AN ANALYSIS OF SURGICAL SITE INFECTIONS IN CLEAN SURGERIES WITH A FOCUS ON PREOPERATIVE ANTIBIOTIC PROPHYLAXIS

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CERTIFICATE

This is to certify that the dissertation titled "**AN ANALYSIS OF SURGICAL SITE INFECTIONS IN CLEAN SURGERIES WITH A FOCUS ON PREOPERATIVE ANTIBIOTIC PROPHYLAXIS**" of **Dr. HIMAGIRISH K. RAO** in partial fulfilment of the requirements for **M.S. Branch – I (General Surgery)** Examination of the Tamilnadu Dr. M.G.R. Medical University to be held in February 2006. The period of study was from June 2003 to May 2005.

UNIT CHIEF **HEAD OF THE DEPARTMENT**

DEAN
Govt. Stanley Medical College & Hospital,
Chennai-600 001.

DECLARATION

I, **Dr. HIMAGIRISH K. RAO solemnly** declare that dissertation titled, "**AN ANALYSIS OF SURGICAL SITE INFECTIONS IN CLEAN SURGERIES WITH A FOCUS ON PREOPERATIVE ANTIBIOTIC PROPHYLAXIS" is** a bonafide work done by me at Govt. Stanley Medical College & Hospital during 2003-2005 under the guidance and supervision of my Unit Chief

Prof. N. CHAKRAVARTHI, M.S.,

Additional Professor of Surgery..

The dissertation is submitted to Tamilnadu, Dr. M.G.R. Medical University, towards partial fulfillment of requirement for the award of **M.S. Degree (Branch – I) in General Surgery.**

Place : Chennai.

Date :

(Dr. HIMAGIRISH K. RAO.)

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CONTENTS

INTRODUCTION

Concepts of surgical wound infection and the prevention of infection have been known to mankind from time immemorial.

Sushrutha, the father of Indian Surgery compiled the knowledge of surgery of his day and age in his classic **Sushrutha Samhita**. He laid emphasis on clean surgical technique.

The **Egyptians' medical papyrus** describes the use of salves and antiseptic to prevent wound infection.

Hippocratic techniques in **ancient Greece** established the use of wine and vinegar to irrigate open wounds before successful secondary closure.

More recently, however in **1553, Anton von Leeuwenhoek**, an Austrian physician first discovered bacteria through the microscope, which had just been invented.

Before the 19^{th} Century, it was common to have post-op "irritative fever" followed by purulent drainage overwhelming sepsis and often death.

Luis Pasteur in **1857** discovered and explained the process of fermentation by micro-organisms.

Semmelweis, an **Austrian** physician was a fervent advocate of hand washing but in those days, people were so averse to such "crazy" ideas that he was shot and killed by his colleagues who were not too eager to bear the "nuisance".

In the late **1860s**, **Joseph Lister** introduced principles of antisepsis. This led to a drastic reduction in post-operative infections and mortality.

Caspar Stromayar in **1880** brought the attention of his colleagues to the importance of pre-operative baths and shaving of the body parts of patients.

The famous **postulates of Koch** regarding infection were postulated in **1884**. This led to a radical change in the way people understood infection.

Halsted is widely regarded as the **father of Modern Surgery**. One among his myriad contributions to surgery was the **use of gloves** in **1890**.

Meleny, who has given his name to a specific ulcer, described the pathophysiology of **necrotising fasciitis** in **1924**.

Alexander Fleming's famous discovery of **penicillin** came about in **1929** and antibiotics have revolutionised medical science since.

The **first cephalosporin** was discovered 57 years ago in **1948**. There have been five generations of cephalosporins since then and the fifth generation drugs of the 21st century act against practically all the bacteria present on earth today.

The **early 60's** saw the synthesis of **quinolones** and **Gentamicin**, two more path breakers along the long winding route that antimicrobial therapy has travelled till date.

Still, wound infections continue to be a menace despite significant improvements in antibiotics, improved anaesthesia, superior instruments, vastly improve concepts of disinfecting and sterilization, earlier diagnosis of surgical problems of improved techniques for postoperative vigilance.

The problem can have a wide spectrum of effects on the patient, ranging from cosmetic disfigurement to prolonged hospital stay to even increased post-operative mortality.

DEFINITIONS

The surgical wound encompasses that area of the body both internally and externally that involves the entire operative site. Wounds are thus categorized into three general categories.

Superficial – Including skin and subcutaneous tissue

Deep – Including deep fascia and muscle

Organ space – Including internal organs of the body.

1. Wound infections

Wound infections are technically referred to as **surgical site infections (SSIs)** by the centres for Disease control and prevention at Atlanta. The CDC has laid out very specific criteria for diagnosis of both superficial and deep SSIs.

Superficial incisional SSIs

- Infection less than 30 days after operation
- Involves only the skin and subcutaneous tissue of incision plus at least one of the following.
  - Purulent drainage with or without laboratory confirmation of infection
  - Organisms isolated from on aseptically obtained culture of fluid or tissue from the incision.
  - At least one of the following signs and symptoms
    - Pain or tenderness at site
    - Localised swelling, redness or warmth
    - Superficial incision deliberately opened by surgeon.
  - Diagnosis of SSI by the attending surgeon or physician

The following are not to be reported as superficial incisional SSIs.

- Stitch abscess
- Infection of episiotomy or circumcision in newborn.
- Infected burn wounds
- Superficial incision, which on opening yields culture-negative fluid.

Deep Incisional SSIs

- Infection less than 30 days after operation with no implant and soft tissue involvement.
- Infection less than 1 year after operation with implant.
- Infection involves deep soft tissues (deep fascia and muscle) plus at least one of the following.
    - Purulent drainage from deep space but not extending into organ space.
    - Abscess found in the deep space on direct or radiological examination or on reoperation.
    - Diagnosis of a deep space SSI by surgeon
    - Symptoms of fever, pain and tenderness lead to dehiscence of wound or opening by a surgeon.

Organ Space SSIs

- Infection less than 30 days after surgery with no implant.
- Infection less than 1 year after surgery with implant and infection, involving any part of

the anatomy (organ/organ space) opened or manipulated during operation **plus** at least **1** of the following.

- Purulent drainage from a drain placed through a slab wound into the space.
- Organisms +ve in aseptically attained culture of fluids or tissue from the organ space.
- Abscess of the organ space.
- Diagnosis of an organ space SSI by the attending surgeon or physician.

2. ***Surgical wounds:***

Surgical wounds have been classified according to the relative risk of postoperative wound infection occurring. The four categories are as below:

1) Clean wound

a. No hollow viscus entered
b. No body cavities (pleural, abdominal, joint) entered
c. No inflammation
d. No breaks in aseptic technique
e. Elective procedure
f. Primary wound closure

2) Clean contaminated

a. Hollow viscus or body cavity entered but controlled

b. No inflammation

c. Primary closure

d. Minor breaks in aseptic technique

e. Mechanical drain used

f. Pre-operative bowel preparation done

3) Contaminated

a. Uncontrolled spillage from viscus

b. Inflammation apparent

c. Open, traumatic wound

d. Major break in aseptic technique

4) Dirty

.a Untreated, uncontrolled spillage from viscus

.b Pus in operative wound

.c Open suppurative wound

.d Severe inflammation.

Wound infections obviously occur because of bacterial contamination of the surgical site. Although bacterial contamination can occur in many ways, the most common source of superficial SSIs is the bacterial flora from surrounding skin.

