

**A STUDY ON THE ANTI-BIOTIC SENSITIVITY PATTERN IN  
THE POST - OPERATIVE WARDS OF A TERTIARY CARE  
HOSPITAL IN ERODE**

Dissertation submitted to

**The Tamil Nadu Dr. M.G.R. Medical University, Chennai-32**

In partial fulfillment of the award of the degree of

**MASTER OF PHARMACY IN  
PHARMACY PRACTICE**

**Submitted by**

**Reg.No.26103187**

**Under the Guidance of**

**Mr. N. Venkateswaramurthy, M.Pharm.**



**DEPARTMENT OF PHARMACY PRACTICE  
J.K.K. NATTRAJA COLLEGE OF PHARMACY  
KOMARAPALAYAM – 638 183  
TAMILNADU SEPTEMBER – 2013**

*Certificates*

# EVALUATION CERTIFICATE

This is to certify that the dissertation work entitled “**A study on the Anti-biotic Sensitivity Pattern in the Post - Operative wards of a Tertiary Care Hospital in Erode**” submitted by the student bearing [Reg. No: 26103187] to “**The Tamil Nadu Dr. M.G.R. Medical University**”, Chennai, in partial fulfillment for the award of Degree of **Master of Pharmacy in Pharmacy Practice** was evaluated by us during the examination held on.....

**Internal Examiner**

**External Examiner**

# CERTIFICATE

This is to certify that the work embodied in this dissertation entitled “**A study on the Anti-biotic Sensitivity Pattern in the Post - Operative wards of a Tertiary Care Hospital in Erode**” submitted to “**The Tamil Nadu Dr. M.G.R. Medical University**”, Chennai, in partial fulfillment to the requirement for the award of Degree of **Master of Pharmacy in Pharmacy Practice**, is a bonafide work carried out by **Mr. P.Balasubramaniam, [Reg.No.26103187]** during the academic year 2012-2013, under the guidance and supervision of **Mr. N. Venkateswaramurthy, M. Pharm.,** Professor and Head, Department of Pharmacy Practice, J.K.K. Nattraja College of Pharmacy, Komarapalayam.

**Place:** Komarapalayam

**Date:**

**Dr.R.SambathKumar M.Pharm., Ph.D.,**

Professor & Principal,

J.K.K. Nattraja College of Pharmacy.

Komarapalayam-638 183



## CERTIFICATE

This is to certify that the work embodied in this dissertation entitled “**A study on the Anti-biotic Sensitivity Pattern in the Post - Operative wards of a Tertiary Care Hospital in Erode**” submitted to “**The Tamil Nadu Dr. M.G.R. Medical University**”, Chennai, in partial fulfillment to the requirement for the award of Degree of **Master of Pharmacy in Pharmacy Practice**, is a bonafide work carried out by **Mr. P.Balasubramaniam, [Reg.No.26103187]** during the academic year 2012-2013, under my guidance and direct supervision in the Department of Pharmacy Practice, J.K.K. Nattraja College of Pharmacy, Komarapalayam.

**Mr. N. VENKATESWARAMURTHY, M.pharm,**  
Professor & Head,  
Department of Pharmacy Practice,  
J.K.K. Nattraja College of Pharmacy,  
Komarapalayam-638183,  
Tamil Nadu.

## DECLARATION

I do here by declared that the dissertation entitled “**A study on the Anti-biotic Sensitivity Pattern in the Post - Operative wards of a Tertiary Care Hospital in Erode**” submitted to “**The Tamil Nadu Dr. M.G.R Medical University**”, Chennai, for the partial fulfillment of the degree of **Master of Pharmacy in Pharmacy Practice**, is a bonafide research work has been carried out by me during the academic year 2012-2013, under the guidance and supervision of **Mr. N. Venkateswaramurthy, M.pharm.**, Professor & Head, Department of Pharmacy Practice, J.K.K. Natraja College of Pharmacy , Komarapalayam .

I further declare that, this work is original and this dissertation has not been submitted previously for the award of any other degree, diploma, associate ship and fellowship or any other similar title. This information furnished in this dissertation is genuine to the best of my knowledge.

**Place :** Komarapalayam

P.Balasubramaniam

**Date:**

**Reg. No.26103187**

# *Acknowledgement*

## ACKNOWLEDGEMENT

I express whole hearted gratitude to my guide **Mr. N.Venkateswaramurthy, M.Pharm.** Professor and Head, Department of Pharmacy Practice, for suggesting solution to problems faced by me and providing indispensable guidance, tremendous encouragement at each and every step of this dissertation work. Without his critical advice and deep-rooted knowledge, this work would not have been a reality.

I am proud to dedicate my deep sense of gratitude to the founder, (Late) Thiru **J.K.K. Nattaraja Chettiar**, providing us the historical institution to study.

My sincere thanks and respectful regards to our reverent Chairperson **Smt. N. Sendamaraai, B.Com.**, Managing Director **Mr. S. Omm Sharravana, B.Com., LLB.**, and Executive Director **Mr. S. Om Singaravel, B.E., M.S.**, J.K.K. Nattaraja Educational Institutions, Komarapalayam for their blessings, encouragement and support at all times.

It is most pleasant duty to thank for our beloved Principal **Dr. Mr. R.SambathKumar M.Pharm., Ph.D.,** J.K.K.Nattaraja College of Pharmacy, Komarapalayam for ensuring all the facilities were made available to me for the smooth running of this project.

It is my privilege to express deepest sense of gratitude towards to **Dr. Mr.Lionalraj MS., DO., FRCS., Agarwal Eye Hospital,** Tirunelveli for providing all facilities, information and a good guidance to me for the completion of this project work.

My sincere thanks to **N. Venkateswaramurthy, M.Pharm.,** Professor and Head, Department of Pharmacy Practice. **Dr. L.Panayappan, M.Pharm.,Ph.D.,** Assistant Professor, **Mrs. S. Thangamani M.Pharm.,** Lecturer, Department of Pharmacy Practice, **Mrs K. Krishna Veni M.Pharm.,** Lecturer, Department of Pharmacy Practice, **Mrs Christy John M.Pharm** Lecturer, Department of Pharmacy Practice and **Mr Anton Vinoth M.Pharm** Lecturer Department of pharmacy practice, for their help during my project.



My sincere thanks to Professor **Mr. R. Sambath Kumar M.Pharm., Ph.D.**, Professor and Head, Department of Pharmaceutics, **Mrs. S. Bhama, M.Pharm.**, Assistant Professor, **Mr. M. Senthilkumr, M.Pharm.**, Assistant Professor, **Mr. R. Kanagasabai, B. Pharm. M.Tech.**, Assistant Professor, **Mr. K. Jaganathan, M.Pharm.**, Lecturer, Department of Pharmaceutics **Mr C. Kannan M.Pharm.**, Lecturer, Department of Pharmaceutics and **Mr Kamalakannan M.Pharm.**, Lecturer, Department of pharmaceutics for their valuable help during my project.

It is my privilege to express deepest sense of gratitude toward **Dr. P. Sivakumar, M.pharm., Ph.D.**, Professor & Vice Principal, Department of Pharmaceutical chemistry, **Mr. M. Vijayabaskaran, M.Pharm.**, Assistant Professor, Lecturer, Department of Pharmaceutical chemistry, **Mr S.V. Arunachalam M.Pharm.**, Lecturer Department of Pharmaceutical chemistry and **Mrs S. Gomathi M.Pharm.**, Lecturer, Department of Pharmaceutical chemistry, for their valuable suggestions and inspiration.

My sincere thanks to **Mr. V. Sekar, M.Pharm.**, Professor and Head, Department of Analysis, **Mr. Senthilraja, M.Pharm.**, Assistant Professor, **Mr. D. Boopathy, M.Pharm.**, Assistant Professor, and **Mr. S. Jayaseelan, M.Pharm.**, Assistant Professor, Department of Pharmaceutical Analysis for their valuable suggestions.

My sincere thanks to **Dr. S. Sureshkumar, M.Pharm., Ph.D.**, Professor and Head, Department of Pharmacognosy and **Mr. P.Balasubramaniam, M.Pharm.**, Lecturer, Department of Pharmacognosy for their valuable suggestions during my project work.

My sincere thanks to **Mr. V. Rajesh, M.Pharm.**, Assistant Professor & Head, Department of Pharmacology, **Mrs. M. Sudha, M.Pharm.**, Lecturer, Department of Pharmacology, **Mrs Kavitha M.Pharm.**, Lecturer, Department of Pharmacology for their valuable suggestions during my project work.

I greatly acknowledge the help rendered by **Mrs. K. Rani**, Office Superintendent, **Mr. K. Sakthivel**, Clerical Assistant, **Miss. Prabha**, **Mrs. V. Gandhimathi, M.A., M.L.I.S.**, Librarian, and **Mrs S. Jayakala B.A., B.L.I.S.**, Asst. Librarian for their co-operation.

I owe my thanks to all the technical and non-technical staff members of the institute for their precious assistance and help.

Last, but nevertheless, I am thankful to my lovable parents and all my friends for their co-operation, encouragement and help extended to me throughout my project work.

**P.Balasubramaniam**

**Reg.No:26103187**

## TABLE OF CONTENTS

| <b>S.NO.</b> | <b>CONTENTS</b>                   | <b>PAGE NO.</b> |
|--------------|-----------------------------------|-----------------|
| <b>01</b>    | <b>INTRODUCTION</b>               | <b>1 - 12</b>   |
| <b>02</b>    | <b>LITERATURE REVIEW</b>          | <b>13 - 20</b>  |
| <b>03</b>    | <b>NEED FOR THE PRESENT STUDY</b> | <b>21 - 22</b>  |
| <b>04</b>    | <b>AIM AND OBJECTIVES</b>         | <b>23</b>       |
| <b>05</b>    | <b>METHODOLOGY</b>                | <b>24 - 25</b>  |
| <b>06</b>    | <b>RESULTS</b>                    | <b>26 - 29</b>  |
| <b>07</b>    | <b>DISCUSSION</b>                 | <b>30</b>       |
| <b>08</b>    | <b>CONCLUSION</b>                 | <b>31</b>       |
| <b>09</b>    | <b>REFERENCES</b>                 | <b>32 - 35</b>  |
| <b>10</b>    | <b>APPENDICES</b>                 | <b>I -III</b>   |

## CONTENTS

| <b>Fig</b> | <b>PARTICULARS</b>        | <b>Page No.</b> |
|------------|---------------------------|-----------------|
| <b>1</b>   | <b>INTRODUCTION</b>       | <b>1</b>        |
| <b>2</b>   | <b>LITERATURE REVIEW</b>  | <b>40</b>       |
| <b>3</b>   | <b>NEED OF THE STUDY</b>  | <b>48</b>       |
| <b>4</b>   | <b>AIM AND OBJECTIVES</b> | <b>50</b>       |
| <b>5</b>   | <b>METHODOLOGY</b>        | <b>51</b>       |
| <b>6</b>   | <b>RESULTS</b>            | <b>53</b>       |
| <b>7</b>   | <b>DISCUSSION</b>         | <b>61</b>       |
| <b>8</b>   | <b>CONCLUSION</b>         | <b>62</b>       |
| <b>9</b>   | <b>REFERENCES</b>         | <b>63</b>       |
| <b>10</b>  | <b>ANNEXURE</b>           | <b>68</b>       |

## LIST OF TABLES

| <b>S.No</b> | <b>CONTENT</b>   | <b>Page No.</b> |
|-------------|--|-----------------|
| <b>1</b>    | The main microorganisms causing infections                                       | <b>2</b>        |
| <b>2</b>    | Classification of antibiotics based on mechanism                                 | <b>31</b>       |
| <b>3</b>    | Classification of antibiotics based on structure                                 | <b>36</b>       |
| <b>4</b>    | Percentage of samples taken in each surgical category                            | <b>56</b>       |
| <b>5</b>    | Antibiotics prescribed in various surgical cases where incision swabs were taken | <b>57</b>       |
| <b>6</b>    | Organisms found in cases   | <b>58</b>       |
| <b>7</b>    | Sensitivity pattern of antibiotics with different microorganisms                 | <b>59</b>       |
| <b>8</b>    | Drugs recommended based on our study   | <b>60</b>       |

## LIST OF FIGURES

| <b>Fig</b> | <b>Content</b>  | <b>Page No.</b> |
|------------|---|-----------------|
| <b>1</b>   | General mechanism of antibiotics                      | <b>31</b>       |
| <b>2</b>   | Percentage of surgical cases                          | <b>53</b>       |
| <b>3</b>   | Percentage of Surgical cases observed                 | <b>54</b>       |
| <b>4</b>   | Antibiotics usage in the surgical wards               | <b>55</b>       |
| <b>5</b>   | Percentage of samples taken in each surgical category | <b>56</b>       |
| <b>6</b>   | Microorganisms found in cases                         | <b>58</b>       |
| <b>7</b>   | Antibiotic sensitivity pattern                        | <b>59</b>       |

# **1. INTRODUCTION**

## **1.1. An introduction about infection**

An infection is caused by the invasion of foreign cells, like bacteria in humans that cause harm to the host organism. Generally the host organism is considered “colonized” by cells that don’t belong to it. These foreign cells must be harmful to the host organism in order for the colonization to be considered an infection<sup>1</sup>.

