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To Compare the Efficacy of Single Dose versus Routine Five Days Prophylactic Antibiotic in Prevention of Post Operative Infection in Gynaecologic and Obstetric Surgeries

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Abstract: Aim:

- *To compare the efficacy of single dose versus routine five days prophylactic antibiotic in prevention of post operative infection in elective gynaecologic and obstetric surgeries.*

Objectives:

- *To decrease the incidence of post surgical wound infection*
- *To improve the outcome, to reduce the time stay at the hospital and to reduce cost of treatment.*

Material And Methods: *This is a prospective, Randomized, comparative study conducted in the department of Obstetrics and Gynaecology for elective surgeries in KIMS hospital over 100 population from June 2017 to May 2018. Patients aged between 25 – 45 years with BMI<30 undergoing elective gynaecological and obstetric surgeries were included in this study.Randomization done using envelope method.*
Patients were divided as :

- *Group 1(50 subjects) receives single dose of parenteral prophylactic antibiotic preoperatively half an hour before surgery.*
- *Group 2(50 subjects) receives single dose of parenteral prophylactic antibiotic preoperatively half an hour before surgery and five days oral antibiotics post operatively.*

Outcome was measured in terms of surgical site wound infection, febrile morbidity and urinary tract infection on Day 3, Day7 and Day 21.

Results: *A total of 100 patients who undergoing elective gynecological and obstetrical surgeries are included. Outcome was measured in terms of surgical site wound infection, febrile morbidity and urinary tract infection on Day 3, Day 7 and Day 21.*
On 3rd POD febrile morbidity is 4%in intervention group and 6% in control group. UTI is 4% in intervention group and 6% in control group and surgical site wound infection cases are 2% in control group and no cases found in intervention group.
On 7thPOD there are no fever cases in both groups and UTI cases are 4% in intervention group and 2% in control group and wound infection cases are 1% in control group and 0% in intervention group.on 21st POD there are no fever and wound infection cases and UTI cases were noted as 2% in both the groups. As the P value is more than 0.05 in all the association analysis, we can conclude that there is no significant difference in proportions of outcome at 3rd, 7th, and 21st POD between the groups.

Conclusion: *Since there was no statistically significant difference in the rate of postoperative wound infection, febrile morbidity and urinary tract infections between the patients who received single dose as compared to multiple doses of prophylactic antibiotic for elective surgeries, it can be concluded that both regimens were equally effective against postoperative infectious morbidity. Single dose antibiotic regimen is cost effective, easy to administer and monitor. Therefore a single dose for antibiotic prophylaxis should be preferred over multiple dose.*

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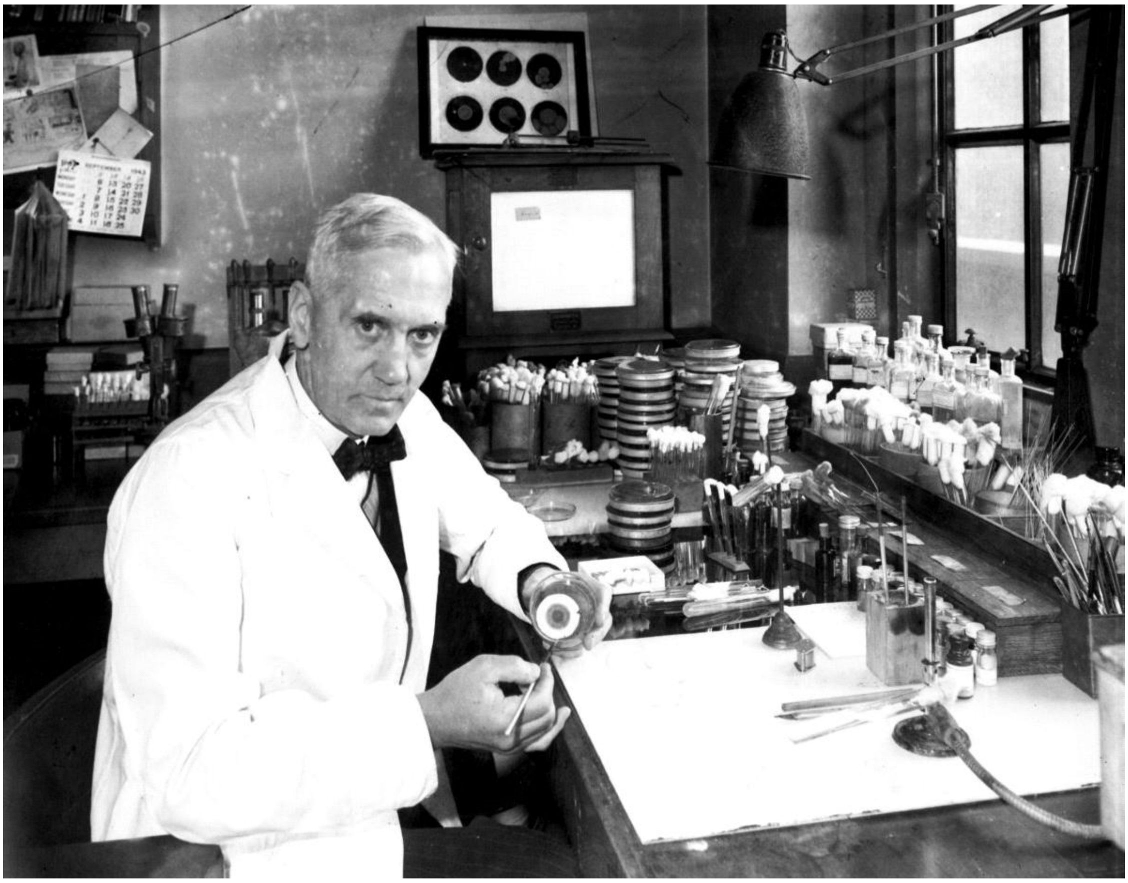
I. Introduction And Background

