EFFICACY OF SINGLE DOSE ANTIBIOTIC PROPHYLAXIS IN INGUINAL HERNIOPLASTY

By

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DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION & RESEARCH, KOLAR, KARNATAKA

In partial fulfilment of the requirements for the degree of M.S. (GENERAL SURGERY)

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ABSTRACT

INTRODUCTION AND OBJECTIVES

Surgical site infection (SSI) is the most frequent complication in inguinal hernioplasty.SSI is related with an increase in length of stay and costs and a decrease in quality of life.

The introduction of tension free hernioplasty has made the use of antibiotic prophylaxis more critical because of the infection risk when prosthetic materials are used.

Use of antibiotics in Lichtenstein's hernia repair is still debatable in a rural set up. Some surgeons use a single dose of pre-operative antibiotic, while the majority use multiple doses of post operative antibiotics claiming that the latter is superior to the former in prevention of surgical site infection in Lichtenstein's repair. Another subject in rural setup that must be addressed in antibiotic prophylaxis is cost-effectiveness. In these cases, the costs of antibiotic administration must be carefully evaluated against the potentials benefits. Only studies particularly designed to answer this question could solve it. This study is intended for the above reasons.

METHODOLOGY

The study will be conducted out between December 2010 to October 2012 on 60 patients undergoing lichtenstein's hernioplasty satisfying the inclusion and exclusion criteria. The patients were assigned alternately

into 2 groups .Cases in Group A received single dose of pre operative antibiotic 30 minutes before surgery and cases in group B received multiple doses perioperatively. The patients were then monitored post operatively from the second day onwards for SSI. The data was collected and statistics done using the Chi square/Fischer exact test to look for significant difference in the rate off SSIs in both the groups and also to find out if it was cost effective.

RESULTS AND INFERENCES

- Incidence of SSI in group A was 3,33%(1 in 30)
- Incidence of SSI in group B was 6.6%(2 in 30)
- Incidence of SSI though higher in group B than group A was not statistically significant when Fischer exact test was applied.
- SSI was identified on the 3rd to 4th post operative day in both groups.
- Bacteria isolated were Klebsiella, Staphylococcus and E.coli
- Average duration of procedure was almost 50 minutes to 90 minutes in all the patients
- Incidence of SSI was higher in both the groups with high ASA Grades and prolonged duration of surgery.
- The cost of antibiotic per patient in group A was Rs.32 while that in group B was between a minimum of Rs.192 in patients without SSI to a maximum of Rs.340 with SSI.
- The difference in cost of antibiotic in both groups was statistically significant.

CONCLUSION

Single dose antibiotic prophylaxis was therapeutically efficient as well as cost effective in comparison with multiple doses of perioperative antibiotics usage for the prevention of surgical site infection in uncomplicated elective cases of Lichtenstein's hernioplasty. The study shows that the cost of management of hernia patients with respect to use of antibiotics can be reduced in a rural set up by use of single dose antibiotic, thereby reducing financial burden on the patient..

Keywords : *inguinal hernia, lichtenstein's repair, SSI, antibiotic, prophylaxis.*

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INTRODUCTION

Surgical site infection (SSI) is the most frequent complication in inguinal hernioplasty[1]. The risk factors for SSI have been identified as sex (greater in women), age (older than 70 years), co morbidity, operative time, and routine use of drainage and prostheses[2-5]. SSI is related with an increase in length of stay and costs and a decrease in quality of life[6,].

However, the introduction of free tension hernioplasty has made the use of antibiotic prophylaxis more critical because of the infection risk when prosthetic materials are used. The use of prosthetic material for inguinal hernia repair has increased dramatically ever since described by Giraud and colleagues using Nylon mesh in 1951. Various meshes have since been developed consisting mainly of non absorbable materials such as polypropylene, polyester and polytetraflouroethylene[7].

The presence of plastic biomaterial increases the incidence of complications relating to the mesh itself, in addition to other recognized complications of the hernia repair. The most serious complication is the development of mesh infection leading to groin sepsis sometimes necessitating the removal of mesh implant.

To prevent mesh infection, antibiotic prophylaxis is often indicated and recommended. Most surgeons have used prophylactic antibiotics for Lichtenstein hernia repair. The incidence of mesh infection of 1.9% to 7.5% has been reported[7].

Available evidence related to the effectiveness of antibiotic prophylaxis for inguinal hernioplasty is found in a meta-analysis, including few RCTs. SSI rate was 1.2% and 3.3%, in the prophylaxis and placebo group respectively. These results concluded there were no statistical differences between groups[8].

A previous meta-analysis by Sanchez-Manuel and Seco-Gil for the Cochrane Collaboration, including 8-high quality RCTs, reported no statistical difference in SSI rates between antibiotic and no antibiotic groups. However, a subgroup analysis suggested that, in mesh hernia repair, a protective effect could exist, undetectable because of the small sample size[9].

Use of antibiotics in Lichtenstein's hernia repair is still debatable in a rural set up. Some surgeons use a single dose of pre-operative antibiotic, while the majority use multiple doses of post operative antibiotics claiming that the latter is superior to the former in prevention of surgical site infection in Lichtenstein's repair. Another subject in rural setup that must be addressed in antibiotic prophylaxis is cost-effectiveness. In these cases, the costs of antibiotic administration must be carefully evaluated against the potentials benefits[10-14]. Only studies particularly designed to answer this question could solve it. This study is intended for the above reasons.

AIM

To assess the efficacy of single dose pre-operative antibiotic compared to multiple doses of peri-operative antibiotic administration in reducing surgical site infection after inguinal hernioplasty.

OBJECTIVES

1. To find out the frequency of surgical site infections in patients receiving single dose of pre operative antibiotic in Lichtenstein's hernioplasty.
2. To find out the frequency of surgical site infections in patients receiving multiple doses of peri operative antibiotic in Lichtenstein's hernioplasty.
3. To find out if single dose of pre operative antibiotic is cost effectively more beneficial than multiple doses of peri operative antibiotic in preventing surgical site infections after Lichtenstein's hernioplasty.

REVIEW OF LITERATURE

Until the middle of the 19th century, when Ignaz Semmelweis and Joseph Lister became the pioneers of infection control by introducing antiseptic surgery, most wounds became infected. In cases of deep or extensive infection this resulted in a mortality rate of 70-80%[15]. Since then a number of significant developments, particularly in the field of microbiology, have made surgery safer. However, the overall incidence of healthcare associated infections (HAIs) remains high and represents a substantial burden of disease.

In 1992, the US Centres for Disease Control (CDC) revised its definition of 'wound infection', creating the definition 'surgical site infection' (SSI) to prevent confusion between the infection of a surgical incision and the infection of a traumatic wound [16]. Most SSIs are superficial, but even so they contribute greatly to the morbidity and mortality associated with surgery. Estimating the cost of SSIs has proved to be difficult but many studies agree that additional bed occupancy is the most significant factor. A review of the incidence and economic burden of SSIs in the US estimated that the mean length of extended stay attributable to SSIs was 7 days, at an average increase of charges by 3000$[17].

DEFINITIONS

Wound infections have been subdivided according to the following clinically related subgroups

Aetiology : in a *primary infection*, the wound is the primary site of infection, whereas a *secondary infection* arises following a complication that is not directly related to the wound;

Time: an *early infection* presents within 30 days of a surgical procedure, whereas an infection is described as *intermediate* if it occurs between one and three months afterwards and *late* if it presents more than three months after surgery;

Severity: a wound infection is described as *minor* if there is discharge without cellulitis or deep tissue destruction, and *major* if the discharge of pus is associated with tissue breakdown, partial or total dehiscence of the deep fascial layers of the wound, or if systemic illness is present.

HEALING BY PRIMARY INTENTION

Surgical wounds may heal by primary intention, delayed primary intention or by secondary intention. Most heal by primary intention, where the wound edges are brought together (apposed) and then held in place by mechanical means (adhesive strips, staples or sutures), allowing the wound time to heal and develop enough strength to withstand stress without support. The goal of surgery is to achieve healing by such means with minimal oedema, no serous discharge or infection, without separation of the wound edges and with minimal scar formation. On occasion, surgical incisions are allowed to heal by delayed primary intention where non-viable tissue is removed and the wound is initially left open. Wound edges are brought together at about 4-6 days, before granulation tissue is visible. This method is often used after traumatic injury[18].