Numerous agents can cause an infection. Not only bacteria, but also viruses, parasites, and fungi can create problems for a host organism. Sometimes these non-host cells actually work in conjunction to keep infection from occurring.

Infectious diseases, also known as transmissible diseases or communicable diseases, comprise clinically evident illness (i.e., characteristic medical signs and/or symptoms of disease) resulting from the infection, presence and growth of pathogenic biological agents in an individual host organism. In certain cases, infectious diseases may be asymptomatic for much or even all of their course in a given host. In the latter case, the disease may only be defined as a "disease" (which by definition means an illness) in hosts who secondarily become ill after contact with an asymptomatic carrier. An infection is not synonymous with an infectious disease, as some infections do not cause illness in a host.

Infectious diseases are sometimes called "contagious" when they are easily transmitted by contact with an ill person or their secretions (e.g., influenza). Thus, a contagious disease is a subset of infectious disease that is especially infective or easily transmitted.

1. The main micro organisms causing infections are as follows<sup>2</sup>

| Name     | Living Conditions   | Examples   | Prevention   | Cure  |
|----------|---|--|--|---|
| VIRUSES  | Unable to live outside other cells. May infect prokaryotes and/or eukaryotes. Replicates inside host cell by coding (with viral nucleic acid) for new viral synthesis there.  | Bacteriophages, Plant mosaic viruses, HIV, Herpes, Influenza, Hepatitis  | Good personal hygiene. Some immunization(e.g. 'flu, polio)                                     | NOT antibiotics. Immune system fights viruses. Recently, some antiviral drugs are developed.                                  |
| BACTERIA | Ubiquitous. In almost all environmental niches. Most are non pathogens. Pathogenic bacteria: <i>Cause disease in eukaryotes</i> . Classified by shape (spheres, rods, spirals). Classified by chemistry (eg Gram +/-) Classified by structures (cilia, flagella) Some produce destructive toxins. | Streptococcus, Salmonella, Staphylococcus, Escherichia coli (E. coli) Mycobacterium tuberculosis, Clostridium tetani | Good personal hygiene. Immunisation (e.g. TB), Public sanitation, Surgical aseptic techniques. | Various antibiotics. (1928 Fleming discovered penicillin, 1938 Florey developed it for human use.) Anti-toxins (e.g. tetanus) |



|           |   |  |  |   |
|-----------|---|--|--|---|
| FUNGI     | Yeasts - Unicellular, divide by binary fission or budding. Can exist as spores. Moulds - Filamentous mat of thread-like hyphae produces a mycelium. Fruiting bodies produce spores. (Some pathogenic fungi can exist as either of the above forms, depending on the environment.)   | Candida (-> thrush)<br>Trichophyton (-> tinea)<br>Aspergillus (-> pneumonia or asthma) | Good personal hygiene.   | Various anti-fungal drugs.  |
| PARASITES | Either ectoparasites (outer surfaces of host) or endoparasites (inside host's body). Many have complex life cycles which include a period away from humans and a time in or on humans. Many have specialised structures for attachment to humans either to prevent dislodgment or obtain nutrients or both. <i>VECTOR</i> = living transmitter of disease (e.g. mosquito -> malaria) <i>RESERVOIR</i> = source of parasite in biotic environment (e.g. contaminated soil or water). | Malaria, Dysentery, Liver fluke, Intestinal worms, Schistoma, Fleas, Ticks, Lice       | Good personal hygiene. Public sanitation. Break life-cycle. Cook meat before eating. | Some insecticides. Some drugs. Surgery to remove cysts. Topical insecticides. |

## 1.2 Epidemiology of Infection<sup>2</sup>

When bacteria infect an ordinarily sterile site, they present a serious medical condition, even if they are not resistant to hosts, including other hospital patients, hospital workers, family members, or schoolmates. The relative importance of these host reservoirs as a source of infection probably declines as a function of proximity to the focal host; the most likely sources are the patients themselves, followed by health care workers, other hospital patients, and family members. The bacteria are transmitted by direct contact, such as touching or sneezing, or indirect contact through an intermediate contaminated object. For example, health care workers can be carriers, or they may be vectors who move bacteria among patients or from contaminated objects in a patient's room. The objects that surround individuals, including furniture and food and water, can become contaminated. Medical devices are a particularly important source of infections: they bring a potentially contaminated surface into contact with living tissue. One problem with medical devices is that their wet surfaces facilitate the growth of biofilms which can help facilitate gene exchange and persistence, protect bacteria from antibiotics, and so provide a natural refuge and gentle exposure that may become important in the evolution of resistance. A potential source of antibiotic resistance in environmental bacteria is the sewage effluent from hospitals and long-term care facilities, which contains large numbers of resistant bacteria. Large amounts of antibiotics are also used in agriculture for prophylaxis or as nutritional supplements, and antibiotic-resistant bacteria can remain in meat through the abattoir and retail (Witte 1998). Most meat is properly cooked in the home or in restaurants, but uncooked meat can cross-contaminate raw foods during preparation. This is a potentially important source of exposure and perhaps colonization. Like hospital sewage, the effluent from farms that use antibiotics can be a source of antibiotic-resistant bacteria in the environment.

### **1.3 Surgical site infection (SSI) <sup>3</sup>**

#### **Definition**

Surgical site infections defined as the infections that occur up to 30 days after surgery (or up to one year after surgery in patients receiving implants) and affecting either the incision or deep tissue at the operation site. Despite improvements in prevention, SSIs remain a significant clinical problem as they are associated with substantial mortality and morbidity and impose severe demands on healthcare resources. The incidence of SSIs may be as high as 20%, depending on the surgical procedure, the surveillance criteria used, and the quality of data collection. In many SSIs, the responsible pathogens originate from the patient's endogenous flora. The causative pathogens depend on the type of surgery; the most commonly isolated organisms are *Staphylococcus aureus*, coagulase-negative staphylococci, *Enterococcus* spp. and *Escherichia coli*. Numerous patient-related and procedure-related factors influence the risk of SSI, and hence prevention requires a 'bundle' approach, with systematic attention to multiple risk factors, in order to reduce the risk of bacterial contamination and improve the patient's defences. The Centers for Disease Control and Prevention guidelines for the prevention of SSIs emphasise the importance of good patient preparation, aseptic practice, and attention to surgical technique; antimicrobial prophylaxis is also indicated in specific circumstances. Emerging technologies, such as microbial sealants, offer the ability to seal and immobilize skin flora for the duration of a surgical procedure; a strong case therefore exists for evaluating such technologies and implementing them into routine clinical practice as appropriate

Surgical site infections (SSIs) are linked to a major cause of patient injury and death and consume substantial health care resources. A large percentage of the number of surgical site infections (40% - 60%) is thought to be preventable and as such, characterized as a "never event" medical error. Surgical site infection rates have been cited in the literature as occurring in 2%-5% of patients after clean extra-abdominal surgeries and up to 20% of patients undergoing intra-abdominal procedures. It is difficult to identify nosocomial infections in patients who have been discharged.

### **1.3.1 Classifications of Surgical Site Infections<sup>4</sup>**

They are classified as either incisional or organ/space infections. Incisional infections are subdivided for those involving only the skin and subcutaneous tissue and for those involving deeper soft tissue. Surveillance can include reviewing patients receiving antibiotic therapy for any reason within the defined period of time after a surgical procedure.

#### **a) Superficial Incisional Infections:**

Infection involving only the skin or subcutaneous tissue of the incision and one or more of the following:

- Purulent drainage from the superficial incision with or without laboratory confirmation.
- Organisms confirmed by culture from either an aseptically fluid or tissue from the superficial incision.
- One or more signs of infection (pain/tenderness, localized swelling, redness or heat) and the superficial incision are deliberately opened by the surgeon unless the incision is culture-negative.
- A surgeon or attending physician diagnoses a superficial incision surgical site infection.

### **b) Deep Incisional Infections:**

Infection involving deep soft tissue of the incision such as facial and muscle layers and one or more of the following:

- Purulent drainage from the deep incision but not from the organ or space component of the surgical site.
- The deep incision spontaneously separates or is deliberately opened by a surgeon when the patient has one or more of the signs of infection (fever over 38°C, localized pain or tenderness) unless the site is culture-negative.
- A surgeon or attending physician diagnoses a deep incision surgical site infection.

### **c) Organ/Space Infections**

Involves any part of the body, for example organs or spaces, other than the incision, which was opened or manipulated during the procedure and one or more of the following:

- Purulent drainage from a drain that is placed through a stab wound into the organ/ space.
- Organisms confirmed by culture from either an aseptically obtained fluid or tissue from the organ/space.

## **1.3.2. Epidemiology of surgical site infection<sup>5</sup>**

Surgical site infections contribute significantly to the morbidity and mortality of the individual patient and impose a burden on the health care resources of the community. With the shift toward streamlined hospitalizations and ambulatory surgery, a majority of surgical site infections

are being diagnosed after discharge. There are several tools available for identifying and risk stratifying patients that include the National Nosocomial Infections Surveillance system and the Study on the Efficacy of Nosocomial Infection Control index. If patients can be identified preoperatively, appropriate prophylactic measures and post discharge surveillance can be undertaken, an underemphasized task faced by hospital systems today.

