ORIGINAL ARTICLE

Single Dose Prophylactic Antibiotic Versus Routine 5 Days Prophylactic Antibiotic in Prevention of Postoperative Infection in Elective, Clean Abdominal Gynecologic Surgeries

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ABSTRACT

Objective — *To compare the efficacy of single dose versus routine five days prophylactic antibiotic in prevention of postoperative infection in elective gynecologic and obstetric surgeries.*

Study design — *Randomized control trial.*

Place & Duration of study — *Department of Obstetrics and Gynaecology Liaquat National Hospital & Medical College Karachi, from August 2010 to August 2011.*

Methodology — *A total of 303 patients undergoing elective gynecologic and obstetric surgeries were included. Patients were randomly divided into two groups with 153 patients each. One group received single dose of antibiotic at the time of induction of anaesthesia and other received 1st dose at induction of anesthesia, 2nd after 12 hours and then two doses daily 12 hourly for 5 days. Rate of postoperative infections in terms of wound infection, urinary tract infection and febrile morbidity, were recorded.*

Results — *The commonest surgical procedure performed were cesarean section in both the groups followed by total abdominal hysterectomy. There was no statistically significant difference in the rates of postoperative wound infection on 2nd (0% vs 2.6%, p = 0.123) and 21st (0.7% vs 0.7%, p = 0.99) postoperative day in both the groups. Similarly febrile morbidity on 2nd postoperative day was (3.3% vs 4.6%, p=0.56) and no fever observed on 21st day of surgery in both the groups. As regards the urinary tract infection there was no statistically significant difference between the groups on 2nd day (22.9% vs 14.4%, ??? p=) and 21st day (5.2% vs 2.6%, p = 0.24).*

Conclusions — *Both the regimens were equally effective against postoperative infectious morbidity. Single dose of prophylactic antibiotic prevented unnecessary long course of antibiotic and potential antibiotic resistance.*

Key words — *Prophylactic antibiotic, Wound infection, Urinary tract infection, Febrile morbidity.*

INTRODUCTION:

Postoperative infection is one of the most serious and common complication after surgery. It is associated with prolong hospital stay and results in increased medical cost. The purpose of antibiotic prophylaxis in surgical procedures is not to sterilize tissues but to reduce the colonization of microorganisms introduced at the time of operation to a level that, the patient's immune system is able to overcome the challenge.[1]

It should be noted that prophylactic antibiotics do not need to cover every possible pathogen that may

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cause infection. Decreasing the bacterial load will usually enable the patient's immunological defence to function adequately.[2] Other factors to consider are low toxicity, safety record and ability to reach an effective concentration in the tissue prior to the procedure.[2]

It has generally been considered that the dosing period of antibacterial drug should be shortened as much as possible in order to prevent the transformation of drug resistant strains.[3,4] The aim of this study was to compare the efficacy of single dose versus routine 5 days prophylactic antibiotic in prevention of postoperative infections in elective gynecological surgeries.

METHODOLOGY:

This study was done in the Department of Obstetrics and Gynaecology, Liaquat National Hospital & Medical College Karachi, from August 2010 to August 2011.

Postoperative wound infection was labelled when at least one of the following was present; a purulent discharge from the surgical site or anyone of the sign and symptoms of infection (pain, tenderness or localized swelling), or an abscess defined as local collection of pus.

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. When urine chemical analysis showed > 5 pus cells and culture and sensitivity either positive or negative, then it was labelled as urinary tract infection.

It was a randomised controlled trial, and a sample size was 306 patients with 156 in each group calculated based upon confidence interval 95%, power of test 80%, P1=15% and P2=5%, alpha= 5%. Patients undergoing elective gynecological surgeries like abdominal hysterectomies, cesarean sections and laparotomies were included. Duration of surgery < 2 hours and age of the patients < 55 year were other inclusion criteria.

Patients with immuno-compromised condition like those on immuno-suppressive therapy or chemotherapy or any autoimmune disorder were excluded. Any associated medical disorder e.g. diabetes mellitus, anemia, jaundice were other exclusion criteria. Patients with localised skin infection, suspected or proven malignancy, emergency procedures, suspected infective surgery, and obesity BMI > 30kg/m^2 were also excluded.

After getting formal informed consent, the patients were randomised into two groups by using opaque envelope technique. Case group received single dose antibiotic (co-amoxiclav 1.2 gm I/V) at the time of induction of anesthesia. Control group received same antibiotic at the time of induction of anesthesia, 2nd dose after 12 hours and 2 doses daily, 12 hours apart for five days.

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 or purulent discharge on Day 3, Day 10 and Day 21. For urinary tract infection urine analysis was done on Day 3 and Day 21. For febrile morbidity temperature was checked 6 hourly.

All data was analysed on SPSS version 13. Descriptive statistics like age was reported as mean and standard deviation. Frequency and percentages were computed for all categorical variables e.g. surgical site infection, febrile morbidity and urinary tract infection. Chi square test and Fisher Exact test were applied to test hypothesis. Statistical significance was defined using p value < 0.05.

RESULTS:

A total of 306 patients who underwent elective gynecological procedures were included. Median age of the patients in interventional group was 31 year (IQR=14) while in control group the age was 33 year (IQR=17). The commonest surgical procedure was cesarean section (n=172) in both the groups followed by total abdominal hysterectomy and bilateral salpingo-opherectomy (n=109).

Outcome on 2nd postoperative day showed that the rate of wound infection was not significant between single dose and multi-dose groups (0% vs 2.6%, p=0.123). Urinary tract infection was high in multi-dose group than single dose group but it was not statistically significant (22.9% vs 14.4%, p = 0.056). Similarly febrile morbidity was also not significant between the single dose and multi-dose groups (3.3% vs 4.6%, p = 0.56). This is given in table I.

