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A COMPARATIVE STUDY BETWEEN SINGLE DOSE CEFTRIAXONE AS A PROPHYLAXIS VERSUS CONVENTIONAL DOSE ANTIBIOTIC IN MAJOR GYNAECOLOGICAL SURGERY IN DHAKA MEDICAL COLLEGE HOSPITAL, DHAKA, BANGLADESH

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ABSTRACT

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Introduction: Wound site infections are a major source of postoperative illness accounting for approximately a quarter of all nosocomial infections. The centers for Disease control and prevention term for infections associated with surgical procedures was changed from surgical wound infection to surgical site infection. Objective: To establish the use of single dose prophylactic injectable antibiotics as well as to compare the rate of wound infection among the gynae post-operative patients treated by only single dose prophylactic versus conventional dose of antibiotics. **Materials and Methods:** This was a prospective study, carried out at Dhaka Medical College Hospital, Dhaka, Bangladesh during the period of July 2005 to May 2006. During this study period 100 cases were taken for the study. The patients were divided into two groups. Group A: Fifty patients received 2 gm ceftriaxone i/v as prophylaxis 1 hour before the incision. Group B: Fifty patients received conventional therapy i.e. Ciprofloxacine and Metronidazole for 7 days. The data were matched for ages, weight, socio-economic condition, anaemia and for surgical procedure and technique. Incidence of infection and length of hospital stay were determined for each patient. Wound swab was taken from infected wound of every patient and causative organism was isolated by culture of infected swab. **Results**: This study was done to establish the efficacy of single dose injection Ceftriaxone prophylaxis in the prevention of surgical site infection. One hundred cases were randomly selected from the admitted patients for major gynaecological surgery. The variables taken for analysis are age, weight, Hb%, duration of operation, wound

infection, length of hospital stay and the risk factors for infection. At the time of randomization, the above mentioned characteristics of the cases in very both group revealed little significant difference. With this aspect it can be sketched that this comparative study was done in almost similar type of cases in two groups and the result was not affected by those minor variations. It was shown that about 52% of the patients were in 35-44 years in group-A and 58% were in the same age in Group-B. Fifty of them received 2g prophylactive Ceftriaxone. Another Fifty received the conventional therapy i.e. Ciprofloxacine & Metronidazole for 7 days. Wound infection was observed in 5 patients (10%) in Group-A and 6 patients (12%) in Group-B. There was no significant difference was observed in both group. Patients of wound infection in both group was treated according to the procedure described in the protocol. The study finding showed only loading dose of 2g prophylactive injection Ceftrixone if given as per protocol is as effective as the multi-drug regimen. But prophylactive single dose group was more beneficial due to their good compliance fewer side effects, cost effectivity and decrease the probability of drug resistance. **Conclusion:** At the discussion the most recent studies about prevention of SSI and prophylactive antibiotic was analyzed. It was seen that the whole world is very much concern about prevention of surgical site infection as well as antibiotic resistance. As both of them cause adverse effect on the patient and cost more. It can be concluded that infection prevention is highly depended on Antibiotic prophylaxis Administration of antibiotic depends.

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I INTRODUCTION

Wound site infections are a major source of postoperative illness accounting for approximately a quarter of all nosocomial infections. The centres for Disease control and prevention term for infections associated with surgical procedures was changed from surgical wound infection to surgical site infection in 1992. There are many bacteria that live on our skin and in other parts of our body where they do no harm. A SSI can occur when bacteria from the skin, other parts of the body or the environment enter the incision made by the surgeon and multiply in the tissues. This results in physical symptoms as the body tries to fight the infection. There may be pus, inflammation, swelling, pain and fever. There are different levels of SSI: (i) Superficial incisional, affecting the skin and subcutaneous tissue. (II) Deep incisional, affecting the facial and muscle layers. (III) Organ or space infection affecting any part of the anatomy opened or manipulated during the operation.[1] The pathogens isolated from infections differ, primarily depending on the type of surgical procedure. In clean surgical procedures, in which the gastrointestinal, gynecologic, and respiratory tracts have not been entered, Staphylococcus aureus from the exogenous environment or the patient's skin flora is the usual cause of infection. In other categories of surgical procedures, including clean-contaminated, contaminated, and dirty, the polymicrobial aerobic and anaerobic flora closely resembling the normal endogenous microflora of the surgically resected organ are the most frequently isolated pathogens.[2] The most critical factors in prevention of