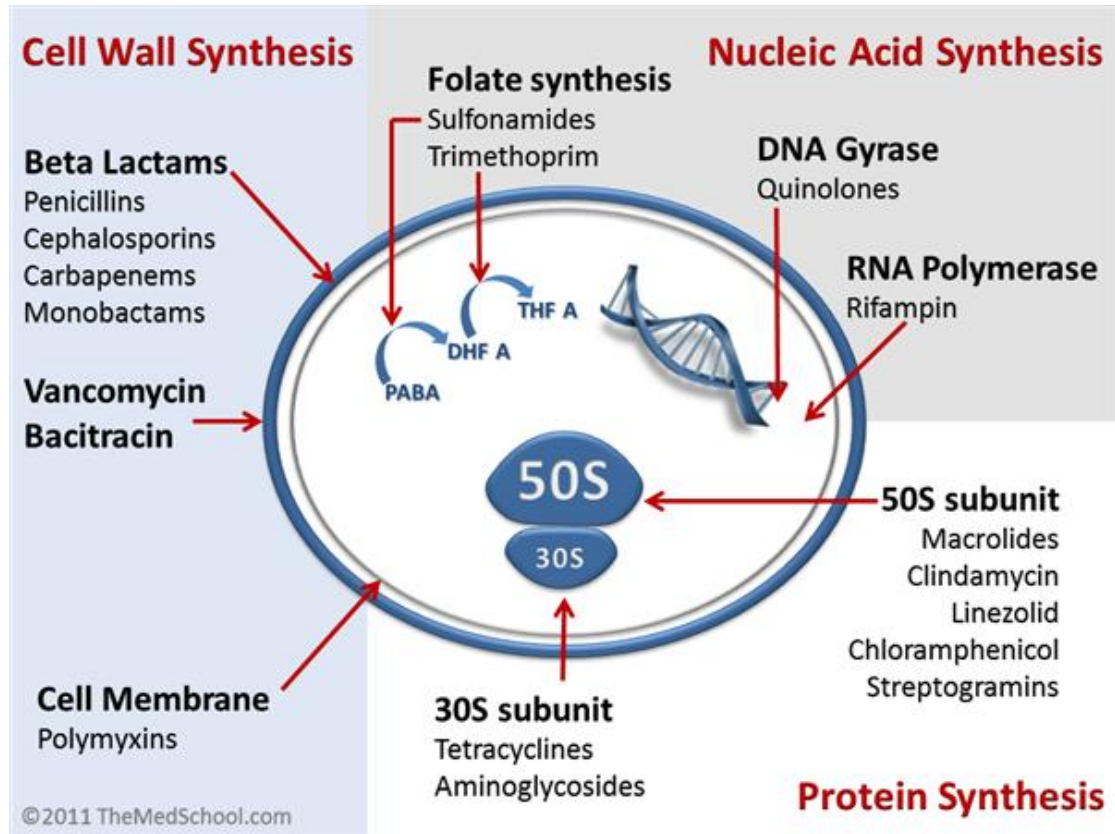
Surgical site infections are the third most common health care-associated infection, accounting for 14% to 16% of these infections in all patients. These complications result in 3.7 million excess hospital days and \$1.6 billion in extra charges. From 1992 to 1998, the NNIS (National Nosocomial Infections Surveillance) recorded 738,393 operations performed in participating hospitals with 19,267 SSIs documented for 44 procedure categories, with the timing of the diagnosis documented in 14,949 of these patients. Interestingly, 54% of these patients were diagnosed after discharge.

#### **1.4. Antibiotics<sup>6,7</sup>**

Antibiotics are chemical compounds used to kill or inhibit the growth of bacteria. Strictly speaking, antibiotics are a subgroup of organic anti-infective agents that are derived from bacteria or moulds that are toxic to other bacteria. However, the term antibiotic is now used loosely to include anti-infectives produced from synthetic and semi synthetic compounds.

The term antibiotic may be used interchangeably with the term antibacterial. However, it is incorrect to use the term antibiotic when referring to antiviral, antiprotozoal and antifungal agents.

Fig.1.General mechanism of antibiotics



## 2. Classification of antibiotics based on mechanism

Table 2.Classification of antibiotics based on mechanism

| Antibiotic Grouping By Mechanism |   |
|----------------------------------|---|
| Cell Wall Synthesis              | Penicillins<br>Cephalosporins<br>Vancomycin<br>Beta-lactamase Inhibitors<br>Carbapenems<br>Aztreonam<br>Polymycin<br>Bacitracin |
| Protein Synthesis Inhibitors     | Inhibit 30s Subunit   |

|                                   |  |
|-----------------------------------|--|
|                                   | Aminoglycosides (gentamicin)<br>Tetracyclines<br><u>Inhibit 50s Subunit</u><br>Macrolides<br>Chloramphenicol<br>Clindamycin<br>Linezolid<br>Streptogramins |
| DNA Synthesis Inhibitors          | Fluoroquinolones<br>Metronidazole  |
| RNA synthesis Inhibitors          | Rifampin   |
| Mycolic Acid synthesis inhibitors | Isoniazid  |
| Folic Acid synthesis inhibitors   | Sulfonamides<br>Trimethoprim   |

### Antibiotic Classification & Indications

| Inhibits Cell Wall Synthesis   |  |   |   |
|--|--|---|---|
| Penicillins  |  |   |   |
| (bactericidal: blocks cross linking via competitive inhibition of the transpeptidase enzyme) |  |   |   |
| <i>Class/Mechanism</i>   | <i>Drugs</i>   | <i>Indications (**Drug of Choice)</i>   | <i>Toxicity</i>                               |
| <b>Penicillin</b>  | Penicillin G<br>Aqueous penicillin G<br>Procaine penicillin G<br>Benzathine penicillin G<br>Penicillin V | <i>Strep. pyogenes (Grp.A)**</i><br><i>Step. agalactiae (Grp.B)**</i><br><i>C. perfringens(Bacilli)*</i><br>* | Hypersensitivity reaction<br>Hemolytic anemia |
| <b>Aminopenicillins</b>  | Ampicillin<br>Amoxicillin  | Above +<br>↑ Gram-negative:<br><i>E. faecalis**</i><br><i>E. Coli**</i>                                       | Above   |
| <b>Penicillinase-resistant-penicillins</b>   | Methicillin<br>Nafcillin<br>Oxacillin<br>Cloxacillin<br>Dicloxacillin                                    | Above +<br>PCNase-producing <i>Staph. aureus</i>  | Above +<br>Interstitial nephritis             |
| <b>Antipseudomonal penicillins</b>   | Carbenicillin<br>Ticaracillin<br>Piperacillin  | Above +<br><i>Pseudomonas aeruginosa**</i>  | Above   |
| Cephalosporins   |  |   |   |



| (bactericidal: inhibits bacterial cell wall synthesis via competitive inhibition of the transpeptidase enzyme) |   |  |   |
|--|---|--|---|
| <b>1st generation</b> ?  | Cefazolin<br>Cephalexin   | <i>Staph. aureus</i> **<br><i>Staph. epidermidis</i> **<br>Some Gram-negatives:<br><i>E. Coli</i><br><i>Klebsiella</i> | Allergic reaction<br>Coombs-positive anemia (3%)  |
| <b>2nd generation</b>  | Cefoxitin<br>Cefaclor<br>Cefuroxime                                   | Above +<br>↑ Gram-negative   | Allergic Reaction<br>ETOH<br>Disulfiram reaction  |
| <b>3rd generation</b>  | Ceftriaxone<br>Cefotaxime<br>Ceftazidime<br>Cefepime (4th generation) | Above +<br>↑ Gram-negative<br><i>Pseudomonas</i>   | Allergic Reaction<br>ETOH<br>Disulfiram reaction  |
| Other Cell Wall Inhibitors   |   |  |   |
| <b>Vancomycin</b> ?<br>(bactericidal: disrupts peptidoglycan cross-linkage)                                    | Vancomycin  | MRSA**<br>PCN/Ceph allergies**<br><i>S. aureus</i><br><i>S. epidermidis</i>  | Red man syndrome<br>Nephrotoxicity<br>Ototoxicity |
| <b>Beta-lactamase Inhibitors</b> ?<br>(bactericidal: blocking cross linking)                                   | Clavulanic Acid<br>Sulbactam<br>Tazobactam                            | <i>S aureus</i> **<br><i>S epidermis</i> **<br><i>E.Coli</i> **<br><i>Klebsiella</i> **                                | Hypersensitivity Reaction<br>Hemolytic anemia     |
| <b>Carbapenems</b>   | Imipenem (+ cilastatin)<br>Meropenem<br>Doripenem<br>Ertapenem        | Broadest activity of any antibiotic (except MRSA, Mycoplasma)  |   |
| <b>Aztreonam</b>   | Aztreonam   | Gram-negative rods<br>Aerobes<br>Hospital-acquired infections  |   |
| <b>Polymyxins</b>  | Polymyxin B<br>Polymyxin E  | Topical Gram-negative infections   |   |
| <b>Bacitracin</b>  | Bacitracin  | Topical Gram-positive infections   |   |
| Protein Synthesis Inhibition   |   |  |   |
| Anti-30S ribosomal subunit   |   |  |   |
| <b>Aminoglycosides</b><br>(bactericidal: irreversible)   | Gentamicin<br>Neomycin  | Aerobic Gram-negatives   | Nephrotoxicity<br>Ototoxicity                     |

|   |   |   |   |
|---|---|---|---|
| binding to 30S) ?   | Amikacin<br>Tobramycin<br>Streptomycin                                | <i>Enterobacteriaceae</i><br><i>Pseudomonas</i>   |   |
| <b>Tetracyclines</b><br>(bacteriostatic: blocks tRNA)   | Tetracycline<br>Doxycycline<br>Minocycline<br>Demeclocycline          | <i>Rickettsia</i><br><i>Mycoplasma</i><br><i>Spirochetes</i> (Lyme's disease)   | Hepatotoxicity<br>Tooth discoloration<br>Impaired growth<br>Avoid in children < 12 years of age |
| <b>Anti-50S ribosomal subunit</b>   |   |   |   |
| <b>Macrolides</b><br>(bacteriostatic: reversibly binds 50S)   | Erythromycin<br>Azithromycin<br>Clarithromycin                        | <i>Streptococcus</i><br><i>H. influenzae</i><br><i>Mycoplamsa pneumonia</i>   | Coumadin Interaction (cytochrome P450)  |
| <b>Chloramphenicol</b><br>(bacteriostatic)  | Chloramphenicol   | <i>H influenzae</i><br>Bacterial Meningitis<br>Brain absces   | Aplastic Anemia<br>Gray Baby Syndrome   |
| <b>Lincosamide</b><br>(bacteriostatic: inhibits peptidyl transferase by interfering with amino acyl-tRNA complex) | Clindamycin   | <i>Bacteroides fragilis</i><br><i>S aureus</i><br><i>Coagulase-negative Staph &amp; Strep</i><br>Excellent Bone Penetration | Pseudomembranous colitis<br>Hypersensitivity Reaction   |
| <b>Linezolid</b><br>(variable)  | Linezolid   | Resistant Gram-positives  |   |
| <b>Streptogramins</b>   | Quinupristin<br>Dalfopristin  | VRE<br>GAS and S. aureus<br>skin infections   |   |
| <b>DNA Synthesis Inhibitors</b>   |   |   |   |
| <b>Fluoroquinolones</b><br>(bactericidal: inhibit DNA gyrase enzyme, inhibiting DNA synthesis)                    |   |   |   |
| <b>1st generation</b> ?   | Nalidixic acid  | <i>Streptococcus</i><br><i>Mycoplasma</i><br><i>Aerobic Gram +</i>  | Phototoxicity<br>Achilles tendon rupture<br>Impaired fracture healing ?                         |
| <b>2nd generation</b>   | Ciprofloxacin<br>Norfloxacin<br>Enoxacin<br>Ofloxacin<br>Levofloxacin | As Above<br>+ <i>Pseudomonas</i>  | as above  |
| <b>3rd generation</b>   | Gatifloxacin  | As above + Gram-positives   | as above  |

|  |  |  |  |
|--|--|--|--|
| <b>4th generation</b>  | Moxifloxacin<br>Gemifloxacin   | As above + Gram-positives + anaerobes                  | as above   |
| <b>Other DNA Inhibitors</b>  |  |  |  |
| <b>Metronidazole</b><br>(bactericidal: metabolic biproducts disrupt DNA)                   | Metronidazole (Flagyl)   | Anaerobics   | Seizures<br>Cerebellar dysfunction<br>ETOH disulfiram reaction |
| <b>RNA Synthesis Inhibitors</b>  |  |  |  |
| <b>Rifampin</b><br>(bactericidal: inhibits RNA transcription by inhibiting RNA polymerase) | Rifampin   | <i>Staphylococcus Mycobacterium</i> (TB) ?             | Body fluid discoloration<br>Hepatotoxicity (with INH)          |
| <b>Mycolic Acids Synthesis Inhibitors</b>  |  |  |  |
| <b>Isoniazid</b>   | Isoniazidz   | TB<br>Latent TB  |  |
| <b>Folic acid Synthesis Inhibitors</b>   |  |  |  |
| <b>Trimethoprim/Sulfonamides</b><br>(bacteriostatic: inhibition with PABA)                 | Trimethoprim/Sulfamethoxazole (SMX)<br>Sulfisoxazole<br>Sulfadiazine | UTI organisms<br><i>Proteus</i><br><i>Enterobacter</i> | Thrombocytopenia<br>Avoid in third trimester of pregnancy      |
| <b>Pyrimethamine</b>   | Pyrimethamine  | Malaria<br><i>T. gondii</i>                            |  |

#### 1.4.2. Classification of antibiotics based on structure<sup>8</sup>

Antibiotics can be classified in several ways. The most common method classifies them according to their chemical structure as antibiotics sharing the same or similar chemical structure will generally show similar patterns of antibacterial activity, effectiveness, toxicity and allergic potential.

