



Category Title

PROPHYLACTIC USE OF PANCHAVALKAL (PENTAPHYTE - P - 5) FOR CHEMOPROPHYLAXIS IN MAJOR GYNAECOLOGICAL SURGERIES

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Pentaphyte - P - 5, an antimicrobial agent of Ayurvedic origin, was studied for its effectiveness in prophylaxis for major gynaecological surgeries. Patients were administered capsule Pentaphyte - P - 5 in a dose of one capsule four times a day - three days prior to surgery followed by the same dose from second post operative day. No antibiotics were given on the day of the surgery. This regimen was continued upto the time of discharge from the hospital. The results obtained were compared with patients in three different control groups i.e. one group receiving no antibiotics at all, second group receiving antibiotics plus Pentaphyte - P - 5 and the third receiving the routine antibiotics such as ampicillin or cipro.oxcin with metronidazole and gentamycin. The post operative results of the study group were evaluated. These were compared with similar studies conducted for use of Cipro.oxacin and Augmentin for prophylaxis in major gynaecological surgeries.

INTRODUCTION

Gynaecological infections are a cause of growing concern for all practising doctors. We encounter a rapidly growing number of micro-organisms daily. What is more alarming is that even more rapidly growing rate at which these micro - organisms are developing resistance to the routinely used range of antibiotics.

In the veritable race between microbes and antimicrobials, the microbes seem to be gaining the upper hand. Newer species of resistant organisms are emerging every new dawn. A classical example is the methicillin resistant Staphylococcus Aureus. Certain species are even resistant to broad spectrum antibiotics like Vancomycin. Thus, the quest for an ideal broad spectrum antimicrobial agent is still on and is a far cry.

Some Facts About Pnachavalkal : Panchavalkal. or Pentaphyte - P - 5 is a combined formulation consisting of barks of .ve Ficus plants. These are advocated as the best treatment in female genital tract infections by all the standard textbooks of Ayurveda like Charak Samhita and Bhavaprakash.

Composition : Panchavalkal contains extracts from barks of the following plants:

Ficus Bengalensis
Ficus Religiosa
Ficus Glomerata
Ficus Infectora
Albizza Lebec

Panchavalkal is formulated by Dr. Palep's Medical Research Foundation as Capsule Pentaphyte - P - 5.

Pharmacology : Capsule Pentaphyte - P - 5 contains phytosteroids, saponins, anthraquinone, glycosides and many other pharmacologically active compounds. These compounds act synergistically to help in removing in.ammatory debris. They also help by promoting growth of healthy granulation tissue and healing through effective capillary growth.

Antibacterial Activity : In vitro laboratory studies have shown that Pentaphyte - P - 5 is effective against aerobic bacteriae such as Staphylococcus aureus, E. Coli, Klb. Aeruginosa and Psuedomonas and anaerobic bacteriae such as Cl Welchii, Cl difficile, Cl Perfringenes, Bacteroides species and Mycoplasma Pneumoniae.

Resistance : Except Mycoplasma Hominis no resistance has so far been reported.

Toxicity : Acute and chronic toxicity studies in mice have shown the drug to be absolutely non toxic.

Therapeutic Dose : Capsule Pentaphyte - P - 5 (500 mg) in q.i.d. doses. **MATERIAL AND METHODS**

Fifty five patients attending the gynaecological OPD in a Government teaching hospital were included in the study. These patients had beenadmitted for major abdominal and vaginal surgeries and were randomly allocated into four groups.

Group A - Received no antibiotics

Group B - Received Capsule Pentaphyte - P - 5

Group C - Received Capsule Pentaphyte - P - 5 and antibiotics

Group D - Received routine antibiotics

Group A : Patients were not given any antibiotics at all.

Group B : Received Capsule Pentaphyte - P - 5 in q.i.d. doses for 3 days prior to surgery followed by similar doses from the second post operative day. These patients received only analgesics and injection Rantac (50 mg) IV SOS on the first day post operatively.

Group C : Patients were given Capsule Pentaphyte - P - 5 as well as routine antibiotics post operatively.

Group D : These patients were administered routine antibiotics i.e. ampicillin + metronidazole + gentamycin or ciprofloxacin + metronidazole post operatively.

Pre-operative blood investigations were done for anaesthetic fitness and the total leucocyte count (TLC) was noted.