An antimicrobial agent or an antibiotic is defined as an agent produced naturally by an organism or prepared synthetically that damages or stops the growth of microbes such as bacteria, fungi, or protozoa. The discovery of antibiotics represented a key medical milestone in the 20th century. The word antibiotic stems from “anti” meaning against and “biota” meaning life. Therefore, by definition, antibiotic translates into “anti-life”.



Alexander Fleming- Biologist, Discovered Penicillins, Noble Prize Winner 1945

The first antibiotic 'penicillin' was discovered in the year 1929 by Sir Alexander Fleming. He discovered that an agar plate that has the bacterium staphylococci on it got contaminated by a Penicillium mold. This mold, which has formed a zone around the Staphylococcus, was of interest to Fleming as he was searching for potential antibacterial compounds. Fleming was interested in this observation and

he did several experiments to prove that culture broth of the mold had prevented the growth of the Staphylococcus even after being diluted up to 8,000 times. After many years, Ernst Chain and Howard Florey were able to develop a way to isolate penicillin which has been used to treat bacterial infections during World War II. Penicillin was introduced to clinical use in 1946 where it made a significant effect

on public health. The discovery of penicillin was a milestone for public health because it reduced the spread of disease. During World War II, there was a high demand for the production of antibiotics to fight off infections.

Infection of the incised skin or soft tissue is a common but potentially avoidable complication of any surgical procedure. Some bacterial contamination of a surgical site is inevitable, either from the patients own bacterial flora or from the environment[1]. Concept of antibiotic prophylaxis was introduced in 1960s which has greatly reduced the rate of postoperative infections.[2, 3.] Prophylactic antibiotics are those that are administered to the patients before contamination has occurred. Optimal prophylaxis ensures that adequate concentrations of an appropriate antimicrobial are present in the serum, tissue and wound during the entire time that the incision is open and at risk for bacterial contamination[4].

Antibiotic prophylaxis is intended to reduce the size of bacterial inoculum and to change the characteristics of the culture medium at the operative site during the brief time that host defenses are impaired by the trauma of surgery[5].Some clinical criteria should be fulfilled to justify perioperative use of prophylactic antibiotics like, there must be a high incidence of postoperative infections in the absence of prophylaxis and sequelae that may result from the primary infection must be significant[5].

Goals of Antibiotic Prophylaxis
1.Reduce the incidence of surgical site infection.
2.Use the antibiotic in a manner that is supported by evidence of effectiveness.
3. Minimize the effect on patient's normal flora.

4. Cause the minimal change to the patients host defences.[1]

Other factors to consider are low toxicity, safety record and ability to reach an effective concentration in the tissue prior to the procedure.[6] The dosing period of antibacterial drug should be shortened as much as possible in order to prevent the transformation of drug resistant strains.[7, 8]Over use of antibiotics resulted in emergence of resistant organism and increased economic burden on health system.[9, 10]

It is important to emphasize that surgical antibiotic prophylaxis is an adjunct to, not a substitute for, good surgical technique. While choosing prophylactic antimicrobial agent, we should consider the following factors. The agent selected must be of low toxicity, established safety record, have a spectrum of activity that includes the microorganisms most likely to cause infection.

