SINGLE DOSE VERSUS MULTI DOSE CEPHRADINE AS ANTIBIOTIC PROPHYLAXIS IN ELECTIVE ABDOMINAL HYSTERECTOMY: A RANDOMIZED CONTROL TRIAL

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ABSTRACT

Objective: *To compare the efficacy of single dose versus 7 days cephradine prophylaxis for the prevention of post operative infection in patients undergoing elective abdominal hysterectomy.*

Material and Methods: *This study was conducted in the department of Obstetrics and Gynaecology, Lady Reading Hospital from January 2006 to March 2007. Twenty patients each were randomly allocated by card method to either group 1 or group II. Patients in group-1 were given one gram of cephradine intravenously 30 minutes before surgery while patients in group-II were given one gram of intravenous cephradine 30 minutes before surgery 2nd dose of one gram was repeated after 12 hours followed by 500 mg of oral dose for next 6 days. Wound was examined on 2nd, 4th and 7th day then after 2 weeks and after 6 weeks. The efficacy was measured in terms of febrile morbidity, surgical and nonsurgical site infection and duration of hospital stay. The statistical analysis was carried out by chi square test.*

Results: *Febrile morbidity was equal in both groups (20%), surgical site infection was 10% in group I and 5% in group II, and duration of hospital stay was equal in both groups. Non surgical site infection occurred in 5% of patients in group-I. There was no statistically significant difference in out come in two groups.*

Conclusion: *Single dose prophylactic antibiotic is as effective as multiple dose antibiotics in elective abdominal hysterectomy.*

Key words: *Antibiotic prophylaxis, single dose, multiple dose, cephradine, abdominal hysterectomy, wound infection, randomized controlled trial.*

INTRODUCTION

Post operative surgical wound infection is a major source of morbidity. The reported incidence of surgical site infection leading to longer hospital stay and increase cost is up to 5%.[1] The frequency of post operative infection has been reported to be high without the use of antibiotic prophylaxis. Prophylactic antibiotics are helpful in preventing post operative infection.[2]

In 1999 the Centre for Disease Control (USA) issued guidelines recommending the prophylactic use of preoperative antibiotic to prevent infection. Various regimens have been used for this purpose. Over use, under use and improper timing of administration of antibiotics occur in 25-50% of surgeries. Short courses of prophylactic antibiotic is as efficacious as longer courses in preventing post operative infection. Many studies have proved the efficacy of antibiotic prophylaxis in preventing surgical infections.[3-9]

Single dose prophylaxis can help in the reduction of medical cost and development of microorganism resistance. Single dose prophylaxis has not been accepted and multiple dose regimens are still used in some centers. In most of the hospitals in our country multiple dose antibiotic are use for 5-7 days to prevent infection.[1]

The aim of this study was to see the effect of single dose versus multiple doses of anti biotic in preventing infection in low risk group with one antibiotic (cephradine). This may help us to establish a proper protocol for prophylactic antibiotic and to prevent the misuse side thus reducing the cost and avoid the effects as well.

INDICATIONS FOR ABDOMINAL HYSTERECTOMY

Indication	Frequency (n=40)	Percentage
Dysfuntional uterine bleeding	20	50%
Fibroid Uterus	12	30%
Chronic Pelvic Pain	3	7.5%
Endometrial Hyperplasia	3	7.5%
Ovarian Cyst	1	2.5%
Adenomyosis	1	2.5%

Table 1

MATERIAL AND METHODS

This randomized controlled study was conducted at the department of obstetrics and gynecology ('B' unit) Postgraduate Medical Institute / Lady Reading Hospital Peshawar from January 2006 to March 2007. Data was collected on a prescribed proforma. The number of patient were limited because of strict inclusion criteria. Forty, low risk patients under-going abdominal hysterectomy were included. The exclusion criteria was obese patients and patients undergoing vaginal hysterectomy, having diabetes mellitis, already on antibiotics and steroids, malignancy and any evidence of genitourinary infection. Written informed consent was obtained from all the patients. Cephradine (1st generation cephalosporin) was used for antibiotic prophylaxis. Patients were randomly allocated by card method to either group-I or group-II. Twenty patients were included in each group. Cephradine was selected because of its broad spectrum, B lactamase stability and its minimum toxicity. Patients in group-1 were given one gram of cephradine intravenously 30 minutes before surgery. Patients in group-II were given one gram of intravenous cephradine 30 minutes before surgery 2nd dose of one gram was repeated after 12 hours followed by 500 mg of oral dose for next 6 days. Each patient was observed in the post operative ward and 4 hourly temperature record was kept for 7 days. Fever developing or persisting for 48 hours after surgery was included as the febrile morbidity. Wound was examined on 2nd, 4th and 7th day then after 2 weeks and after 6 weeks. It was inspected for evidence of superficial or deep infection, pus discharge, abscess formation, wound dehiscence, vault hematoma and pelvic abscess. Patients were also assessed for respiratory, or urinary tract infection (all patients had catheter for 24 hours). Urine examination was done on 3rd post operative day for all patients. Urine culture, high vaginal swab for C/S and pelvic ultrasound was done in patients having fever for more then 48 hours or developed fever after 48 hours. The out come measures were the febrile morbidity, wound infection, chest infection, UTI, dehiscence of scar and patients needing other antibiotics. The results were expressed in percentage for categorical data. Results were tested by chi square test. A P-Value of <0.05 was considered as statistically significant. Calculations were done on SPSS 10.0.