postoperative infection although difficult to quantify are the sound judgment and technique of the surgeon and surgical team as well as the nutritional status and co morbidities of the patient Most patients of the hospitals in a developing country like Bangladesh come from low socio-economic group. Their general health seam of symptoms or diseases like anemia over populated. So the patient burden in our best men dinicult to keep the wand tidy ilan so he chance more. To prevent this consequence we will give conventional antimicrobial therapy i.c. ciprofloxacine and metronidazole for 7 days. In order to lessen the cost of the patient and to minimize the side effect of long time conventional therapy we have to look for alternative opties. The proper duration of antimicrobial use for the prevention of postoperative surgical tale has been a subject of controversy. Currently more than 40 published clinical trials are available in which the efficacy of single dose surgical prophylaxis with parenteral antimicrobials has been studied. These studies have compared single dose versus multiple doses of same agent, single doses of various antimicrobials and single doses of one antimicrobials versus multiple doses of another antimicrobial In all trials in which single dose regimens were compared with multiple dose regimens. The single dose regimens resulted in similar frequency of postoperative wound infection. Single antimicrobials usually cephalosporines given immediately before operation are effective in preventing wound infections in billiary, gastric, transurethral and major gynaecological surgeries.[4] The antibiotic which has better tissue penetration, prolong half life and broad spectrum in activity should be used Ceftriaxone is the parenteral 3rd generation group of cephalosporines with a long elimination half life which is stable to B-lactamases particularly the produced by gram negative bacteria. In common with most of other 3rd generation agents it has an aminothiazolyl substitution at the R l position of the B-lactam ring. Since the mid 1980 Ceftriaxone was first introduced the drug has been used extensively because of improved stability against B-lactamase, efficacy in a broad range of infections and its pharmacokinetics & tolerabity profile. Like other cephalosporines and Penicillin it kills bacteria by interfering with the synthesis of bacterial cell wall.[5] Its mean elimination half-life is about 6-9 hours that is much longer than that of any other cephalosporines.In healthy patients 30 minutes after 2gm injection mean peal plasma concentration was 257mg.1-1 It excretes unchanged via kidney & liver. In 48 studies for a total 406 patients were given Ceftriaxone and 525 patients were given other antibiotics as prophylaxis in different hospitals in Naples, Italy. Meta-analysis shows that Ceftriaxone is superior to other antibiotics in preventing local and remote post-operative infection.[6,7] The aim of this study is to detect the efficacy of single dose Ceftriaxone as a prophylaxis in major gynaecological operations in a Medical College Hospital in a developing country as well as to compare it with conventional antibiotic therapy usually we use Ciprofloxacine and Metronidazole for 7 days).

II AIMS AND OBJECTIVES

General objective:

- To establish the use of single dose prophylactic injectable antibiotics as well as to compare the rate of wound infection among the gynae post-operative patients treated by only single dose prophylactic versus conventional dose of antibiotics.

Specific objectives:

- To observe single dose prophylactic injectable antibiotic is sufficient to control the post-operative wound infection in a government hospital in Bangladesh.
- To estimate and compare the incidence of surgical site infection in both groups.
- To compare the cost effectiveness of the two groups.

III MATERIALS AND METHODS

This was a prospective study, carried out at Dhaka Medical College Hospital, Dhaka, Bangladesh during the period of July 2005 to May 2006. During this study period 100 cases were taken for the study. The patients were divided into two groups. Group A: Fifty patients received 2 gm ceftriaxone i/v as prophylaxis 1 hour before the incision. Group B: Fifty patients received conventional therapy i.e. Ciprofloxacine and Metronidazole for 7 days.