HEALING BY SECONDARY INTENTION

Healing by secondary intention happens when the wound is left open, because of the presence of infection, excessive trauma or skin loss, and the wound edges come together naturally by means of granulation and contraction.

Experimentally as well as clinically it has been shown that a delay in wound closure of four to five days increases the tensile strength of the wound as well as resistance to infection. The overall rate of SSIs in traumatic war wounds using delayed principles was 3-4%, compared with more than 20% after primary closure[19]. In civilian practice, delayed healing has been used successfully in cases of severe incisional abscesses, mainly after laparotomy. Another benefit of delayed closure is the cosmetic result after healing. The appearance of a wound after a delay of four to five days is comparable to that of primary closure. A wider scar follows late closure (after 10-14 days), although this is cosmetically much better than the result obtained after the healing of an open granulating wound.

Many factors influence surgical wound healing and determine the potential for, and the incidence of, infection . The level of bacterial burden is the most significant risk factor, but modern surgical techniques and the use of prophylactic antibiotics havereduced this risk.

A system of classification for operative wounds that is based on the degree of microbial contamination was developed by the US National Research Council group in 1964. Four wound classes with an increasing risk of SSIs were described: clean, clean-contaminated, contaminated and dirty[20,21].

CLASSIFICATION OF OPERATIVE WOUNDS BASED ON DEGREE OF MICROBIAL CONTAMINATION	
Classification	**Criteria**
Clean	Elective, not emergency, non-traumatic, primarily closed; no inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered.
Clean-contaminated	Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not encountering infected urine or bile; minor technique break.
Contaminated	Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered.
Dirty	Purulent inflammation (e.g. abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old.

DEFINITIONS OF PERIOPERATIVE AND PERIPROCEDURAL SURGICAL PROPHYLAXIS[22.]

Perioperative prophylaxis implies the use of antibiotics in elective surgical procedures in patients without previous signs of inflammation or infection aimed at preventing the occurrence of surgical site infection.

Periprocedural prophylaxis implies the use of antibiotics aimed at preventing the spread of infection after invasive diagnostic-therapeutic procedures in surgery and other nonsurgical medical areas (e.g. endoscopic procedures).

Primary goal of antimicrobial prophylaxis is to reduce microbial contamination in surgical site in order to prevent infection.

Perioperative and peri procedural prophylaxis are primarily intended for prevention of surgical site infections, but not any other infections that may occur as a consequence of hospitalization (e.g. hospital acquired pneumonia).

LEVEL OF RECOMMENDATION[23].

Level	Recommendation
A	Requires at least one randomized controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. (Evidence levels Ia, Ib)
B	Requires the availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation. (Evidence levels IIa, IIb, III)
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. (Evidence level IV)

RISK FACTORS FOR SURGICAL SITE INFECTIONS

SYSYTEMIC AND LOCAL RISK FACTORS

Antimicrobial perioperative prophylaxis should be applied in patients with increased risk for infection due to general or local risk factors which are listed factors associated with an increased risk of surgical site infection[24,25.]

Systemic factors	Local factors
Diabetes	Foreign body
Corticosteroid use	Electrocautery
Obesity	Injection with epinephrine
Extremes of age	Hair removal with razor
Malnutrition	Previous irradiation of surgical site
Recent surgery, ASA class 3, 4 or 5	
Massive transfusion	
Multiple (3 or more) preoperative co morbid medical diagnoses	

RISK ASSOCIATED WITH ASA CLASS

According to the preoperative risk score devised by the American Society of Anaesthesiologists (ASA), the risk for wound infection is associated with general assessment of the patient`s physical status.

ASA CLASSIFICATION OF THE PATIENT`S PHYSICAL STATUS:

1 – Normal healthy patient,

2 – Patient with a mild systemic disease,

3 – Patient with a severe systemic disease that limits activity, but is not incapacitating,

4 – Patient with an incapacitating systemic disease that is a constant threat to life,

5 – Moribund patient not expected to survive 24 hours with or without operation.

If ASA score >2, the risk for wound infection is increased[26].

Risk associated with the insertion of prosthetic implants

- Insertion of any type of prosthetic implants increases the risk for infection.

Risk associated with the duration of surgery

- The risk for surgical site infection is directly proportional to the duration of surgical procedure[27,28].

COMMON SURGICAL SITE INFECTION PATHOGENS[29.]

The majority of surgical site infections are caused by bacteria the patient is colonized with and are part of the normal human flora.

Exceptionally, in patients with prolonged hospital stay, multiple resistant hospital pathogens can be expected.

The most common bacterial pathogens causing surgical site infections

- *Staphylococcus aureus*
- Coagulase-negative staphylococci (CONS)
- *Enterococcus* spp.
- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Enterobacter* spp.
- *Proteus mirabilis*
- *Klebsiella pneumoniae*
- Streptococci
- *Candida albicans*

CLASSIFICATION OF SURGICAL SITE INFECTIONS[30]

Superficial incisional SSI - occur within 30 days after the operation; involve Skin and subcutaneous tissue of the incision and at least *one* of the following signs :

1. Purulent discharge,
2. Organism isolated from an aseptically obtained culture,
3. At least one of the following symptoms:
   Pain,
   Swelling,
   Redness,
   Heat.

Deep incisional SSI – occur within 30 days after the operation (within 1 year if implant is in place), involve deep soft tissue of the incision, and at least *one* of the following signs:

1. Purulent discharge from the deep incision (but not from the organ/space component of the surgical site)
2. Spontaneous dehiscence or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms:
   Fever, localized pain, redness, heat.
3. An abscess.

   The diagnosis of superficial infection is made by surgeon of supervising physician.

Organ/space SSI - occur within 30 days after the operation (within 1 year if implant is in place), involve organs or spaces exposed to operation with at least *one* of the following:

1. Purulent discharge from a drain that is placed into the organ/space
2. Organism isolated from an aseptically obtained culture of tissue or fluid in the organ/space
3. An abscess found on direct examination, during reoperation or according to radiologic or histopathological finding .

If an infection involves tissues below deep fascia , it should be treated as deep incisional infection. If an organ space infection is drained through incision it should be treated as organ space infection.

ANTIBIOTICS IN SURGICAL PROPHYLAXIS

The antibiotic chosen for prophylaxis should cover the most common SSI pathogens, however not necessarily all possible pathogens.

The choice of antibiotic primarily depends on anatomic location of the surgical procedure. Also, the antibiotic used in prophylaxis should differ from other drugs used in the therapy for the same anatomic area in order to prevent the development of resistance and preserve those medications efficient for the treatment of infections in a particular anatomic area.

If a contamination with anaerobic pathogens is possible, e.g. during colorectal, gynaecological and head and neck procedures, the use of antibiotic with anaerobic activity is recommended.

If a patient is already receiving an antibiotic that covers targeted organisms for that particular surgical procedure, prophylaxis is not needed.

ROUTE OF ANTIBIOTIC ADMINISTRATION [32]

Intravenous administration of prophylactic antibiotic is recommended. This route of antibiotic administration can achieve necessary concentration of drug in blood and tissues during surgical procedure.

The absorption of drug after oral or intramuscular administration varies individually.

TIMING OF ANTIBIOTIC ADMINISTRATION [33]

- Antibiotic should optimally be given half an hour before incision, when the patient has stabilized after anaesthesia induction.
- Vancomycin when used should be given in a slow infusion which should terminate one hour before incision, that is, the infusion should start within 3 hours from incision .

DURATION OF PROPHYLAXIS [33.]

- A critical period for the development of surgical site infections is 4 hours from bacterial entrance into the wound.
- Perioperative antimicrobial prophylaxis has to ensure an optimal drug concentration in the plasma and extracellular fluid of potentially contaminated tissues during the procedure itself and for several hours after wound closure.

- One dose of antibiotic ½ hour before skin incision is considered sufficient. The administration of an additional dose of antibiotic should be Considered if the procedure lasts longer than the double antibiotic half life ($T_{1/2}$)

ANTIBIOTIC DOSAGE[34]

- The dose of antibiotic for prophylaxis is in most circumstances the same as it would be use in therapy.
- Antibiotic dose should be proportional to the patient`s body mass index, i.e. the patient`s weight.
- Studies in patients over 85 kg have indicated the need for a double dose in perioperative prophylaxis in order for drug concentrations in blood and tissues to be above the minimal inhibitory concentration.

