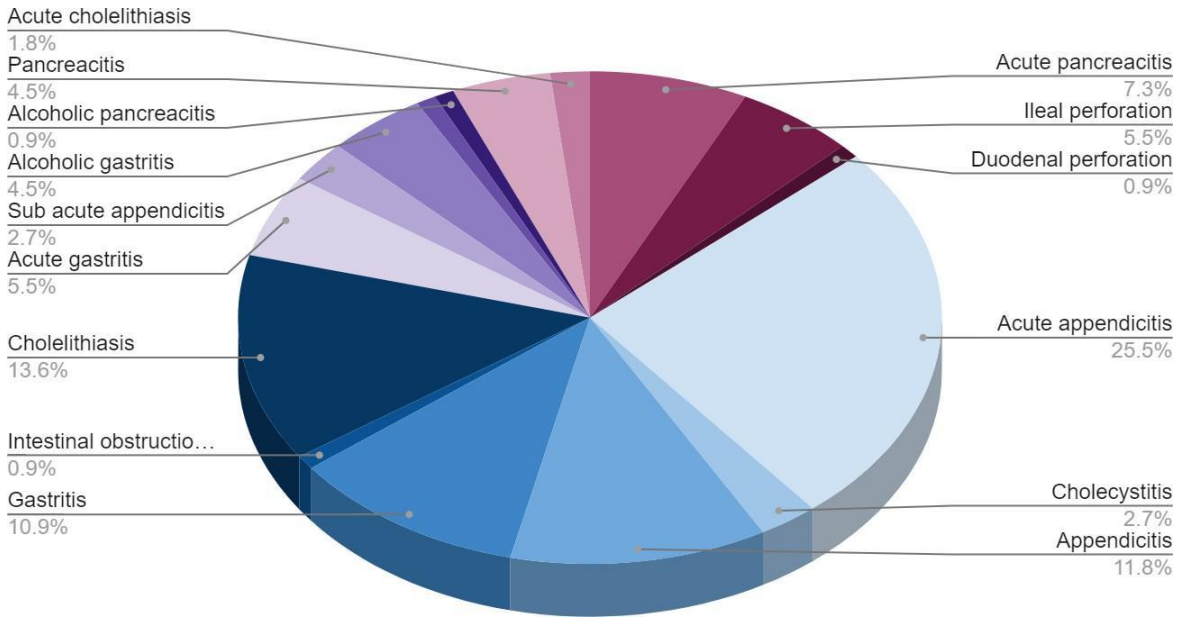
Based on the calculation on BMI ratio, 39 patients out of 110 had <23 kg/m^2, which is about 35.5% , 31 patients out of 110 had 23-25 kg/m^2 which is about 28.18% , 40 patients out of 110 had ≥ 25kg/m² which is about 36.3%

Various types of Surgical Condition:

Table 8: shows the Frequency of SSI with respect to surgical procedures that patients underwent

Disease	No	Yes	Grand Total
Acute appendicitis	26	2	28
Acute cholelithiasis	2		2
Acute gastritis	6		6
Acute pancreatitis	7	1	8
Alcoholic gastritis	5		5
Alcoholic pancreatitis	1		1
Appendicitis	11	2	13
Cholecystitis	3		3
Cholelithiasis	14	1	15
Chronic pancreatitis	1		1
Duodenal perforation	1		1
Gastritis	11	1	12
Ileal perforation	6		6
Intestinal obstruction perforation	1		1
Pancreatitis	4	1	5
Sub-acute appendicitis	3		3
Grand Total	102	8	110

Figure 7: shows the count of various type of surgical condition that were undergone for Clean contaminated surgery



Among the 110 patients in our study, 25.2% were affected by acute appendicitis, 13.6% by cholelithiasis, 11.8% by appendicitis, 10.9% by gastritis, 7.3% by acute pancreatitis, 5.5% by ileal perforation and acute gastritis, 4.5% by pancreatitis and alcoholic gastritis, 2.7% by cholecystitis and subacute appendicitis, 1.8% by acute cholelithiasis, and 0.9% by duodenal perforation, alcoholic pancreatitis and Intestinal obstruction perforation.