Exclusion criteria:

1. Patients with malignancy.
2. Patients with DM.
3. Patients with acute or chronic infection.

Before operation, patients were randomly assigned to receive either loading dose of 2 gm ceftriaxone (group A) preoperatively or conventional dose of Antibiotic (group B). Careful clinical data about patient's post-operative progress were recorded. The data were matched for ages, weight, socio-economic condition, anaemia and for surgical procedure and technique. Incidence of infection and length of hospital stay were determined for each patient. Wound swab was taken from infected wound of every patient and causative organism was isolated by culture of infected swab.

Dose schedule of drug and timing: Group A 2 gm Ceftriaxone intravenous 1 hour before the incision. Group B Ciprofloxacin: Injection Ciprofloxacine 500 mg intravenous 12 hourly for 24 hours followed by Tab. Ciprofloxacine 500 mg 12 hourly orally for 6 days more. Metronnidazole: Injection Metronnidazole 500 mg intravenous 8 hourly for 24 hours followed by Tab. Metronidazole 500 mg 8 hourly orally for 6 days more.

Management of wound infection: Wound swab was taken from every infected wound and by culture organism was isolated and drug sensitivity for each organism was seen and antibiotic was added accordingly. For the abdominal wound infection proper dressing was done with eusol and secondary stitch was given.

Data collection and analysis: Relevant data of the study patients were collected on predesigned proforma. (Appendix-1). Data was analyzed using SPSS program with the consultation of the statistician Because of nature of the analysis, only Chi-square (X^2) tests was applied.

IV OBSERVATION & RESULTS

During the study period from June 2005 to May 2006, the total number of randomly selected cases were 100. The place of the study was Dhaka Medical College Hospital, Dhaka, Bangladesh. All the data were presented in detail in tabulated form. The variables taken for analysis are age, weight, Hb%, duration of operation, wound infection, length of hospital stay and the risk factors for infection. At the time of randomization, the above mentioned characteristics of the cases in very both group revealed little significant difference (Table-I to Table-IV). With this aspect it can be sketched that this comparative study was done in almost similar type of cases in two groups and the result was not affected by those minor variations. In Table-I, it was shown that about 52% of the patients were in 35-44 years in group-A and 58% were in the same age in Group-B. There was very little difference in age between the two groups of patients. Table-Il shows distribution of weight among the cases.52% of the cases in group-A was within 55-59 kg and 40% cases of Group-B were in the same range. Only 2(4%) cases of Group-B are of overweight. Table-III shows 25(50%) patients in group-A and 29(58%) patients Group-B had Hb% within 55-64% range. Table-IV shows Socio-economic condition of the cases. Socio-economic condition can be categorized on the basis of monthly income. Low+<Tk. 5000/-per month Middle-Tk.5000/- Tk 10000/-per month per month High -> Tk15000/- Most of the patients are of the low income group. Only (2%) is of high income group. Table-V Shows types of

operation taken for study. Out of all the cases abdominal Hysterectomy 56%, vaginal Hysterectomy 32% and ovarian cystectomy 12% Group-A. Whereas abdominal Hysterectomy 58% VH 32% and ovarian cystectomy 10% in Group-B. Table-VI Summarizes average time taken for operation. Among all the cases 50% in group-A and 52% in group B need 75-89 minute to complete the operation Times taken for most of the operations are within 1-1.5 hours. Only 2% of the operations in both groups taken time of 2 or more hours.