The purpose of this study is to compare the efficacy of single dose versus routine 5 days prophylactic antibiotic in prevention of postoperative infections in elective gynecological and obstetrics surgeries. Most common surgery done is cesarean section followed by total abdominal hysterectomy. It is recommended that prophylactic antibiotic should be administered prior to surgical incision to reduce surgical sight infections. Most common Complications following above surgeries are fever, wound infections, endometritis, bacteremia, pelvic abscess, septic shock, necrotizing fasciitis, septic pelvic vein thrombophlebitis and urinary tract infections.[11,12,13] Endometritis and wound infections are still the most significant causes of postoperative infectious morbidity,[11]While the incidence of endometritis is between 20%-85% without antibiotic prophylaxis, severe complication rates associated with wound infections are reported as 25%.[14] The administration of prophylactic antibiotics decreases the incidence of infectious morbidity following cesarean by a rate of 75% in both planned and emergent caesarean deliveries.[15,16,17]

The use of first generation cephalosporin such as cefazoline provides activity against Urea plasmas and Mycoplasma but may cause and increase in the resistant organisms like anaerobes.[18, 19]Hence, there is rationale for adding agents such as metronidazole, clindamycin or azithromycin to extend the cover. Four randomized controlled trails compared use of narrow range antibiotic prophylaxis with broad spectrum antibiotics regimens.[20-23] Broad spectrum were associated with a statistically significant reduction in infection rates,[20] Ceftriaxone a third generation cephalosporin, has been clinically useful in obstetrics and Gynaecology by virtue of its broad –spectrum coverage.

Post-operative infections comprise a major portion of morbidity experienced in obstetrics. Hence, increased cost of medical care and the increased demand of hospital beds have given added impetus to search for new methods to decrease post-operative morbidity and shorten the duration of hospital stay. The present study is conducted to compare the infectious morbidity with single dose and multiple dose antibiotics in elective gynecological and obstetrics surgeries at KIMS Hospital. Hospital antibiotic policy is to give preoperatively stat dose antibiotic followed by antibiotic for 2 to 4 days depending up on patient clinical condition.

II. Aims & Objectives

Aim :

- To compare the efficacy of single dose versus routine five days prophylactic antibiotic in prevention of postoperative infection in elective gynaecologic and obstetric surgeries.

Objectives :

- To decrease the incidence of post - surgical wound infection
- To improve the outcome, to reduce the time stay at the hospital and to reduce cost of treatment.

material and methods

Study site: Patients of Obstetrics & Gynecology Department, in KIMS hospital

Study population: Patients admitted in the Department of Obstetrics &
Gynecology for elective surgeries

Study Design: A prospective, Randomized, comparative study

Sample Size: 100

This is a prospective, Randomized, comparative study and assuming that new treatment and standard treatment are equally effective, the formula for calculating sample size for equivalence trials is

$$N = 2 \times \left(\frac{z_{1-\frac{\alpha}{2}} + z_{1-\beta}}{\delta_0} \right)^2 \times p \times (1-p)$$

where

N=size per group;

p=the response rate of standard treatment group, which is 0.98(from karachi study-where the the no wound infection rate of control group at 2nd & 21st post op day is 97.4% and 99.3% respectively. The average of these two is 98%(0.98)

z= the standard normal deviate for a one or two sided test
δ0= a clinically acceptable margin, which assumed as 0.1(10%)
Significance level(α)=0.05
β=0.20(β=1-power; where power assumed to be 80% or 0.8, then β is 1-0.8=0.20)
Applying the above formula, sample is calculated as follows
N=2*(1.96+0.854/0.1)2 *0.98*(1-0.98)
N=30 per group i.e. 30 in experimental group and 30 in control group
Study Period : June 2017 till May 2018

Inclusion criteria:

- Female subjects who is undergoing elective gynaecologic and obstetric surgeries
- Age between 25 – 45 years
- BMI < 30

Exclusion criteria:

- Female subjects with diabetes and anaemia
- Patients who are immuno compromised
- BMI>30
- Age>45 years
- Patients undergoing emergency surgeries
- Patients with premature rupture of membranes
- Subjects known to be hypersensitive to antibiotic given in study

III. Methodology:

Patients undergoing elective gynecological surgeries like abdominal hysterectomies, caesarean sections and laparotomies are included in this study. Randomization done using envelope method.
Patients are divided as:

- Group 1 (50 Subjects) receives single dose of parenteral prophylactic antibiotic preoperatively half an hour before surgery.
- Group 2 (50 Subjects) receives single dose of parenteral prophylactic antibiotic preoperatively half an hour before surgery and five days oral antibiotics post operatively.