Type of antibiotic given:

Figure 8: shows the choice of antibiotics for the n=110 surgeries performed

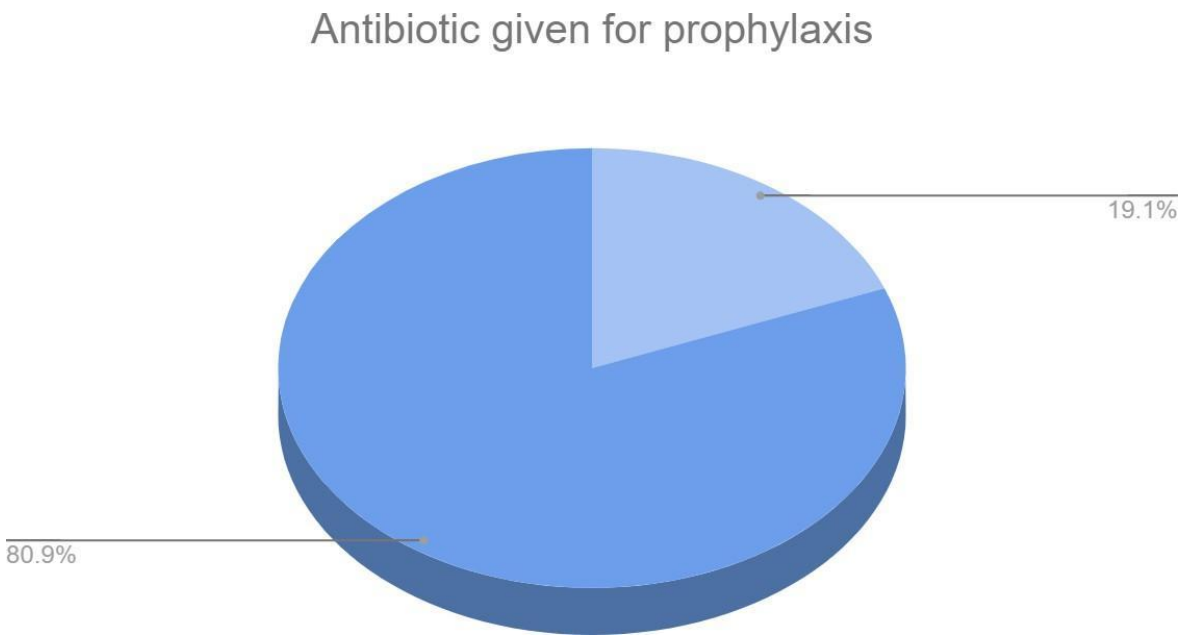
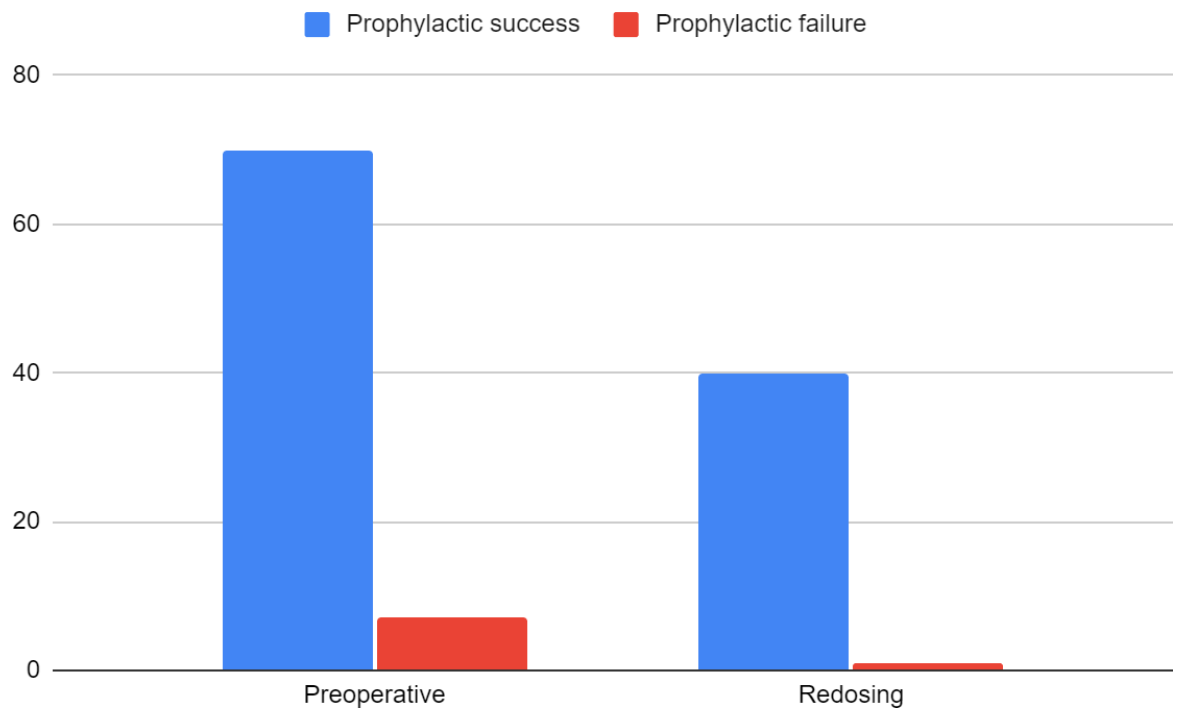