Post operatively all patients were monitored for rise in TLC. The urine was sent for routine and culture examination on the third and fifth post operative day. The patients were also observed for induration, fever and condition of wound like induration, discharge and gape. Any additional medication if required were taken note of e.g. antimalarials and antibiotics.

The results obtained in the study were compared with other published data i.e. Study for Prophylactic Intravenous ciprofloxacin in major gynaecological surgeries (Dr. S Gupta and Dr. P Agarwal, Department of Obs and Gynaec, MGIMS, Wardha - The Journal of Obstetrics and Gynaecology of India Vol. 49 No. 6 December 1999).

OBSERVATIONS AND RESULTS

Table 1 shows the comparative data of the study and control groups. The study in Group - A was abandoned as the patient developed generalised peritonitis with a TLC of above 20,000 per cubic mm and had to be given higher antibiotics.

Organism	Zone of Inhibition
G. Vaginalis	8 mm
S. Aureus	12 mm
Can. Albicans	13 mm
E. Epidermidis	10 mm
Str. Haemophilus	10 mm
Ps. Aeruginosa	11 mm
Ps. Vulgaris	12 mm

TABLE 1 Zone of Inhibition for Various Organisms

As is evident from the table, the number of cases in Group B and D compare well. The number of patients in the different age groups is also similar with most of the patients being in the 30 to 50 years age group. The number of patients with other associated medical complications was higher in Group D.

The number of patients when divided according to type of surgery were also same with majority of patients having undergone hysterectomy. The number of patients who required post-op blood transfusion were same in both the groups. In the post -op monitoring, the number of patients exhibiting rise of TLC with its subsequent return to normal was in fact less in the Pentaphyte - P - 5 group. The urine culture which was positive on D 3 returned to normal in all patients of the study group B as compared to only 50% normal in control group D.

The number of patients who developed fever on D 3 was almost the same. However, .ve patients in Group B had repeated spikes of temperature until D 5 which was not observed in Group D. The post-op period was uneventful in 67% of patients in Group B while Group D showed a better outcome with 83% patients having an uneventful recovery. The number of patients demonstrating induration at wound was 3 in both groups. The only patient with gape in Group B had a subcutaneous pus collection due to subcuticular sutures taken for skin closure. The wound had thus to be opened and resutured subsequently. The average number of days of post -op stay in hospital was almost similar. In group B it was 9.8 days while in control group D it was 8.08 days a difference of 1.72 days which was not very significant.

Finally, the number of patients requiring change of medication was slightly higher in the study group B. Two patients required use of antimalarials while four patients were given antibiotics. One of these required injection metronidazole for diarrhea while two were given T Ciprofloxacin as they had a positive Widal test. The fourth patient was the one with subcutaneous pus collection who was given injection Ciprofloxacin and Amikacin after wound swab culture. In the control group D one patient required antimalarials while two had a positive Widal test and hence were given T. Ciprofloxacin - BD.

Table 3 : Compares our study with results from a similar study done for Inj. Augmentin. As is evident from the data only one patient had a wound swab culture showing Staph aureus. These results compare well with those in the Augmentin group. The number of patients with negative urine culture were, however, more in the augmentin group. The results were better for the wound discharge culture in the pentaphyte group.

Table 4 : This table compares the overall morbidity associated with the three studies performed for the use of P - 5, Ciprofloxacin and Augmentin for chemoprophylaxis in major gynaecological surgeries. The data displayed is proof enough of the wide spectrum anti-microbial action of Pentaphyte - P - 5. It also establishes its efficacy in chemoprophylaxis against all common pathogens. As is evident, the overall morbidity associated was the least in the Pentaphyte group when compared with similar data for the other two studies. **DISCUSSION**

The results presented in Table 2 show that the end points compare well for all the categories. The results are within the same range and at places, even weighing in favour of Pentaphyte - P - 5. The drug was well tolerated and did not have any untoward side effects. The results of Table 3 show that Pentaphyte - P - 5 is an effective anti - microbial agent when used for routine prophylaxis. It was effective against most of the major pathogens encountered in surgical practice.