SSIs, with their multitude of causative factors, can be dealt with in various ways, one of the important ways being antibiotic prophylaxis.

3. Antibiotic prophylaxis with respect to time of administration:

There have been attempts to determine the optimum duration of time before surgery when antibiotic prophylaxis seems to work best.

Early prophylaxis – 24 hrs – 2 hrs prior to surgery.

Pre-operative prophylaxis – within 2 hrs prior to surgery

Perioperative prophylaxis – within 3 hrs after incision

Postoperative prophylaxis – 3 – 24 hrs after incision.

It is with a background of these concepts that literature on the subject of surgical site infections was reviewed.

REVIEW OF LITERATURE

1) **Balthazar** et al reported in **July 1982** about pre-operative skin preparation with respect to hair removal. 200 patients undergoing inguinal herniorrhaphy were studied. They found out that **clipping significantly reduced the risk of SSIs as opposed to shaving.**

2) **Olson MM** et al did a similar study in **Feb. 1986**. A survey of wound infection rates among 4580 patients was done. There was no significant change in wound infection rates whether hair was shared or clipped.

3) **Dipiro J** et al made a few observations about single dose antibiotic prophylaxis for surgical wound infections. Studies compared single dose Vs placebo, single dose Vs multiple dose of the same agent, single doses of various antibiotics and single dose of one agent Vs multiple doses of a different drug. A single dose of antibiotics, usually cephalosporins, given immediately before surgery was found to be the most effective in preventing wound infections in gastric surgeries, biliary procedures, transurethral operations, hysterectomies and caesarean sections.

4) **Classen D C** et al, in **January 1992**, studied the appropriate timing of administration of prophylactic antibiotics that was required for optimum prevention of SSIs.

   They classified the time of administration of antibiotics with respect to surgery into early (24 hrs – 2 hrs pre-op), pre-operative, perioperative (within 3 hours after incision) and post-operative (3-24 hours post-incision) prophylaxis. Rates of SSIs were found to be least in when the drug was given pre-operatively.

5) **Greif R** et al of Vienna, Austria in **January 1992** studied incidence of SSIs after supplemental perioperative oxygen. Patients were given either 60% O_2 or 30% O_2. The rate of SSIs was lower in those given 60% oxygen.

6) **Dellinger** and colleagues found out that diabetes mellitus and postoperative hyperglycaemia were independently associated with an increased risk of SSIs.

7) **Joan Robinson** and Colleagues from Edmonton in Canada reported in **2002** about the practical aspects of choosing an antibiotic for patients with reported allergy to drugs.

If penicillin allergy is present, likelihood of cross reactivity to cephalosporins increases 2 – fold. However, with a third generation cephalosporin, that risk is lower than the risk with other alternatives.

8) **Melling A C** et al reported the effects of normothermia and pre-operative warming on the incidence of SSIs after clean surgery after a randomized control trial. Warming and the normothermia that was produced as a result was found to lower risk of SSIs.

9) **Dale Bratzler** & **Peter M Houck** have reviewed on advisory statement from the National Surgical Infection Prevention Project in the Journal of Clinical Infectious Diseases, **2004**.

According to them, SSIs are the second most common cause of nosocomial infections.

Some recommendations of the project have been reviewed:

- The goal of preoperative prophylaxis is to achieve serum and tissue drug levels that exceed the minimum inhibitory concentration of the drug for the organisms most likely to infect the wound. Ideally, the drug has to be administered as near to incision time as possible - usually within 60 min before incision.

- **Prophylaxis after wound closure unnecessary, since most studies show no benefit.**

- While screening patients for beta-lactam allergy, proper history of previous drug reactions like hypersensitivity, fever and Toxic Epidermal Necrolysis has to be taken. Also, past history of allergy, urticaria, bronchospasm, arrhythmias, hypotension, has to be taken.

- In patients with penicillin allergy, cephalosporins are the appropriate alternate antibiotics, since cephalosporin allergy is very rare even in cases of penicillin allergy.

10) The **Department of surgery** at **University of Washington**, Seattle, brought out a report on SSIs. 44 hospitals, which recorded data on 35,543 surgical cases, reported a reduction in rates of SSIs associated with appropriate antibiotics selection timing and duration of prophylaxis normothermia, oxygenation, euglycemia and appropriate hair removal.

11) **Kurz A** and colleagues from **San Francisco** have studied the effect of perioperative hypothermia and normothermia on wound healing and SSIs. Hypothermia will lead to thermoregulatory vasoconstriction. This causes reduced oxygenation of tissues and oxidative killing by neutrophils. The study revealed a significant increase in the incidence of SSIs in the hypothermic patients.

12) **Kirkland KB** & **Briggs JP** from **Duke University Medical Centre** studied the

impact of SSIs attributable to mortality, excess length of hospitalization and extra costs. They found that the extra hospital stay attributable to SSIs was 1 week. Also, postoperative mortality in-patient who had SSIs was twice that of those who didn't.

13) Another study of pre-operative antibiotics prophylaxis for herniorrhaphy and breast surgery reveals that rate of SSIs is halved by giving the prophylaxis.

14) **Bennett S N** et al published a report in the New England Journal of Medicine in **July 1995**. Between June 1990 and February 1993, the CDC conducted investigations at 7 hospitals because of unusual outbreaks of bloodstream infections, SSIs and acute febrile episodes after surgical procedures. Exposure to Propofol, a lipid-based anaesthetic agent was found to be significantly associated with the development of SSIs. Interviews with and observation of the anaesthesiology personnel revealed a wide variety of lapses in aseptic techniques.

15) **Nichols R L**, in his article in the American Journal of Medicine in **1984**, showed that the pathogens most frequently isolated from the infected wounds were polymicrobial aerobic and anaerobic flora that closely resembled the endogenous microflora that normally inhabited the resected organ.

16) **Burke J F** et al reported about the effective period of preventive antibiotic action in experimental incisions and dermal lesions in 1961. To greatly reduce the infection caused by penicillin-sensitive Staphylococcus aureus, the penicillin had to be in the skin shortly before or at the time of the incision and bacterial exposure. This brought to light the perils of administering the first dose of antibiotic in the postoperative recovery room.

17) **Platt R** et al reported on the efficacy of perioperative antibiotics for herniorrhaphy and breast surgery in 1990. A randomized controlled trial was conducted on 1218 patients undergoing surgery for inguinal hernias and pathological conditions of the breast including excision of breast mass, mastectomy, reduction mammoplasty and axillary node dissection.

A single dose of 1g of Cefonicid was given intravenously approximately 30 minutes before surgery. The patients who received prophylaxis had 48% fewer probable or definite infections compared to those who didn't receive the prophylactic dose.

18) **Ko W** et al have reported in **1992** about a study to investigate the effects of hair removal methods on the incidence of SSIs. Nearly 2000 patients undergoing thoracic surgery were randomised to manual shaving Vs electrical clipping of hair before the incision. The infection rate was significantly high in the manually shaved group.

18) **Lazenby W D** et al have reported on the practice of irrigation of wounds just before closure and the effect on infection rate. Patients were irrigated with saline or povidone iodine solution just before closing the wound. The patients irrigated with saline had a significantly lower rate of infection.

18) **Burke J P** et al have reported in **2001** regarding errors in antimicrobial prophylaxis for surgical patients. Failure to administer the drug within the 2-hour window prior to incision is associat4ed with a 2- to 6-fold increase in rates of SSIs.

