

# USE OF SINGLE DOSE PROPHYLACTIC ANTIBIOTIC IN ROUTINE ABDOMINAL HYSTERECTOMY – A RANDOMIZED CONTROLLED TRIAL

ZAIDA RAHMAN

Assistant Professor, Department of Pharmacology & Therapeutics, Enam Medical College, Savar, Dhaka

### ABSTRACT:

*A randomized controlled trial was conducted in one unit of Gynecology and Obstetrics Dept. of a Govt. hospital by giving a single dose preoperative prophylactic antibiotic and the results were compared with a control group who received a conventional prophylactic regimen of antibiotic combination. A total of 60 samples were taken from the patients currently admitted and undergoing total abdominal hysterectomy in one unit of the Department of Obstetrics & Gynecology of a Govt. hospital for this trial and they were divided into two groups - 30 Cases and 30 Control. Case group were given a single dose cephadrine 1 gm IV just before induction of anesthesia. Control group were given Inj. Ciprofloxacin 200 mg IV 12 hrsly plus inj. Metronidazol 500 mg 8 hrsly till oral feeding followed by oral tab. Ciprofloxacin 500 mg 12 hrsly plus tab. Metronidazol 400 mg 8 hrsly in the remaining days which was then practicing in that gynecology unit of the Govt. hospital. Variables measured for the trial were total cost and duration of antimicrobial therapy, rate of postoperative infection and side effects of antimicrobial therapy. While comparing the outcome between the case and control group, it was observed that both the duration and cost ( $P < 0.001$ ) and also the side effects ( $P < 0.05$ ) of antimicrobial therapy were significantly higher in control group than the case group (duration of antimicrobial therapy was  $2.9 \pm 0.88$  days in case group and  $8.9 \pm 0.58$  days in control group and cost of antimicrobial therapy was  $113.06 \pm 24.53$  taka in case group and  $957.376 \pm 32.05$  taka in control group). But the rate of post operative infection which is the main objective of giving preoperative antibiotic prophylaxis, was significantly higher in case group than the control group ( $P < 0.05$ ). But this infection rate could be reduced if the sterilization procedure of the operation theatre and general conditions of the patients were improved. If these risk factors could be minimized, single dose preoperative prophylactic antibiotic could be effectively practiced in our country.*

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### INTRODUCTION:

Antibiotics are the most commonly prescribed drugs today. Rational use of antibiotic is extremely important as injudicious use can adversely affect the patient, cause emergence of antibiotic resistance and increase the cost of health care <sup>1,2</sup>.

The use of antibiotic prophylaxis has been shown to prevent post surgical wound infection. When employed rationally, significant reduction in the mortality and morbidity and saving in resources can be achieved <sup>3,4</sup>.

The prophylactic use of antimicrobial agent to reduce postoperative infection has been frequently advocated. The objective of preoperative antibiotic prophylaxis is to prevent postoperative infections, which are the primary

cause of morbidity and mortality in patients undergoing surgery today <sup>5</sup>. Investigations have demonstrated that proper aseptic technique alone could decrease but not completely eliminate bacterial contamination of the surgical field. Therefore, the need for antibiotics to supplement aseptic technique become more widely accepted <sup>6</sup>.

Chambers (2001) mentioned that cefazolin – the 1<sup>st</sup> generation cephalosporin is the drug of choice for surgical prophylaxis. 2<sup>nd</sup> or 3<sup>rd</sup> generation cephalosporin offer no advantage for most procedures, are far more expensive, and generally should not be used for that purpose <sup>7</sup>.

For major gynecological procedures, one gram loading dose of cephadrine preoperatively is as effective as conventional multi-dose regimen of Amoxicillin plus Metronidazol for 7 days. Loading dose group of patient is benefited due to their easy drug administration, fewer side effects and cost effectiveness <sup>8</sup>.