Table 3. Classification of antibiotics based on structure

| <b>Class (Based on chemical structure)</b>                               | <b>Mechanism of action</b>            | <b>Examples</b>  |
|--|---------------------------------------|--|
| Beta - lactam antibiotics<br>Penicillin<br>Cephalosporins<br>Carbapenems | Inhibit bacterial cell wall synthesis | Penicillin <ul style="list-style-type: none"> <li>• Penicillin G</li> <li>• Amoxicillin</li> <li>• Flucloxacillin</li> </ul> Cephalosporins <ul style="list-style-type: none"> <li>• Cefoxitin</li> <li>• Cefotaxime</li> <li>• Ceftriaxone</li> </ul> Carbapenem <ul style="list-style-type: none"> <li>• Imipenem</li> </ul> |
| Macrolides   | Inhibit bacterial protein synthesis   | <ul style="list-style-type: none"> <li>• Erythromycin</li> <li>• Azithromycin</li> <li>• Clarithromycin</li> </ul>   |
| Tetracyclines  | Inhibit bacterial protein synthesis   | <ul style="list-style-type: none"> <li>• Tetracycline</li> <li>• Minocycline</li> <li>• Doxycycline</li> <li>• Lyme cycline</li> </ul>   |
| Fluoroquinolones   | Inhibit bacterial DNA synthesis       | <ul style="list-style-type: none"> <li>• Norfloxacin</li> <li>• Ciprofloxacin</li> </ul>   |

|                 |  |  |
|-----------------|--|--|
|                 |  | <ul style="list-style-type: none"> <li>• Enoxacin</li> <li>• Ofloxacin</li> </ul>          |
| Sulphonamides   | Blocks bacterial cell metabolism by inhibiting enzymes | <ul style="list-style-type: none"> <li>• Co-trimoxazole</li> <li>• Trimethoprim</li> </ul> |
| Aminoglycosides | Inhibit bacterial protein synthesis                    | <ul style="list-style-type: none"> <li>• Gentamicin</li> <li>• Amikacin</li> </ul>         |
| Imidazoles      | Inhibit bacterial DNA synthesis                        | <ul style="list-style-type: none"> <li>• Metronidazole</li> </ul>                          |
| Peptides        | Inhibit bacterial cell wall synthesis                  | <ul style="list-style-type: none"> <li>• Bacitracin</li> </ul>                             |
| Lincosamides    | Inhibit bacterial protein synthesis                    | <ul style="list-style-type: none"> <li>• Clindamycin</li> <li>• Lincomycin</li> </ul>      |
| Other           | Inhibit bacterial protein synthesis                    | <ul style="list-style-type: none"> <li>• Fusidic acid</li> <li>• Mupirocin</li> </ul>      |

### 1.5. Antibiotic Resistance<sup>9</sup>

The overuse and inappropriate use of antibiotics has led to antibiotic resistance. Bacteria that were once susceptible to antibiotics have developed ways to survive the drugs that were meant to kill or weaken them. This is also known as antibacterial resistance or drug resistance. Some diseases such as tuberculosis, gonorrhoea and childhood bacterial ear infections that were once easily treated with antibiotics are now again becoming difficult to treat as bacteria have become resistant to these drugs. About 70% of bacteria that cause infections in hospitals are resistant to at least one of the antibiotics most commonly used to treat infections. Methicillin

(meticillin) resistant *Staphylococcus aureus* (MRSA) is a particular problem for patients with skin diseases, ulcers and surgical wounds. Antibiotic resistance is becoming a cause for increasing concern and is the most common cause of treatment failure in bacterial infections diseases. Antibiotic resistance is classified into two broad types.

**a) Intrinsic:** This type is also known as innate. In this type the inherent properties of the bacterium are responsible for preventing antibiotic action. This is always chromosomally mediated.

**b) Acquired:** This occurs when bacteria which were previously susceptible become resistant, usually, but not always, after exposure to the antibiotic concerned. This occurs by mutation in the chromosome.

### **1.5.1. Epidemiology of Antibiotic Resistance<sup>10</sup>**

Antibiotic resistance is the inevitable consequence of antibiotic use. This has been a painful lesson for virtually all treatable microbes, including all major categories: bacteria, fungi, viruses, and parasites. In general, there needs to be a sharp distinction between the resistance problems in the health care setting (nosocomial infections) and those encountered in the community (community-acquired infections) based on vast differences in pathogens and resistance patterns. Nevertheless, there has recently been the development of a hybrid form, referred to as "healthcare-associated infections" in reference to patients who have frequent contact with the medical care system, as with a chronic care facility or on outpatient basis. A fundamental principle is the concept that in all settings, extensive use of antibiotics will lead to resistance ("use it and lose it"). Despite the rule, history has taught that we have great difficulty in predicting evolutionary patterns of resistance.

This review will concentrate on practical issues for consideration by primary care physicians for their role in the prevention of resistance in the management of community-acquired acute respiratory infections. To respond to this threat, World Health Organisation has developed the first Global Strategy for Containment of Antimicrobial Resistance. Strategies for decreasing antibiotic resistance include:

1. Use narrow spectrum agents.
2. Do not use antibiotics for non-infections.
3. Use short courses and at correct time.
4. Avoid usage of last line antibiotics for serious infection and use only where simple agents would be ineffective.
5. Education about antibiotic usage to health care professionals and general public use antibiotic sensitivity profiles and antibiotic guidelines.
6. Surveillance of antibiotic usage, quantities used and their resistance.

## 2. LITERATURE REVIEW

1. Musher et al<sup>11</sup>, conducted the sensitivity study of 105 patients with pneumococcal pneumonia proven by blood culture. Gram staining revealed gram-positive cocci in pairs and chains, and culture yielded pneumococci in only 31% and 44% of all cases, respectively. However, sputum specimens were never submitted for examination in 31 cases; in 16 others, the specimen was inadequate and a culture was not done. Excluding these cases, the sensitivities of Gram staining and culture were 57% and 79%, respectively. If patients receiving antibiotics for >24 h had been excluded, Gram staining would have suggested pneumococci in 63%, and culture results would have been positive in 86%. Sensitivity increased in inverse proportion to the duration of antibiotic therapy. Microscopic examination of sputum samples before antibiotics were administered and performance of culture within 24 h of receipt of such treatment yielded the correct diagnosis in >80% of cases of pneumococcal pneumonia

2. Annie<sup>12</sup>, conducted a study to prospectively evaluate empirical antimicrobial prescribing at a large university teaching hospital using the suggested outcome and process measurements. A total of 137 patients who received empirical therapy during the study were reviewed. Nearly half were prescribed empirical therapy for surgical prophylaxis; the potential cost savings was \$92 per treatment course. Other areas of empirical therapy that resulted in increased expenditures, adverse effects, and super infections included continuation of empirical therapy despite negative culture results in 45 patients (37%) and failure to modify therapy based on culture and sensitivity results in 12 patients (9%). The study concluded that an appropriate empirical therapy can lead to significant cost and negative outcomes.



3. Gorden et al<sup>13</sup> conducted a study to examine use of third-generation cephalosporins alone and in association with vancomycin hydrochloride as a risk factor for vancomycin-resistant Enterococcus (VRE) infection in surgical patients. Surgical inpatients with vancomycin-resistant enterococcus infections between were matched with patients with vancomycin-sensitive enterococcus infections. Matches were based on surgical procedure, initial infection site, and immunosuppressant. Matches were found for 32 of 50 surgical patients with vancomycin-resistant enterococcus twenty matched pairs of patients were recipients of solid organ transplants. This matched control study showed that use of third-generation cephalosporins, alone or concurrently with vancomycin was a risk factor for vancomycin-resistant Enterococcus infection in surgical patients. Judicious administration of third-generation antibiotics is warranted in surgical patients with other risk factors for vancomycin-resistant Enterococcus

4. Giacometti et al<sup>14</sup>, conducted a study that included 676 surgery patients with signs and symptoms indicative of wound infections, who presented over the course of 6 years. Bacterial pathogens were isolated from 614 individuals. A single etiologic agent was identified in 271 patients, multiple agents were found in 343, and no agent was identified in 62. A high preponderance of aerobic bacteria was observed. Among the common pathogens were Staphylococcus aureus (191 patients, 28.2%), Pseudomonas aeruginosa (170 patients, 25.2%), Escherichia coli (53 patients, 7.8%), Staphylococcus epidermidis (48 patients, 7.1%), and Enterococcus faecalis (38 patients, 5.6%). The study concluded that there is a high percentage of inappropriate use of antimicrobials raises concerns about the development and spread of drug resistance, which must be addressed.

5. Siguan et al<sup>15</sup>, conducted a prospective survey of the microbiological causes of surgical wound infection encountered in the Department of Surgery, Cebu Velez General Hospital. From

the 774 operations performed during the study, the overall infection rate was 7.8%. The most common aerobic organisms isolated were *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Acinetobacter calcoaceticus*, *Enterobacter cloacae* and *Enterobacter agglomerans* comprising 80% of all isolates. The sensitivity and resistance patterns of the commonly used antibiotics were presented and convincingly showed a changing trend towards unsatisfactory drug performance

6. Deep et al<sup>16</sup>, conducted a study in Pediatric ICU of a teaching hospital to estimate the incidence of nosocomial infections, establish the clinical and bacteriological profile and identify probable exogenous source from the environment and personnel. 95 suspected cases of nosocomial infections were studied prospectively, identified as per the guidelines laid down by the Centre for Disease Control and Prevention. The rate of nosocomial infections was 27.3% with an incidence of 16.2 per 100 patient days. The incidence of urinary, respiratory and intravascular catheter related infections was 56.52%, 34.78%, 10.52% respectively. *Klebsiella* (33.33%) was the most common isolate with maximum sensitivity to amikacin. During the study, an outbreak of methicillin resistant *Staphylococcus aureus* nosocomial infection was encountered and the source was traced to portable suction pump. The risk of nosocomial infection was found to be directly related to the duration of stay in the Pediatric ICU and duration of placement of indwelling catheters /tubes

7. Herington et al<sup>17</sup> conducted a study on the rate of surgical site infections and the frequency of various pathogens causing surgical site infection with their antibiotic resistance pattern in general surgery units in 190 patients admitted for surgery (clean and clean-contaminated elective cases) were assessed preoperatively, intraoperatively and postoperatively. Normal microbial flora was studied within 24 to 48 hours of admission and patients were followed up to 30 days

postoperatively. Infected wounds were studied bacteriologically and clinically. The overall infection rate was 8.95%. Surgical site infection rate was 3.03% in clean surgeries and 22.41% in clean-contaminated surgeries. Significant increase was seen in surgical site infection rate with an increase in preoperative stay. The increase in duration of surgery was associated with a significant rise in the rate of surgical site infection. Surgical site infection rate was much higher (22.41%) in cases where a drain was used than in non -drained wounds (3.03%). The most common isolate was *Staphylococcus aureus* followed by *Pseudomonas aeruginosa*

8. Kirk et al<sup>18</sup>, conducted a study on the antibiotic sensitivity patterns. Most notable were the decreased sensitivities of *Streptococcus pneumoniae* to penicillin (96% to 63%), coagulase-negative *Staphylococcus* to oxacillin (50% to 38%), and *Pseudomonas aeruginosa* to amino glycosides [(gentamycin (85% to 64%), tobramycin (96% to 83%), amikacin (92% to 74%) and ciprofloxacin (85% to 69%). These decreased antibiotic sensitivities reflect increased bacterial selection pressure as a result of widespread antibiotic use. The study concluded that a combined approach involving infection-control specialists, infectious disease physicians, and hospital administrators is necessary to address this increasingly difficult problem.