Table-I: Distribution of age in years (n=100)

Age	Group	
	Group-A (n=50)	**Group-B (n=50)**
25-34	7(14.0%)	8(16.0%)
35-44	26(52.0%)	29(58.0%)
45-54	15(30.0%)	7(14.0%)
55-64	2(4.0%)	6(12.0%)

$X^2 = 162$, df = 3, p = 0.630(not significant)

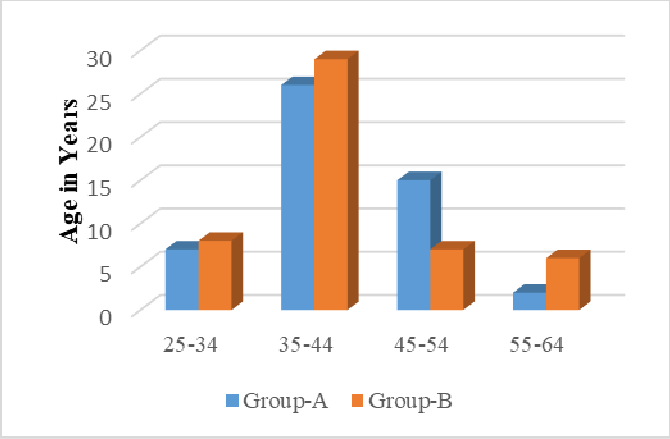

Fig-1: Distribution of age in years.

Table-II: Weight in kg (n=100)

Weight	Group	
	Group-A (n=50	Group-B (n=50)
50-54	13(26.0%)	14(28.0%)
55-59	26(52.0%)	20(40.0%)
60-64	8(16.0%)	11(22.0%)
65-69	3(6.0%)	3(6.0%)
70-74	0(0%)	2(4.0%)

$X^2 = 0.510$, df = 4, p = 0.047(significant)

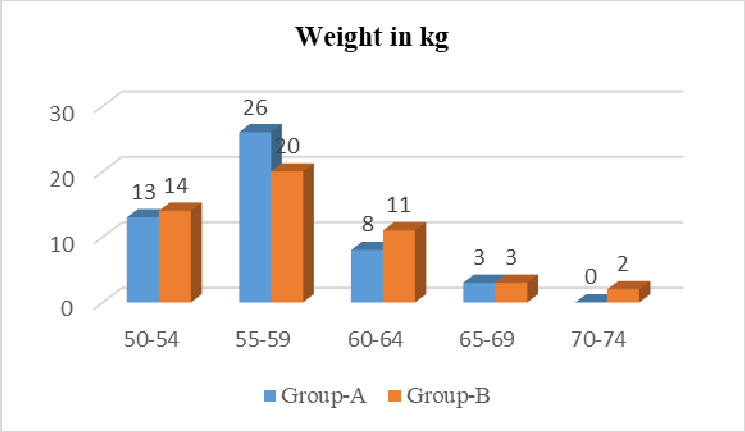

Fig-2: Weight in kg.

Table-III: Haemoglobin in percentage (n=100).

Haemoglobin (Hb %)	Group	
	Group-A (n=50	Group-B (n=50)
45-54	14(28.0%)	14(28.0%)
55-64	25(50.0%)	29(58.0%)
65-74	11(22.0%)	7(14.0%)

$X^2 = 1.185$, df = 2, p = 0.616(not significant)

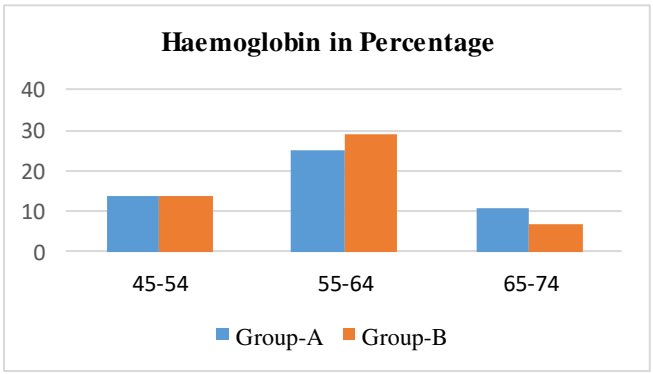

Fig-3: Haemoglobin in percentage.

Table-IV: Socioeconomic condition (n=100).