Written consent was taken from all the patients with prior information about the study protocol and procedure. Ethical clearance was taken from the Hospital Ethical Committee by giving written form of all the study procedures and steps.

Baseline assessment including vitals, general physical, systemic and gynaecological examination was performed along with routine blood analysis (CBC, RBS, RFT) and urine analysis, urine culture and sensitivity, high vaginal swab culture and sensitivity.

Outcome was measured in terms of surgical site wound infection, febrile morbidity and urinary tract infection .For surgical site infection, wound was inspected for redness, pain, abscess formation/purulent discharge on Day 3, Day 7 and Day 21. For urinary tract infection urine analysis is done on Day 3 and Day 7. For febrile morbidity temperature is checked 6 hourly. Febrile morbidity was defined as body temperature of more than 37.8 ^{0}C that developed after 48 hours of surgery and remained for at least 24 hours.

As mentioned above, outcome on day 3 was measured during hospital stay and patient is discharged on day 4 or day 5 and patient was advised to come on day 7 for follow up. Again patient was advised to come for follow up on day 21.

In each visit outcome was measured as mentioned above.

IV. Results:

A total of 100 patients who undergoing elective gynecological and obstetrical surgeries are included

Table 1: Distribution of intervention and control groups by age group

Age group	Intervention group Frequency (%)	Control group Frequency (%)	Total Frequency (%)
25-30	23(46.0)	20(40.0)	43(43.0)
31-35	6(12.0)	6(12.0)	12(12.0)
36-40	3(6.0)	3(6.0)	6(6.0)
41-45	18(36.0)	21(42.0)	39(39.0)
Total	50(100.0)	50(100.0)	100(100.0)

Diagram 1: Distribution of intervention and control groups by age group

Table 2: Distribution of intervention and control groups by type of surgery

Type of surgery	Intervention group Frequency (%)	Control group Frequency (%)	Total Frequency (%)
LSCS	29(58.0)	27(54.0)	56(56.0)
TAH	15(30.0)	20(40.0)	35(35.0)
Laparotomy	6(12.0)	3(6.0)	9(9.0)
Total	50(100.0)	50(100.0)	100(100.0)

Diagram 2: Distribution of intervention and control groups by type of surgery

Table 3: Comparison of outcome between the groups at 3rd POD

Outcome		Intervention group N=50	Control group N=50	P value
Fever	Yes	2(4.0%)	3(6.0%)	1.00#
	No	48(96.0%)	47(94.0%)	
UTI	Yes	2(4.0%)	3(6.0%)	1.00#
	No	48(96.0%)	47(94.0%)	
Wound infection	Yes	0(0.0%)	1(2.0%)	1.00#
	No	50(100%)	49(98.0%)	

Fisher exact test is used as expected count is less than 5 in some cells

Diagram 3: Comparison of outcome between the groups at 3rd POD

Table 4: Comparison of outcome between the groups at 7th POD

Outcome		Intervention group N=50	Control group N=50	P value
Fever	Yes	0(0.0%)	0(0.0%)	*
	No	50(100%)	50(100%)	
UTI	Yes	2(4.0%)	1(2.0%)	1.00#
	No	48(96.0%)	49(98.0%)	
Wound infection	Yes	0(0.0%)	1(2.0%)	1.00#
	No	50(100%)	49(98.0%)	

*P value cannot be calculated as there are no fever cases
Fisher exact test is used as expected count is less than 5 in some cells

Diagram 4: Comparison of outcome between the groups at 7th POD

Tabl e 5: Comparison of outcome between the groups at 21st POD

Outcome		Intervention group N=50	Control group N=50	P value
Fever	Yes	0(0.0%)	0(0.0%)	*
	No	50(100%)	50(100%)	
UTI	Yes	1(2.0%)	1(2.0%)	1.00#
	No	49(98.0%)	49(98.0%)	
Wound infection	Yes	0(0.0%)	0(0.0%)	1.00#
	No	50(100%)	50(100%)	

*P value cannot be calculated as there are no fever cases
Fisher exact test is used as expected count is less than 5 in some cells