**Address of correspondence:** Dr. Zaida Rahman, Assistant Professor, Department of Pharmacology & Therapeutics, Enam Medical College, Savar, Dhaka

In spite of extensive knowledge about the effectiveness of antibiotic prophylaxis, administrative regimens are often inappropriate in practice. One main problem is the duration of prophylaxis, which is often longer than recommended<sup>9,10</sup>.

For some gynecological operations prophylactic antimicrobials are effective in reducing the risk of wound or operative site infection. A multitude of clinical trials have demonstrated that a single dose of parenteral antibiotic given just before an operation provides an optimal antimicrobial prophylaxis for procedures lasting up to 2 hours. First generation cephalosporins have been widely used for prophylaxis in gynecologic surgery. They have not been shown to be less effective than second or third generation agents. Cefazolin, because it has a longer half-life than other 1<sup>st</sup> generation cephalosporin, is viewed as cephalosporin of choice for prophylaxis<sup>11</sup>.

Abdominal Hysterectomy is one of the most frequently performed major operations in gynecology<sup>12</sup>. In our country, abdominal hysterectomies are performed for more or less similar indications as those performed in advanced countries. In most of the hospitals and clinics of our country, it was observed that, conventional antibiotic therapy is given after abdominal hysterectomy to prevent postoperative infection. Combined antibiotic therapy is given usually for 7 to 10 days. It increases the cost of the patient, increase the workload of the hospital staff; there may be chance of emergence of antimicrobial resistance. There is also chance of adverse reaction of antibiotic. Use of single dose prophylactic antimicrobial if proved effective in preventing postoperative infection, significant reduction in the mortality and morbidity and saving in resources can be achieved. Since total abdominal hysterectomy is one of the most common surgical procedures performed in Gynecology, An attempt was made to conduct a randomized controlled trial by giving a single dose prophylactic antibiotic - cephadrine 1gm IV just before induction of anesthesia<sup>13,14</sup> to see whether this single dose prophylactic agent is sufficient to control post operative infectious morbidity and equally effective as conventional surgical chemoprophylaxis.

#### MATERIAL AND METHODS:

A total of 60 samples were taken from the patients currently admitted and undergoing total abdominal hysterectomy in one unit of the Obstetrics & Gynecology Department of a Govt. hospital. They were randomly assigned as Case and Control:

- Group-A- 30 cases à receiving single dose Cephadrine 1 gm IV just before induction of anesthesia.
- Group-B- 30 control à receiving conventional antibiotic therapy that was then practicing in that unit of the Govt. hospital.

Variables measured for the trial were total cost, duration, side effects of antimicrobial therapy and rate of postoperative infection. In addition, information on duration of operation and patients' socioeconomic conditions were collected.

Patients were included with age between 35-60 years, Hb% of the patients not below 55%, Height was between 5'-5'2", and weight was between 50-60 kg.

#### OBSERVATION AND RESULTS:

While comparing the outcome, it was observed that both the duration and cost of antimicrobial therapy were significantly higher ( $p < 0.001$ ) in control group than the case group (duration of antimicrobial therapy was  $2.9 \pm 0.88$  days in case group and  $8.9 \pm 0.58$  days in control group and cost of antimicrobial therapy was  $113.06 \pm 24.53$  taka in case group and  $957.376 \pm 32.05$  taka in control group). Side effects of antimicrobial therapy were also significantly higher in control group than the case group ( $p < 0.05$ ). But the rate of postoperative infection, which was the objective of giving preoperative prophylactic antibiotic, was significantly higher in case group than the control group. Risk factors for developing postoperative infection were analyzed in the case group. It was observed that out of 30 patients, 5 patients in the case group developed postoperative infection. 60% (3 out of 5) patients aged 45-55 years. One patient was 37 years of age and one was 40 years of age. 80% of patients were of lower socio-economic group. In 80% (4 out of 5) of patients, Hb% was between 55-60%. Duration of operation in 80% of patients was between 1.16-1.33 hours.