BLOOD LOSS, FLUID REPLACEMENT AND ANTIBIOTIC PROPHYLAXIS [35]

- In adult patients, the influence of blood loss or fluid replacement on serum concentration of the prophylactic drug is negligible.
- An additional dose of prophylactic antibiotic should be given if blood loss is greater than 1500 ml, or haemodilution is up to 15 ml/kg.

RISKS OF ANTIBIOTIC PROPHYLAXIS [36,37]

- Even proper use of antibiotics in perioperative prophylaxis increases the incidence of *Clostridium difficile* colitis.
- Antimicrobial prophylaxis in surgery can influence the resistance of bacteria to antibiotics.
- There is always a risk of drug allergy.

COMMON ANTIBIOTICS USED FOR PROPHYLAXIS[38].

ANTIBIOTIC	*HALF –LIFE(HOURS)*
CEFAZOLIN	1.8
VANCOMYCIN	3-9
CEFOXITIN	0.6-1
CLINDAMYCIN	2.4-3
AMINOGLYCOSIDES	2
METRONIDAZOLE	8
CIPROFLOXACIN	3-5

PROCEDURE SPECIFIC RECOMMENDATIONS FOR PROPHYLAXIS[39-57]

The chart below summarizes the recommendations of several prospective, randomized controlled studies as well as several systematic literature reviews addressing the use of prophylactic antibiotics in various surgical procedures.

Procedure	Likely Pathogen(s)	Recommended Drug[a]	Alternative Regimen[d]
Cardiothoracic	*Staph epi*, *Staph aureus*, *Streptococcus*, *Corynebacteria*, enteric-Gram-negative bacilli	Cefazolin	Clindamycin
General Surgery			
• Appendectomy (non-perforated)	Enteric Gram(-) bacilli	Cefazolin + Metronidazole[b]	Clindamycin + Aminoglycoside
• Colorectal Surgery	Enteric Gram(-) bacilli, *Enterococcus*, anaerobes	Cefazolin + Metronidazole[b]	Clindamycin + Aminoglycoside
• High-risk esophageal[c], gasto-duodenal, or biliary surgery[3]	Enteric Gram(-) bacilli, Gram(+) cocci	Cefazolin	Clindamycin + Aminoglycoside
• Penetrating abdominal trauma	Enteric Gram(-) bacilli, *Enterococcus*, anaerobes	Cefazolin + Metronidazole[b]	Clindamycin + Aminoglycoside
Gynecologic Surgery			Clindamycin + Aminoglycoside
• C-section (after cord-clamping)	*Staph epi*, *Staph aureus*, Group B *Strep*, *Enterococcus*	Cefazolin	Clindamycin + Aminoglycoside
• Hysterectomy	Enteric Gram(-) bacilli, Group B *Strep*, *Enterococcus*	Cefazolin	Clindamycin + Aminoglycoside
Head and Neck Surgery	Anaerobes, *Staph aureus*, Gram(-) bacilli	Clindamycin	Cefazolin + Metronidazole
Neurosurgery			
• Clean	*Staph aureus*, *Staph epi*	Cefazolin	Clindamycin
• Skull fracture, CSF leak	Anaerobes, *Staph epi*, *Staph aureus*	Cefazolin	Clindamycin
• Penetrating trauma	*Staph*, *strep*, Gram(-) bacilli, anaerobes	Ceftriaxone, Clindamycin	N/A
• Spine	*Staph aureus*, *Staph epi*	Cefazolin	Clindamycin
Orthopedic Surgery			
• Closed fracture	*Staph epi*, *Staph aureus*	Cefazolin	Clindamycin
• Open fracture	*Staph*, *strep*, Gram(-) bacilli, anaerobes	Cefazolin + Gentamicin	Clindamycin + Gentamicin
Urologic Surgery			
• Genitourinary (high risk only)[e]	Gram(-) bacilli, *Enterococcus*	Cefazolin	Ciprofloxacin
Vascular Surgery	*Staph epi*, *Staph aureus*, Gram(-) bacilli, *Enterococcus*	Cefazolin	Clindamycin

PREVENTIVE TECHNIQUES

The surgical technique used can affect the infection rate in various ways, for example in relation to skin preparation, shaving and wound closure.

Skin preparation: The skin is colonised by various types of bacteria, but up to 50% of these are *Staphylococcus aureus*. In analyses of contamination rates after cholecystectomy, the main source of wound contamination was found to be the skin of the patient .For this reason, preoperative preparation should be performed. Evidence has shown that the use of a preoperative wash containing chlorhexidine decreases the bacterial count on skin by 80-90%, resulting in a decrease in preoperative wound contamination .The effect on SSI incidence has, however, been more difficult to demonstrate and it is possible that prolonged washing releases organisms from deeper layers of the skin.[58,59]

Shaving: It is now recognised that shaving damages the skin and that the risk of infection increases with the length of time between shaving and surgery. In one study, if the patient had been shaved more than two hours before surgery the clean wound infection rate was found to be 2.3% .However, if patients had not been shaved but their body hair had

been clipped the rate was 1.7%, and if they had not been shaved or clipped the rate dropped to 0.9%. If shaving is essential, it should be performed as close to the time of surgery as possible[60,61].

Wound closure: The healing of closed surgical wounds depends on many factors, one of the most complex of which is the influence of technique and expertise[62]. The incidence of SSIs in relation to the different types of closure techniques used is shown here.

Incidence of SSIs following closure/delayed closure of an infected wound	
Opening and re-closure times	**Reinfection rate**
Opening and re-closure at once	50%
Opening and re-closure after two days	20%
Opening and re-closure after four days	5%
Opening and re-closure after nine days	10%

METHODOLOGY

DESIGN

A prospective comparative study

COLLECTION OF DATA AND SOURCES

Source of data

1. The study was conducted in R.L.Jalappa Hospital and Research centre and SNR Hospital, Kolar on 60 patients from December 2010 to October 2012.
2. The population for the study were from surgical units in R.L.Jalappa Hospital, Tamaka, Kolar and SNR hospital ,Kolar.

Method of collection of data

The study was conducted between December 2010 to October 2012. All patients presenting to Department of General Surgery with primary inguinal hernia, planned for hernioplasty after satisfying the inclusion criteria were enrolled into the study. A written informed consent in words best understood by the patient was taken. A detailed medical history including demographic data, chief complaints related to the hernia, and associated medical disorders were elicited and recorded. A detailed physical examination was conducted and other findings elicited.

CRITERIA FOR SELECTION OF STUDY GROUP:

A. Inclusion criteria :

- Adult patients with primary inguinal hernia.

B. Exclusion criteria :

- 1.Paediatric age group,
- 2.Patients with recurrent, complicated hernias,
- 3.Immunocompromised patients,
- 4.Patients with skin and soft tissue infections,
- 5.Patients who have received antibiotics within past 48 hours,
- 6.Patients with cardiac valvular disease, prosthetic valves,
- 7.Patients with uncontrolled Diabetes Mellitus and Hypertension

GROUP SELECTION

Alternate cases were assigned into two groups A and B.

1. Group A received 1 gram of Cefazolin intra venously 30 minutes before the surgical incision.
2. Group B received 1 gram of Cefazolin intra venously peri operatively and twice daily post operatively for 3 days

PRE-OPERATIVE PREPARATION.

- Standard aseptic precautions as for any other surgery.
- All diabetic patients had strict glycemic control and
- Normal FBS and urine acetone negative before surgery in diabetics.

OPERATIVE PROCEDURE

- Pre-operative preparation of the surgical site done according to standard principles.
- Lichtenstein's repair using the same technique, including skin closure, was done in all patients.
- Dressing done after surgery.
- Surgical site inspected after 48 hours.

Follow up

The surgical site was inspected daily from second post operative day onwards based on the following criteria for SSI.

Surgical site infection surveillance criteria

1. Presence of erythema, extending atleast 2 cms beyond the wound edges and purulent discharge.
2. Wound dehiscence.

When there was no SSI sutures were removed on the 7th post operative day and the patient was discharged. In patients who had SSI, culture and sensitivity tests were done and appropriate antibiotics were given.

