

## CEFAZOLIN IN SURGICAL PROPHYLAXIS FOR GYNAECOLOGICAL AND OBSTETRIC CASES REPORT OF A STUDY IN PRACTICE CONDITIONS

A. G. BHIDE ● S. N. DAFTARY ● V.K. NAYAK ● U.K. SHARMA

### SUMMARY

An open, multicentric, rater-blind study of the efficacy and safety of Cefazolin, for single dose prophylaxis was carried out in three centres, enrolling 48 female patients, undergoing routine elective gynaecologic and obstetric surgeries. Evaluation of efficacy and safety of Cefazolin was carried out by applying a scoring system. Results showed that Post-treatment score for overall assessment, were highly significant ( $P < 0.001$ ), while those for efficacy were also slightly significant ( $D < 0.05$ ). There were no post treatment adverse events. Thus, cefazolin appears to be an efficacious antimicrobial agent for single dose prophylaxis in routine elective gynaecologic and obstetric surgeries.

### INTRODUCTION

Prophylactic antibiotics in surgery are intended to prevent morbidity and mortality as well as reduce the duration and cost of hospitalization. Despite the advent of antibiotics, infections in gynaecologic and obstetric practice continue to pose major problems, particularly in developing coun-

tries. When an episiotomy or laceration is being repaired the likely source of contamination is bacterial from the perineal skin or the anus - it is common for instruments or suture materials to touch these areas during manipulations to expose the vaginal wound. On the other hand, the source of wound infection and genital tract infection after caesarean section are primarily bacteria from the patients abdominal skin introduced during or after the incision,

*Dept. of Obs. & Gyn., Nowrosjee Wadia Maternity Hospital, Bombay and Lupin Laboratories Ltd., Bombay  
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and bacteria ascending from the vagina before, during or after the operation. (Turner & Hawkins, 1992).

Vaginal surgery carries the risk of post-operative infection, because of several reasons like presence of potentially pathogenic organisms in the operative field, ascending spread when the peritoneum is opened during vaginal hysterectomy and increased need for post-operative bladder drainage (Maclean, 1992). Even diagnostic dilatation and curettage appears to have some risk of Post-operative infection, probably from the introduction of vaginal or cervical organisms at the time of uterine instrumentation (Maclean, 1992). While several clinical trial have shown that prophylactic antibiotics reduce infectious complications following vaginal hysterectomy and other major gynaecological and obstetric procedures, (McEniry & Gorbah, 1987; Houang, 1991) the ideal prophylactic antibiotics for gynaecological procedures has been less well established.

Cefazolin is one of the most widely used antibiotic for surgical prophylaxis because of favourable pharmacological attributes like long elimination half-life, anti-staphylococcal action, action against gram-negative bacteria and safety (Donowitz & Mandell, 1990).

The present study was therefore carried out to evaluate the efficacy and safety of Cefazolin in routine, elective, gynaecologic and obstetric surgical procedures.

#### **MATERIAL AND METHODS**

An open and multicentric rater-blind study was carried out in female patients undergoing routine elective gynaecologic and obstetric surgeries such as laparoscopy,

dilatation and curettage, caesarean section etc. in three hospitals in Bombay. The exclusion criteria were hypersensitivity to cephalosporins, pre-existing infection, concomitant systemic disease such as uncontrolled diabetes mellitus, hypertension, renal or hepatic diseases; patients on pre-treatment with other antibiotics, emergency cases, obstetric cases with leaking membranes and patients with asthma or respiratory insufficiency. Patients were administered one gram of Cefazolin intravenously at the start of the procedure.

The effect of Cefazolin treatment was evaluated by assessment of the wound, presence of abnormalities in temperature, respiration and haemodynamics. Presence of systemic infection, tolerability of the drug, overall assessment of the investigator and adverse reactions were also recorded. Evaluation was carried out by a scoring system. Rating scores are depicted in the respective tables. Assessment of wound had scores ranging from 5 to 0 based on severity. Abnormalities in temperature, respiration and haemodynamics were rated as 0 for absence or 1 for presence, efficacy and tolerability were both rated from 5 for excellent to 0 for inefficiency. Overall assessment : 2 for better and 0 for worse and adverse events rates as 1 for absent and 0 for present.

#### **RESULTS**

Forty-eight female patients in the age group of 22 to 63 years (mean  $31.54 \pm 1.17$  years, completed the study, and were available for evaluation. Of these, 15 were cases of medical termination of pregnancy, 8 were normal deliveries, with episiotomies, 5 each were laproscopic sterilizations and

dilatation and curettage and 3 were caesarean sections.

Results showed that post-treatment scores for abnormalities of temperature, respiration and haemodynamics (Table II), presence of systemic infections (Table III), were not statistically significant. Post treatment wounds were rated normal (Table I). However, the post-treatment scores for efficacy of Cefazolin were statistically significant ( $p < 0.01$ ) (Table IV), scores for tolerability were slightly significant ( $p < 0.05$ ) (Table V) and for overall assessment were highly significant ( $p < 0.001$ ) (Table VI).

The post-treatment scores for adverse reactions (Table VII) were favourable towards Cefazolin.

### DISCUSSION

Ledger et al (1975) proposed a set of guidelines for successful chemoprophylaxis in obstetric and gynaecological surgeries. A few of these guidelines relating to the antibiotics used for prophylaxis were that (a) they (the antibiotics) should have laboratory evidence of effectiveness against some of the contaminating micro-organisms (b) they should be present in the wound in an effective concentration at the time of incision. (c) a short term low-toxicity regimen of antibiotics must outweigh the potential dangers of their use routinely.

In this study, Cefazolin when administered intravenously in the dose of one gram in various gynaecological and obstetric surgeries was found to be efficacious and had significantly improved post-treatment scores, cefazolin has been reported to be significantly more effective than placebo (Lett et al, 1993) and as effective as

cephaloridine (Lett et al, 1993), cefotaxime (Periti et al 1988, Hemsell et al 1987), and cefoxithin (Hemsell et al, 1987a) for surgical prophylaxis in patients undergoing various gynaecological and obstetric surgeries. Moreover, Houang (1991) reported that per-or pre-operative antimicrobials can prevent infection after emergency caesarean section in high-risk situations such as active labour or premature rupture of membranes, after first-trimester abortion in some women and also after mid-trimester abortions. Post-treatment adverse events scores for Cefazolin were  $1.00 \pm 0.00$  indicating that there were no adverse events, in this study. Donowitz and Mandel (1990) have reported that Cefazolin is well tolerated after intramuscular or intravenous injections. Moreover, experience of various investigators thus far indicates that single-dose regimen of first or second generation cephalosporins or other agents equally well tried give similarly efficacious results in prophylaxis as do regimens of multiple doses. They also have the added advantage of safety and tolerance. This has been demonstrated by their wide prescription (McEniry & Gorbach, 1987). Moreover, the relatively short half-life of these agents may be an added advantage because the impact of the antibiotic on the normal flora of the patient and the environment would be less compared with that of drugs with longer half-lives.

The consultants of the Medical Letter (1993) have recommended the use of Cefazolin as a prophylactic agent of choice because it is cheap and effective. Similar views have been expressed by Smaill (1992). Moreover, Donowitz and Mandell (1990) have reported that Cefazolin is usually the

preferred first generation cephalosporin in surgical prophylaxis since it can be administered less frequently. Thus results from the study indicate that Cefazolin is an effective antimicrobial agent for routine prophylactic use in single dose in elective gynaecological and obstetric surgeries.

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