Table 9: shows the frequency of SSI in context to selection of antibiotic for prophylaxis

Antibiotic given	Frequency	Percentage	SSI Frequency	SSI Percentage %
Inj.Cefotaxime	89	80.9	6	75.0
Inj.Ceftriaxone	21	19.1	2	25.0

Figure 9: shows the rate of SSI frequency when given prophylactically single dose vs 2nd dose intraoperative Redosing



Out of 110 patients, we found that 8 individuals suffered SSI, of those, 6 had prophylactic injections of cefotaxime, while 2 patients received prophylactic injections of ceftriaxone.

Table 10: shows the rate of SSI frequency of prophylactic antibiotic given Preoperative and Redosing intra-operatively

Prophylactic Procedure	n=110	Percentage	SSI Frequency	SSI Percentage
Preoperative	70	63.64	7	87.5
Redosing Intraoperative	40	36.36	1	12.5

Surgical procedure:

Figure 10: shows the type of surgery procedure

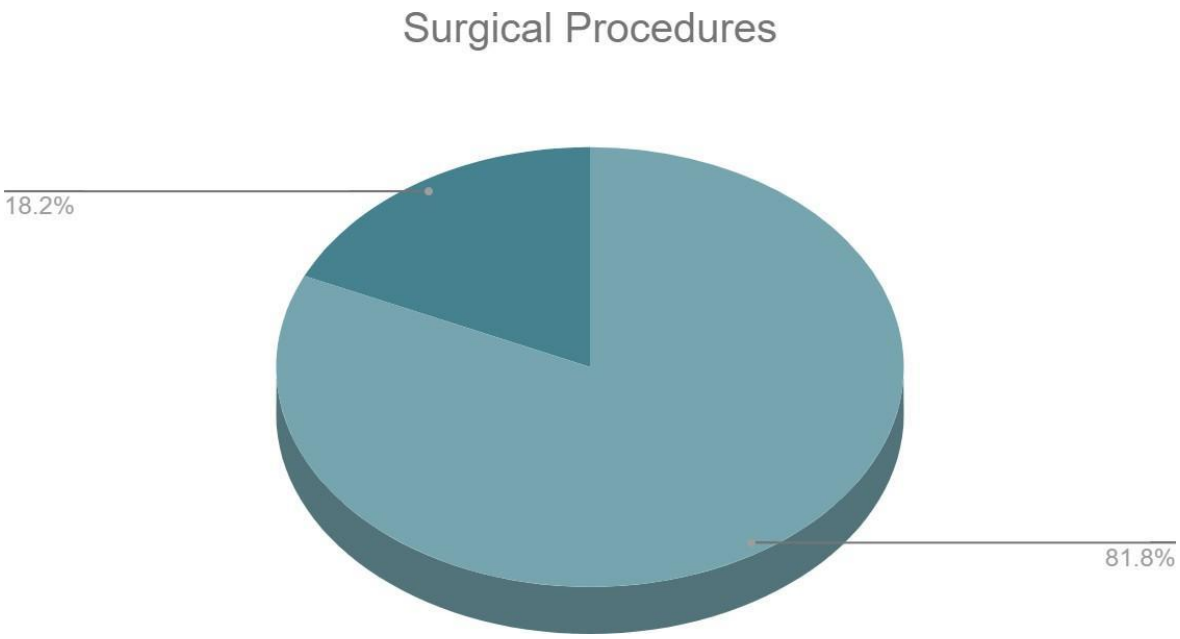


Table 11: shows the type of surgery and frequency of SSI

Type of surgery	n=110	Percentage%	SSI	SSI %
Elective	20	18.18	1	12.5
Emergency	90	81.81	7	87.5

Among 110 patients, it was observed that 18.2% had elective surgery while 81.8% had emergency type surgery.

