

# AN EVALUATION OF TINIDAZOLE PROPHYLAXIS AGAINST INFECTIONS IN OBSTETRICAL AND GYNAECOLOGICAL SURGERY

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## SUMMARY

The study was carried out in 100 patients who underwent different types of obstetrical and gynaecological surgery. A single oral dose of 2 Gm Tinidazole was given to patients 24 hours before undergoing surgery.

Varying degrees of post-operative infection developed in 4% cases who received prophylactic tinidazole as compared to 20% cases in the control series.

4 patients in group B who developed severe post-operative infection were subsequently treated with tinidazole. All of them showed remarkable improvement.

No serious untoward effects were observed with tinidazole therapy apart from mild nausea, vomiting headache on the first post-operative day.

## Introduction

In spite of the increasing awareness regarding asepsis at the time of surgery, post-operative wound infection still continues to mar the results of excellently performed surgical procedure. Until the late sixties the concentration was focussed on the aerobic bacteria as the causative agents and there was ignorance, apathy and scepticism towards the role of anaerobes in post-surgical sepsis. Recent reports show that the non-sporing anaerobic bacteria are involved in a wide variety of

human infections (Finegold and Rosenblat, 1973). It is now considered that most of these post-operative infections are due to anaerobic organisms which are commensals of the female genital tract (Finegold and Sutter, 1974 and Gorbach and Bartlett, 1974).

Nitronidazoles which include metronidazole, tinidazole and ornidazole are now established as an effective bactericidal against anaerobic organisms. They are of low molecular weight and bactericidal at low concentrations. In vitro studies have shown Tinidazole to be bactericidal against *bacteroides fragilis* in significantly lower concentration than metronidazole (Jokipii, 1977). Tinidazole is rapidly absor-

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*Accepted for publication on 13-8-84.*

bed from the gut and a bactericidal serum concentration may be produced for 2 to 3 days with a single oral dose of 2 Gms.

The prophylactic role of Tinidazole either alone or in combination with conventional antibiotics in abdominal surgery and gynaecological or obstetrical procedures has been suggested by a number of investigators (Ando and Cassel, 1979; Hunt *et al*, 1977; Karhunen *et al*, 1980; and Mishra, 1983).

The present study was carried out to evaluate the role of Tinidazole as prophylaxis against infections in obstetrical and gynaecological surgery.

#### Material and Methods

The study was carried out in 100 patients who were admitted to the obstetrical and gynaecological ward of Govt. Women Hospital, Amritsar for elective hysterectomy, caesarean section and laparotomy (Table I). The study under review is entirely clinical assessment. No anaerobic cultures could be done. The antibiotics used in the post-operative period were limited to chloramphenicol (hysterectomy and laparotomy cases) and ampicillin (Caesarean cases) and gentamycin and cephaloridine in a few cases. The cases

TABLE I  
Distribution of Cases

Operation performed	No. of cases	
	Group A	Group B
Abdominal hysterectomy	30	28
Caesarean section	15	16
Salpingectomy (Ect. Preg.)	2	2
Ovarian cystectomy	1	2
Ovariectomy	1	1
Recanalisation	1	1
Total:	50	50

were randomly allocated to the following groups.

#### Group A (Study Camp):

Fifty patients received 2 gms of Tinidazole (4 tablets of 500 mg) orally 24 hours before operation and they were given antibiotics for seven to ten days post-operatively.

#### Group B (Control Group):

Fifty patients received only antibiotics post-operatively for seven to ten days.

#### Group C:

Patients in group B who developed serious wound infection were treated with Tinidazole 300 mg B. D. for 7 days.

All the patients were carefully examined clinically and their post-operative progress was recorded with special reference to any clinical evidence of infection in the form of pyrexia, abdominal wound infection or purulent vaginal discharge. Specimens of pus, wound exudates were collected from infected wounds and were subjected to the culture and sensitivity tests against aerobic organisms as facilities for anaerobic cultures were not available. Urine examination for pus cells was done in all cases with sepsis, culture and sensitivity test of urine was done if positive for pus cells.

#### Observations and Results

Abdominal wound complications (Table II).