RESULTS

In this study 40 patients under going abdominal hysterectomy were included. Indications for abdominal hysterectomy are given in Table-1. Comparison of outcome measures between the two groups is given in Table-2.

Patients with febrile morbidity were 4(20%) in group-I and 4(20%) in group-II. Over all difference in proportion of post operative wound infection was statistically not significant between two groups (OR=1). The causes of febrile morbidity are given in Table-3. One patient in group-I and two patients in group-II had vault hematoma. Hematoma formation although a contributory factors for febrile morbidity is not a contributory factors for our outcome measure in this study. Superficial wound infection was in one patient (5%) in group-I. Superficial wound induration was noted in one (5%) patient in each group. This also does not show any statistical significance difference (P =1).

Chest infection was noted in one patient in group-I. Duration of stay in the hospital is given Table-4. Patient requiring other antibiotics were 2(10%) in group-I and 3 (15%) in group-II. No

COMPARISON OF OUT COME MEASURES BETWEEN TWO GROUPS

Postoperative infection	Group No-I (n=20)		Group No-II (n=20)		Statistical Analysis
	Frequency	%age	Frequency	%age	
Postoperative febrile morbidity	4	20	4	20	OR=1
Superficial wound induration	1	5	1	5	OR=1
Superficial wound infection	1	5	0	0	OR=2 (P=1.0)
Chest infection	1	5	0	0	OR=2 (P=1.00)

Table 2

CAUSES OF FEBRILE MORBIDITY

Cause	Group No-I (n=20)		Group No-II (n=20)		Statistical Analysis
	Frequency	%age	Frequency	%age	
Vault haematoma	1	5	2	10	OR=0.65 (P=1.00)
Wound induration	1	5	1	5	OR= 1 (P=1.50)
Superficial wound infection	1	5	0	0	OR=2.8 (P=1.00)
Chest infection	1	5	0	0	OR= 2.8 (P=1.00)
Unknown	0	0	1	5	

Table 3

patient had urinary tract infection in either groups. The results show no statistically significant difference between two groups in terms of post operative febrile morbidity (OR=1) superficial wound infection (OR=2, P=1.0) and chest infection (OR=2.8, P=1.00).

DISCUSSION

Post operative infection remains the main cause of morbidity in gynaecological surgery. The risk is particularly high in developing countries because of malnutrition, overcrowding and environmental pollution. Prophylactic antibiotics have been recommended by many research workers.[10-13] Prophylaxis is achieved by giving antibiotics preoperatively and peak serum and tissue concentration is achieved within 20 minutes. Several antibiotics have been used in various combinations, single dose, or multiple dose regimens given preoperatively or over the course of several days. Gynaecological infections are usually recorded in terms of febrile morbidity, superficial or deep wound infection, vault infection, chest infection and urinary tract infection. Single dose antibiotic prophylaxis has been proved as effective as multiple-dose in prevention of post operative infections. Moreover shortening the duration of therapy reduces the medical cost and prevents the micro organism resistance.[14-17] A study conducted by Her-Young has shown that the single dose of antibiotic prophylaxis can reduce the antibiotic cost by 75-80%.[18] Another study has also shown that considerable cost saving can be achieved with a single dose.[19] Results of a series of three double blind controlled clinical studies by Mc Gregar JA has shown that single dose Ceftizoxine was as effective as adjunctive chemotherapy in patients at risk of post operative infection after vaginal or abdominal hysterectomy.[20]

In our study, only low risk patients undergoing elective abdominal hysterectomy were included. Our result has shown that febrile morbidity was similar in both groups. In both groups febrile morbidity was 20%. Tanos V in his study used single dose antibiotic prophylaxis and found reduced febrile morbidity (p <0.001).[21] Superficial induration of wound was detected in one patient in each group i.e 5%. Superficial wound infection was seen in one patient (5%) in group 1 while no infection was seen in group 2. Nisa M has shown 5% wound infection in their study.[22] Vault haemotoma resulting in febrile morbidity was observed in 5% of patients in group 1 and in 10% patients in group 2. In our study post operative chest infection was observed in 5% of patients in group 1 only. Urinary tract infection was not detected in any group. Broodt JP reported reduction in the number of urinary tract infection in his study with single dose regimen.[23]

Hospital stay was the same in both groups. In both groups, 5% of patients had a longer stay for more than 10 days. Itskovitz J has concluded in his study that short course of Cefazoline prophylaxis effectively decreases the febrile morbidity, serious post operative infection and hospital stay[24] Tchabo JG also reported non significant difference in the incidence of post operative infection and mean duration of hospital stay, when comparing single dose antibiotic versus multiple dose given.[25]

CONCLUSION

There was no statistically significant difference in the frequency of post operative wound infections between the patients who received single dose as compared to multiple doses. It shows that single dose prophylaxis can be recommended. This is of particular significance in developing countries because of limited health budget and financial restrains.

DURATION OF STAY

No of days	Group-I (n=20)	Group-II (n=20)
7days	19 (95%)	18 (90%)
7-10 days	0	1 (5%)
> 10 days	1 (5%)	1 (5%)

Table 4

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