Single dose prophylactic antibiotic administration vs. intraoperative Antibiotic redosing:

Figure 11: shows the frequency of SSI found in clean contaminated cases antibiotic given preoperative vs. redosing intraoperatively

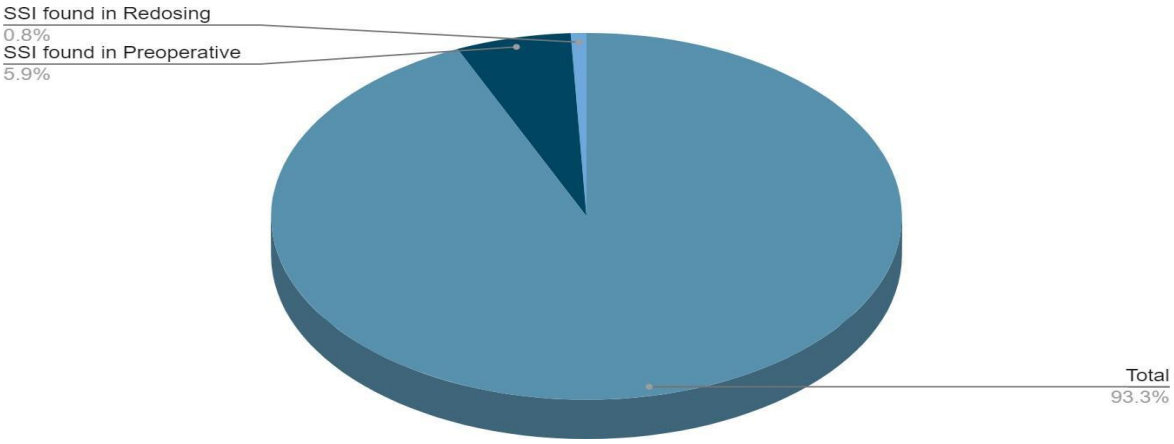


Table 12: shows the frequency of SSI found in clean contaminated cases antibiotic given ½ hour before skin incision vs intraoperatively

Preoperative	*Redosing*	SSI in Pre operative	SSI in Re dosing	SSI in Pre operative	SSI in Re dosing	SSI in Pre operative	SSI in Re dosing
No	No	102	102			102	102
	Yes			7	7	7	7

No Total		102	102	7	7	109	109
Yes	No			1	1	1	1
Yes Total				1	1	1	1
Grand Total		**102**	**102**	**8**	**8**	**110**	**110**

Table 13: shows the Percentage of SSI found in clean contaminated cases antibiotic given ½ hour before skin incision vs additional intraoperative redosing

SSI	*Antibiotic given Preoperative*	*Antibiotic given Redosing*	Antibiotic given for Preoperative	Antibiotic given for Redosing
No	1	1	35.45%	35.45%
	1 Total		35.45%	35.45%
	2	2	57.27%	57.27%
	2 Total		57.27%	57.27%
No Total			92.73%	92.73%
Yes	1	1	0.91%	0.91%
	1 Total		0.91%	0.91%
	2	2	6.36%	6.36%
	2 Total		6.36%	6.36%
Yes Total			7.27%	7.27%

According to the observation, the SSI was found to be 5.9% when single dose antibiotic given as prophylaxis, in contrast to redosing, where it was reported to be 0.9%, showing the decreased rate of SSI in patients.

Table 14: Age incidence

Age(in years)	Frequency of SSI	Percentage (%)	Mean age
<20	1	12.5	18.375
21 - 30	1	12.5	25.44
31 - 40	2	25.0	34.888
41 - 50	0	0	46.347
>50	4	50.0	61.74
			p-value = 0.000254 *t*-value = 5.6022

The *t*-value and *p*-value were found to be 5.6022 and 0.000254 respectively The result is significant at $p < 0.05$.