9. Riahi1 et al<sup>19</sup> conducted a study to assess changes in macrolide and ketolide resistance among *Streptococcus pyogenes* in Europe and to examine the relationship of resistance to antimicrobial usage. Results: The erythromycin resistance rate during 2004–05 (11.6%) was similar to 2002–03 (10.4%). The proportion of macrolide-resistant isolates increased from 29.3% (2002–03) to 45.7% (2004–05). Telithromycin resistance increased from 1.8% in 2002–03 to 5.2% in 2004–05. For Western Europe, associations of telithromycin and erythromycin resistance, respectively, were found with azithromycin use, clarithromycin use and total macrolide/lincosamide use. For Eastern Europe, associations of antimicrobial use with resistance were not apparent. The 162

telithromycin-resistant isolates with 68.5% in eight major groups. The *erm* gene was detected in 155 of the 162 telithromycin-resistant isolates. Significant increases in telithromycin resistance occurred from 2002–03 to 2004–05 in Europe. Macrolide use appears to be a factor in the emergence of ketolide resistance among *S. pyogenes* in Western Europe.

10. Uwaezuoke et al<sup>20</sup>, conducted a survey of antibiotic resistant *Staphylococcus aureus* strains from clinical specimens was carried out. A total of 100 different clinical specimens were investigated with a yield of 48 *Staphylococcus aureus* isolates. A high resistance of 95.8% to penicillin, 89.6% to ampicilline, 87.5% to tetracycline, and 75.0% to chloramphenicol by *Staphylococcus aureus* strains were recorded. High susceptibility of 91.7% to gentamycin and 85.4% to cloxacillin were also recorded. The high percentage resistance to the antibiotics studied attributed the prevailing usage and abuse in the area under study. The implication of the high percentage recorded for the antibiotics is that *Staphylococcus aureus* infections could be effectively treated with gentamycin and cloxacillin and not with penicillin, ampicilline, tetracycline, and chloramphenicol in the area under study..

11. Hariharan et al<sup>21</sup> conducted a study on antibiotic resistance patterns in the surgical intensive care unit (ICU) of a tertiary care university teaching hospital and the organisms reported were Enterobacteriaceae, *Pseudomonas* species, *Staphylococcus aureus*, and enterococci. Organisms were highly resistant to amoxicillin and first-generation cephalosporins because of the wide use of these drugs in the hospital. *Pseudomonas* species showed a 25% increase in resistance to piperacillin-tazobactam and an 18% increase to ciprofloxacin, which was correlated with the increased use of these antimicrobial agents (82% and 200% increases, respectively). This study provided data of antimicrobial resistance in a developing country with tourism as the main industry for epidemiologic comparison with other countries.

12. Currie et al<sup>22</sup> assessed the prevalence of vancomycin-resistant enterococcal rectal colonization in a 750-bed hospital (including assessment of the impact of antibiotic use on prevalence) and to compare this method of surveillance to that of monitoring sterile body fluid cultures. A rectal swab culture survey was conducted on a randomly chosen sample of 131 patients who were stratified by prior antibiotic use. The study concluded that periodic rectal swab culture surveys were more sensitive in detecting the prevalence of vancomycin-resistant enterococcal colonization and provided strategic information to guide infection control activities. And restriction of oral and parenteral vancomycin therapy as well as restriction of cephalosporin therapy (Cefoxitin, ceftriaxone, and ceftazidime) may contribute significantly to reducing the prevalence of vancomycin-resistant enterococcal colonization..

13. AbulaT et al<sup>23</sup>, assessed the pattern of antibiotic usage in surgical in-patients of a teaching hospital in north west of Ethiopia. The average number of antibiotics and the mean duration of particularly prophylactic antibiotic therapy were somehow increased. The use of antibiotics on empirical basis was a routine prescribing practice. The rationale of some antibiotic combinations required evaluation; and the establishment of antibiotic policy and treatment guidelines with periodic assessment of the sensitivity pattern of pathogenic organisms was recommended.

14. Salehi<sup>24</sup> conducted a study designed to find the predominant pathogens and their antimicrobial resistance in a University hospital intensive care unit. We obtained samples from patients who had no signs and symptoms of infection on admission in ICU but showed infection signs at least after 48 hours. Cultures were obtained and antibiogram tests were done. Thereafter appropriate antibiotics were administered. Caution is responsible for antibiotic resistance. The study showed the necessity of prevention of infections with use of proper antibiotics.

15. Ikeagwu IJ et al<sup>25</sup>, conducted a study to investigate the sensitivity pattern of *Staphylococcus aureus* isolates obtained from clinical specimens including urine, wound high vaginal swab and semen to commonly used antibiotics. The susceptibility patterns of these isolates were determined using the disc diffusion and agar well diffusion methods. Out of 174 samples, 51 (29.2%) yielded *Staphylococcus aureus* with the highest isolation from semen (66.7%) and for Ofloxacin (65%) while the least was for Co-trimoxazole (6%). Amoxicillin, Ampicillin, Tetracycline and Cloxacillin recorded 37%, 19%, 8% and 11% respectively. The study recommends the use of Ofloxacin in the treatment of *S.aureus* infections in the study area. It also underscores the need for sensitivity testing before the administration of antibiotics for the treatment of Staphylococcal infections

16. Lari J et al<sup>26</sup>, conducted a bacteriological study of 110 emergency appendicectomies. In two-thirds of these the appendix was inflamed or gangrenous, and in 45 cases positive cultures were obtained from swabs taken at operation. *Bacteroides* were found frequently in these swabs and also in those taken from wound infections. Although this study is too small to draw any definite conclusions, it is felt that *bacteroides* should be considered an important pathogen in appendicitis and should be taken into account in the few ill patients where antibiotic treatment is contemplated. It was also noted that swabs taken from the surface of the appendix itself were more often positive than those from the peritoneal cavity, and this difference appears to be significant.

17. Shankar et al<sup>27</sup>, conducted a study to determine the prescribing frequency and rationality of use of antimicrobials. Here totals of 297 records of patients were admitted to the intensive treatment unit of the Manipal teaching hospital. About half (50.2%) of the patients received an antimicrobial; 84.6% of the antimicrobials were used without obtaining bacteriologic evidence of

infection. The commonest organisms isolated on culture were *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Streptococcus pneumoniae*, and *Staphylococcus aureus*. Prescriber education to improve prescribing patterns and regular auditing of antimicrobial prescriptions to prevent their inappropriate use and unnecessary cost to the patients is required. The high percentage of inappropriate use of antimicrobials raises concerns about the development and spread of drug resistance, which must be addressed.

### 3. NEED OF THE STUDY

India has an enormous and growing problem in anti-biotic abuse. Infection of incised skin or soft tissue is a common but potentially avoidable complication of any surgical procedure. Some bacterial contamination of surgical site is inevitable, patient's own bacterial flora or from the environment.

It is considered as one of the most common nosocomial infection. The post operative complication has brought about considerable financial burden, undue discomfort to the patient, and sometimes even death. There has been an introduction of many antimicrobial agents in the market. This has lead surgeon to a wide range of antibiotics to choose from. Some of this antimicrobial agent is so effective that they invite complacency on the part of die attending surgeon so that no documentation of causative organism is made. Many troves found it convenient to shift from one kind of antibiotics to another prompt by transient clinical response followed by a recrudescence of the initial problem and ending up with the need to do culture and sensitivity testing only after a series of trial antibiotic treatment had been administered. They have been responsible for the increasing cost, morbidity and mortality related to surgical operations and continues to be a major problem even in hospitals with most modern facilities and standard protocols of preoperative preparation and antibiotic prophylaxis. The laboratory testing of antibiotic susceptibility contributes directly to patient care and the expertise of the microbiology laboratory can have powerful influence on antibiotic usage<sup>29</sup>.

This practice is overshadowed by the fact that many investigations have showed the potential benefits of a more systematic recording of the causative factors which encouraged us to assess our local situations.



Surgical site infections rank third among nosocomial infections, representing a global threat, associated with the emergence of multi-drug-resistant bacteria.

Monitoring institutional resistance patterns is vital in order to make required formulary changes in response to emerging resistance patterns and to determine the most effective agents given prevailing susceptibility patterns<sup>30</sup>. The study will be useful in reducing the incidence of surgical site infection, identify the operations for which routine prophylaxis is supported by evidence, minimize the effect of antibiotics on the patient's normal bacterial flora and minimize adverse effects and the antibiotics chosen for the prophylaxis can be those used for active treatment of infection and cause minimal change to the patient's host defenses.

#### **4. AIM AND OBJECTIVES**

##### **Aim**

Study was conducted to determine the anti-biotic sensitivity pattern among the surgical cases in a tertiary hospital in erode and use the result to format an antibiotic policy for the usage in the surgical wards of the hospital.

##### **Objectives**

To conduct survey on the surgeries conducted in the tertiary hospital in erode

To study the antibiotics usage pattern in the surgical wards of tertiary hospital in erode

To identify the common bacteria isolated from the surgical wound of the patients in the post operative wards of tertiary hospital in erode

To analyze the antimicrobial activity pattern of the commonly used antibiotics in the surgical wards of tertiary hospital in erode

To prepare an antibiotic policy for the antibiotic treatment in the surgical wards Tertiary Hospital in Erode, on the basis of the study findings.

## 5. METHODOLOGY

### 1. Study Site:

Tertiary hospital in Erode among which 87 beds goes for the Surgical wards

### 2. Study Duration: 6 months study(march-2013 to august-2013) (tertiary hospital in erode).

### 3. Study design:

Prospective observational study on the surgical patients for whom surgery was done

### 4. Study Criteria:

#### a) Inclusion criteria

Patient in the post operative wards after surgery. Presence of at least one of the following signs and symptoms of infection: pain or tenderness, localized swelling, purulent drainage site of incision, redness or heat and demonstration of infection on deliberate opening of the wound by a surgeon.

#### b) Exclusion criteria

Patients with non-willing to give the study sample

### 5. Study Procedure

a. The antibiotic usage survey in the surgical wards to be done.

b. The patients who are satisfying the inclusion criteria will be enrolled after getting their signature or thumb impression in the informed consent form (ANNEXURE I).

- c. The patient details were entered into the data collection form (ANNEXURE II) which included details such as: socio-demographic data (age and sex of the patient), clinical diagnosis, duration of hospitalization, drug data (drug name, dosage form, route and duration of therapy), basis of treatment (empirical or definitive), and other relevant information. Culture Sensitivity testing
- d. selection of patients based on the willingness and collection of swabs from the surgical sites of the patients using sterile Hiculture collecting device (Himedia).
- e. The collected incision swabs were then streaked into the previously prepared agar plates. The plates were then incubated for 24 hours at 32<sup>0</sup>C. The antimicrobial sensitivity testing was carried out using standard techniques.
- f. The zones of inhibition around the antibiotic disc in the plates were measured using normal measuring scale. Thereby the antibiotic sensitivity level was measured.
- g. The data obtained will be recorded to develop an antibiotic policy for treatment in the surgical wards.

## 6. RESULTS

The study was conducted in the post operative ward of the tertiary hospital in erode for a period of 6 months.

### 6.1. Demographic details

A total of 213 surgeries took place in the surgical wards during the study period of 6 months. Among which 140 (65.72%) were male patients and 73 (34.27) were female patients who were admitted in the surgical wards (Fig 6.1).