18) **Karen L. Stierman** and **Ronald W. Deskin**, in their review of antibiotics in head and neck surgery have classified wounds into four classes based on the guidelines for

prevention of SSIs.

Class I - Clean wounds

Class II - Clean – contaminated wounds

Class III - Contaminated wounds

Class IV - Dirty wounds

However, the most extensive single body of literature on surgical site infections consists of the guidelines for prevention of SSIs published by the centre for disease control and prevention (CDC), based in Atlanta, Georgia in U.S.A.

Apart from the definition of SSIs and criteria for diagnosis, there are guidelines for inclusion and exclusion criteria's information about the microbiology of SSIs, the pathogenesis, the risk factors, the guidelines for prevention of SSIs and the principles of antimicrobial prophylaxis against SSIs.

Microbiology and pathogenesis:

The most frequent pathogens incriminated in surgical site infections are Staphylococcus aureus, coagulase –ve Staphylococci, Enterococci and Escherichia coli, all primarily aerobic in nature.

Multidrug resistant Staphylococcus aureus (MRSA) and Candida are now on the rise. Pathogens like Clostridium perfringens and Rhizopus are unusual.

A minimal degree of microbial contamination is necessary for an SSI to set in.

$$\text{Risk of SSI} = \frac{\text{Dose of contaminant x Virulence of organisms}}{\text{Resistance of the host}}$$

Quantitatively, the risk is very high if dose is more than 10^6 organisms per gram of tissue.

In most cases of SSI, the pathogens are endogenous flora on the patient's body – on the skin, mucous membranes and in hollow viscera.

However, pathogens of SSIs also have exogenous sources like surgical personnel, operating room environment, including the air, the tools, instrument and materials brought to the sterile field during the surgery, etc.

Risk factors

The term *risk factor* has a particular meaning in epidemiology and, in the context of SSI pathophysiology and prevention, strictly refers to a variable that has a significant independent association with the development of SSI after a specific operation.

The various risk factors have been classified into patient – dependent and operation – dependent factors, as shown in the table below.

Patient – dependent risk factors:

- Advanced age
- Diabetes mellitus
- Nicotine use
- Steroid usage
- Nutritional status – malnutrition

- Prolonged pre-operative hospital stay
- Pre-operative colonization of nares with Staph. aureus.
- Perioperative transfusion leading to altered immune response
- Obesity

Operation-dependent risk factors:

- Duration of scrub
- Skin antisepsis
- Pre-operative skin preparation
- Duration of operation
- Antimicrobial prophylaxis
- Operating room ventilation
- Sterilization of instruments
- Foreign material in surgical site
- Drain placement
- Technique of operation –
    - Poor Haemostasis
    - Failure to obliterate dead space, etc.
    - Tissue trauma.

Patient Characteristics

In certain kinds of operations, patient characteristics possibly associated with an increased risk of an SSI include coincident remote site infections or colonization, diabetes, cigarette smoking, systemic steroid use, obesity (>120% of ideal body weight), extremes of age, poor nutritional status and perioperative transfusion of certain blood products.

a. Diabetes

Recent preliminary findings from a study of patients who underwent coronary artery bypass graft showed a significant relationship between increasing levels of glycosylated haemoglobin and SSI rates. Also, increased glucose levels (>200 mg/dL) in the immediate postoperative period (<48 hours) were associated with increased SSI risk.

b. Nicotine use

Nicotine use delays primary wound healing and may increase the risk of SSI. In a large prospective study, current cigarette smoking was an independent risk factor for sternal and/or mediastinal SSI following cardiac surgery. Other studies have corroborated cigarette smoking as an important SSI risk factor.

c. Steroid use

Patients who are receiving steroids or other immunosuppressive drugs preoperatively may be predisposed to developing SSIs. In a study of long-term steroid use in patients with Crohn's disease, SSI developed significantly more often in patients receiving preoperative steroids (12.5%) than in patients without steroid use (6.7%). In contrast, other investigations have not found a relationship between steroid use and SSI risk.

d. Malnutrition

For some types of operations, severe protein-calorie malnutrition is crudely associated with post-operative nosocomial infections, impaired wound healing dynamics or death.

Theoretical arguments can be made for a belief that severe preoperative malnutrition should increase the risk of both incisional and organ-space SSIs. Preoperative malnutrition causes impairment in protein synthesis and therefore impairment in the process of wound healing and repair, thus increasing the chances of infection of the wound.

In the modern era total parenteral nutrition (TPN) and total enteral alimentation (TEA) have enthusiastic acceptance by surgeons and critical care specialists. However, the benefits of preoperative nutritional repletion of malnourished patients in reducing SSI risk are unproven. This inability to prove that nutritional support reduces infection-related risk is therefore an indirect evidence of the high risk of SSI associated with malnutrition.

e. Prolonged preoperative hospital stay

Prolonged preoperative hospital stay is frequently suggested as a patient characteristic associated with increased SSI risk. However, length of preoperative stay is likely a surrogate for severity of illness and co-morbid conditions requiring inpatient work-up and/or therapy before the operation.

f. Preoperative nares colonization with Staph. aureus

S. *aureus* is a frequent SSI isolate. This pathogen is carried in the nares of 20% to 30% of healthy humans. It has been known for years that the development of SSI involving S. *aureus* is definitely associated with preoperative nares carriage of the organism in surgical patients. A recent multivariate analysis demonstrated that such carriage was the most powerful independent risk factor for SSI following cardiothoracic operations.

Mupirocin ointment is effective as a topical agent for eradicating S. *aureus* from the nares of colonized patients or healthcare workers. A prospective, randomized clinical trial has recently been completed on patients in Iowa. Five types of operations in two facilities were observed. Preliminary analysis showed a significant association between nasal carriage of S. *aureus* and subsequent SSI development. The effect of mupirocin on reducing SSI risk is yet to be determined.

g. Perioperative transfusion

It has been reported that perioperative transfusion of leukocyte-containing allogeneic blood components is an apparent risk factor for the development of postoperative bacterial infections, including SSI. In three of five randomized trials conducted in patients undergoing elective colon resection for cancer, the risk of SSI was at least doubled in patients receiving blood transfusions. However, on the basis of detailed epidemiologic reconsiderations, there is currently no scientific basis for withholding necessary blood products from surgical patients as a means of either incisional or organ/ space SSI risk reduction.

Operative Characteristics: Preoperative Issues

a. Preoperative antiseptic showering

A preoperative antiseptic shower or bath decreases skin microbial colony counts. In a study of more than 700 patients who received two preoperative antiseptic showers, chlorhexidine reduced bacterial colony counts nine fold, while povidone-iodine reduced colony counts by 1.3 and 1.9 fold, respectively. Chlorhexidine gluconate-containing products require several applications to attain maximum antimicrobial benefit; so repeated antiseptic showers are usually indicated. Even though preoperative showers reduce the skin's microbial colony counts, they have not definitively been shown to reduce SSI rates.

b. Preoperative hair removal

Preoperative shaving of the surgical site the night before an operation is associated with a significantly higher SSI risk than either the use of depilatory agents or no hair removal. In one study, SSI rates were 5.6% in patients who had hair removed by razor shave compared to a 0.6% rate among those who had hair removed by depilatory or who had no hair removed. The increased SSI risk associated with shaving has been attributed to microscopic cuts in the skin that later serve as foci for bacterial multiplication. Shaving immediately before the operation compared to shaving within 24 hours preoperatively was associated with decreased SSI rates (3.1% vs. 7.1%); if shaving was performed more than 24 hours prior to operation, the SSI rate exceeded 20%. Clipping hair immediately before an operation also has been associated with a lower risk of SSI than shaving or clipping the night before an operation (SSI rates immediately before 1.8% vs. night before 4.0%). Although the use of depilatories has been associated with a lower SSI risk than shaving or clipping, depilatories sometimes produce hypersensitivity reactions. Other studies showed that preoperative hair removal by any means was associated with increased SSI rates and suggested that no hair be removed,

c. Patient skin preparation in the operating room.