Table 15: shows the rate of SSI frequency of prophylactic antibiotic given Preoperative and Redosing intra-operatively

Prophylactic Procedure	n=110	Percentage	SSI Frequency	SSI Percentage
Preoperative	70	63.64	7	87.5
Redosing Intraoperative	40	36.36	1	12.5
				p-value = 0.0396 *t*-value = 3.33397

The *t*-value and *p*-value were found to be 3.33397 and 00396 respectively. The result is significant at $p < 0.05$

The results in the age group were statistically significant at a

$p = 0.000254$. While the outcomes of the single vs redosing group was also established to be significance at $p = 0.0396$ ($p < 0.05$)

DISCUSSION

DISCUSSION:

The population under survey (n=110 patients) for estimating the incidence of an infection of surgery site comparing Single dose prophylaxis to single dose and additional intraoperative redosing had a demographic distribution of 26.4% (n=29) females to 73.6% (n=81) males, revealing an effective ratio of 1:3 respectively in relation to the 6 months of data aggregation timeline, of which n=3 (out of 29 patients; 2.5%) and n=5 (out of 81 patients; 4.2%) were affected respectively which was in agreement with the results of Alemkere G et al, associating male gender to increased relative risk of infection compared to females [7].

The age incidence emerged to be 7.3% (<20), 22.7 (21-30), 24.5 (31-40), 20.9% (41-50), 24.5 (>50).

SSI amidst various age groups reported <20 (n=8, mean - 18.37, SSI - 12.5%), 21 - 30 (n=25, mean - 25.44, SSI - 12.5%), 31 - 40 (n=27, mean - 34.88, SSI - 25%), 41 - 50 (n=23, mean - 46.37, SSI - nil), >50 (n=27, mean - 61.74, SSI - 50%).

Amongst the survey population, their BMI index highlighted that most clean contaminated classes were from the category of Obese grade 2 and above i,e $\geq 25\ kg/m^2$ (n=36.3%), followed by <23 kg/m^2 (n=35.5%), 23 - 25 kg/m^2 (n=28.2%) with adjusted mean of 21.225, 24.02, 27.84 respectively.

The procedure wise surgery count calculated - 25.2% acute appendicitis, 13.6% cholelithiasis, 11.8% appendicitis, 7.3% acute pancreatitis and 4.5% pancreatitis co relating to 25%, 12.5%, 25%, 12.5% 12.5%, 12.5% respectively for incidence of infection.

Antibiotics administered were Cefotaxime (n=89), percentage wise frequency of 75% and Ceftriaxone (n=21) with a frequency of 25%.

All the cases gathered belonged to the clean contaminated wound segment, specifically abdominal surgeries which was also reported by M Nivitha and colleagues during their quest to identify prevalence and risk factors reported an abdominal site surgical manipulation of about 61.2%.

Elective procedures had lower risk of infection rate of about 5% (n=20) compared to emergency procedures of 7.7% (n=90), reported similarly by Ansul K and Arpita Rai in their retrospective analysis in RIMS, Ranchi to be about 12.5 % and 17.7 % respectively

[34] and 2.6 times increment in emergency cases estimated by Ratnesh et al [26].

Apart from these, choice of antibiotics was compliant to the 2nd line of suggested international ASHP guidelines.

CONCLUSION

CONCLUSION:

In conclusion, this analysis at Tiruppur Government Medical College and Hospital found a number of significant parameters connected to SSI in clean contaminated surgical patients. These variables included age, gender, antibiotic prophylaxis regimens, and maybe BMI. The study suggests that combining antibiotic prophylaxis with redosing can significantly reduce the risk of SSI.

REFERENCE

REFERENCE

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ANNEXURE

ANNEXURES

GOVERNMENT MEDICAL COLLEGE,TIRUPPUR
INSTITUTION HUMAN ETHICAL COMMITTEE (IHEC)
PROVISIONAL REG. NO. EC/NEW/INST/2022/3218

Ref No.3019 /ME1/2023

Office of the Dean,
Government Medical College,
Tiruppur.
Dated.07.07.2023

To
Dr.D.Krishna Kumar, Prathiba.I, Ritu yadav.R,
Selshica.J, Shubhajit Paul,
The Erode College of Pharmacy,
Erode

Guide : Dr.Raju

Ref: Project No .**50/2023**

CERTIFICATE OF APPROVAL

The Institutional Ethics Committee of Government Medical College, Tiruppur reviewed and discussed application for approval of the proposal entitled **"A PROSPECTIVE STUDY ON THE EFFECTS OF FIRST DOSE ANTIBIOTIC PROPHYLAXIS GIVEN IN CLEAN CONTAMINATED CASES ADMINISTERED HALF AN HOUR BEFORE SKIN INCISION VS ADMINISTERED INTRAOPERATIVELY ON POSTOPERAIVE INFECTIONS"**

The above proposal was **approved** by the Ethics Committee Members.