Fig 2 Percentage of surgical cases

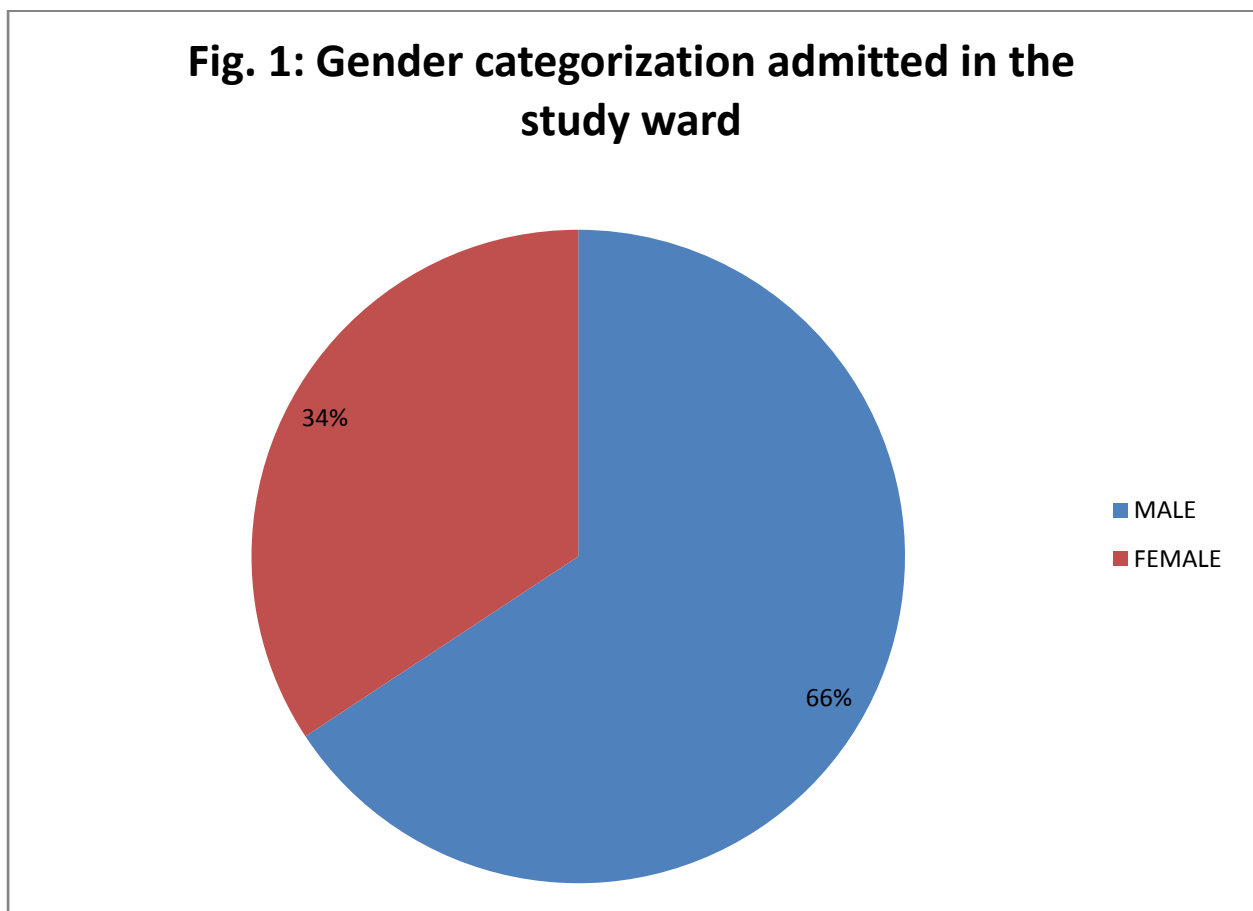
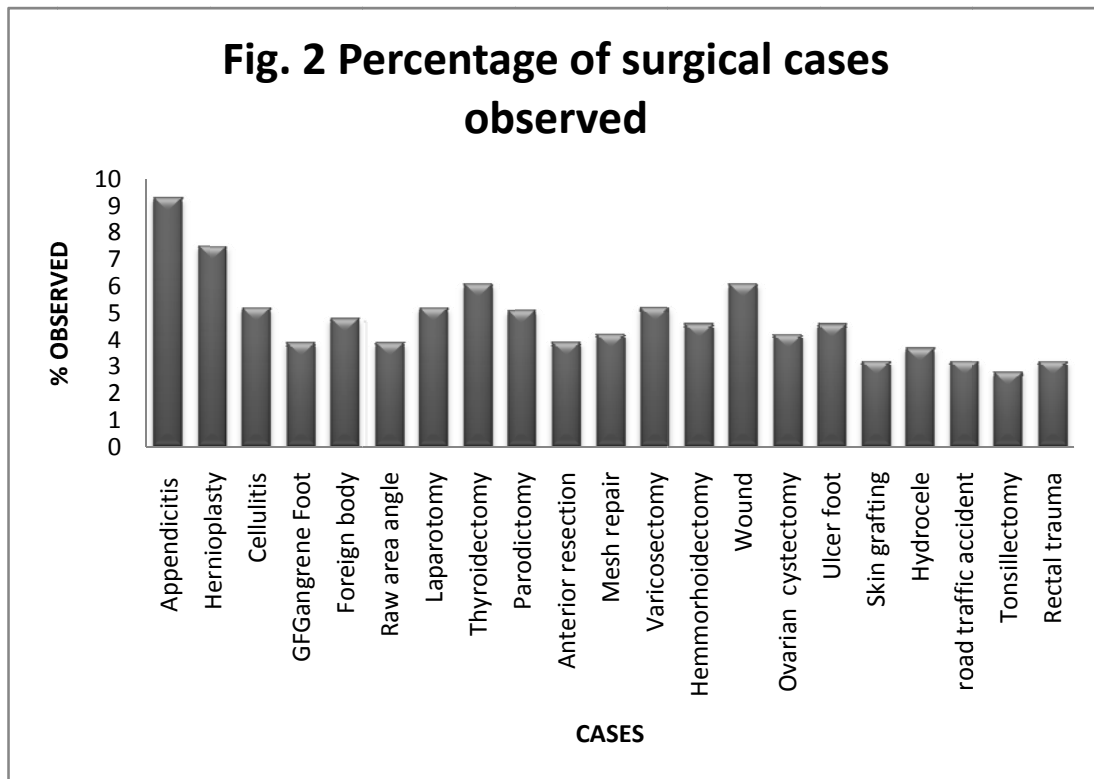


Figure 2 Represents the percentage of different surgical cases observed in the ward. Among the 213 patients 20 (9.3%) patients came for Appendicitis operation; 16 (7.5 %) patients came under Hernioplasty; 11 (5.1%) patients under Cellulitis; 12 (5.6%) patients had Gangrene Foot; 8 (3.7%) patients for Foreign body removal; 10 (4.6%) patients came under Raw area angle; 8 (3.7%) patients for Laparotomy; 11 (5.1%) patients for Thyroidectomy; 13 (6.1%) patients came under Superficial parodictomy with mesh repair; 11 (5.1%) patients came under Anterior resection; 6 (2.8%) patients came under mesh repair; 9 (4.2%) patients came under Varicosectomy; 11 (5.1%) patients came under Hemmorhoidectomy; 10 (4.6%) patients came under wound; 12(5.6%) patients came under Ovarian cystectomy; 8 (3.7%) patients came under ulcer foot; 10 (4.6%) patients came under skin grafting; 7 (3.2%) patients came under snake bite; 8 (3.7%) patients came under road traffic accident; 4 (1.8%) patients came under tonsillectomy; 6 (2.8%) patients came under rectal trauma and 3 (1.4 %) patients came under raw area in the angle.

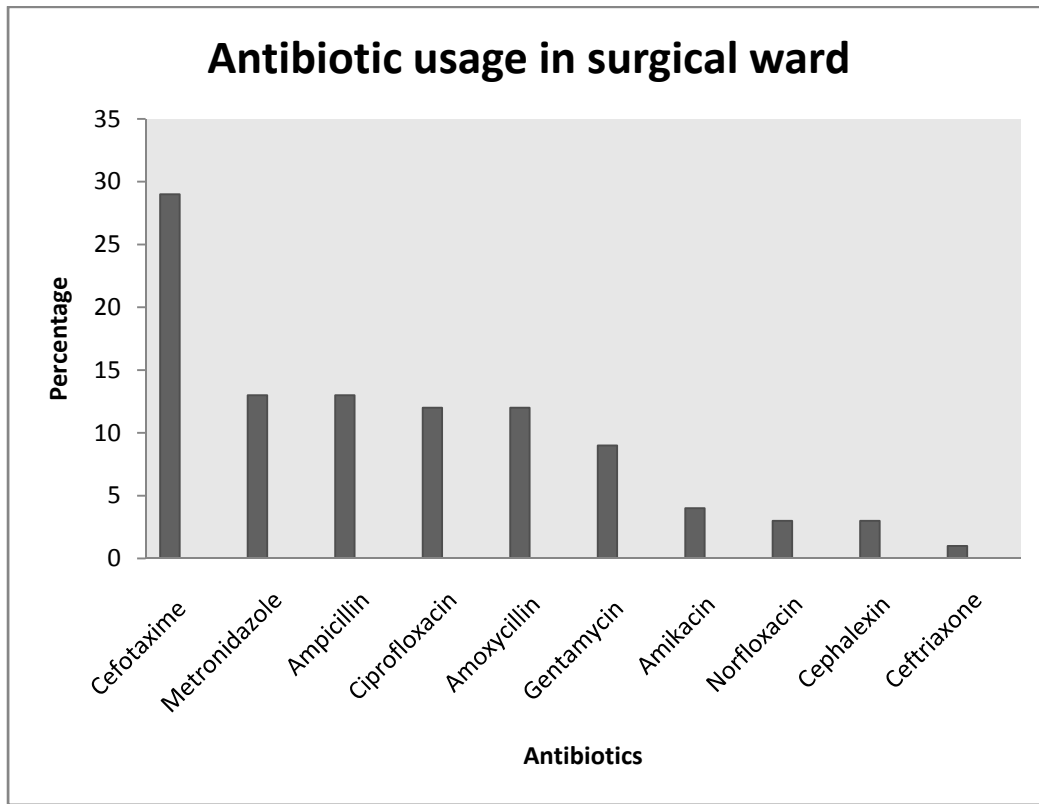
Fig.3. Percentage of Surgical cases observed



### 6.3. Survey of Antibiotic usage.

Figure 3 represents the percentage of antibiotic usage in surgical wards. The mostly used were Cefotaxime (29%), Metronidazole (13%), Ampicillin (13%), Ciprofloxacin (12%), Amoxycillin (12%), Gentamycin (9%), Amikacin (4%), Norfloxacin (3%), Cephalexin (3%), and Ceftriaxone(1%).

Fig 4. Antibiotics usage in the surgical wards



### 6.4. Patient sample details taken during the study

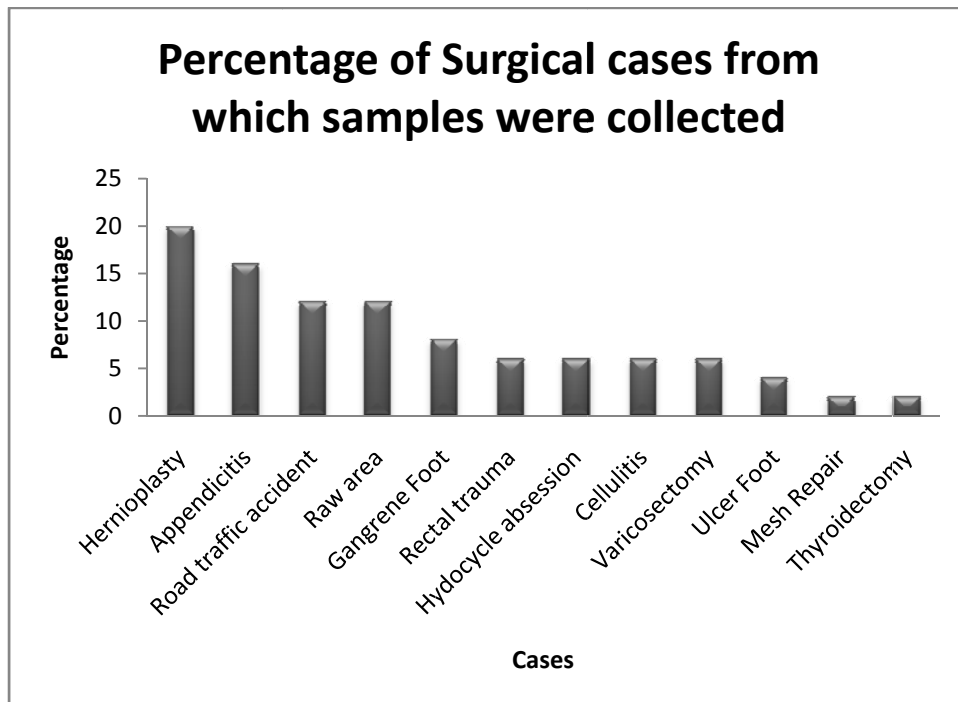
A total of 50 incision samples were collected during the study period. Table 1 and fig 4 represents the number and percentage of samples taken in each surgical category. 20% of the samples were collected from Hernioplasty surgical cases, 16% of samples from Appendicitis, 12% of samples both Road traffic accident and Raw area, 8% of samples from Gangrene Foot, 6% 29of samples each from Rectal trauma, Cellulitis Hydrocele abscess and Varicosectomy,