Socio-economic condition	Group	
	Group-A (n=50	Group-B (n=50)
Low	35(70.0%)	33(66.0%)
Middle	13(26.0%)	14(28.0%)
High	2(4.0%)	3(6.0%)

$X^2 = 0.862$, df = 2, p= 0.364(not significant)

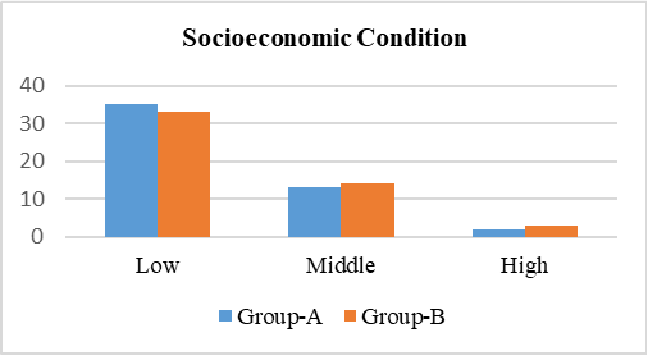

Fig-4: Socioeconomic condition.

Table-V: Type of operation (n=100)

Operation	Group	
	Group-A (n=50	Group-B (n=50)
Abdominal hysterectomy	28(56.0%)	29(58.0%)
Vaginal hysterectomy	16(32.0%)	16(32.0%)
Ovarian cystectomy	6(12.0%)	5(10.0%)

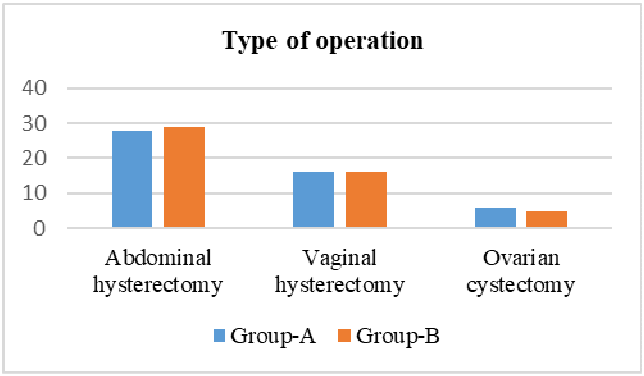

Fig-5: Type of operation.

Table-VI: Duration of operation (n=100)

Duration	Group	
	Group-A (n=50	Group-B (n=50)
60-74	11(22.0%)	10(20.0%)
75-89	25(50.0%)	26(52.0%)
90-104	13(26.0%)	13(26.0%)
105-120	1(2.0%)	1(2.0%)

$X^2 = 0.771$, df = 2, p = 0.692

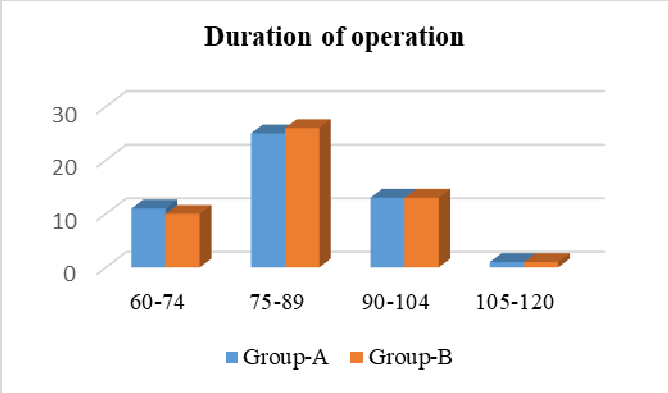

Fig-6: Duration of operation.

Table-VII: Length of postoperative hospital stay (n=100).