DATA COLLECTION AND ANALYSIS

The following data were collected and analysed.

1. Patients demographic profile,
2. Clinical type of hernia (direct / indirect),
3. Biochemical parameters,
4. Anaesthesia variables such as
    - ASA grade,
    - Type of anaesthesia,
    - Duration of anaesthesia.

STATISTICAL ANALYSIS

1. Analysis of the data was done with primary objective to find out if single dose of pre operative antibiotic is cost effectively more beneficial than those receiving multiple doses of peri operative antibiotic in preventing surgical site infections after Lichtenstein's repair.
2. Association between a group and a SSI will be assessed using Chi square test/Fischer exact test.

STATISTICAL SOFTWARE.

The Statistical software namely SPSS 16.0 and Stata 12.0 were used for the analysis of the data, and Microsoft word and Excel have been used to generate graphs, tables etc.

OBSERVATIONS & RESULTS

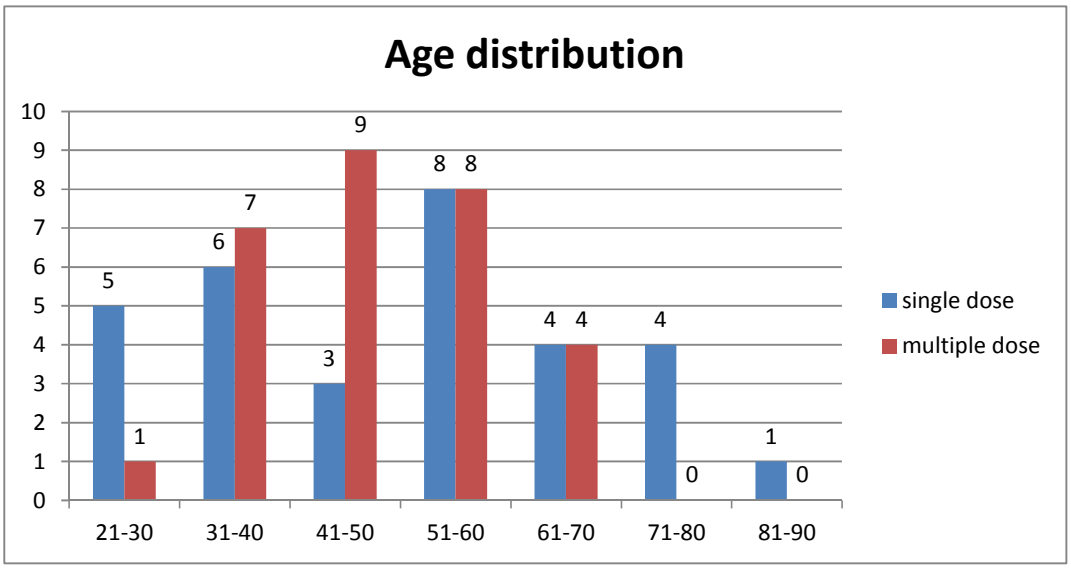
AGE DISTRIBUTION

16 cases belonged to the age group 51-60; 1 patient was more than 80 years old.

Table 1

Age in years	**Single dose**	**Multiple dose**
21-30	5	1
31-40	6	7
41-50	3	9
51-60	8	8
61-70	4	4
71-80	4	0
81-90	1	0

Figure 1



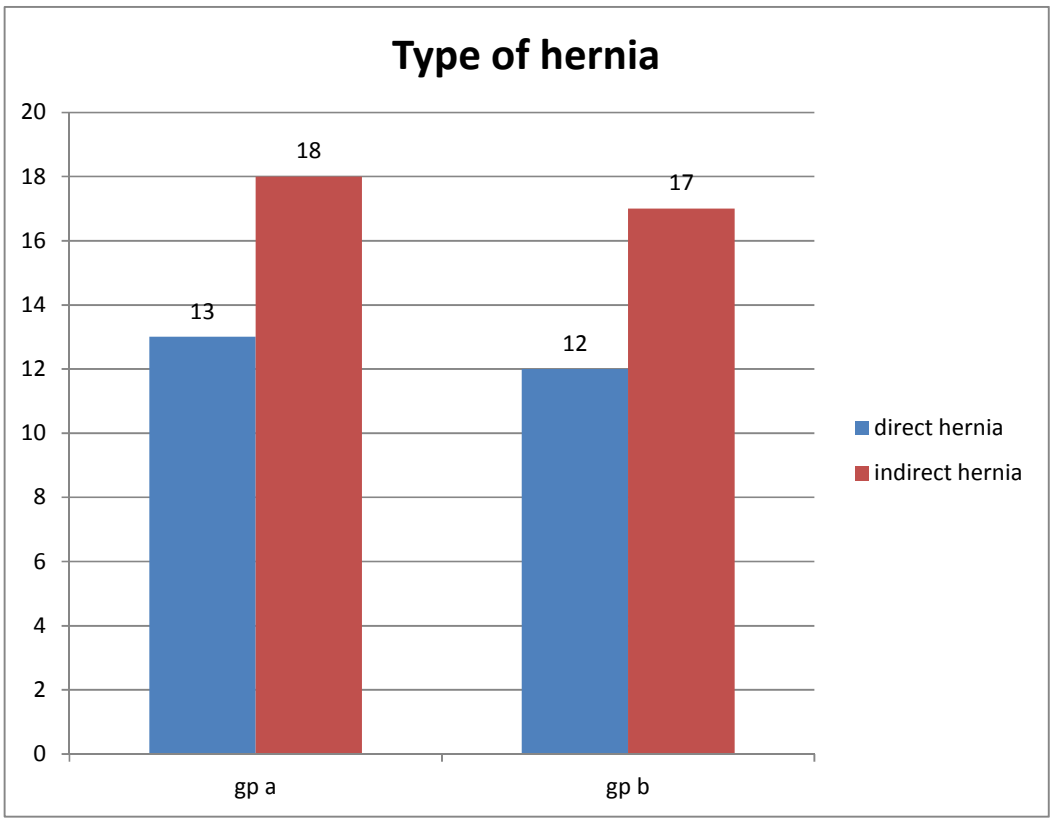
TYPE OF HERNIA

35 patients had indirect inguinal hernia and 25 patients had direct inguinal hernia

Table 2

	Group A	Group B	
Direct hernia	13	12	25
Indirect hernia	18	17	35
			60

Figure 2



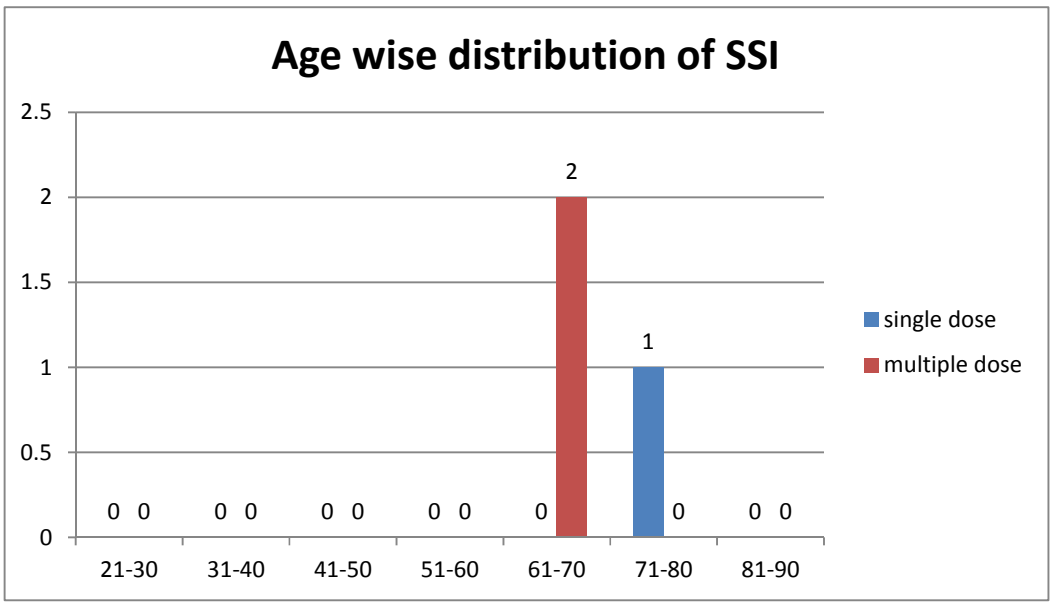
AGE WISE DISTRIBUTION OF SSI

SSI was noted in only patients older than 60 years,in accordance with the studies(*Taylor EW et al*), which concluded that increased age was a risk factor for SSI.