4% of samples was collected from Ulcer Foot and 2% of samples each from Mesh Repair and Thyroidectomy

Table 4. Percentage of samples taken in each surgical category

| Surgical cases for which incision swabs were collected | Number of cases (N= 50) | Percentage of cases |
|--|-------------------------|---------------------|
| Hernioplasty   | 10                      | 20                  |
| Appendicitis   | 8                       | 16                  |
| Road traffic accident                                  | 6                       | 12                  |
| Raw area   | 6                       | 12                  |
| Gangrene Foot  | 4                       | 8                   |
| Rectal trauma  | 3                       | 6                   |
| Hydocycle absession                                    | 3                       | 6                   |
| Cellulitis   | 3                       | 6                   |
| Varicosectomy  | 3                       | 6                   |
| Ulcer Foot   | 2                       | 4                   |
| Mesh Repair  | 1                       | 2                   |
| Thyroidectomy  | 1                       | 2                   |

Fig. 5. Percentage of samples taken in each surgical category





### 6.5. Antibiotics usage in the cases where incision swab was taken

Table 2 represents antibiotics prescribed in various surgical cases and Figure 5 represents the Percentage of antibiotics prescribed for the different surgical cases were collected. Mostly the antibiotics were given as prophylactics. The most prescribed antibiotics were Cefotaxime (25%), Metronidazole (12%), Ampicillin (12%), Amoxicillin (12%), Gentamycin (12%), Ciprofloxacin (9%), Ceftriaxone (6%), Norfloxacin (6%), Cephalexin (3%), and Amikacin (2%).

Table 5. Antibiotics prescribed in various surgical cases where incision swabs were taken

| Diagnosis             | Antibiotics Prescribed |               |            |            |               |             |             |          |             |            |
|-----------------------|------------------------|---------------|------------|------------|---------------|-------------|-------------|----------|-------------|------------|
|                       | Cefotaxime             | Ciprofloxacin | Ampicillin | Gentamycin | Metronidazole | Amoxicillin | Ceftriaxone | Amikacin | Norfloxacin | Cephalexin |
| Hernioplasty          | 5                      | 1             | 3          | -          | 2             | 1           | -           | -        | -           | -          |
| Appendicitis          | 3                      | 1             | 3          | 1          | 2             | 1           | 1           | 1        | -           | -          |
| Road traffic Accident | 1                      | 1             | -          | 2          | -             | 2           | -           | 1        | -           | 1          |
| Raw area              | 1                      | -             | -          | -          | -             | -           | -           | 1        | 2           | 2          |
| Gangrene Foot         | 1                      | 1             | -          | -          | -             | 2           | -           | -        | -           | -          |
| Rectal trauma         | 1                      | -             | -          | -          | 2             | -           | 1           | -        | -           | -          |
| Hydocele Absession    | 1                      | 1             | -          | 2          | -             | -           | -           | -        | -           | 1          |
| Celluliti             | 1                      | -             | 2          | 2          | -             | -           | -           | -        | -           | -          |
| Ulcer Foot            | 1                      | -             | 2          | 1          | -             | 2           | 1           | 1        | -           | -          |
| Thyroidectomy         | 1                      | -             | -          | 1          | -             | 1           | -           | 1        | -           | -          |

Table.6. Organisms found in cases

| Diagnosis             | Organisms |       |      |        |
|-----------------------|-----------|-------|------|--------|
|                       | Stap      | Strep | Pseu | E.coli |
| Hernioplasty          | P         | N     | P    | N      |
| road traffic accident | P         | P     | N    | N      |
| Rectal trauma         | P         | N     | N    | N      |
| Hydrocele obsession   | N         | N     | N    | P      |
| Raw area angle        | N         | P     | N    | P      |
| Cellulitis            | N         | P     | P    | N      |
| Gangrene Foot         | N         | N     | N    | N      |
| Ulcer foot            | N         | P     | N    | P      |
| Appendicitis          | P         | N     | P    | N      |
| Appendicitis          | P         | P     | N    | N      |
| Mesh repair           | P         | N     | N    | N      |
| Thyroidectomy         | N         | N     | N    | N      |
| Total                 | 6         | 5     | 3    | 3      |

P – POSITIVE

N – NEGATIVE

Fig 6. Microorganisms found in cases

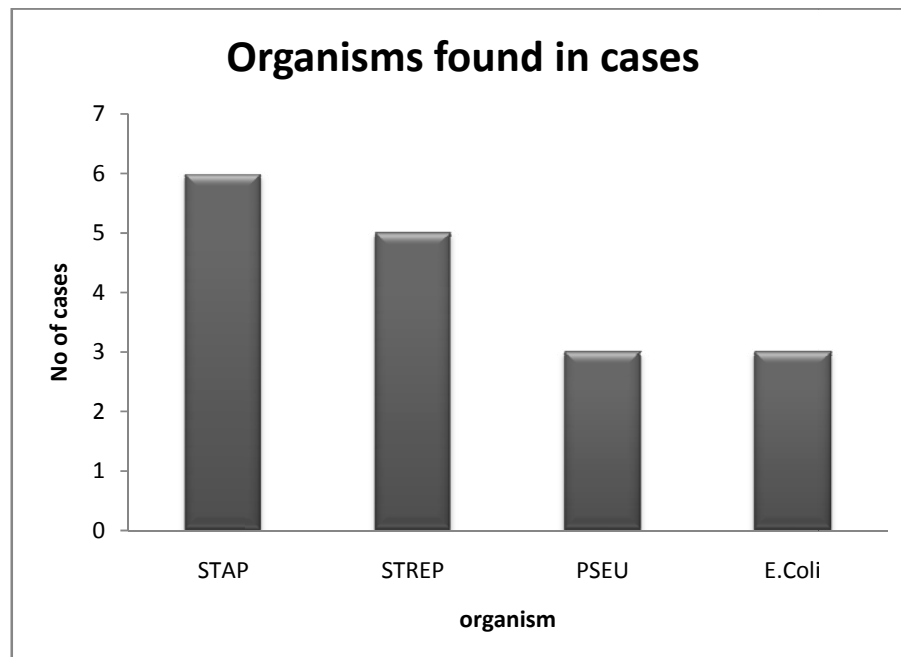


Table.7. Sensitivity pattern of antibiotics with different microorganisms

| S.No | Antibiotic    | Organisms |       |        |      |
|------|---------------|-----------|-------|--------|------|
|      |               | STAP      | STREP | E.Coli | PSEU |
| 1    | Cefotaxime    | R         | R     | R      | R    |
| 2    | Metronidazole | R         | R     | HS     | HS   |
| 3    | Ampicillin    | R         | LS    | R      | R    |
| 4    | Ciprofloxacin | HS        | HS    | HS     | HS   |
| 5    | Amoxycillin   | MS        | R     | R      | R    |
| 6    | Gentamycin    | R         | R     | R      | LS   |
| 7    | Ceftriaxone   | LS        | R     | R      | R    |

| Scoring table for antibiotic sensitivity |   |
|--|---|
| R (Resistant)                            | 0 |
| LS (Low sensitive)                       | 1 |
| MS (Moderately sensitive)                | 2 |
| HS (Highly sensitive)                    | 3 |

Fig7. Antibiotic sensitivity pattern

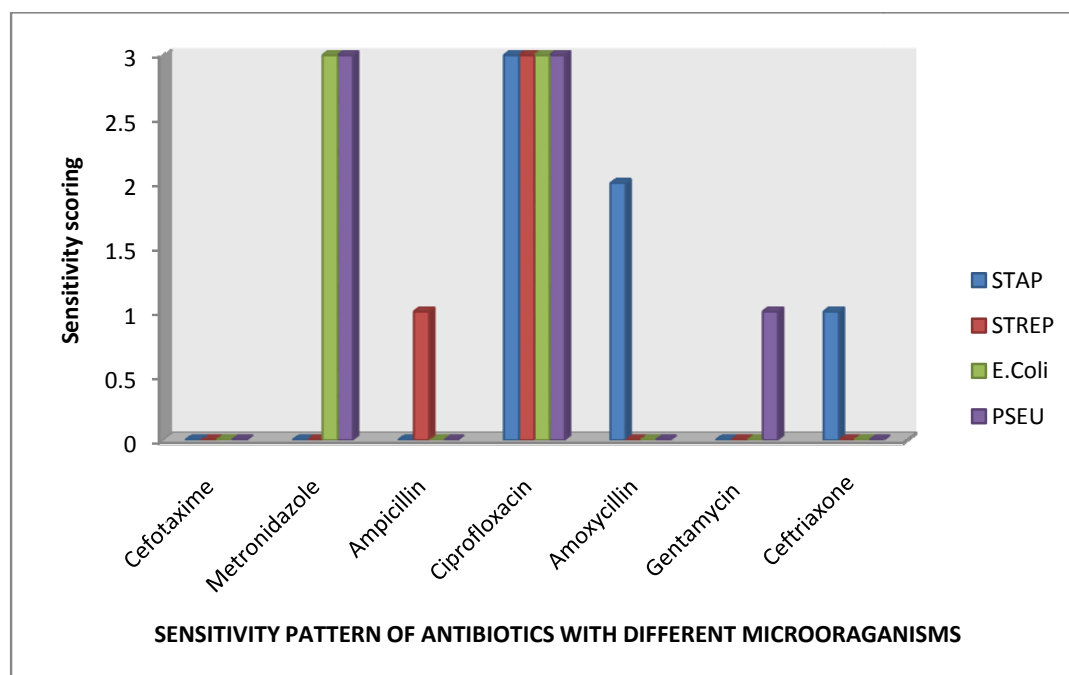


Table.8. Drugs recommended based on our study

| S.No | Diagnosis             | Doctor prescribed                               | Present organisms                         | Identified sensitive antibiotics           |
|------|-----------------------|---|---|--|
| 1    | Hernioplasty          | Cefotaxime                                      | Staphylococcus aureus,pseudomonas         | Ciprofloxacin                              |
| 2    | Road traffic Accident | Amoxicillin<br>Norfloxain                       | Staphylococcus aureus<br>streptococcus    | Ciprofloxacin                              |
| 3    | Rectal trauma         | Metronidazole                                   | Staphylococcus                            | Ciprofloxacin,<br>Amoxicillin              |
| 4    | Hydocele<br>Absession | Gentamycin<br>ciprofloxain                      | E. coli                                   | Ciprofloxacin<br>Metronidazole             |
| 5    | Raw area angle        | Amikacin,<br>cefotaxime                         | Streptococcus,<br>E.coli                  | Ciprofloxacin<br>Metronidazole             |
| 6    | Cellulities           | Ampicillin,<br>Gentamycin                       | Streptococcus,<br>pseudomonas             | Ciprofloxacin<br>Metronidazole             |
| 7    | Ulcer food            | Ampicillin,<br>Amoxicillin                      | Streptococcus<br>E.coli                   | Ciprofloxacin<br>Metronidazole             |
| 8    | Thyroidectomy         | Amoxicillin<br>Amikacin,<br>cefotaxime          | Negative                                  | -  |
| 9    | Appendicitis          | Ciprofloxain<br>Ampicillin(R),<br>Metronidazole | Streptococcus<br>staphylococcus<br>E.coli | Ciprofloxacin<br>metronidazole,Amoxicillin |

## 7. DISCUSSION

From Tertiary Care Hospital in Erode totally 213 operations were conducted in surgical ward, among which the incision swab was collected for culture and sensitivity testing for 50 cases. Mainly 4 micro-organisms were identified and isolated, namely *Staphylococcus aureus*, *Streptococcus*, *Escherichia coli* and *Pseudomonas*. The study showed that some drugs prescribed in the hospital were resistant to the micro organism isolated. Here high preponderance of the aerobic bacteria was observed.