The Institutional Ethics Committee expects to inform about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/ informed consent and to provide a copy of the final report.

Member Secretary
Ethics Committee
Government Medical College
Tiruppur - 641 608.

Chairperson
Ethics Committee
Government Medical College
Tiruppur - 641 608.

PRO-FORMA

A PROSPECTIVE LONGITUDINAL STUDY ON THE EFFECTS OF FIRST DOSE ANTIBIOTIC PROPHYLAXIS GIVEN IN CLEAN CONTAMINATED CASES ADMINISTERED HALF AN HOUR BEFORE SKIN INCISION VS ADMINISTERED INTRAOPERATIVELY ON POSTOPERATIVE INFECTIONS.

Name	
Age/Sex	
IP.no/Ward	
DOA	
DOS	
Weight	
Past medication history	
Past medical history	
Past Surgical history	
Blood group	
Allergy if any	
Comorbidities	

DATA COLLECTION FORM

CLINICAL EXAMINATION	
Temperature	
PR	
BP	
RR	
BMI	
Spo2	

INVESTIGATION	
Hb	
PVC	
Blood Sugar	
Blood Urea	
Sr.Creatinine	
Sr. Electrolyte	
WBC	
PLT	

QUESTIONNAIRES:

1.Do you suffer any pain/itching in the wound after surgery?

If yes, _____

2.Do you regularly follow your medication after surgery?

If yes,_____

3.Do you follow any specific diet pattern?

If yes,_____

4.Has the wound been smelly?

If yes,_____

TREATMENT CHART :

GENERIC NAME	**DOSE**	**FREQUENCY**	**ROUTE OF ADMINISTRATION**	**FOLLOW UP**

INFORMED CONSENT FORM

Title of the study: **A PROSPECTIVE LONGITUDINAL STUDY ON THE EFFECTS OF FIRST DOSE ANTIBIOTIC PROPHYLAXIS GIVEN IN CLEAN CONTAMINATED CASES ADMINISTERED HALF AN HOUR BEFORE SKIN INCISION VS ADMINISTERED INTRAOPERATIVELY ON POSTOPERATIVE INFECTIONS IN GOVERNMENT MEDICAL COLLEGE AND HOSPITAL, TIRUPUR**

Name of the participant:

Name of the guardian and relationship with the patient:

Name of the investigators: Prathiba I, Ritu Yadav R, Selshica J, Shubhajit Paul.

Name of the institution: THE ERODE COLLEGE OF PHARMACY AND RESEARCH INSTITUTE.

Study site: Department of Surgery, Tirupur Government medical college and hospital

Name of the guide: Dr. Krishna Kumar D, M. Pharm, Ph. D, HOD Clinical practice.

Name of the clinical guide: Dr. N. Raju, M.B.B.S, M.S, Asst. professor., Tirupur GMCH.

Name and address of the sponsor/agency (if any):

Documentation of the informed consent of the guardian

I _____ have read the information in this form (or it has been read to me) and am willing to give my consent on _____ to be included as a participant as a

part of this study. I shall provide any required information that needs to be answered related to the investigation.

1. I have read this consent form and it was explained to me and understood the information provided to me.
2. The nature of the study was explained to me.
3. I have been explained my rights and responsibilities by the investigator.
4. I have informed the investigator about all the treatments the patient is taking or has taken in the past_____ months including my native (alternative) treatment.
5. I have been advised about the risks associated with the patient's participation in this study.
6. The patients have not participated in any research study within the past_____ month(s).
7. The patients have not donated the blood within the past_____ months- add if the study involves extensive blood sampling.
8. I am aware that we can opt out of the study at any time without any reason and this will not affect the patient's future treatment in this hospital.
9. I have understood that the patient's identity shall be confidential, if my data is presented publicly.
10. I have had my questions answered to my satisfaction.
11. I have decided to include my_____ in the research study.

Guardian's signature, name and date	Investigator's signature, name and date