Outcome at 21st postoperative day showed that the rate of wound infection was not significant between the groups (0.7% vs 0.7%, p = 0.99). Urinary tract infection was high in multi-dose group than in single dose group (5.2% vs 2.6%, p = 0.24). No febrile morbidity noted in both groups observed. Single dose and multiple dose antibiotics were equally effective in preventing wound infection, febrile morbidity and urinary tract infection at 21st postoperative day (table II). Data was also stratified and analysed with respect to age and surgical

Table I: Comparison of Outcome Between Groups At 2ND Postoperative Day				
Outcomes		**Intervention Group n=153**	**Control Group n=153**	**p-Values**
Wound Infection	Yes No	0 (0%) 153 (100%)	4 (2.6%) 149 (97.4%)	0.123†
Urinary Tract Infection	Yes No	22 (14.4%) 131 (85.6%)	35(22.9%) 118(77.1%)	0.056
Febrile Morbidity	Yes No	5 (3.3%) 148 (96.7%)	7 (4.6%) 146 (95.4%)	0.56

†Fisher Exact Test, Chi-Square Test

Table II: Comparison of Outcome Between Groups At 21st Postoperative Day				
Outcomes		**Intervention Group n=153**	**Control Group n=153**	**p-Values**
Wound Infection	Yes No	1 (0.7%) 152 (99.3%)	1 (0.7%) 152 (99.3%)	0.99†
Urinary Tract Infection	Yes No	4 (2.6%) 149 (97.4%)	8 (5.2%) 145 (94.8%)	0.24
Febrile Morbidity	Yes No	0 (0%) 153 (100%)	0 (0%) 153 (100%)	0.99

†Fisher Exact Test, Chi-Square Test

Table III: Comparison of Outcome Between Groups At 21st Postoperative Day After Stratification				
Outcomes		**Intervention Group n=92**	**Control Group n=86**	**p-Values**
Wound Infection	Yes No	0 (0%) 92 (100%)	0 (0%) 86 (100%)	0.99
Urinary Tract Infection	Yes No	3 (3.3%) 89 (96.7%)	6 (7%) 80 (93%)	0.258
Febrile Morbidity	Yes No	0 (0%) 91 (100%)	0 (0%) 86 (100%)	0.99

†Fisher Exact Test

procedure but rate of wound infection, UTI, febrile morbidity and effectiveness at 21st postoperative day were not significant between the groups (table III).

DISCUSSION:

Postoperative infections are major cause of morbidity in gynecological surgeries and sometimes may lead to mortality in surgical patients. The risk is particularly high in developing countries because of many social factors like literacy level, socio- economic status and environmental pollution. It also incurs significant expenses on the treatment of each infected patient. With the demands of private practice and obvious need to reduce postoperative morbidity and expenses, it is not surprising that gynecologists and obstetricians wish to take all possible measures to reduce post surgical complications.

Concept of antibiotic prophylaxis was introduced in 1960s which has greatly reduced the rate of postoperative infections.[5,6] Over use of antibiotic

has resulted in emergence of resistant organism and increased economic burden on health system.[7,8] In our study the incidence of urinary tract infection (UTI) was high in both the groups 22.9% in multi dose group vs 14.4% in single dose group, but it was not statistically significant. Our result was comparable with that of Dar LR, who showed significant reduction in UTI in single dose group compared to the group which received antibiotic for 10 days.[9] Two studies are quoted which state that duration of indwelling catheter has a significant role in developing UTI.[10,11] Occult bacteriuria, bladder trauma and catheterization are also the risk factors for UTIs.[12] Moreover proper antiseptic measures during the process of catheterization are important in preventing infections. While some may cast doubt about the role of single dose prophylaxis in preventing UTIs, it is worth noting that only 14.4% of patients who received single dose developed infection while 85.6% remained well.

In our study only six (2%) patients had wound infection, one in single dose group and five in multi dose group, which is quite encouraging as compared to that given in literature. Besides, all patients with wound infection did not grow any organism on culture and were treated by local measure of washing with normal saline and dressing. Nisa M has shown 5% wound infection rate in their study and Siddiqui et al had wound infection rate of 13.27% in their study.[13,14]

A large case control study performed to determine clinically relevant independent risk factors for surgical site infection (SSI) concluded that development of subcutaneous hematoma after the procedure, operation performed by the university teaching service and a higher BMI at admission were important variables. Closing skin with staples was also important, though the relationship between the use of staples for skin closure and SSI remained unresolved.[15] Different results were found in a study by Jabeen et al which showed 10% and 5% SSI in single dose and multiple dose groups.[16] However this difference was not statistically significant. Careful operative techniques to avoid hematoma formation, avoidance of dead space and intraoperative antibiotic prophylaxis are important measures against wound infections.[17]

In our study the febrile morbidity was observed in 12 patients (3.92%), five in single dose group and seven in multi dose group however these findings were not statistically relevant and were comparable to the findings of Rouzi et al, Dimitrov et al and Bagratee et al.[18,19,20] Febrile morbidity in ten patients was associated with UTI and in one with wound infection. Only one patient in single dose group had febrile morbidity that was not associated with any clinical features of infections nor was there any laboratory evidence of infection. Patients developing fever within 48 hours of surgery were considered as having febrile reaction. Some investigators exclude first 48 hours postoperatively in their definition of febrile morbidity.[1,14] Same was followed in this study. Several studies have compared single dose vs multiple doses of prophylactic antibiotics and all of them concluded that single dose of antibiotic is as effective as multiple doses.[14,17]

CONCLUSIONS:

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, so it may be argued that both regimens were equally effective against postoperative infectious morbidity. So single prophylaxis is recommended.

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