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Randomized Clinical Trial of Different Regimens of Antibiotic Prophylaxis in Obstetric and Gynecological Surgeries

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Summary

An open randomized clinical study was conducted to analyse the efficacy of different regimens of antibiotic prophylaxis (Group I, Single dose; group II – three doses and Group III – 5 days antibiotic therapy) in Obstetric & Gynecological elective and emergency surgeries involving 120 patients, 40 in each of the three study groups.

Febrile illness, wound infection, duration of hospital stay and any other complications, if occurred were compared among all three groups.

Twenty percent of the patients had post operative complications; 15% of them had afebrile illness, and wound infection was seen in 5% of the patients. Wound infection in group I, II & III was 7.5%, 8.3% & 5% respectively. Febrile illness was seen in 5%, 6.6% & 3.3% of patients in group I, II & III respectively.

Conclusion: There was no statistically significant difference in post-operative morbidity in these study groups ($P<0.05$), hence single dose, chemoprophylaxis given perioperatively suffices in elective and emergency surgeries.

Introduction

Antibiotics are extensively used and misused in all fields of medicine, with no exception in the field of Obstetrics & Gynecology. Antibiotics were initially meant to treat the infection but prevention of infection constitutes the major indication for antibiotic therapy now.

Chemoprophylaxis, that is using the antibiotics to prevent infection is controversial. There is no set regimen regarding the dose, duration of therapy and the type of drug to be used for prophylaxis. In clean surgical cases its indication is still not clear.

Ideal is to identify the common microbes causing post-operative infection, and their antibiotic sensitivity to enable us to use the proper drug for chemoprophylaxis. Single dose antibiotic prophylaxis is recommended perioperatively. It is found that prolonged antibiotic therapy does more harm than any benefit, by facilitating the development of resistant strains.

A randomized clinical study was conducted using, ampicillin and metronidazole in different regimens for their efficacy as chemoprophylaxis in Obstetric & Gynecological surgeries.

Objectives of the study

1) To study the efficacy of single dose versus three doses and 5 days antibiotic therapy in Obstetric and Gynecological surgeries.
2) To assess the prevalence and type of post operative morbidity.
3) To analyse the associated factors which influence

the post operative morbidity

Type of Study: Randomized Clinical Trial

Materials and Methods

This study was conducted in the department of Obstetrics & Gynecology of M.S. Ramaiah Medical Teaching Hospital, Bangalore. The study period was one year from June 1997 to July 1998. One hundred and twenty patients undergoing elective or emergency, Obstetric and Gynecological surgery were included in this study. Patients were divided into 3 groups using random tables.

Group I : 40 patients were given single dose of 2 gms of ampicillin IV & 500mg of metronidazole on the operating table after induction of anesthesia.

Group II : 40 patients had 3 doses each of ampicillin 500mg given 6 hourly and metranidazole, 500mg given 8 hourly starting perioperatively as in Group – I.

Group III : 40 patients had ampicillin 500mg 6 hourly and metranidazole 500mg IV 8 hourly starting perioperatively as in Group - I for 48 hrs, followed by ampicillin 500mg 6 hourly & metranidazol 400mg 8 hourly orally for another 3 days.

Patients with known infection, those who were already on antibiotic therapy, those with known allergy to ampicillin and obstetric patients with PROM were excluded from the study.

The variables used to compare the efficacy of different regimens of prophylactic antibiotic therapy and to assess the postoperative morbidity were post operative febrile illness, wound infection, urinary tract infection, DVT, duration of hospital stay and any other major infection. Temperature of more than 38° c occurring 24 hrs. after the surgery and persisting for more than 48 hrs was considered as febrile illness. Any type of discharge, (serous, serosangunous & purulent), induration and or gaping of the wound (superficial & deep) were considered as wound infection. Duration of hospital stay was counted from the day of the surgery to the day of discharge of the patient from the hospital.

The results were analysed by using χ^2 test of assessment and analysis variance technique.

Results

Table – I shows demographic data of the patients. No significant difference was noted in age & parity of the three study groups.

Twenty four percent of patients (n=29) had associated medical problems like anemia, diabetes, hypertension and asthma (10 in Group I, 12 in Group II and 7 in Group III).