Days	Group	
	Group-A (n=50	Group-B (n=50)
5-9	28(56.0%)	29(58.0%)
10-14	16(32.0%)	16(32.0%)
15-19	6(12.0%)	5(10.0%)

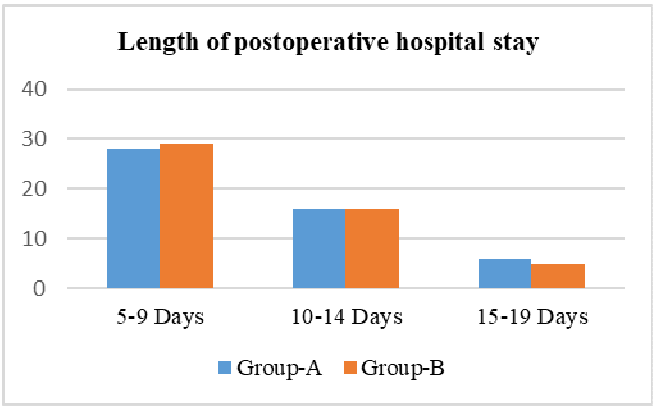

Fig-7: Length of postoperative hospital stay.

Table-VIII: **Abdominal wound infection.**

	Group-A	Group-B
Grade-1		
Grade-2	2	1
Grade-3	2	3
Grade-4		
Wound infection including vaginal hysterectomy		
Abdominal hysterectomy	4	4
Vaginal hysterectomy	1	2

Laparotomy	Nil	Nil

Table-IX: Risk factors for infection (Following 11 (Eleven) patients developed infection from the study group).

No. of patients	Age	Weight	Socio-economic condition	Hb%	Type of Operation	Duration of Operation in min
1	55	65	Low	52	TAH	120
2	50	70	Middle	58	VH	90
3	58	67	High	65	TAH	90
4	59	54	Low	53	TAH	120
5	53	66	Middle	62	TAH	60
6	57	58	Low	54	TAH	90
7	59	54	Low	54	TAH	120
8	52	72	Middle	58	VH	90
9	54	55	Low	53	VH	90
10	40	55	Low	53	VH	80
11	46	55	Low	52	VH	90

Table-X: Cost of drugs.

Group-A	Group-B
Inj. Ceftriaxone (2g)	Inj. Ciprofloxacine Inj. Metronidazole
	Tab. Ciprofloxacine Tab. Metronidazole

Table-VII shows length of postoperative hospital stay. Most patients were discharged from hospital after stitch off on 6th post-operative day. 2(40%) patients of group-A and 1(16%) patient of Group-B has grade II wound infection. Purulent discharge was sent for culture and according to culture report antibiotic was given and 2 days dressing was done and discharge on 9th post-operative day without any problem. 2(40%) patients in group-A and 3(50%) patients in Group-B have grade III wound infection and wound gap. Wound swab was taken and C/S was done. They got dressing with eusol for 4 days and then secondary stitch was given and which was removed and patient was discharged without any problem. They had to stay in hospital more than 15 days. Table-VIII shows there are 4 wound infections in group-A 2(40%) were in grade II and 2(40%) is grade III.1(16%) cases in grade II and 3(50%) is grade III of Group-B. 1(20%) patient of group-A and 2(33%) patient of Group-B suffered wound infection after vaginal hysterectomy. Table-IX shows risk factors for infection. 6(54%) cases were above 55 years of age. The weight of the 5(45%) patients were above 65 kg. 7(63%) patients were of low socio-economic condition. As consequence most of the patient's Hb% was within 50-55% Table-X shows the cost of drug in Group-B is significantly higher than that of Group-A.

V DISCUSSION

In spite of taking utmost asepsis bacterial contamination of the inevitable. The in vivo Interaction between the inoculated