Table 3

	Single dose	Multiple dose
21-30	0	0
31-40	0	0
41-50	0	0
51-60	0	0
61-70	0	2
71-80	1	0
81-90	0	0

Figure 3



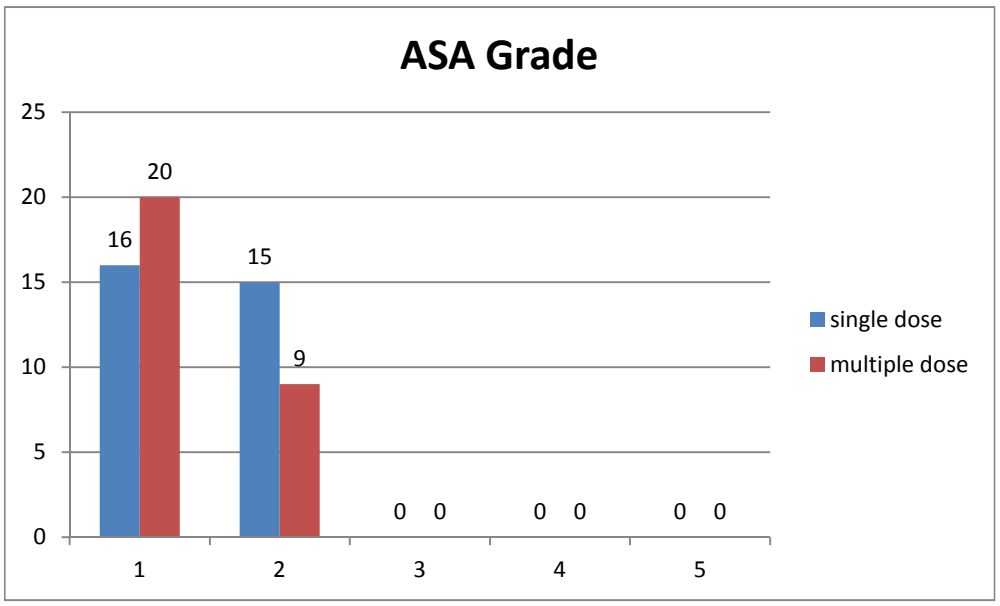
ASA GRADE

36 patients were classified as having ASA grade 1; 24 patients belonged to ASA grade2.There were no patients belonging to higher ASA grades

Table 4

ASA grade			
	Single dose	**Multiple dose**	**Total**
1	16	20	36
2	15	9	24
3	0	0	0
4	0	0	0
5	0	0	0

Figure 4



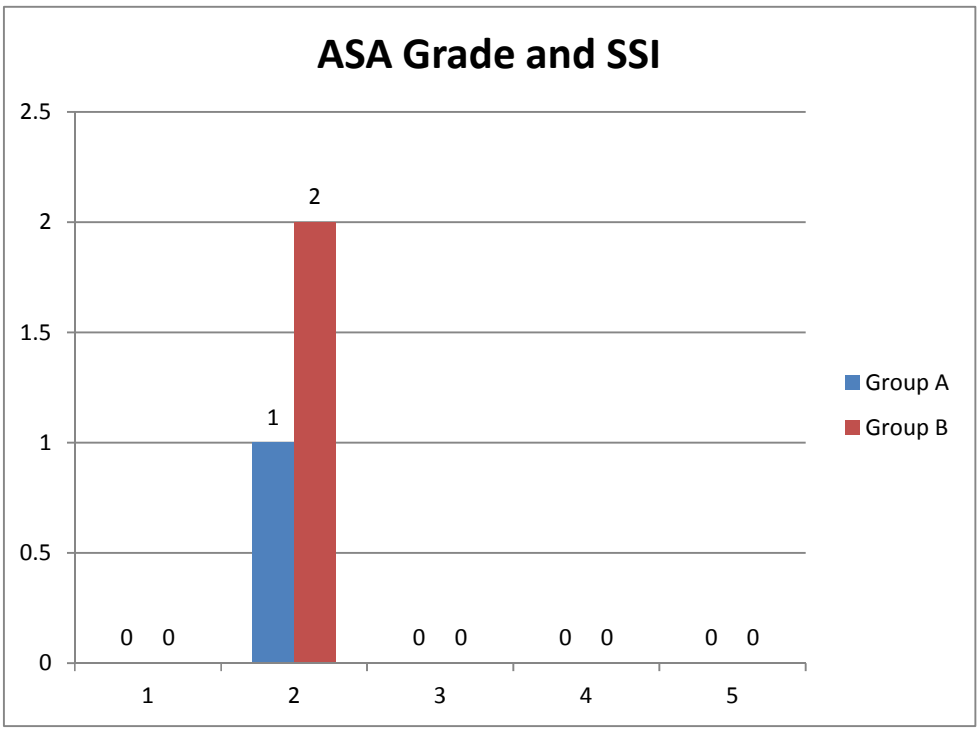
ASA GRADE AND SSI

Of the 3 cases with SSI, 2 patients belonged to ASA grade 2. As per the studies quoted before *(Haley RW et al)*which concluded that higher grade of SSI is a risk factor for SSI, this study is in accordance with the same.

Table 5

ASA grade		
	Group A	**Group B**
1	0	0
2	1	2
3	0	0
4	0	0
5	0	0

Figure 5



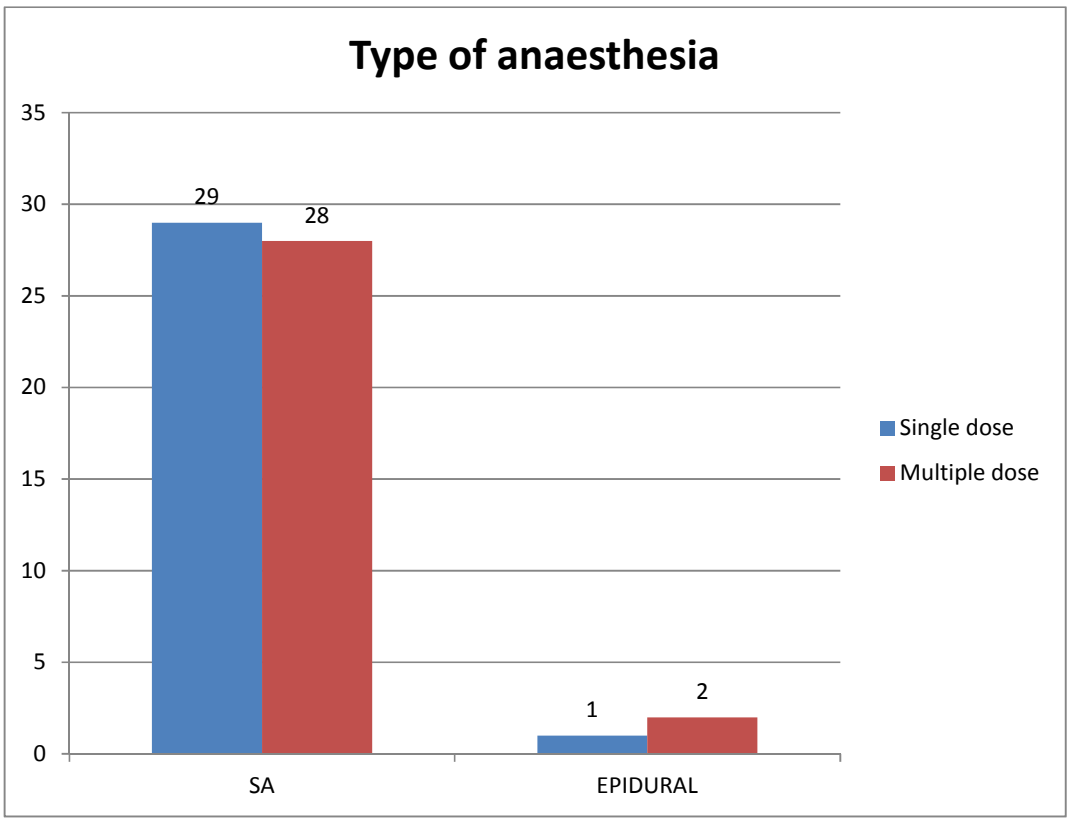
TYPE OF ANAESTHESIA

57 cases were done under spinal anaesthesia and 3 cases under epidural anaesthesia,2 of which were bilateral indirect inguinal hernia