Diagram 5: Comparison of outcome between the groups at 21st POD

Table 6: Comparison of outcome between the groups at 21st POD

Outcome		Intervention group N=17	Control group N=19	P value
Fever	Yes	0(0.0%)	0(0.0%)	*
	No	17(100%)	19(100%)	
UTI	Yes	0(0.0%)	1(5.3%)	1.00#
	No	17(100.0%)	18(94.7%)	
Wound infection	Yes	0(0.0%)	0(0.0%)	*
	No	50(100%)	50(100%)	

*P value cannot be calculated as there are no fever and wound infection cases
Fisher exact test is used as expected count is less than 5 in some cells

As the P value is more than 0.05 in all the association analysis, we can conclude that there is no significant difference in proportions of outcome at 3rd, 7th, and 21st POD between the groups. Hence single dose antibiotic is equally effective as compared with multiple dose antibiotics.

V. Discussion:

The primary aim of prophylactic antibiotics is to reduce the infection and thereby reduce morbidity and mortality. The risk is particularly high in developing countries because of many social factors like literacy level, socio- economic status and environmental pollution. A high resistance of antibiotic resistance has been a globally concern regarding the misuse of antibiotics leading to suboptimal treatments.[44-46] So appropriate antibacterial selection remains the complex problem followed by frequency, duration and timing of each dose.[47]The results of present study show that prophylactic single dose antibiotic is equally effective as compared with multiple dose antibiotics in low risk cases.

Out of 100 patients most common surgery performed is LSCS(56%), followed by TAH(35%) and Laparotomy (9%).Most common indication for LSCS is previous LSCS (37 patients out of 56).Most common indication for Total abdominal hysterectomy is abnormal uterine bleeding due to fibroids, adenomyosis.

In our study, predominant age groups were 25-30 Years (43% of Total subjects) and 41-45 Years (39% of Total subjects). Mean body mass index was 26.31 Kg/mt^2 in Intervention Group and Control Group was 26.53 Kg/mt^2.

In our study only 2 (2%) patients had wound infection, zero subjects in single dose group and two subjects in multi dose group, Similar to study of Humaira Tahseen et.al.

Conmparision of Wound infection results of our study with various study

Study	Intervention group	Control group
Our study	0%	2%
Humaira Tahseen et.al	0.3%	1.7%
Shagufta shaheen et. al	8%	8%
Babeeta et. Al	8%	10%

In our study, febrile morbidity was observed in 5 patients (5% of total subjects). 2 patients in intervention group and 3 patients in control group. Similar to study of Humaira Tahseen et.al and Babeeta et.al

Conmparision of febrile morbidity results of our study with various study

Study	Intervention group	Control group
Our study	2%	3%
Humaira Tahseen et.al	1.6%	2.3%
Shagufta shaheen et. al	10%	10%
Babeeta et. Al	5%	6%

In our study, UTI was observed in 10 patients (10% of total subjects). 5 patients in intervention group and 5 patients in control group. Similar to study of Shagufta shaheen et.al and Babeeta et.al

Conmparision of UTI results of our study with various study

Study	Intervention group	Control group
Our study	5%	5%
Humaira Tahseen et.al	14.4%	22.9%
Shagufta shaheen et. al	4%	2%
Babeeta et. Al	7%	9%

Hospital stay was almost the same in both groups i.e., intervention group (Mean 4.1 days) versus control group (Mean 4.4 days). Similar to study of Shagufta shaheen et.al.

Out of 100 patients, two patients (subject-1 and subject-2) of intervention group had wound infection. Subject-1 had induration with erythema. Subject-2 had induration, erythema and serous discharge. Subject-1 with no serous discharge, antibiotics continued for 5 days post operatively. Subject-2 with serous discharge, wound swab taken for culture and sensitivity, which is sterile. So continued with antibiotics for 5 days post operatively.

VI. Conclusion:

Since there was no statistically significant difference in the rate of postoperative wound infection, febrile morbidity and urinary tract infections between the patients who received single dose as compared to multiple doses of prophylactic antibiotic for elective surgeries, it can be concluded that both regimens were equally effective against postoperative infectious morbidity. Frequent and excessive use of antibiotics (over several days) is a potential risk for development of microbial resistance to the antibiotics and their inefficacy for the purpose of prophylaxis against surgical site infections. Single dose antibiotic regimen is cost effective, easy to administer and monitor. Therefore a single dose for antibiotic prophylaxis should be preferred over multiple dose.

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