**Table-I**

*Comparative analysis of the total duration, cost, rate of infection and side effects of antimicrobial therapy between case group and control group*

Parameters used	Case group (n=30)	Control group (n=30)
Duration of antimicrobial therapy in days (Mean $\pm$ SE)	2.9 $\pm$ 0.88	8.9 $\pm$ 0.581***
Cost of antimicrobial therapy in Taka (Mean $\pm$ SE)	113.06 $\pm$ 24.533	957.376 $\pm$ 32.05***
Rate of postoperative infection	5 (16.66%)	2 (6.66%)*
Side effects of antimicrobial therapy	0	4*

\*\*\* P < 0.001- Highly significant when compared the duration and cost of antimicrobial therapy between case and control group.

\* P < 0.05 - Significant when compared the rate of infection and side effects of antimicrobial therapy between case and control group.

**Table-II**  
*Analysis of risk factors for infection in the study group.*

No. of patients	Age	Weight(lbs)	Socioeconomic status	Hb%	Duration of operation in minutes
1	40	132	Economic status-II	67%	70
2	55	121	Economic status-III	60%	50
3	45	121	Economic status-III	60%	75
4	45	127	Economic status-III	55%	80
5	37	132	Economic status-III	60%	70

#### DISCUSSION:

A randomized controlled trial was conducted in one unit of the Obstetrics & Gynecology, Department of a Govt. hospital to compare the efficacy of single dose cephradine as prophylaxis versus conventional therapy in total abdominal hysterectomy to prevent postoperative infection.

In the present study, it was observed that the rate of postoperative infection was significantly higher ( $p < 0.05$ ) in case group than the control group. Among the patients developed postoperative infection, 80% were from lower socioeconomic group, were anemic (Hb% was 55-60 %) and the duration of operation was also prolonged (70-75 minutes). These factors like Hb% and nutritional status have marked influence on postoperative infection, which was observed in earlier study<sup>15</sup>.

This was also observed that the duration of antimicrobial therapy was much lower in case group than the control group. The patients with case group need cost of only Tk. 65/- while the patients with control group need of about Tk. 932/-, which was significantly higher ( $p < 0.001$ ) than case group. So, single dose prophylactic antibiotic supports the economy to the patients.

Single dose offers patient's compliance. Patients of control group complaint of many side effects, say nausea, vomiting, dizziness, constipation etc. with conventional treatment, which did not occur with that of the single dose prophylactic antibiotic. Most of the complaints were due to the use of metronidazol. Single dose prophylaxis also decreases the workload of the hospital staff<sup>8</sup>.

Finally it can be concluded that though single dose prophylactic antibiotic offer a great advantage regarding cost effectiveness, patient's compliance, reducing side effects, decreasing workload of the hospital staff, the rate of postoperative infection which was the primary concern was significantly higher ( $p < 0.05$ ) with this single dose regimen. Postoperative infection is not only dependent on antibiotic use but also on many other factors, such as age, nutritional status, hygienic condition, anemic status, duration of operation, blood loss during operation and amount of blood transfusion also. This

can be hypothesized that the infection rate could be reduced if sterilization procedure of the operation theatre and patients with better general condition could be selectively included. This finding and explanation needs further exploration restricting the possible influencing factors so as to confirm the limitation. Only after exploration, this single dose prophylactic antibiotic in routine abdominal hysterectomy can be effectively practiced in our country.

#### CONCLUSION:

The present study was just an initiative to develop acceptability among the prescribers to use optimal antimicrobial prophylaxis in gynecological procedures. From this preliminary study, it can be concluded that the single dose prophylactic antibiotic will be effective in reducing postoperative infection if following measures can be taken:

- Proper aseptic precaution should be taken during surgery.
- Proper sterilization procedure of the operation theatre should be maintained
- Correction of anemia should be done before surgery, not after so that tissue can carry more oxygen and take the benefit of prophylactic antibiotic.
- Improvement of the nutritional status of the patient and bring awareness among the patient about personal hygiene.

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