bacteria and prophylactically administered antibiotic is one of the most important determine the state of the surgical site. Systemie antibiotic prophylaxis is based on the belief that antibiotics the host tissues can augment naturalisme defense med and help to kill bacteria that are inoculated into the wound A single dose of a parenteral antibiotic given at induction or up to 10 minutes before induction usually provides adequate tissue concentrations for several hours Antibiotic prophylaxis should therefore be given during this time period Studies have shown that prophylaxis administered after commencement of surgery is of for less benefit. When surgery is prolonged or massive blood loss occurs, a second de is advisable. Post-operative doses of prophylactic drugs are unnecessary Bratzler et al[8] reported in their study, if the use of antimicrobial met three parameters of published guidelines for their use to prevent SSIs: whether they were given within one hour before the surgical incision, the selection of safe and effective antimicrobials consistent with current published guidelines and the discontinuation 24 hours after surgery when the patient is no longer receiving benefit, it cause significant reduction of SSI as well as antibiotic resistance Chalkiadakis et al[9] reported preincisional injection of 2 created in high antibiotic concentrations in the wound tissue and wound Huld. No local or general complications arose in any of the patients. They suggested that perincia administration of ceftriaxone for prophylaxis is very effective" This is how supported by the present study findings that only single dose prophylactic and can prevent post-operative wound infection effectively. Richards et al[10] tells age proved to be an important factor: the rate of wound infection for 15 to 24-year-old patients was only 10% but increased significantly for those over 65 years of age. The extent of SSI was doubled for obese patients. The duration of surgical operation also proved to be a significant factor only 3% of operations lasting 30 minutes or less led to infection, while for operations lasting more than 6 hours this rate leapt to 18%. SSI rate increased with longer durations of length of pre-operative hospital stay.[11] Carol (2003) et al shows in their study the SSI rate was 9.5% (10 of 105) excluding those patients with known preoperative infections. Two statistically significant risk factors for surgical site infection in these patients emerged in the multivariate analysis: blood transfusion (P = .007) that was required for the patients with low Hb% and obesity (P=.016)[12] Habte-Gabr (1988) et al shows SSI increases with obesity, one reason being a decrease in blood circulation in fat tissues[13]. Malnutrition is another factor predisposing to SSI. In this study they considered a BMI of above 30 obese and that of below 20 as malnutrition.[13] Zeynep et al[14] shows a significant increase in the total number of nosocomial infections was determined in obese patients compared with the normal weight patients ($p<0.05$). High-density lipoprotein cholesterol below the 10th percentile increased risk of surgical site infection.[14] Haley (1985) et al shows that the duration of surgery is one factor that influences the wound infection rate. Procedures that take longer than two hours are associated with higher infection rates[14] In our study 11 patients developed surgical site infection, the age the 6 (54%) cases were above 55 years, 5(45%) were overweight, the Hb% of7(63%)were<55%among them all were from low socio-economic condition which indicate nutritional status. The duration of the operation was two hours in 3(27%) cases, so the findings of present study suggested that surgical site infection was markedly influenced by other contributing factors. All the other study results cited above supported our findings. In spite of the use of prophylactic antibiotics, SSIs are still a real risk of surgery and represent a substantial burden of disease for both patients and healthcare services in terms of morbidity,

mortality and economic cost. Changes in definition have focused attention on infection of the surgical incision, and factors associated with SSIs are now being studied with a view to limiting the risk of infection.

VI CONCLUSION AND RECOMMENDATIONS

At the discussion the most recent studies about prevention of SSI and prophylactive antibiotic was analyzed. It was seen that the whole world is very much concern about prevention of surgical site infection as well as antibiotic resistance. As both of them cause adverse effect on the patient and cost more. It can be concluded that infection prevention is highly depended on Antibiotic Prophylaxis Administration of antibiotic depends on 3 classic criteria: -

- Selection of the antibiotic properly
- It should be given appropriate time that is 1 hour prior to give incision.
- It should not be used for prolong time. It should be discontinuous within 24 hours of surgery to limit the development of drug resistance.

From the data analysis and the review of literature, it should be recommended that, every Hospital specially the Govt. Medical College Hospitals where the patient's characteristics, word environment are more or less same should establish a uniform protocol about the use of antibiotic in operation as well as in the treatment of any infection especially in gynaec & obs department. Only a written protocol can establish the rational use of antibiotics of the service providers. To establish a protocol more and more study about use of antibiotic and surgical site infection prevention in the perspective of our country should be done. A multisectoral approach can make it more fruitful and we should revise "Hospital Infection Control Practices Advisory Committee (HICPAC) Partial Recommendations for the Prevention of Surgical Site Infection-1999". The SSIP protocol by ICSI which is shown below can act as a model to do it.

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