Several antiseptic agents are available for preoperative preparation of skin at the incision site. The iodophors (e.g., povidone-iodine), alcohol-containing products, and chlorhexidine gluconate are the most commonly used agents.

Alcohol is defined by the FDA as having one of the following active ingredients: ethyl alcohol, 60% to 95% by volume in an aqueous solution, or isopropyl alcohol, 50% to 91.3% by volume in an aqueous solution. Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic. Aqueous 70% to 92% alcohol solutions have germicidal activity against bacteria, fungi, and viruses, but spores can be resistant. One potential disadvantage of the use of alcohol in the operating room is its flammability.

Both chlorhexidine gluconate and iodophors have broad spectra of antimicrobial activity. In some comparisons of the two antiseptics when used as preoperative hand scrubs, chlorhexidine gluconate achieved greater reductions in skin microflora than did povidone-iodine and also had greater residual activity after a single application. Further, chlorhexidine gluconate is not inactivated by blood or serum proteins. Iodophors may be inactivated by blood or serum proteins, but exert a bacteriostatic effect as long as they are present on the skin.

Before the skin preparation of a patient is initiated, the skin should be free of gross contamination (i.e., dirt, soil, or any other debris) . The patient's skin is prepared by applying an antiseptic in concentric circles, beginning in the area of the proposed incision. The prepared area should be large enough to extend the incision or create new incisions or drain sites, if necessary. The application of the skin preparation may need to be modified, depending on the condition of the skin (e.g., burns) or location of the incision site (e.g., face).

There are reports of modifications to the procedure for preoperative skin preparation which include:

(1) removing or wiping off the skin preparation antiseptic agent after application,

(2) using an antiseptic-impregnated adhesive drape,

(3) merely painting the skin with an antiseptic in lieu of the skin preparation procedure described above, or

(4) using a "clean" versus a "sterile" surgical skin preparation kit. However, none of these modifications has been shown to represent an advantage.

d. Preoperative hand/forearm antisepsis

Members of the surgical team who have direct contact with the sterile operating field or sterile instruments or supplies used in the field wash their hands and forearms by performing a traditional procedure known as scrubbing (or the surgical scrub) immediately before donning sterile gowns and gloves. Ideally, the optimum antiseptic used for the scrub should have a broad spectrum of activity, be fast acting, and have a persistent effect. Antiseptic agents commercially available in the United States for this purpose contain alcohol, chlorhexidine, iodine/iodophors, parachloro-meta-xylenol, or triclosan.

Alcohol is considered the gold standard for surgical hand preparation in several European countries. However, when 7.5% povidone-iodine or 4% chlorhexidine gluconate was compared to alcoholic chlorhexidine (60% isopropanol and 0.5% chlorhexidine gluconate in 70% isopropanol), alcoholic chlorhexidine was found to have greater residual antimicrobial activity, No agent is ideal for every situation, and a major factor, aside from the efficacy of any product, is its acceptability by operating room personnel after repeated use. No clinical trials have evaluated the impact of scrub agent choice on SSI risk.

Recent studies suggest that scrubbing for at least 2 minutes is as effective as the traditional 1 minute scrub in reducing hand bacterial colony counts, but the optimum duration of scrubbing is not known. The first scrub of the day should include a thorough cleaning underneath fingernails (usually with a brush). It is not clear that such cleaning is a necessary part of subsequent scrubs during the day. After performing the surgical scrub, hands should be kept up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows. Sterile towels should be used for drying the hands and forearms before the donning of a sterile gown and gloves.

A surgical team member who wears artificial nails may have increased bacterial and fungal colonization of the hands despite performing an adequate hand scrub. Hand carriage of gram-negative organisms has been shown to be greater among wearers of artificial nails than among non-wearers. An outbreak of *Serratia marcescens* SSIs in cardiovascular surgery patients was found to be associated with a surgical nurse who wore artificial nails.

e. Management of infected or colonized surgical personnel

Surgical personnel who have active infections or are colonized with certain micro-organisms have been linked to outbreaks or clusters of SSIs. Thus, it is important that health care organizations implement policies to prevent transmission of micro-organisms from personnel to patients.

f. Antimicrobial prophylaxis

Surgical antimicrobial prophylaxis (AMP) refers to a very brief course of an antimicrobial agent initiated just before an operation begins. AMP is not an attempt to sterilize tissues, but a critically timed adjunct used to reduce the microbial burden of intraoperative contamination to a level that cannot overwhelm host defences. AMP does not pertain to prevention of SSI caused by postoperative contamination. Intravenous infusion is the mode of AMP delivery used most often in modern surgical practice. Essentially all confirmed AMP indications pertain to elective operations in which skin incisions are closed in the operating room.

Four principles must be followed to maximize the benefits of AMP:

- Use an AMP agent for all operations or classes of operations in which its use has been shown to reduce SSI rates based on evidence from clinical trials or for those operations after which incisional or organ/space SSI would represent a catastrophe.
- Use an AMP agent that is safe, inexpensive, and bactericidal with an in vitro spectrum that covers the most probable intraoperative contaminants for the operation.
- Time the infusion of the initial dose of antimicrobial agent so that a bactericidal concentration of the drug is established in serum and tissues by the time the skin is incised.
- Maintain therapeutic levels of the antimicrobial agent in both serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room,

Because clotted blood is present in all surgical wounds, therapeutic serum levels of AMP agents are logically important in addition to therapeutic tissue levels. Fibrin-enmeshed bacteria may be resistant to phagocytosis or to contact with antimicrobial agents that diffuse from the wound space.

A simple way to organize AMP indications is based on using the surgical wound classification scheme that has already been outlined in the definitions, which employs descriptive case features to *postoperatively* grade the degree of intraoperative microbial contamination. A surgeon makes the decision to use AMP by anticipating *preoperatively* the surgical wound class for a given operation.

AMP is indicated for all operations that entail entry into a hollow viscus under controlled conditions.

AMP is sometimes indicated for operations that entail incisions through normal tissue and in which no viscus is entered and no inflammation or infection is encountered. Two well-recognized AMP indications for such clean operations are:

a) When any intravascular prosthetic material or a prosthetic joint will be inserted, and
b) For any operation in which an incisional or organ/space SSI would pose catastrophic risk. Some have advocated use of AMP during all operations on the breast.

By definition, AMP is not indicated for an operation classified as contaminated or dirty. In such operations, patients are frequently receiving therapeutic antimicrobial agents preoperatively for established infections.

Cephalosporins are the most thoroughly studied AMP agents. These drugs are effective against many gram-positive and gram-negative micro-organisms. They also share the features of demonstrated safety, acceptable pharmacokinetics, and a reasonable cost per dose. In particular, Cefazolin is widely used and generally viewed as the AMP agent of first choice for clean operations. If a patient is unable to receive a cephalosporin because of penicillin allergy, an alternative for gram-positive bacterial coverage is either Clindamycin or Vancomycin.