Table 6

	SA	EPIDURAL
Single dose	29	1
Multiple dose	28	2

Figure 6



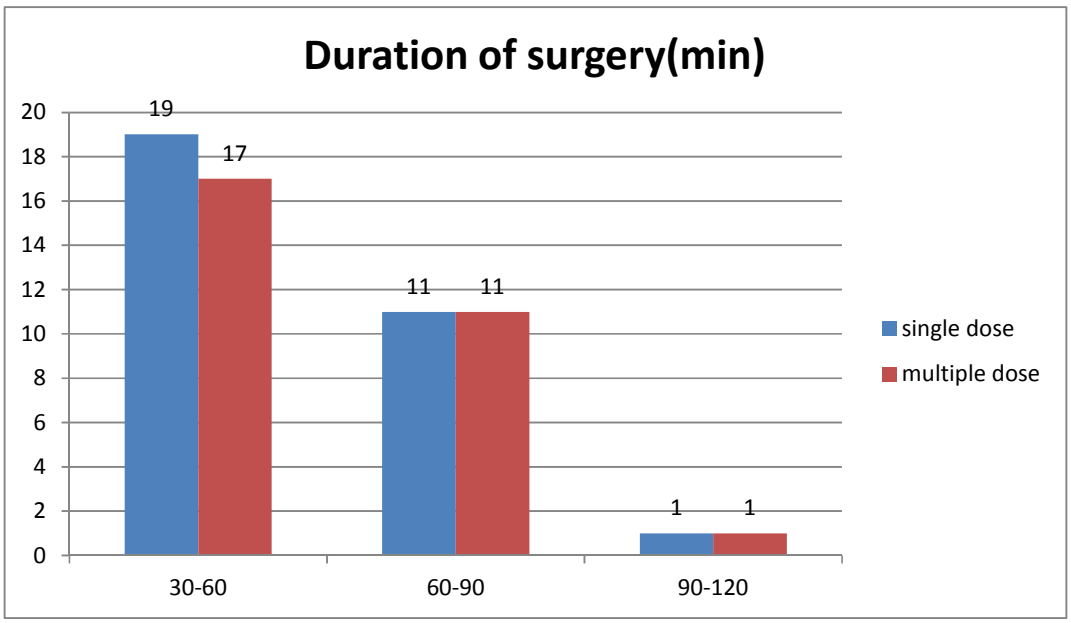
DURATION

58 cases were done within 90 minutes and 2 cases took more than 90 minutes.

Table 7

Duration of surgery		
	Single dose	Multiple dose
30-60	19	17
60-90	11	11
90-120	1	1

Figure 7



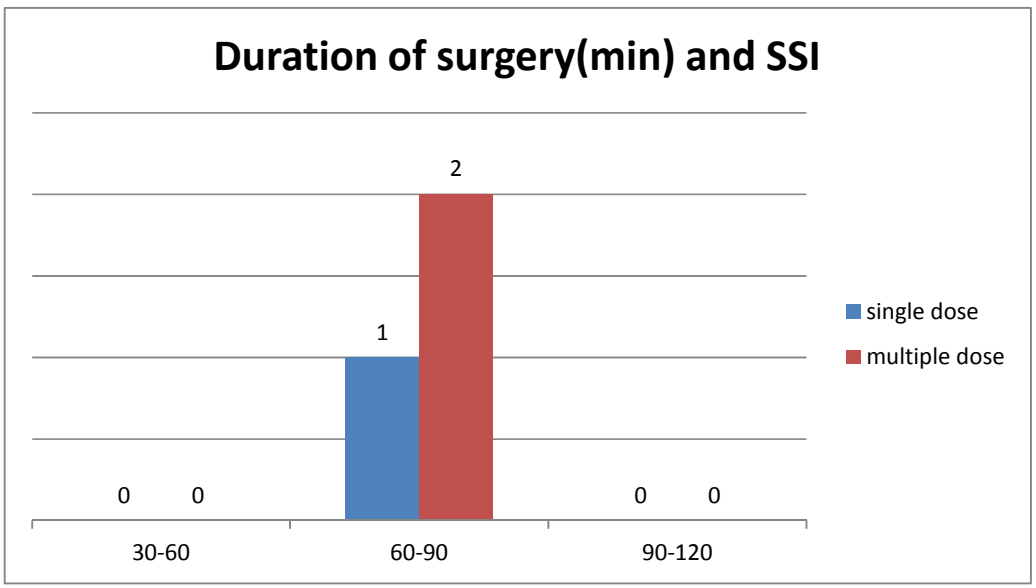
DURATION OF SURGERY AND SSI

SSI was seen in 3 patients, all of which took more than 60 minutes to operate which is in accordance with the study conducted by *Jepsen OB, Larsen SO, Thomsen VF,* which concluded that prolonged duration of surgery is a risk factor for developing SSI.

Table 8

Duration of surgery and SSI		
Mins	**Single dose**	**Multiple dose**
30-60	0	0
60-90	1	2
90-120	0	0

Figure 8

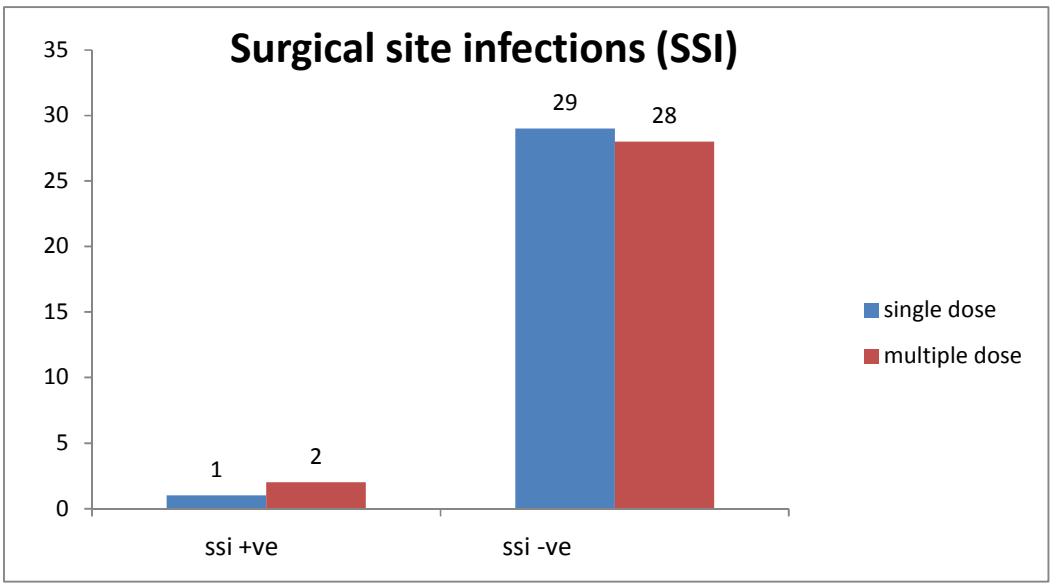


INCIDENCE OF SSI

Table 9.

	Ssi +ve	Ssi –ve	
Single dose	1	29	30
Multiple dose	2	28	30
			60

Figure 9



Incidence of SSI (%)	Single dose	Multiple dose
	3.45	6.67

Fischer's exact test	p value-0.606		
Formula	(a+b)!(c+d)!(a+c)!(b+d)!/a!b!c!d!n!		

There is no significant difference in the occurrence of surgical site infection between the two groups.