In the present study of 50 cases in Group A who had prophylactic tinidazole preoperatively and antibiotics in post-operative period only 2(4%) cases developed post-operative abdominal wound complications. They were cases of hysterectomy

TABLE II  
Abdominal Wound Infection

Group	Total No. of cases	Healthy wound	Serous discharge	Serosanguinous discharge	Pus discharge
A	50	48 (96%)	2 (4%)	—	—
B	50	40 (80%)	4 (8%)	2 (4%)	4 (8%)

1, caesarean section 1, while post operative abdominal wound infection developed in 10 out of 50 (20%) patients belonging to control group B, who received only routine antibiotics in post-operative period. Of the patients who developed post-operative abdominal wound sepsis 4 had caesarean section, 1 ovariectomy and 1 abdominal wound infection developed laparotomy (Salpingectomy). The symptoms of infection developed within 5th 7th post-operative days. Pyrexia, pain and discharge were the presenting features of these cases. The discharge was serous in 4(8%) cases, serosanguinous in 2(4%) cases and frank pus in 4(%) cases.

In control group B, 6(12%) cases had superficial gaping of the wound while in Tinidazole group only 2 cases (4%) cases had dehiscence of the wound for which resuturing was done, whereas in the study group none of the patients needed resuturing.

Post-operative febrile morbidity (Table III):

TABLE III  
Post-operative Pyrexia

Group	Total cases	No. of cases	Percentage
A	50	1	2
B	50	5	10

There was 1(2%) patient with febrile morbidity in Tinidazole group and

5(10%) patients with febrile morbidity in control group.

Abnormal Vaginal discharge in hysterectomy cases (Table IV) :

TABLE IV  
Abnormal Vaginal Discharge in Abdominal Hysterectomy Cases

Group	Total No. of cases	Cases showing abnormal discharge	Percentage
A	30	—	—
B	28	3	10.6

Abnormal vaginal discharge was seen in 3(10.6%) cases out of total 28 cases of abdominal hysterectomy whereas it was seen in none of the cases in study group. In control group in 6 cases out of 10 cases who developed post-operative sepsis, the infection was mild and was treated with change of antibiotics from chloramphenicol to combination of Ampicillin and Gentamycin or Cephaloridine. In 4 cases where the infection was serious and the discharge had a foul smell were treated with Tinidazole 300 mg B.D. in addition to change of antibiotics. The results were dramatic. The temperature came down to normal within 24 hours with cessation of discharge within 2-5 days.

### Side effects

Apart from mild nausea, vomiting and headache on the first post-operative period in 4 out of 50 cases there was no serious side effects of the drug noted.

### Discussion

Mitra *et al* (1978) in a study of 70 patients observed that none of the patients who had prophylactic metronidazole in combination with antibiotics developed any post-operative complications while post-operative infection developed in 5 of 35 patients (14%) in control group who received only antibiotics. Karhunen *et al* (1980) in a study of 140 patients 70 control and 70 on prophylactic Tinidazole found that one patient (1.4%) in prophylactic drug therapy group and 10(14%) cases in the control group had a temperature of 38°C at some times after the first post-operative day. Mishra (1983) in a study of 185 cases (90 study and 95 control cases) found that febrile morbidity was seen in 2(2.2%) patients and 12 patients (12.6%) in study and control groups respectively and results of these workers are comparable to our results i.e. 1(2%) case in study group and 5 (10%) cases in control group had febrile morbidity. According to Karhunen *et al* (1980) 1 patient among the study group (1.4%) and 7(10%) cases among the control group had abscess formation. According to Mishra (1983) none of the cases had abdominal wound infection in study group and 3 cases (3.1%) had abdominal wound infection in control group. Whereas in the present study 2(4%) cases in study group and 10(20%) cases in control group (Table II) had abdominal wound infection. Purulent vaginal discharge was seen in 9(6.3%) cases of control group and 1(1.1%) case of study group (Mishra,

1983) whereas it was seen in none of the cases in study group in the present study.

Applebaum *et al* (1980) studied the influence of prophylactic Tinidazole therapy on vaginal carriage rates of anaerobes and the development of post-operative infection in 100 women undergoing abdominal hysterectomy. Tinidazole prophylaxis (50 patients) led to decrease of anaerobic vaginal carriage rate from 50% pre-operatively to 10 to 30% on the third and seventh post-operative days respectively.

Thus the oral single dose of 2 Gms of Tinidazole substantially reduces infections following obstetrical and gynaecological surgery. This was supported by numerous studies (Ledger, 1975), study group (1975) and Mishra *et al*, (1983).

### Conclusions

The lack of side effects associated with tinidazole therapy suggests that one day prophylactic tinidazole could be beneficial in decreasing post-operative complications and lowering the cost and amount of post-operative antibiotics. It requires further study to see whether bacterial resistance to tinidazole develops or not.

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