The aminoglycosides are seldom recommended as first choices for antimicrobial prophylaxis, either as single drugs or as components of combination regimens. The routine use of Vancomycin in AMP is not recommended for any kind of operation. However, Vancomycin may be the AMP agent of choice in certain clinical circumstances, such as when a cluster of MRSA mediastinitis or incisional SSI due to Methicillin-resistant coagulase-negative Staphylococci has been detected.

Agents most commonly used for AMP (i.e., cephalosporins) exhibit time-dependent bactericidal action. The therapeutic effects of such agents are probably maximized when their levels continuously exceed a threshold value best approximated by the minimal bactericidal concentration value observed for the target pathogens in vitro. When the duration of an operation is expected to exceed the time in which therapeutic levels of the AMP agent can be maintained, additional AMP agent should be infused. That time point for Cefazolin is estimated as 3 to 4 hours. In general, the timing of a second (or third, etc.) dose of any AMP drug is estimated from three parameters: tissue levels achieved in normal patients by a standard therapeutic dose, the approximate serum half-life of the drug, and awareness of approximate MIC_{90} values for anticipated SSI pathogens. Basic "rules of thumb" guide decisions about AMP dose sizes and timing.

For example, it is believed that a full therapeutic dose of cefazolin (1-2 g) should be given to adult patients no more than 30 minutes before the skin is incised. There are a few exceptions to this basic guide. With respect to dosing, it has been demonstrated that larger doses of AMP agents are necessary to achieve optimum effect in morbidly obese patients. Simple protocols of AMP timing and oversight responsibility should be locally designed to be practical and effective.

Operative characteristics: Intraoperative issues

a. Operating room environment

(1) Ventilation

Operating room air may contain microbial-laden dust, lint, skin squames, or respiratory droplets. The microbial level in operating room air is directly proportional to the number of people moving about in the room. Therefore, efforts should be made to minimize personnel traffic during operations. Outbreaks of SSIs caused by group A beta-haemolytic streptococci have been traced to airborne transmission of the organism from colonized operating room personnel to patients.

Operating rooms should be maintained at positive pressure with respect to corridors and adjacent areas. Positive pressure prevents airflow from less clean areas into more clean areas. All ventilation or air conditioning systems in hospitals, including those in operating rooms, should have two filter beds in series, with the efficiency of the first filter bed being 30% and that of the second filter bed being 90%. Conventional operating room ventilation systems produce a minimum of about 15 air changes of filtered air per hour, three (20%) of which must be fresh air. Air should be introduced at the ceiling and exhausted near the floor.

Laminar airflow and use of DV radiation have been suggested as additional measures to reduce SSI risk for certain operations. Laminar airflow is designed to move particle-free air (called "ultra clean air") over the aseptic operating field at a uniform velocity (0.3 to 0.5 m/sec), sweeping away particles in its path. Laminar airflow can be directed vertically or horizontally.

(2) Environmental surfaces

It is important to perform routine cleaning of these surfaces to re-establish a clean environment after each operation. There are no data to support routine disinfecting of environmental surfaces or equipment between operations in the absence of contamination or visible soiling. When visible soiling of surfaces or equipment occurs during an operation, an Environmental Protection Agency (EPA)-approved hospital disinfectant should be used to decontaminate the affected areas before the next operation to reduce the risk of SSI.

(3) Microbiologic sampling

Because there are no standardized parameters by which to compare microbial levels obtained from cultures of ambient air or environmental surfaces in the operating room, routine microbiologic sampling cannot be justified. Such environmental sampling should only be performed as part of an epidemiologic investigation.

(4) Conventional sterilization of surgical instruments

Inadequate sterilization of surgical instruments has resulted in SSI outbreaks. Surgical instruments can be sterilized by steam under pressure, dry heat, ethylene oxide, or other approved methods. The importance of routinely monitoring the quality of sterilization procedures has been established. Microbial monitoring of steam autoclave performance is necessary and can be accomplished by use of a biological indicator.

b. Surgical attire and drapes

In this section the term *surgical attire* refers to scrub suits, caps/hoods, shoe covers, masks, gloves, and gowns. Although experimental data show that live micro-organisms are shed from hair, exposed skin, and mucous membranes of operating room personnel, few controlled clinical studies have evaluated the relationship between the use of surgical attire and SSI risk. Nevertheless, the use of barriers seems prudent to minimize a patient's exposure to the skin, mucous membranes, or hair of surgical team members, as well as to protect surgical team members from exposure to blood and bloodborne pathogens (e.g., human immunodeficiency virus and hepatitis viruses).

(1) Masks

The wearing of surgical masks during operations to prevent potential microbial contamination of incisions is a longstanding surgical tradition. However, some studies have raised questions about the efficacy and cost-benefit of surgical masks in reducing SSI risk. Nevertheless, wearing a mask can be beneficial since it protects the wearer's nose and mouth from inadvertent exposures (i.e., splashes) to blood and other body fluids.

(2) Surgical caps/hoods and shoe covers

Surgical caps/hoods are inexpensive and reduce contamination of the surgical field by organisms shed from the hair and scalp. SSI outbreaks have occasionally been traced to organisms isolated from the hair or scalp (*Staph. aureus* and group A *Streptococcus),* even when caps were worn by personnel during the operation and in the operating suites.

(3) Sterile gloves

Sterile gloves are put on after donning sterile gowns.

A strong theoretical rationale supports the wearing of sterile gloves by all scrubbed members of the surgical team. Sterile gloves are worn to minimize transmission of micro-organisms from the hands of team members to patients and to prevent contamination of team members' hands with patients' blood and body fluids. If the integrity of a glove is compromised (e.g., punctured), it should be changed as promptly as safety permits. Wearing two pairs of gloves (double-gloving) has been shown to reduce hand contact with patients' blood and body fluids when compared to wearing only a single pair.

(4) Gowns and drapes

Sterile surgical gowns and drapes are used to create a barrier between the surgical field and potential sources of bacteria. Gowns are worn by all scrubbed surgical team members and drapes are placed over the patient.

c. Asepsis and surgical technique

(1) Asepsis

Rigorous adherence to the principles of asepsis by all scrubbed personnel is the foundation of surgical site infection prevention. Others who work in close proximity to the sterile surgical field, such as anaesthesia personnel who are separated from the field only by a drape barrier, also must abide by these principles. SSIs have occurred in which anaesthesia personnel were implicated as the source of the pathogen. Anaesthesiologists and nurse anaesthetists perform a variety of invasive procedures such as placement of intravascular devices and endotracheal tubes, and administration of intravenous drugs and solutions. Lack of adherence to the principles of asepsis during such procedures, including use of common syringes and contaminated infusion pumps and the assembly of equipment and solutions in advance of procedures, have been associated with outbreaks of postoperative infections, including SSI. Recommendations for infection control practices in anaesthesiology have been published.

(2) Surgical technique

Excellent surgical technique is widely believed to reduce the risk of SSI. Such techniques include maintaining effective haemostasis while preserving adequate blood supply, preventing hypothermia, gently handling tissues, avoiding inadvertent entries into a hollow viscus, removing devitalized (e.g., necrotic or charred) tissues, using drains and suture material appropriately, eradicating dead space, and appropriately managing the postoperative incision.