CHARACTERISTICS OF SSI PATIENTS

- **Incidence of SSI in group A was 3,33%(1 in 30)**
- **Incidence of SSI in group B was 6.6%(2 in 30)**
- **SSI was identified on the 3rd post operative day in 2 patients and on 4th post operative day in 1 patient.**
- **Bacteria isolated were Klebsiella, staphylococcus and E.coli**

Table 10.

Sl no.	Group	Age	Detected on pod	Organism
1	Single dose	75	3	Staph aureus
2	Multiple dose	70	4	Klebsiella
3	Multiple dose	65	3	E .coli

COST OF ANTIBIOTIC

- **The cost of Inj.Cefazolin 1gm was Rs32.**
- **The cost of antibiotic in patients who belonged to group A without SSI was Rs 32.**
- **The total cost of antibiotic(6 doses) in patients who belonged to group B was Rs 192.**
- **1 patient in Group A had SSI,the total cost for antibiotic being Rs160.**
- **2 patients in Group B had SSI,the total cost of antibiotic being Rs 310 and Rs 340.**

Table 11.

Cost (independent t test)						
Group	**N**	**Mean**	**St. Dev**	**degree of freedom**	**t value**	p value
single dose	31	36.1	23	48	-21.64	<0.001
multiple dose	29	201.2	34.5			

The cost difference between the two groups is statistically significant (p <0.001)

CALCULATION

- Null hypothesis: There is no significant difference in infection rates between pre-operative and peri-operative administration of antibiotics.
- Alternate hypothesis: Pre-operative antibiotic administration results in significantly lower infection rates.

- **X2 = € ((O-E) 2/E)**
- Expected value E= (row total x column total)/overall total
- E1= (30 x 5)/60 = 2.5
- E2= (30 x 5)/60 = 2.5
- E3= (30 x 110)/60 = 55
- E1= (30 x 110)/60 = 55
- X2 = (1.48^2)/2.5 + (1.48^2)/2.5 + (1.48^2)/55+ (1.48^2)/55
- X2 = 0.87+0.039+0.87+0.039
- **X2 = 1.81**
- Value of X2 is less than value of X2 at degree of freedom 1 at 0.05 level(3.84)
- Thus, null hypothesis is true.

OBSERVATIONS AND RESULTS

- 60 patients were recruited to the study from December 2010 to October 2012.
- Patients were assigned into two groups A(n=30) and B (n=30),to receive single dose or multiple dose antibiotics respectively.
- The baseline characteristics were similar in both groups.
- There was no statistically significant age specific infection risk.
- Type of anaesthesia, and ASA grade were similar in both groups.
- Average duration of procedure was almost 50 minutes to 90 minutes in all the patients.
- SSI was identified on the 3^{rd} to 4^{th} post operative day in both groups.
- Bacteria isolated were Klebsiella, staphylococcus and E.coli
- Incidence of SSI in group A was 3,33%(1 in 30)
- Incidence of SSI in group B was 6.6%(2 in 30)
- Incidence of SSI though higher in group B than group A was not statistically significant when Fischer exact test was applied.

- Incidence of SSI was higher in both the groups with higher ASA Grade and prolonged duration of surgery.
- The cost of antibiotic per patient in group A was Rs.32 while that in group B was between a minimum of Rs.192 in patients without SSI to a maximum of Rs.340 with SSI.
- The difference in cost of antibiotic in both groups was statistically significant.

DISCUSSION

Inguinal hernia is the commonest problem amongst all external hernias and inguinal hernia repair is most frequent procedure in general surgery accounting for 10–15% of all operations. The age incidence is distributed in all decades of life. Incidence of inguinal hernia is race related. It is at least three times more common in black Africans than in the white population.

About 80–90% of repairs are done in males. The most frequent type is right sided indirect inguinal hernia. Direct inguinal hernias are rare in females.

Due to its common nature and increased incidence of recurrence and wound infection, a wide variety of surgical procedures and different materials were being used from time to time for hernia repair.

All these procedures and materials have equivocal results and are beyond the level of satisfaction for different surgeons. All these modifications and surgical techniques have showed a common disadvantage i.e. suture line tension, which leads to increased incidence of recurrence and other complications.

Post operative wound infection remains a common complication after hernia repair.

With the use of modern mesh prosthesis, it is now possible to repair all hernias without distortion of the normal anatomy and with no suture line tension.

Modern mesh is strong monofilament, inert, and readily available. It is unable to harbour infection, is very thin and porous. Its interstices become completely infiltrated with fibroblasts and remain strong permanently .It is not subjected to deterioration or rejection or it cannot be felt by patients or surgeons postoperatively.

Many factors including antimicrobial prophylaxis affect surgical site infection. For eg., beginning antibiotic prophylaxis during the immediate preoperative period reduces the risk of wound infection fourfold. Maintaining therapeutic antibiotic levels in the serum and tissues throughout the operation until, at most, a few hours after incision closure reduces this risk.

Both in the US and Europe,more than 1 million inguinal hernia repair are performed anually,of which Lichenstein's open meshplasty is the most popular.A trial conducted in 2004 showed that infection rate was low (1.7%)after Lichtenstein meshplasty[63].

Another study conducted in 2004 showed that the overall incidence of post operative complications was 11%, all complications were treated conservatively and removal of mesh was not required postoperatively[64].

In another study conducted in 2005,to report late mesh infection occurring years after open hernioplasty, it was proved that late graft infection does not correlate to neither the administration or not of antibiotic prophylaxis,nor to the presence or not of previous superficial wound infection[65].

The debate still continues as to the clinical use of antibiotic prophylaxis,and stratification of the risk factors so as to help differentiate between the high and low risk patients.A meta analysis conducted in 2007 showed that prophylactic antibiotic in hernioplasty reduced the rate of SSI by 50%.[66]

A randomized double blind placebo controlled study conducted in 2008 showed that 10.3% of the patients in the antibiotic group and 15.3% of patients in the placebo group had wound infections,proving that there was no stasitically significant difference observed between the two groups[67]

In this study, patients in Group A received a single dose of Inj. Cefazolin 1 g at induction time and patients in Group B received perioperative doses of Inj. Cefazolin 1 g, twice daily for 3 days Indiscriminate use of antibiotics leads to proliferation of resistant organisms and was probably responsible for high rate of surgical site infection of 6% in Group B when compared with group A 3.3%. Pathogens encountered in these patients were *E.coli, Staphylococcus aureus, Klebsiella.*

CONCLUSIONS

Single dose antibiotic prophylaxis was therapeutically efficient as well as cost effective in comparison with multiple doses of postoperative antibiotics usage for the prevention of surgical site infection in uncomplicated elective cases of Lichtenstein's hernioplasty. The study shows that the cost of management of hernia patients with respect to use of antibiotics can be reduced in a rural set up by use of single dose antibiotic, thereby reducing financial burden on the patient.

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ANNEXURE

CONSENT FORM

I hereby give my consent to participate in the study entitled "EFFICACY OF SINGLE DOSE ANTIBIOTIC PROPHYLAXIS IN INGUINAL HERNIOPLASTY" conducted by Dr.Pavan.B.K, under the guidance of Dr. A. Bhaskaran, Professor in the Department of General Surgery, Sri Devaraj Urs Medical College, Tamaka, Kolar. I have been explained in my own language about the pros and cons of the study and I have the freedom to withdraw from the study at any time.

Signature of patient

Signature of witness

Date

Place

PROFORMA

Case No.