The present study showed that the *Staphylococcus aureus* was the most common micro-organism isolated from the swab samples which was the most common cause for the surgical site infection. This study finding coincided with the results of the studies conducted by Siguan et al<sup>15</sup> and Giacometti et al<sup>14</sup>.

The antibiotic sensitivity analysis showed that Ciprofloxacin to be highly sensitive antibiotic to all of the micro organisms isolated. Metronidazole was found to be highly sensitive to *Escherichia coli* and *Pseudomonas*. Amoxyllin was found to be medium sensitive to *Staphylococcus aureus*. Gentamycin was found to be low sensitive to *Pseudomonas*. Ampicillin was found to be low sensitive to *Streptococcus*. Ceftriaxone was found to be low sensitive to *Staphylococcus aureus*.

In our study, the sensitivity pattern of antibiotics with respect to the different microorganisms in different cases were monitored. The results were discussed in the table 6.4 and 6.5. In the Tertiary Care Hospital, the physicians were commonly prescribed the antibiotics such as Cefotaxime, Metronidazole, Ampicillin, Amoxicillin, Gentamycin, Ciprofloxacin, Ceftriaxone, Norfloxacin, Cephalexin, and Amikacin. Based on our study, among the above antibiotics Ciprofloxacin and Metronidazole were found to as highly sensitive with all the selected four microorganisms.

The result of this study clearly emphasizes that the magnitude of surgical wound infection problem may be increasing because of many of the causative organism have probably started to develop some form of resistance to the currently used antibiotics. The overall infection rate in this hospital was 6 % which is relatively high based on the generally acceptable surgical infection rate of 5 %. Undoubtedly efforts on infection on surveillance and control have become indispensable in a

hospital which values optimum patient care and which hopes to prevent the occurrence of surgical wound infection. Surveillance of surgical site infection with the feedback of appropriate data to surgeons would be desirable to reduce the surgical site infection

## 8. CONCLUSION

From tertiary hospital in erode totally 213 operations were conducted in surgical ward of erode hospital Among which the incision swab was collected for culture and sensitivity testing for 50 cases. Mainly 4 micro-organisms were identified and isolated, namely Staphylococcus aureus, Streptococcus, Escherichia coli and Pseudomonas. The study showed that the micro organisms isolated from the swabs were resistant to some of the antibiotics prescribed in the hospital. The antibiotic therapy observed in the study was empirical. The various antibiotic sensitivity and resistance pattern of commonly used anti microbial agents were presented to show a changing trend towards unsatisfactory drug performance. The increasing rate of surgical site infection in

This hospital should be seriously looked into before this pattern escalates into epidemic proportions. The development of effective control programs through adoption of measures that restrict use of specific antibiotics, establishment of therapeutic guideline, a constant monitoring of antibiotic resistant pattern of the common pathogenic organism in the hospital are recommended in order to improve the use of antibiotics. This information can guide surgeons in particular and physicians in general in the fight against surgical site infection. Only with this scheme we can sincerely offer patients a more optimistic outlook on their change of acquiring this post operative complication.

## 9. REFERENCES

1. Christensen TE. Surgical site infection. <http://www.wisegeek.org/what-does-a-surgical-technician-do.htm>. Accessed October 3, 2013
2. Chong T, Sawyer R. Update on the Epidemiology and Prevention of Surgical Site Infections. *Current Infectious Diseases Rep* 2002;4:484-490.
3. Nichols RL. Preventing surgical site infections: a surgeon's perspective. *Emerging Infectious Diseases*.institute for clinical system improvement-Prevention of surgical site infection, first edition 2006 page 5-6
4. Lilani SP, Jangale N, Chowdhary A, Daver GB. Surgical site infection in clean and clean-contaminated cases. *Indian Journal of Medical Microbiology* 2005;23:249-52
5. Chong T, Sawyer R. Update on the Epidemiology and Prevention of Surgical Site Infections. *Current Infectious Diseases Rep*2002;490-494
6. Rosen P, Barkin RM, eds. *Emergency Medicine:Concepts and Clinical Practice*. 6<sup>th</sup> edition mosby-year book;1992.2
7. Tintinalli JE, Krome RL, Ruiz E. *Emergency Medicine: A Comprehensive Study Guide*. 4th ed. McGraw-Hill; 1995.
8. Antibiotics(online).2005(cites2008);Availabl from: URL:<http://www.dermnetnz.org/> accessed date October 4 2013
9. Hugo WB.and Rusell AD.Bacterial resistance to antibiotics.Pharmaceutical microbiology. 6th ed.chapter 9.page no; 181-182
10. Spellberg B, Powers JH, Brass EP, Miller LG, Edwards JE. Trends in Antimicrobial Drug Development: Implications for the Future. *Clinical infectious diseases* 2004; 38:1279-86.



11. Musher DM, Wanahita A. Diagnostic Value of Microscopic Examination of Gram-Stained Sputum and Sputum Cultures in Patients with Bacteremic Pneumococcal Pneumonia. *Clinical Infectious Diseases* 2004;39:165–169.
12. Annie, Beringer W. Empirical Antimicrobial Prescribing: Impact on Outcomes and Cost. *Hospital Pharmacy* 1998 (10):1208-13.
13. Gordon A, Isaacs D. Late onset infection and the role of antibiotic prescribing policies. *Current Opinion Infectious Diseases* 2004; 17: 231-236.
14. Giacometti A, Cirioni O, Schimizzi AM, Del Prete MS, Barchiesi F, D'Errico MM. Epidemiology and Microbiology of Surgical Wound Infections. *Journal of clinical microbiology* 2000; 38:918-922.
15. Siguan SS, Aug SB, Pala MI, Baclig MR. Aerobic surgical infection:A surveillance on microbiological etiology and antimicrobial sensitivity pattern of commonly used antibiotics. *Philippines Journal of Microbiological Infectious diseases* 1990;19:27-33
16. Deep A, Ghildiyal R, Kandian S, Shinkre N. Clinical and Microbiological Profile of Nosocomial Infections in the Pediatric Intensive Care Unit (PICU). *Indian Pediatrics* 2004; 41:1238-46.
17. Herington J. Organism that cause disease (online). 1997.Available from URL:[http:// www.dermnetnz.org/](http://www.dermnetnz.org/) accessed date: October 5 2013
18. Kirk M. Study on the antibiotic sensitivity patterns. *Southern Medical Journal* 2004;53:28-52
19. Riahi F, Lomas GJ, Ferech M, Goossens H, Doern GH ,Beekmann SE. Increasing telithromycin resistance among *Streptococcus pyogenes* in Europe. *Journal of Antimicrobial Chemotherapy* 2008; 61:603–11.

20. Uwaezuoke, JC, Aririatu, LE. A Survey of Antibiotic Resistant Staphylococcus Aureus Strains from Clinical Sources in Owerri. *Journal of Applied Sciences and Environmental Management* 2006; 10:103-107.
21. Hariharan, Seetharaman, Nanduri, Srikrishna B, Moseley, Harley et al. Global Issues in Surgical Infections and Surveillance. *American Journal of Infection Control* 2003:280-287
22. Currie BP, Gnass S, Levi MH. A hospital-based rectal swab culture survey to detect vancomycin-resistant enterococci: Utility and application *International journal of infectious diseases* volume 1996:87-91
23. AbulaT, Kedir,M The pattern of antibiotic usage in surgical in-patients of teaching hospital, northwest Ethiopia. *Ethiopian Journal of Health* 2004;18(1):35-38
24. Salehi H. The Most Common Bacterial Agents and Their Antibiotic Sensitivity in ICU Patients of AL-Zahra Hospital in Isfahan. *Journal of Research in Medical Sciences* 2004;4:178-181
25. Ikeagwu IJ, Amadi ES, Iroha IR. Antibiotic sensitivity pattern of staphylococcus aureus in Abakaliki, Nigeria. *Pakistan journal of medical science* 2008 24:231-35.
26. Lari J, KirkD, Howden R. Bacteriological survey of acute appendicitis in children. *British Journal of Surgery* 2005 63: 643 – 46.
27. Shankar, Ravi P, Partha, Praveen, Shenoy, Nagesh et al. Investigation of antimicrobial use pattern in the intensive treatment unit of a teaching hospital in western Nepal. *American Journal of Infection Control* 2003 :410-14.
28. Rachel A, Dahms BS, Eric M, Johnson, Catherine L, Statz et al. Third-Generation Cephalosporins and Vancomycin as Risk Factors for Postoperative Vancomycin-Resistant Enterococcus Infection. *Archives of Surgery* 1998;133:1343-6.
29. Isaacs D. Neonatal Sepsis:The Antibiotic Crisis. *Indian Pediatrics* 2005 J;42:9-13.

30. Gold R, Barbara A. Prevention of Surgical site infections. American Journal of Nursing 2003 ;103 :64-69

## ANNEXURE - I

### INFORMED CONSENT FORM

I, \_\_\_\_\_ exercising my free power of choice, hereby give my consent to be included as a patient in the clinical study “**Study on the Anti-biotic Sensitivity Pattern in the Post Operative Wards of a Secondary Care Hospital in =====**”

*I agree to the following:*

1. I understand that I will not be given any new study medication for participation in the study.
2. I understand that, since I am already taking the drug as prescribed by doctor, I become eligible to be included in the study.
3. I also understand that I may need to give blood samples on different days that will be used for the estimation. This information will be correlated with my clinical progress by the doctor who will decide if I am receiving the right drug.
4. I also understand that the information thus gathered will be helpful in optimizing my drug therapy.
5. I have been informed to my satisfaction by the attending physician about the purpose of the clinical study and study procedures including the investigations to monitor and safeguard my body functions.
6. I have been given a full explanation by the supervising doctor of the nature, purpose, likely duration of the study and about what I will be expected to do. I have fully understood the information sheet given to me.
7. I have been given the opportunity to question the attending doctor on all the aspects of the study, and I have understood the advice and information as a result.
8. I have informed to the doctor about all medications that I have taken in the recent past and those I am currently taking.
9. I have not taken part in any investigational study for the past one month.
10. I am also aware of my right to opt out of the study at any time without giving any reason for doing so.
11. I hereby give permission for the doctors in charge of this study to release the information regarding or obtained as a result of the participation in the study

to Mr.----- I understand that medical records that reveal my identity will remain confidential except that they will be provided as noted above or as may be required by law.

-----  
Signature of the patient\* with date

-----  
Signature of the impartial witness\* with date

I confirm that I have explained the nature, purpose and possible hazards of the above study to \_\_\_\_\_

-----  
Signature of the Investigator with date

*\* Signature of the impartial witness is required only if the patient is illiterate; Impartial witness will ensure that the patient information sheet and patient consent form were explained to the patient in a language understood by the patient.*

Name and address of the impartial witness \_\_\_\_\_

ANNEURE – II

**Patient Data Collection Form**

Name of the patient: Age: Sex:  
Weight: Height: Employment.  
Clinical diagnosis:  
Co- morbid conditions:  
Drugs taken before admission(if any):

| Sl. No. | Drug name and strength | Dosage form | Route of Administration | Duration of therapy |
|---------|------------------------|-------------|-------------------------|---------------------|
|         |                        |             |                         |                     |

Surgical procedure:

Surgery categorization:  Major  Minor

Duration of hospitalization before surgery:

Duration of hospitalization after surgery:

**Drug data**

| Sl. No.                         | Drug name and strength | Dosage form | Route of Administration | Duration of therapy |
|---------------------------------|------------------------|-------------|-------------------------|---------------------|
| 1. Pre surgical drug treatment  |                        |             |                         |                     |
|                                 |                        |             |                         |                     |
| 2. Post surgical drug treatment |                        |             |                         |                     |
|                                 |                        |             |                         |                     |

Basis of treatment: Empirical  Definitive

Other relevant information: