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### RESEARCH ARTICLE

#### A STUDY OF SINGLE DOSE PRE-OPERATIVE ANTIBIOTIC PROPHYLAXIS VERSUS CONVENTIONAL MULTIPLE DOSE POST OPERATIVE ANTIBIOTIC THERAPY IN INGUINAL HERNIA REPAIR SURGERY

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#### Abstract

**Background:** Elective inguinal hernioplasty is considered to be a clean procedure which does not require antibiotic prophylaxis but prosthetic material like polypropylene mesh is routinely used during procedure. This makes the topic debatable because the use of prosthetic material like mesh increases the risk of surgical site infection. The incidence of surgical site infection (SSI) after inguinal hernioplasty ranges from 0% to 14 % in international literature. It is also more controversial whether single dose antibiotic or conventional multiple doses of antibiotics for 5 to 7 days is effective. Hence our study aims to compare the efficacy of single dose versus multiple dose antibiotic prophylaxis in open inguinal hernioplasty

**Patients And Methods:** A total of 120 cases of inguinal hernia admitted in Gadag Institute of Medical Sciences in the Department of general surgery underwent Lichtenstein tension free mesh hernioplasty and received either pre-op single dose or post-op multiple dose antibiotic therapy. The two groups were then compared for SSI.

**Conclusion:** Our study shows that a single dose of antibiotics given half an hour prior to open surgery in elective uncomplicated inguinal hernia repair surgery is as effective as multiple doses of antibiotics post-operatively in preventing post-operative surgical site infection.

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#### Introduction:-

Hernia repair is one of the most commonly performed general surgical procedures worldwide.<sup>1</sup>

Mesh repair is, rapidly becoming the most popular technique for repair of Inguinal hernia,<sup>2-3</sup> of the mesh repair techniques, the Lichtenstein hernia repair is most frequently used. The Lichtenstein technique is a tension free repair of the weakened inguinal floor using polypropylene mesh.<sup>4</sup> Many randomized trials and meta-analysis have shown that mesh repair reduces the risk of hernia recurrence, and is worldwide accepted as the gold standard in inguinal hernia repair.

SSI (surgical site infection) is the most frequent complication in inguinal hernioplasty<sup>6</sup>. Though there is no controversy in the use of prophylactic antibiotics in clean contaminated, contaminated and dirty wounds, there is still some controversy surrounding the use of prophylactic antibiotics in clean wounds like Lichtenstein mesh hernioplasty.

Antibiotic resistance has become a global menace and WHO in 2012 had given a clear call to reduce the antibiotic use and prevent resistance to antibiotics.

In this era of antibiotics, the corner stone of infection control such as meticulous surgical skill, respectful tissue handling, environmental sanitation, adequate preoperative preparation, adequate wound care are given less priority.

Reported surgical wound infection rates in elective operations vary from 2% for inguinal hernia repair to 26% for colectomy, and even higher for emergency surgeries.

It is important to emphasize that surgical antibiotic prophylaxis is an adjunct to, and not a substitute for good surgical technique. Numerous clinical studies have clearly shown that appropriately timed "single shot" prophylaxis is as effective as multiple dose prophylaxis<sup>8-9</sup>.

**Aims And Objectives:-**

1. To assess the efficacy of a single dose pre-operative antibiotic prophylaxis in prevention of surgical site infection in elective inguinal hernia repair surgery.
2. To compare the rate of SSI in patients receiving a single dose pre-operative prophylactic antibiotic with that in patients receiving prolonged post-operative antibiotic therapy.

**Materials And Methods:-**

SOURCE OF DATA: All the patients of Inguinal hernia presenting to the Department of General Surgery at Gadag Institute of Medical Sciences and District Hospital, Gadag Karnataka undergoing open mesh hernioplasty within the inclusion criteria.

**Duration Of Study:**

JUNE 2022 to JUNE 2023

**Sample Size:**

120 cases.

**Study Design:**

Prospective study.

**Study Place:**

Gadag Institute of Medical Sciences and District Hospital, Gadag, Karnataka

**Sampling Method:**

Purposive sampling

**Inclusion Criteria:**

1. Adult patients of either sex between 18 and 65 years, who consented for the study.
2. Both Direct and Indirect inguinal hernia.
3. Patients scheduled for routine open hernioplasty.

**Exclusion Criteria**

1. Patients posted for emergency surgeries.
2. Patients with complicated hernia.
3. Patients having pre-existing infection at surgical site.
4. Patients with severe co-morbid diseases like Diabetes, Cardiovascular diseases, immunocompromised or on steroids are excluded from the study.

**Method of collection of data:-**

These patients presented with either swelling in the groin/pain in the groin area of varying duration. Patients with these symptoms were admitted to surgical ward with the diagnosis of direct or indirect uncomplicated inguinal

hernia. A detailed relevant clinical history was taken and physical examination including general, systemic and local examination was done.

Investigations were carried out to assess the fitness of patients for surgery and to exclude other co-morbid conditions.

Once the patients were deemed fit, patients were distributed into two groups i.e., Group A and Group B in a systematic manner (even serial numbers in group A and odd serial numbers in group B). Group A received single dose preoperative antibiotic prophylaxis i.e., Inj. ceftriaxone 1gm I/V half an hour before skin incision at the commencement of surgery (All even cases). Group B received multiple doses of postoperative antibiotic i.e., Inj. ceftriaxone 1gm I/V BD for 3 days followed by Tab. Cefadroxil 500 mg BD for next 4 days. All the procedures were carried out by consultant surgeons under standard aseptic precautions.

#### Operative Technique:

Lichtenstein tension free mesh repair was done using a 6x3-inch polypropylene mesh, tailored, to fit the patient's inguinal floor and placed after soaking it in diluted gentamycin solution (80mg in 250 ml normal saline).

#### Follow Up:

Patients wound was inspected for infections as per Southampton wound score on 3rd, 5th, 8th, 14th post-operative day and 1 month after surgery for surgical site infection. Wounds that showed signs of infection were given a trial of broad-spectrum antibiotics, surgical drainage of the wound done at the earliest indication and specific antibiotics started based on C/S report.

### Observation And Result:-

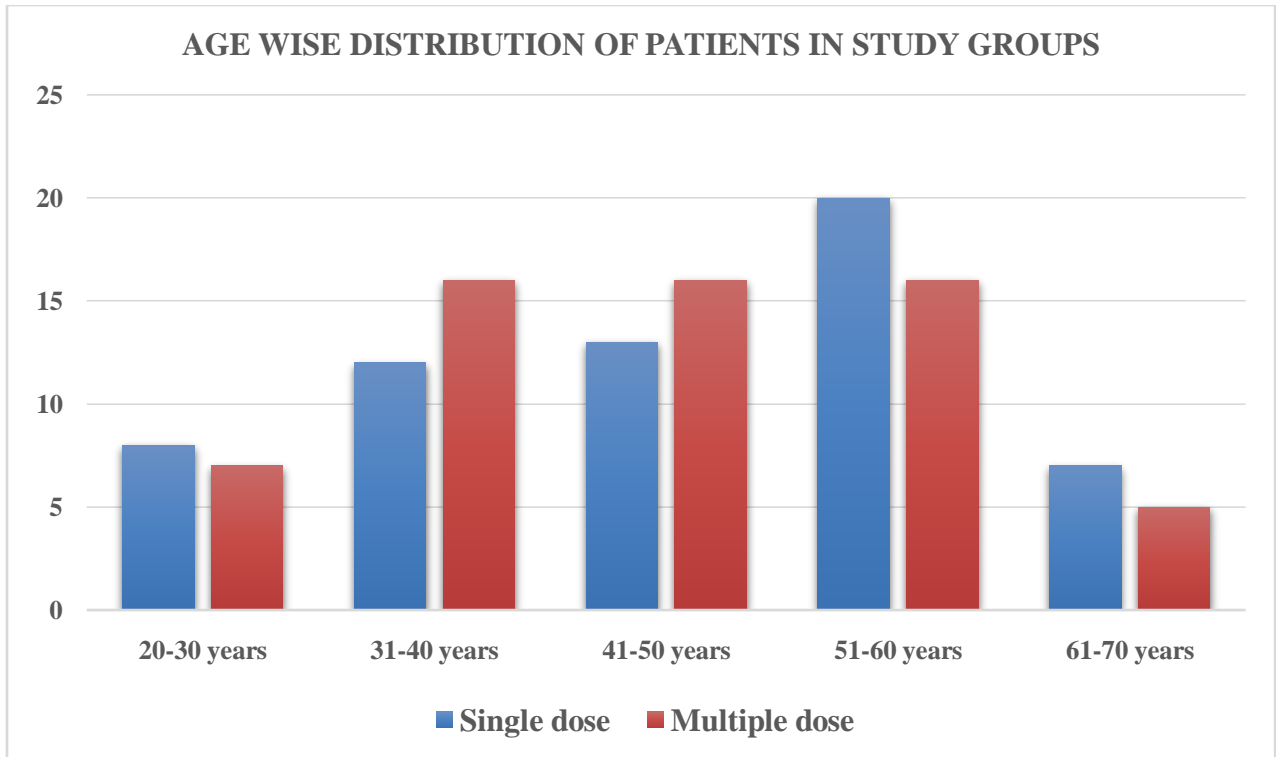
#### 1. Demographic Details

A total of 60 patients undergoing hernioplasty were included in each study group.

DEMOGRAPHIC DETAILS OF ENROLLED PATIENTS			
Parameters assessed	Single dose antibiotic prophylaxis (n=60)	Multiple dose antibiotic therapy (n=60)	P value
Mean age	46.92+/- 12.77	45.6+/-11.65	0.73
Median age	50	45.5	
Maximum age	68	65	
Minimum age	20	23	
Patients below median age	28	31	0.68%
Patients above median age	32	29	

\*P>0.05 considered no significant difference by Unpaired t test

#P>0.05 considered no significant difference by Chi-square test



**2. Post-operative surgical site infections:-**

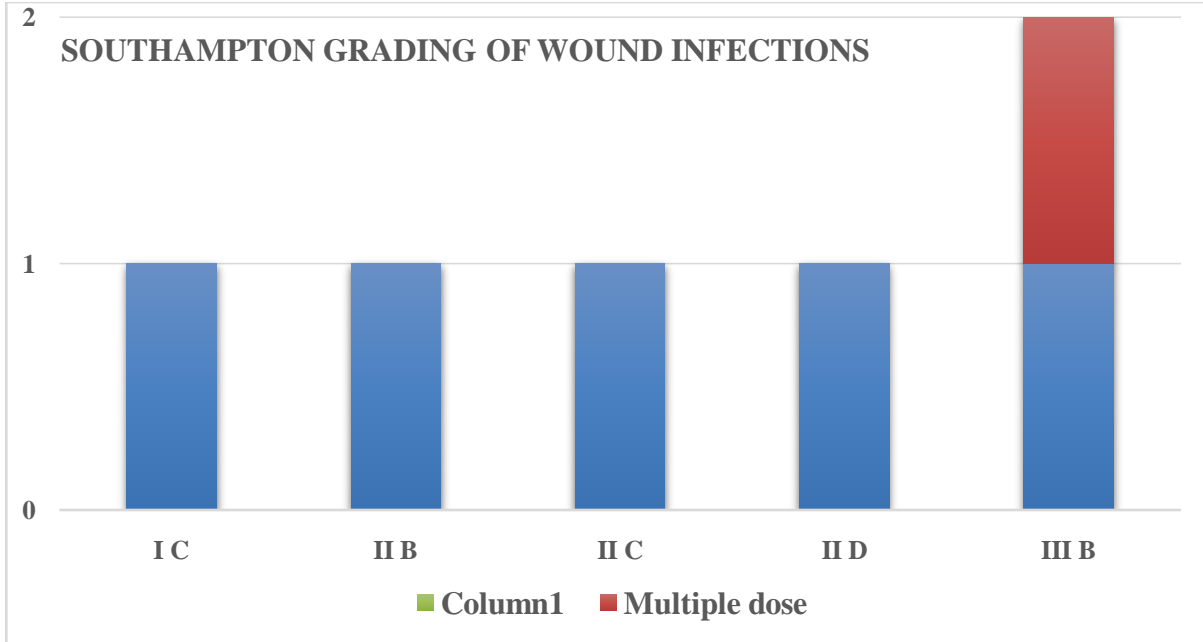
A total of 5 patients in the single dose antibiotic prophylaxis suffered from the surgical site infections (SSI) while only 1 patient in the multiple dose antibiotic therapy suffered from SSI. The association between the dose of antibiotic and SSI occurrence was not found to be significant.

ASSOCIATION BETWEEN THE DOSE OF ANTIBIOTIC AND SSI OCCURRENCE		
	SSI Present	SSI Absent
Single-dose antibiotic prophylaxis	5	55
Multiple-dose antibiotic prophylaxis	1	59
P value	0.21	

P>0.05, not considered significant by Chi- square test

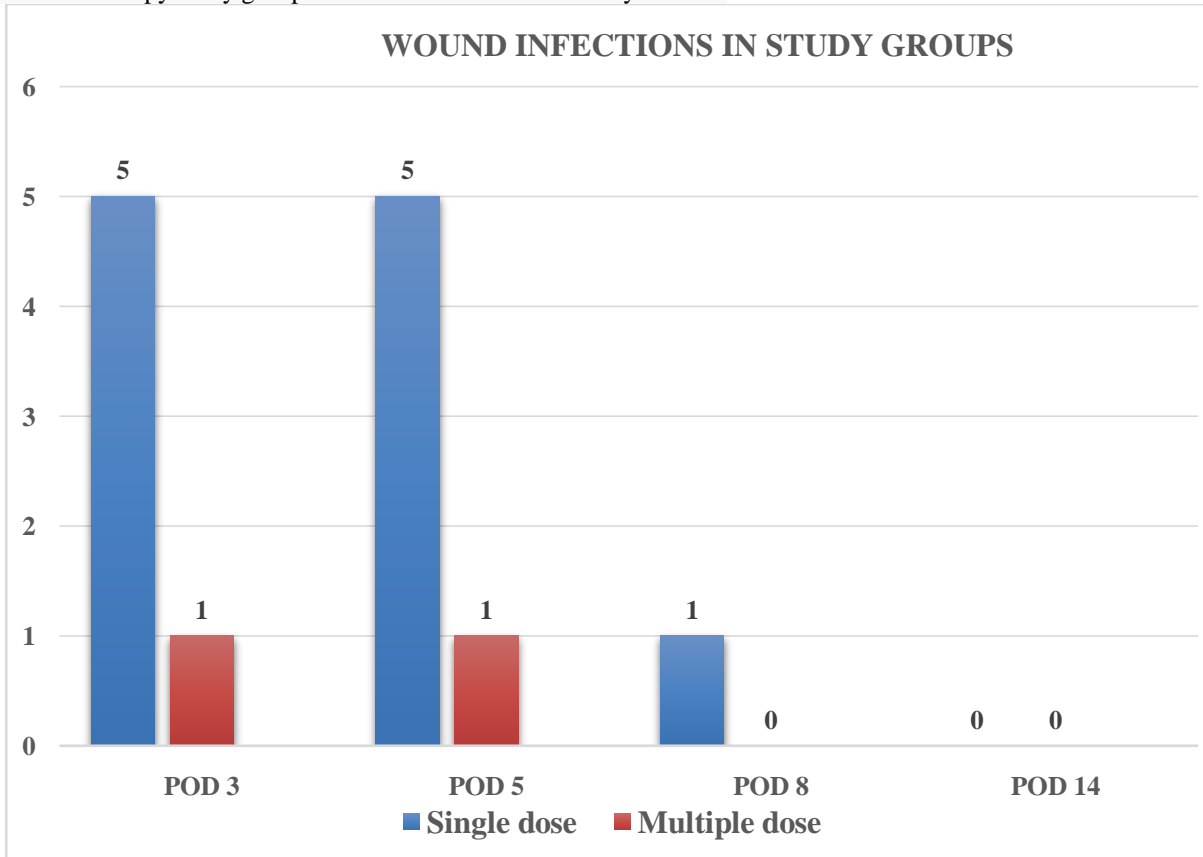
**3.Southampton Wound Infection Scoring: -**

None of the patients in the study groups suffered from deep infection. Based on the scoring system, a graphical representation of the patient distribution in both study groups is given below.



**4. Resolution of SSI based on post-operative day (POD):**

4 out of the 5 patients in the single-dose antibiotic prophylaxis study group had their SSI resolved by day 8 POD, while one patient had it resolved in the 2nd week post-operatively. The single SSI patient in the multiple-dose antibiotic therapy study group had their infection resolved by POD-8.



**5. Duration of surgery and its association with SSI:**

The mean and median duration of surgery was calculated in both the study groups. The association between the higher duration of surgery and resultant SSI was also found to be significant by chi-square analysis ( $p < 0.05$ ).

<b>DURATION OF SURGERY OF ENROLLED PATIENTS</b>			
<b>Parameters assessed</b>	<b>Single dose antibiotic prophylaxis (n=60)</b>	<b>Multiple dose antibiotic therapy (n=60)</b>	<b>P value</b>
<b>Mean duration</b>	<b>48.1+/- 8.12</b>	<b>47.61+/-7.14</b>	<b>0.83*</b>
<b>Median duration</b>	<b>45</b>	<b>45</b>	
<b>Maximum duration</b>	<b>75</b>	<b>75</b>	
<b>Minimum duration</b>	<b>40</b>	<b>40</b>	
<b>Patients below median duration</b>	<b>33</b>	<b>32</b>	<b>0.88<sup>#</sup></b>
<b>Patients above median duration</b>	<b>27</b>	<b>28</b>	

\* $P > 0.05$  considered no significant difference by Unpaired t test

# $P > 0.05$  considered no significant difference by Chi-square test

Duration of surgery in minutes

<b>ASSOCIATION BETWEEN THE DURATION OF SURGERY AND SSI OCCURRENCE</b>		
	<b>SSI Present</b>	<b>SSI Absent</b>
<b>Duration below median of 45 minutes</b>	<b>0</b>	<b>65</b>
<b>Duration above median of 45 minutes</b>	<b>6</b>	<b>49</b>
<b>P value</b>	<b>0.01*</b>	

$P < 0.05$ , considered significant by Chi- square test

**6. Duration of hospital stay and its association with SSI:**

The mean and median duration of hospital stay was calculated in both the study groups. The association between the higher duration of hospital stay and SSI was also found to be significant by chi-square analysis ( $p < 0.05$ ).

DURATION OF HOSPITAL STAY OF ENROLLED PATIENTS			
Parameters assessed	Single dose antibiotic prophylaxis (n=60)	Multiple dose antibiotic therapy (n=60)	P value
Mean duration	7.73+/- 2.25	7.73+/-1.03	0.83*
Median duration	7	7	
Maximum duration	16	15	
Minimum duration	7	7	
Patients below median duration	55	59	0.21 <sup>#</sup>
Patients above median duration	5	1	

\* $P > 0.05$  considered no significant difference by Unpaired t test

<sup>#</sup> $P > 0.05$  considered no significant difference by Chi-square test

**Duration of hospital stay in days**

ASSOCIATION BETWEEN THE DURATION OF HOSPITAL STAY AND SSI OCCURRENCE		
	SSI Present	SSI Absent
Duration at or below median of 7 days	0	114
Duration above median of 7 days	6	0
P value	0.01*	

**Discussion:-**

Surgical site infections (SSIs) remain an important global issue across all surgeries. They are the third most reported nosocomial infection and contribute for over a fifth healthcare associated infection. Inguinal herniorrhaphy is no different, where SSI is the commonest complication. Most surgical centres endorse the use of multiple dose antibiotic prophylaxis that continues for 24 to 48 hours and often until all the drain tubes are removed. However, many centres and evidence also proclaim that single-dose prophylaxis may be enough to control infections, thereby decreasing the cost-burden as well. Incorrect use of antimicrobials for the purpose of surgical chemoprophylaxis may cause greater surgical site infection rate. On the other hand, overzealous use of antibiotics is also related with

augmented costs, undesirable drug side effects and appearance of resistant strains. The Indian evidence pertaining to the utility of single-dose and multiple-dose antibiotic prophylaxis usage is lacking.

A Cochrane meta-analysis related to this topic was published in 2004. The article concluded that antibiotic prophylaxis in mesh repair of inguinal hernias can neither be endorsed nor rejected. Given the closeness of the groin region to the perineum as well as the genitals, the meta-analysis raises an important point as to whether it would be healthier to consider this surgery as a clean-contaminated operation, for which antibiotic prophylaxis is required. Another meta-analysis published in 2007 by Sanabria et al. included six randomized controlled studies consisting of 2507 patients to evaluate the SSI frequency in the antibiotic versus the non-antibiotic group. The SSI rate was found to be 1.3% in the antibiotic group versus 2.89% in the non-antibiotic group (OR: 0.48, 95% CI -0.27-0.85,  $p < 0.05$ ). Thus, this meta-analysis revealed that usage of antibiotic can help reduce the rate of SSI by almost 50%.

On assessment of the post-operative SSIs in the two study groups in this study, it was found that out of 120 cases, a total of 6 cases overall showed the development of SSI, which accounts to 5% of the cases. This is very similar to the SSI frequency noted in scientific literature in the inguinal hernia repair surgeries (0% to 9%).

In a study by Yerdel et al., 0.7% patients in the antibiotic prophylaxis group developed wound infection. In another study by Perez et al., the SSI rate was found to be 1.7% in the prophylaxis group, while the same was found to be 2.5% in the study by Tzovaras et al. However, an Indian study published in 2019 by Maheshwari et al. found that the antibiotic prophylaxis group had an infection rate of 12%, which is higher than that found in our study. Another study conducted in India by Jayalal et al. found an SSI rate of 6.66% (4/60 patients) amongst those receiving single dose or multiple dose antibiotic regimen.

Below is a tabular representation of the SSI rates in various studies.

SSI rates in various studies	
Study	Total SSI rate
<b>This study</b>	5%
<b>Tzovarass et al.</b>	2.5%
<b>Perez et al.</b>	1.7%
<b>Yerdel et al.</b>	0.7%
<b>Maheshwari et al.</b>	12%
<b>Jayalal et al.</b>	6.66%

It was found that though numerically the number of surgical site infections were found to be higher in the single dose prophylaxis group, the number was statistically comparable to that seen in the multiple dose antibiotic group (5 vs. 1,  $p = 0.21$  considered not significant). This shows that statistically, it can be said that the effectiveness of single dose prophylaxis antibiotic regimen is comparable to that of multiple dose antibiotic regimens, in case of hernia repair. 5 of the total 6 infections noted in the study resolved in the first week post-surgery. This finding goes in sync with various other similar studies.

In a study published by Garg et al. in 2018, 4 of the 80 patients in the single dose prophylaxis group suffered from SSI, while none of the multiple dose group patients suffered from any SSI. However, even this finding was comparable between the two groups, just like our study ( $p = 0.295$ , considered not significant)."

In another similar study published in 2017 by Umman et al., 31 patients who underwent elective hernia repair were given either single dose antibiotic prophylaxis ( $n = 16$ ) or multiple dose antibiotic dosage ( $n = 15$ ). It was found that only 1 patient in the single dose group developed infection, while none of the patients in the multiple dose groups



developed wound infection. Hence, the authors concluded that there is no increased risk of infection even if single dose prophylaxis of antibiotics is used in patients undergoing hernia repair.

In a study published in 2015 by Jayalal et al., a comparison was done between the single-dose antibiotic prophylaxis group and the conventional antibiotic regimen group to check for infection incidence. 2 patients each in the two groups (n=30 each group) developed infections, again indicating that single dose prophylaxis was comparable to conventional antibiotic regimens in infection control.

#### Comparison of SSI Rates after Single dose or Multiple dose antibiotics administration in various studies

Study	Single dose Antibiotic	Multiple dose Antibiotic	P value
<sup>3</sup> This study	8.33%	1.67%	>0.05
Garg et al.	5%	0%	>0.05
Umman et al.	6.25%	0%	>0.05
Jayalal et al.	6.67%	6.67%	>0.05

In this study it was found that all the infections were found to be superficial in nature. All the infections were of grade 1 to grade 3 (Southampton wound score) intensity, indicating lack of deep nature of the SSI. An interesting finding in this study was that there was a significant association between the increased duration of surgery above median of 45 minutes and SSI occurrence ( $p < 0.05$ ). All the patients who suffered from SSI had a median surgery duration of more than 45 minutes. Also, there was a significant association between prolonged duration of hospital stay beyond the median of 7 days and the SSI occurrence ( $p < 0.05$ ). This also indicates that prolonged surgery duration may lead to SSI occurrence while that will significantly prolong the hospital stay.

Antibiotic stewardship must be endorsed through incentivizing and calculating prescriber compliance with the antibiotic formulary, encouraging antibiotic stewardship within programs of continuing professional development and communicating with the public the rational anticipation of not being prescribed antibiotics except in cases where clearly indicated.

Some limitations of this study were, that the sample size was less (n=120) and the study was done only at one tertiary care health centre. Future research with a larger sample size and more centre enrolment will help in creating more robust evidence pertaining to this topic.

#### Conclusion:-

Our study shows that a single dose of antibiotic given half an hour prior to open surgery in elective uncomplicated inguinal hernia repair is as effective as multiple doses of antibiotics post-operatively in preventing post-operative surgical site infection. The P value was found to be 0.21 ( $> 0.05$ ), which was not significant. Thus, it can be concluded from this study that a single dose antibiotic prophylaxis prior to surgery is sufficient to prevent post-operative surgical site infections thus preventing adverse outcomes of inadvertent antibiotic usage, such as multi-drug resistance, drug toxicity and its cost effective.

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