STUDY GROUP: SINGLE DOSE PRE-OP(A)/ MULTIPLE DOSES PERI-OP(B)

Name :

Age / Sex :

Address :

Hospital No. :

Chief complaint :

Diagnosis :

Pre existing co-morbid conditions (If any) :

General Examination

Pulse -

B.P -

Respiratory rate -

Temperature -

Systemic Examination

C.V.S :

R.S :

C.N.S :

Per-Abdominal examination :

Local examination :

Investigations :

Hb%	**Blood Glucose**	**S.Urea**	**S.Creatinine**	**Others(specify)**

Date of Admission :

Date of Surgery :

Date of discharge :

Wound infection : Yes / No

If yes, type

Erythema	Serous discharge	Purulent discharge	Wound dehiscence	Mesh exposed	Fever

Culture sensitivity

Organism isolated	Antibiotic sensitivity	Antibiotic ,Dose and duration

OUTCOME OF THE CASE

Wound uninfected **Wound infected**

DEEP SURGICAL SITE INFECTION

DEEP SSI- 4TH POD

DEEP SSI- 9TH POD

DEEP SSI- 14TH POD

WOUND CLOSURE

STAPLERS

SILK

PROLENE

TYPES OF SSI

ERYTHEMA >2 cm

SEROUS DISCHARGE

PURULENT DISCHARGE

WOUND GAPING

MASTER CHART

Name	Age	Gender	Hosp no	Diagnosis	Side	Date of surgery	ASA grade	Group	Duration of surgery (Mins)		SSI	Infection code	SSI code	Post OP day	Cost of antibiotic (rupees)	Type of anaethesia	Type of organism
Narayana Reddy	70	1	652966	2	1	06-12-2010	2	1	60	a	-	0	0	-	32	1	-
Anwar Ulla Sharief	62	1	660712	1	1	22-12-2010	1	2	45	a	-	0	0	-	192	1	-
Amarnath	45	1	662485	1	1	29-12-2010	1	1	65	b	-	0	0	-	32	1	-
Khaleel	26	1	665529	2	1	11-01-2011	1	2	45	a	-	0	0	-	192	1	-
Bachanna	60	1	665376	1	2	21-01-2011	2	1	40	a	-	0	0	-	32	1	-
Mahadeviah	35	1	670519	1	2	31-01-2011	1	2	40	a	-	0	0	-	192	1	-
Jayaram Reddy	56	1	682316	1	1	31-01-2011	2	1	50	a	-	0	0	-	32	1	-
Markandachari	35	1	667412	1	2	02-02-2011	1	2	75	b	-	0	0	-	192	1	-
Munivenkatamma	66	2	670817	2	1	03-02-2011	2	1	90	b	-	0	0	-	32	1	-
Subramani	50	1	665900	1	1	04-02-2011	2	2	70	b	-	0	0	-	192	1	-

Byreddy	75	1	681230	1	2	16-02-2011	2	1	55	a	-	0	0	-	32	1	-
Nanjundappa	42	1	678203	1	2	21-02-2011	1	2	60	a	-	0	0	-	192	1	-
Muniraju	26	1	677978	2	2	23-02-2011	1	1	40	a	-	0	0	-	32	1	-
Kumar.B.R	45	1	669830	2	1	16-03-2011	1	2	60	a	-	0	0	-	192	1	-
Ramu	30	1	685703	1	1	24-03-2011	1	1	75	b	Erythema	0	0	2	32	1	-
Shivappa	50	1	691342	2	3	11-03-2011	1	2	45	a	-	0	0	-	192	1	-
Aslam Pasha	40	1	695730	1	1	27-04-2011	1	1	55	a	-	0	0	-	32	1	-
Subbanna	60	1	694488	2	3	12-05-2011	2	2	60	a	-	0	0	-	192	2	-
Sudheer	25	1	699422	2	1	18-05-2011	1	1	60	a	-	0	0	-	32	1	-
Muneer Ahmed	40	1	695711	2	3	18-05-2011	1	2	85	b	-	0	0	-	192	1	-
Ramareddy	32	1	695988	2	1	20-05-2011	1	1	70	b	-	0	0	-	32	1	-
Srinivas	38	1	702102	2	1	20-05-2011	1	2	65	b	-	0	0	-	192	1	-
Chowda Reddy	75	1	703520	1	3	08-06-2011	2	1	90	b	-	0	0	-	32	2	-

Ranganath	26	1	8909	2	2	04-07-2011	1	1	70	b	-	0	0	-	32	1	-
Eijaz Khan	47	1	8767	2	1	04-07-2011	1	2	65	b	-	0	0	-	192	1	-
Perumal	65	1	9043	1	1	06-07-2011	2	1	50	a	-	0	0	-	32	1	-
Subbareddy	44	1	9143	2	1	08-07-2011	1	2	60	a	-	0	0	-	192	1	-
Venkatappa	60	1	8675	2	1	11-07-2011	2	1	65	b	-	0	0	-	32	1	-
Muniyappa	45	1	8743	2	1	13-07-2011	1	2	60	a	-	0	0	-	192	1	-
Nararyan Reddy	81	1	9476	1	2	15-07-2011	2	1	45	a	-	0	0	-	32	1	-
Ananthappa	65	1	9913	1	1	22-07-2011	2	2	85	b	Present	1	1	3	310	1	E.Coli
Nagendra	37	1	9797	2	2	29-07-2011	1	1	45	a	-	0	0	-	32	1	-
Munishamappa	54	1	10078	1	1	29-07-2011	1	2	60	a	-	0	0	-	192	1	-
Jameer Ahmed	40	1	11018	2	1	18-08-2011	1	1	80	b	-	0	0	-	32	1	-
Muniyamma	40	1	11016	1	2	18-08-2011	1	2	75	b	-	0	0	-	192	1	-
Shafi	60	1	11351	2	2	25-08-2011	2	1	80	b	-	0	0	-	32	1	-

Krishnamurthy	32	1	765515	2	1	05-12-2011	1	2	60	a	-	0	0	-	192	1	-
Narayanappa	70	1	760046	1	1	20-12-2011	1	1	80	b	-	0	0	-	32	1	-
Venkatesh	44	1	761231	2	2	23-12-2011	1	2	60	a	-	0	0	-	192	1	-
Muniyappa	60	1	767473	2	2	09-01-2012	2	1	55	a	-	0	0	-	32	1	-
Nanjunda Murthy	55	1	772353	2	3	03-02-2012	2	2	60	a	-	0	0	-	192	1	-
Muniraju	37	1	699272	2	1	08-02-2011	1	1	50	a	-	0	0	-	32	1	-
Vijayendra	59	1	777244	1	1	13-02-2012	2	2	70	b	-	0	0	-	192	1	-
Manjunath	45	1	717333	2	1	14-02-2012	1	1	60	a	-	0	0	-	32	1	-
Narasappa	70	1	775875	1	2	21-02-2012	2	2	80	b	Present	1	1	4	340	1	Klebsiella
Nagraj	80	1	767541	1	1	07-03-2012	2	1	60	a	-	0	0	-	32	1	-
Sriramulu	61	1	790122	2	3	09-04-2012	2	2	70	b	-	0	0	-	192	2	-
Gantlappa	51	1	792481	2	3	09-04-2012	1	1	45	a	-	0	0	-	32	1	-
Munivenkatappa	60	1	787018	1	1	09-04-2012	2	2	50	a	-	0	0	-	192	1	-

Raheen Baig	55	1	770264	2	3	13-04-2012	2	1	60	a	-	0	0	-	32	1	-
Byrappa	55	1	790043	2	1	13-04-2012	1	2	80	b	-	0	0	-	192	1	-
Gangadhar	52	1	801039	1	1	09-05-2012	2	1	45	a	-	0	0	-	32	1	-
Sathyanarayanappa	55	1	805478	2	3	25-04-2012	1	2	60	a	-	0	0	-	192	1	-
Venkatappa	75	1	814933	1	2	27-06-2012	2	1	75	b	Present	1	1	3	160	1	Staph. Aureus
Narayanappa	47	1	812817	2	3	27-06-2012	1	2	60	a	-	0	0	-	192	1	-
Ramakrishna	38	1	809913	2	1	04-07-2012	1	1	45	a	-	0	0	-	32	1	-
Narayana Shetty	60	1	818150	1	1	09-07-2012	2	2	95	c	-	0	0	-	192	1	-
Ramappa S	45	1	831070	2	2	16-07-2012	1	1	110	c	-	0	0	-	32	1	-
Suresh	32	1	825752	2	1	02-08-2012	1	2	60	a	-	0	0	-	192	1	-
Chalapathi	28	1	830083	2	2	16-08-2012	1	1	50	a	-	0	0	-	32	1	-

KEY TO MASTER CHART

Hosp No. - Hospital number

Code for Gender:

1- Male.

2- Female.

Code for diagnosis:

1-Direct

2-Indirect

Code for side:

1-Right

2-Left

3-Bilateral

Code for group:

1-Group A(single dose)

2-Group B(multiple dose)

Code for SSI:

0-Absent

1-Present

Code for type of anaesthesia:

1-Spinal anaesthesia

2-Epidural anaesthesia