Any foreign body, including suture material, a prosthesis, or drain, may promote inflammation at the surgical site and may increase the probability of SSI after otherwise benign levels of tissue contamination. Extensive research compares different types of suture material and their presumed relationships to SSI risk. In general, monofilament sutures appear to have the lowest infection-promoting effects.

Drains placed through an operative incision increase incisional SSI risk. Many authorities suggest placing drains through a separate incision distant from the operative incision. It appears that SSI risk also decreases when closed suction drains are used rather than open drains. Closed suction drains can effectively evacuate postoperative haematomas or seromas, but timing of drain removal is important. Bacterial colonization of initially sterile drain tracts increases with the duration of time the drain is left in place.

Operative Characteristics: Postoperative Issues

a. Incision care

The type of postoperative incision care is determined by whether the incision is closed primarily (i.e., the skin edges are re-approximated at the end of the operation), left open to be closed later, or left open to heal by second intention. When a surgical incision is closed primarily, as most are, the incision is usually covered with a sterile dressing for 24 to 48 hours. Beyond 48 hours, it is unclear whether an incision must be covered by a dressing or whether showering or bathing is detrimental to healing. When a surgical incision is left open at the skin level for a few days before it is closed (delayed primary closure), a surgeon has determined that it is likely to be contaminated or that the patient's condition prevents primary closure (e.g., oedema at the site). When such is the case, the incision is packed with a sterile dressing. When a surgical incision is left open to heal by second intention, it is also packed with sterile moist gauze and covered with a sterile dressing. The American College of Surgeons, CDC, and others have recommended using sterile gloves and equipment (sterile technique) when changing dressings on any type of surgical incision.

b. Discharge planning

In current practice, many patients are discharged very soon after their operation, before surgical incisions have fully healed. The lack of optimum protocols for home incision care dictates that much of what is done at home by the patient, family, or home care agency practitioners must be individualized. The intent of discharge planning is to maintain integrity of the healing incision, educate the patient about the signs and symptoms of infection, and advise the patient about whom to contact to report any problems.

SSI surveillance

Surveillance of SSI with feedback of appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk.

RECOMMENDATIONS FOR PREVENTION OF SURGICAL SITE INFECTION

Rationale:

The Guideline for Prevention of Surgical Site Infection, 1999, provides recommendations concerning reduction of surgical site infection risk. Each recommendation is categorized on the basis of existing scientific data, theoretical rationale, and applicability.

Category I A. Strongly recommended for implementation and supported by well-designed experimental, clinical, or epidemiological studies.

Category I B. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and strong theoretical rationale.

Category II. Suggested for implementation and supported by suggestive clinical or epidemiological studies or theoretical rationale.

No recommendation; unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.

Recommendations:

1. Preoperative

a. Preparation of the patient

1. Whenever possible, identify and treat all infections remote to the surgical site before elective operation and postpone elective operations on patients with remote site infections until the

infection has resolved. ***Category IA***

2. Do not remove hair preoperatively unless the hair at or around the incision site will interfere with the operation. ***Category IA***

3. If hair is removed, remove immediately before the operation, preferably with electric clippers. ***Category IA***

4. Adequately control serum blood glucose levels in all diabetic patients and particularly avoid hyperglycaemia perioperatively. ***Category IB***

5. Encourage tobacco cessation. At minimum, instruct patients to abstain for at least 30 days before elective operation from smoking cigarettes, cigars, pipes, or any other form of tobacco consumption (e.g., chewing/dipping). ***Category IB***

6. Do not withhold necessary blood products from surgical patients as a means to prevent SSIs. ***Category IB***

7. Require patients to shower or bathe with an antiseptic agent on at least the night before the operative day. ***Category IB***

8. Thoroughly wash and clean at and around the incision site to remove gross contamination before performing antiseptic skin preparation. ***Category IB***

9. Use an appropriate antiseptic agent for skin preparation. ***Category IB***

10. Apply preoperative antiseptic skin preparation in concentric circles moving toward the periphery. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary. ***Category II***

11. Keep preoperative hospital stay as short as possible while allowing for adequate preoperative preparation of the patient. ***Category II***

12. No recommendation to taper or discontinue systemic steroid use (when medically

permissible) before elective operation. ***Unresolved issue***

13. No recommendation to enhance nutritional support for surgical patients solely as a means to prevent SSIs. ***Unresolved issue***

14. No recommendation to preoperatively apply mupirocin to nares to prevent SSIs. ***Unresolved issue***

15. No recommendation to provide measures that enhance wound space oxygenation to prevent SSIs. ***Unresolved issue***

b. Hand/forearm antisepsis for surgical team members

1. Keep nails short and do not wear artificial nails.

Category IB

2. Perform a preoperative surgical scrub for at least 2 to 5 minutes using an appropriate antiseptic. Scrub the hands and forearms up to the elbows. ***Category IB***

3. After performing the surgical scrub, keep hands up and away from the body (elbows in flexed position) so that water runs from the tips of the fingers toward the elbows. Dry hands with a sterile towel and don a sterile gown and gloves. ***Category IB***

4. Clean underneath each fingernail prior to performing the first surgical scrub of the day.

Category II

5. Do not wear hand or arm jewellery. ***Category 11***

6. No recommendation on wearing nail polish.

Unresolved Issue

c. Management of infected or colonized surgical personnel

1. Educate and encourage surgical personnel who have signs and symptoms of a transmissible infectious illness to report conditions promptly to their supervisory and occupational health

service personnel. ***Category IB***

2. Develop well-defined policies concerning patient care responsibilities when personnel have potentially transmissible infectious conditions. These policies should govern (a) personnel responsibility in using the health service and reporting illness, (b) work restrictions, and (c) clearance to resume work after an illness that required work restriction. The policies also should identify persons who have the authority to remove personnel from duty. ***Category IB***

3. Obtain appropriate cultures from, and exclude from duty, surgical personnel who have draining skin lesions until infection has been ruled out or personnel have received adequate therapy and infection has resolved. ***Category IB***

4. Do not routinely exclude surgical personnel who are colonized with organisms such as *Staph. aureus* (nose, hands, or other body site) or group A *Streptococcus,* unless such personnel have been linked epidemiologically to dissemination of the organism in the healthcare setting. ***Category IB***

d. Antimicrobial prophylaxis

1. Administer a prophylactic antimicrobial agent only when indicated, and select it based on its efficacy against the most common pathogens causing SSI for a specific operation and published recommendations. ***Category IA***

2. Administer by the intravenous route the initial dose of prophylactic antimicrobial agent, timed such that a bactericidal concentration of the drug is established in serum and tissues when the incision is made. Maintain therapeutic levels of the agent in serum and tissues throughout the operation and until, at most, a few hours after the incision is closed in the operating room. ***Category IA***

3. Before elective colorectal operations in addition to the above, mechanically prepare the

colon by use of enemas and cathartic agents. Administer nonabsorbable oral antimicrobial agents in divided doses on the day before the operation. ***Category lA***

4. For high-risk Caesarean section, administer the prophylactic antimicrobial agent immediately after the umbilical cord is clamped. ***Category lA***

5. Do not routinely use Vancomycin for antimicrobial prophylaxis. *Category IB*

2. *Intraoperative*

a. Ventilation

1. Maintain positive-pressure ventilation in the operating room with respect to the corridors and adjacent areas. ***Category IB***

2. Maintain a minimum of 15 air changes per hour, of which at least 3 should be fresh air. ***Category IB***

3. Filter all air, re circulated and fresh, through the appropriate filters per the American Institute of Architects' recommendations. ***Category IB***

4. Introduce all air at the ceiling, and exhaust near the floor. ***Category IB***

5. Do not use DV radiation in the operating room to prevent SSIs. ***Category IB***

6. Keep operating room doors closed except as needed for passage of equipment, personnel, and the patient. ***Category IB***

7. Consider performing orthopaedic implant operations in operating rooms supplied with ultra clean air. ***Category 11***

8. Limit the number of personnel entering the operating room to necessary personnel. ***Category II***

b. Cleaning and disinfection of environmental surfaces

1. When visible soiling or contamination with blood or other body fluids of surfaces or

equipment occurs during an operation, use an EPA-approved hospital disinfectant to clean the affected areas before the next operation. ***Category IB***

2. Do not perform special cleaning or closing of operating rooms after contaminated or dirty operations. ***Category IB***

3. Do not use tacky mats at the entrance to the operating room suite or individual operating rooms for infection control. ***Category IB***

4. Wet-vacuum the operating room floor after the last operation of the day or night with an EPA-approved hospital disinfectant. ***Category II***

5. No recommendation on disinfecting environmental surfaces or equipment used in operating rooms between operations in the absence of visible soiling. ***Unresolved issue***

c. Microbiologic sampling

1. Do not perform routine environmental sampling of the operating room. Perform microbiologic sampling of operating room environmental surfaces or air only as part of an epidemiologic investigation. ***Category IB***

d. Sterilization of surgical instruments

1. Sterilize all surgical instruments according to published guidelines. ***Category IB***

2. Perform flash sterilization only for patient care items that will be used immediately (e.g., to reprocess an inadvertently dropped instrument). Do not use flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time. ***Category IB***

e. Surgical attire and drapes

1. Wear a surgical mask that fully covers the mouth and nose when entering the operating room if an operation is about to begin or already under way, or if sterile instruments are exposed.

Wear the mask throughout the operation. ***Category IB***

2. Wear a cap or hood to fully cover hair on the head and face when entering the operating room. ***Category IB***

3. Do not wear shoe covers for the prevention of SSIs

Category IB

4. Wear sterile gloves if a scrubbed surgical team member. Put on gloves after donning a sterile gown. ***Category IB***

5. Use surgical gowns and drapes that are effective barriers when wet (i.e., materials that resist liquid penetration). ***Category IB***

6. Change scrub suits that are visibly soiled, contaminated, and/or penetrated by blood or other potentially infectious materials. ***Category IB.***

7. No recommendations on how or where to launder scrub suits, on restricting use of scrub suits to the operating suite, or for covering scrub suits when out of the operating suite. ***Unresolved issue***

f. Asepsis and surgical technique

1. Adhere to principles of asepsis when placing intravascular devices (e.g., central venous catheters), spinal or epidural anaesthesia catheters, or when dispensing and administering intravenous drugs. ***Category IA***

2. Assemble sterile equipment and solutions immediately prior to use. *Category II*

3. Handle tissue gently, maintain effective haemostasis, minimize devitalized tissue and foreign bodies (i.e., sutures, charred tissues, necrotic debris), and eradicate dead space at the surgical site. ***Category IB***

4. Use delayed primary skin closure or leave an incision open to heal by second intention if the

surgeon considers the surgical site to be heavily contaminated (e.g., Class III and Class IV). ***Category IB***

5. If drainage is necessary, use a closed suction drain. Place a drain through a separate incision distant from the operative incision. Remove the drain as soon as possible. ***Category IB***

3. Postoperative incision care

a. Protect with a sterile dressing for 24 to 48 hours postoperatively an incision that has been closed primarily. ***Category IB***

b. Wash hands before and after dressing changes and any contact with the surgical site. ***Category IB***

c. When an incision dressing must be changed, use sterile technique. ***Category II***

d. Educate the patient and family regarding proper incision care, symptoms of SSI, and the need to report such symptoms. ***Category II***

e. No recommendation to cover an incision closed primarily beyond 48 hours, nor on the appropriate time to shower or bathe with an uncovered incision. ***Unresolved Issue***

4. Surveillance

a. Use CDC definitions of SSIs without modification for identifying SSI among surgical inpatients and outpatients. ***Category IB***

b. For inpatient case-finding (including readmissions), use direct prospective observation, indirect prospective detection, or a combination of both direct and indirect methods for the duration of the patient's hospitalization. ***Category IB***

c. When post-discharge surveillance is performed for detecting SSI following certain operations (e.g., coronary artery bypass graft), use a method that accommodates available resources and data needs.

Category II

d. For outpatient case-finding, use a method that accommodates available resources and data needs. ***Category IB***

e. Assign the surgical wound classification upon completion of an operation. A surgical team member should make the assignment. ***Category II***

f. For each patient undergoing an operation chosen for surveillance, record those variables shown to be associated with increased SSI risk (e.g., surgical wound class, ASA class, and duration of operation). ***Category IB***

AIM

After having reviewed the extensive amount of literature on the subject of Surgical Site Infections, the aim of the study was formulated keeping in mind the limitations of the set-up.

This is a descriptive study of superficial SSIs in clean surgeries with pre-operative antibiotic prophylaxis using intravenous Cefotaxime and intravenous Ampicillin with the following objectives:

- To document the frequency of surgical site infections in cases of clean surgeries in our surgical unit.
- To compare the rates of infection with each of the two drugs used.
- To observe the rates of infection in men and women undergoing surgeries.
- To document the duration of stay of the patients included in the study and to compare the length of stay of the patients who developed SSIs with that of those who didn't.
- To study the cost of treatment incurred.

MATERIALS AND METHODS

A descriptive study was conducted in Govt. Stanley Hospital in our Surgical Unit from June 2003 to May 2005. Selection and exclusion criteria were laid out.

Patients between the ages of 15 and 70 years were selected. At one extreme, paediatric physiology differs considerably from adult physiology especially in the way the body metabolized drugs and so, dosages differ. At the other extreme, people older than 70years of age are at a higher risk for SSIs due to various reasons.

Diagnoses, which involved clean surgeries as treatment, were selected.

Any patients for whom perineal exploration was required (hydroceles, etc) were excluded from the study due to high microbial contamination of the perineal skin and therefore, higher risk of infection.

Any procedure, which involved entry into body cavities or manipulation of viscera, was excluded – these are, by definition, not clean procedures.

Re-operative surgery was excluded.

Poor blood supply and vascularisation in the scar tissue due to the previous surgery puts the wound at risk of delayed healing and therefore, increased risk of infection.

Incisional hernias, which form a sizeable chunk of the number of cases requiring re-operation, were excluded. One of the cardinal risk-factors for development of these hernias is wound infection and so, incisional hernias by definition can't be regarded as clean cases.

Smoking habits of patients were taken into account. However, the ubiquitous practice of smoking and high percentage of smokers, especially among the male population, made it difficult to exclude patients on this basis. We would have had substantially fewer patients in the group.

An intact immune status is essential for combating infection. So, immuno-compromised states put patients at a higher risk for infection. Conditions like diabetes, malignancy, steroid administration and malnutrition, which compromise the immunity of the body, were considered and therefore, patients with these diseases were excluded.

Nutritional status of the patients was assessed with the help of weight of patient, height in metres and Quetelet's BMI. This was used to exclude the undernourished and overnourished patients.

History of Allergy was considered

EXCLUSION CRITERIA

- Age below 15 years and over 70 years
- Perineal lesions (Hydroceles, lumps and bumps over perineal skin, etc.)
- Diabetes mellitus
- Malignancy
- Steroid usage (asthmatics, etc.)

- Malnutrition (BMI < 20)
- Obesity (BMI > 30).
- Re-operative surgeries and including incisional hernias.
- Patients already on antibiotics for other causes.

CASES INCLUDED

Clean Surgeries – Inguinal hernias, benign conditions of the female and male breast, thyroid surgery, parotid and submandibular surgery excision of lumps and bumps over skin.

Once the patients were selected based on the above criteria, the date of admission was planned in such a way that the patients got admitted one or two days prior to the date of surgery.

The antibiotics to be used were assigned randomly after checking allergy with the help of a test dose on the day before surgery.

Each patient was to be administered 1g of Ampicillin or Cefotaxime intravenously on the morning of the surgery within 2 hours prior to the time of incision.

Provisions and protocols were placed for usage of alternative drugs in case of drug allergy, which was tested with an intradermal dose of the drug on the day prior to the surgery. If found allergic to Ampicillin, the patient was to be given Cefotaxime. In case of Cefotaxime allergy, the patient was to be given Ciprofloxacin, two available drugs in this hospital.

The skin was prepared on the day of surgery.

The first prophylactic dose of antibiotic was given pre-operatively via the intravenous route.

The duration of surgery was noted.

Attention was given to tissue handling, haemostasis, dead space obliteration, removal of devitalised tissue and operating time.

Top-up dose of the same antibiotic was given 3 hours after incision in case the surgery took longer than 3hours.

The postoperative course and recovery was observed.

Date of suture removal was noted.

After discharge, each patient was followed-up weekly for the first 1 month.

In cases warranting surveillance for longer, monthly follow-up was done after the first month upto a period of 1 year.

The results were then tabulated.

OBSERVATIONS AND RESULTS

A total of 114 patients were included in the study, out of which 57 were men and 57 were ladies.

Intravenous Cefotaxime was used in 54 of the 114 cases, while intravenous Ampicillin was used in 60 patients.

Inguinal herniorrhaphy for groin hernias was the most frequently performed surgery. Other surgeries done have been shown in the graph below:

Out of the patients, 12 patients developed SSIs, the diagnosis of which was made in accordance with the CDC guidelines for prevention of SSIs. The Cefotaxime arm and Ampicillin arm had 6 cases of SSIs each. No patient developed drug allergy to either of the drugs used.

Overall, 12 patients out of the total of 114 developed surgical site infections, an incidence of 10.5 %(95% C.I. 5.8% – 17.2%).

In the Cefotaxime arm, 6 out of 54 patients developed SSIs (incidence rate 11.1%) while in the Ampicillin arm, 6 out of 60 patients developed SSIs (incidence of 10.0%). The difference of 1.1% wasn't statistically significant ($p=1.0$).

Out of 57 male patients included, 7 developed SSIs (incidence of 12%) and out of the 57 female patients in the study, 5 developed SSIs (incidence of 8.8%). This difference was insignificant as well.

The average duration of hospital stay was 5.4 days in the non-infected group, compared to 9.6 days in the infected group.

The cost for 1g of Ampicillin was Rs.15, while the cost for 1g of Cefotaxime was Rs.40.

DISCUSSION

In the study conducted, the rate of surgical site infections was 10.5% overall, as already mentioned. As far as our hospital is concerned, there was no significant difference between the usage of Ampicillin and Cefotaxime, even though from references worldwide, Ampicillin is believed to be no longer active against Staph. aureus, presumably the most common pathogen implicated in superficial SSIs.

The length of stay in hospital was significantly higher in cases that developed SSIs, which justifies the practice of pre-operative antibiotic prophylaxis.

The cost of Cefotaxime is almost thrice that of Ampicillin. Also, usage of Cefotaxime doesn't appear to confer any specific advantage as far as risk of SSI is concerned. In our set-up, in which the establishment bears the cost of treatment in the vast majority of patients, this is a very significant observation. Judicious use of a particular drug will potentially save a lot of expenditure to the exchequer.

However, the overall incidence of SSIs is much higher than the world standard of 2-5%. Various factors have influenced the high rate of infection.

1) Firstly, the atmosphere and environment prevalent in this part of the world is a big influence on infection, with the ambient temperature hovering around 33ºC – 38ºC all the year round. The humidity in the air approaches 85-90% for most part of the year. As a result, the skin is warm and moist, very much favouring bacterial proliferation.

2) In the study conducted, the majority of subjects come from the lower strata of the

socioeconomic ladder. As a result, patient awareness about the need for hygiene is low, increasing the risk of bacterial contamination of the skin and hence of the wound.

3) From the literature reviewed, it is evident that smoking increases the risk of infection significantly. Tobacco smoke contains metalloproteinases among its 5000 constituents. These cause breakdown of structural proteins like collagen, thus hindering the process of fibrosis in a wound. This increase chances of developing a wound infection. Smoking as a habit is ubiquitous among the patients of this hospital, especially the males. Regardless of the attempts of health care personnel to educate the patients about the ill-effects of smoking and the required precautions to be taken, there lies a serious question mark as regards to patient compliance in this respect.

4) Pre-operative colonization of nares with Staphylococci, which is an important promoter of infections, is widespread.

5) \The system of ventilation of the operating room is less than ideal in this set up. This is another important determinant of the rate of surgical site infections.

6) Last, but definitely not the least, lies the role of the surgeon. The face off of reliable experience versus youthful exuberance has been, is and will forever be a topic of raging controversy and contradiction.

Surgery is, after all, an art which can only be imbibed with diligent practice. After all, one can only lead the horse to the waterhole. Obviously, the learning curve will come into consideration. Gentle handling of tissues, reduction of dead space, maintenance of perfect haemostasis, complete removal of devitalised tissue and operating time are some aspects of surgery which have to be perfected with time. In letting the youngsters learn, the experienced teachers show immense magnanimity. Inherent adverse effects necessary disadvantages of this process are exemplified by the high infection rate, the price mankind pays.

CONCLUSIONS

- In the study conducted, the rate of surgical site infections was 10.5% overall, as already mentioned.
- As far as our hospital is concerned, there was no significant difference between the usage of Ampicillin and Cefotaxime.
- The length of stay in hospital was significantly higher in cases that developed SSIs, which justifies the practice of pre-operative antibiotic prophylaxis.
- The cost of Cefotaxime is almost thrice that of Ampicillin. Also, usage of Cefotaxime doesn't appear to confer any specific advantage as far as risk of SSI is concerned.
- In our set-up, in which the establishment bears the cost of treatment in the vast majority of patients, this is a very significant observation.
- Judicious use of a particular drug will potentially save a lot of expenditure to the exchequer.

PROFORMA

Name : Age/Sex: IP No.:

Height / Weight: BMI :

Diagnosis :

Past Medical History especially :

Diabetic : Yes / No

Malignancy : Yes / No

Hypertension

Previous Surgeries if any:

History of Allergy :

Drug history - Long-term medications, especially corticosteroids.

Date of Admission :

Date of Surgery :

Details :

Tissue Handling :

Duration of Surgery :

Haemostasis :

Dead space obliteration :

Antibiotic given :

Allergic reaction to test dose:

Time of administration :

Any additional dose given :

Post-operative course :

Dose of Suture removal :

Date of discharge :

Follow-up :

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