Table I: Age & Parity distribution

Age	Group – I	Group – II	Group – III	Total	Percentage
19-29	12	14	15	41	
30-39	12	09	11	32	
40-49	09	10	09	28	
> 50 yrs	07	07	05	19	
Total	**40**	**40**	**40**	**120**	
Parity					
Nulliparous	5	7	9	21	
1-3	24	26	22	72	
4-5	8	5	6	19	
> 5	3	2	3	8	
Total	**40**	**40**	**40**	**120**	

Table II: Type of Surgery

Type of Surgery	Group I	Group II	Group II	Total
Emergency	6	9	12	27
Elective	34	31	28	93
Total	**40**	**40**	**40**	**120**

Type of Surgery : 22.5% of patients had emergency surgery and the rest (77.5%) underwent elective surgery (Table II). Commonest surgery performed was hysterectomy (53%) followed by caesarean section (30%) (Table III).

Complications : 20% of all patients had post operative complications (Table IV).

Fifteen percent of the patients had febrile illness, out of 18 patients with febrile illness 6, 8 and 4 were from group I, II & III respectively. Nine of these 18 patients needed change of antibiotic and one among them had culture proved UTI from Group I. The rest recovered with symptomatic treatment. There was no significant association between type of surgery, antibiotic regimen & febrile illness (Table IV).

Five percent of the study group had wound infection, except one patient from Group III, who had wound dehiscence, others had induration and minimal discharge from the wound which subsided by local dressings and all of them had no problem with wound healing.

Hospital Stay : Average post operative hospital stay was 7 days in all groups (Table V). The shortest stay was 4 days and the longest was 13 days. Most of them stayed

Table III: Surgical Procedure

Type of Surgery	Group I	Group II	Group II	Total
LSCS and LSCS Tubectomy	09	16	16	41
Abdominal Hysterectomy	16	10	12	38
Vaginal Hysterectomy	13	12	11	36
Myomectomy	00	01	01	02
FotherGill's	01	01	00	02
Ovarian Cyst (Ovariotomy)	01	00	00	01
Total	**40**	**40**	**40**	**120**

Table IV: Post operative Morbidity

Type of Problem	Group I	Group II	Group III	Total
UTI	01	00	00	01
Wound Infection	02	02	02	06
Febrile Illness	06	08	04	18
Total	**09**	**10**	**06**	**25**

$P > 0.05$

Table V: Hospital Stay in days

Dose	Number of Patients	Mean	SD
Group – I (Single)	40	7.1	1.4
Group –II (Three Doses)	40	7.0	1.4
Group – III (Five Days)	40	7.5	1.3

$P > 0.05$ (Analysis variance technique)
(w.r. – with relation)

for long, as they had come from far off villages though they did not require 7 days stay.

Discussion

Prophylactic antibiotics are given in a timely fashion, to prevent infection when a surgical procedure is likely to result in bacterial contamination of normally sterile tissue or blood. Clinical trials have demonstrated that chemoprophylaxis may not be effective in all situations, causing failure of chemoprophylaxis, which is defined as persistent fever for 48-72 hrs. after treatment, which warrants for a detailed search for hidden infection or super infection.

Chemoprophylaxis is advocated in patients undergoing dirty surgery, in epidemics of disease and in patients who are at risk to develop infection, but its use is controversial in clean surgery. It is used in later cases mainly to prevent post operative wound infection for which single dose therapy is recommended. No data recommends prolonged antibiotic prophylaxis. Therapy beyond 24-72 hrs after surgery may have adverses effects. Various drugs recommended for chemoprophylaxis are, ampicillin, cephalosporines, aminoglycosides and metranidazole.

In this study, ampicillin & metronidazole were used as they are supplied by the hospital & could be used for all category of patients (poor & rich)

Single dose of ampicillin & metronidazole were found to be effective as 3 doses or 5 days therapy.

No statistically significant difference was noted among all three groups with regard to febrile illness, post operative wound infection ($P > 0.05$) and duration of hospital stay ($P > 0.05$) (Table IV & V)

Except for anemia, no other factor like age, parity, other medical problems like diabetes, type and duration of surgery, suture materials used had any association with post operative morbidity.

Conclusion

This study shows that single dose perioperative antibiotic prophylaxis is enough for all clean surgical procedures (both elective & emergency) with added advantage of reducing the cost of the patient and avoiding side effects and development of resistance.