Table 4 compares the results of our study with the morbidity observed in similar studies for use of Cipro.oxacin and Augmentin as chemoprophylactic agents. As is obvious, the general morbidity was much less in the Pentaphyte - P - 5 group when

S. No.		Group B CAP Pentaphyte - P - 5	Group C P - 5 + Antibiotics	Group D Antibiotics
1.	Number of cases	21	09	24
2.	Age (in years)			
	30-50	16 (76%)	08 (89%)	20 (83%)
	51-64	04 (19%)	Nil	04 (17%)
	65 and above	01 (5%)	01 (11%)	Nil
3.	Associated medical complications e.g. anaemia, diabetes	04 (19%)	02 (22%)	08 (33%)
4.	Type of surgery			
	Vaginal hysterectomy	10 (48%)	02 (22%)	09 (37.5%)
	Abdominal hysterectomy	09 (43%)	06 (67%)	12 (50%)
	Exploratory laparotomy	Nil	01 (11%)	01 (04%)
	A - P Repair	01 (5%)	Nil	01 (04%)
	myomectomy	01 (5%)	Nil	01 (04%)
5.	Pre and post op blood given	06 (29%)	01 (11%)	06 (25%)
6.	Post op TLC			
	D-3 rise 08	08 (38%)	01 (11%)	14 (58%)
	D-5 return to normal	06 (75%)	01 (100%)	07 (50%)
7.	Fever			
	Day - 3 Post - op	06 (29%)	Nil	05 (21%)
	Day - 5 Post - op	05 (24%)	Nil	Nil
8.	Urine culture			
	Day - 3 Post - op	04 (19%) 3 E Coli, 1 Kleb	02 (22%) 1 E Coli, 1 Kleb	05 (21%) 3 E Coli, 5 Kleb
	Day - 5 Post - op - N	04 (100%)	01 (50%) 1 Kleb	03 (60%) 3 Kleb
9.	Post op period			
	Uneventful	14 (67%)	08 (89%)	21 (88%)
	Others	7 (33%)	01 (11%)	03 (12%)
10.	Wound			
	Good	14 (67%)		
	Induration	03 (43%)	08 (89%)	19 (79%)
	Discharge	03 (43%)	01 (11%)	03 (12.5%)
	Gape	01 (14%)		02 (8%)
11.	Duration of stay in Hospital			
	7 days	11 (42%)	07 (78%)	19 (79%)
	8-12 days	08 (38%)	02 (22%)	05 (21%)
	13-21 days	02 (10%)	Nil	Nil
12.	Average number of days in hospital	9.8	6.66	8.08
13.	Change of medication			
	Anti-malarials	02 (9.5%)	Nil	01 (4%)
	Antibiotics	04 (19%)	01 (11%)	02 (8.3%)

TABLE 2: Comparative data of study and control groups

Organisms	Pentaphyte - P - 5				Augmentin group		Urine	
	Wound Discharge		Urine		Wound Discharge			
Control	Case	Control	Case	Control	Case	Control	Case	
E Coli	Nil	Nil	04 (33%)	05 (29%)	Nil	02 (8%)	03 (12%)	Nil
Klebsiella (8%)	Nil	Nil	04 (33%)	03 (06%)	Nil	01 (4%)	Nil	02
Staph.								

Aureus	01 (5%)	Nil	Nil	Nil	Nil	03 (12%)	Nil	Nil
Proteus (4%)	Nil	Nil	Nil	Nil	Nil	01 (4%)	Nil	01

TABLE 3: Bacteria cultured wound discharge and urine - A comparison between pentaphyte - p - 5 and augmentin


Parameters	Pentaphyte - P - 5		Cipro.oxacin		Augmentin	
	Cases (20)	Control (23)	Cases (150)	Control (150)	Cases (25)	Controls (25)
Fever	25%	17%	19%	16%	Nil	16%
Vomiting	Nil	Nil	10%	14%	Nil	Nil
Distension	Nil	Nil	2%	8%	Nil	Nil
Rash	Nil	Nil	1%	2%	Nil	Nil
Flushing	Nil	Nil	3%	2%	Nil	Nil
Discharge	20%	Nil	9%	14%	Nil	8%
Induration	15%	Nil	8%	18%	Nil	28%
Stitch Abscess	5%	Nil	7%	10%	Nil	Nil
Resuturing	5%	Nil	Nil	2%	Nil	Nil

TABLE 4: Comparison of pentaphyte - P - 5/cipro.oxacin/augmentin study and control groups compared with the ciprofloxacin group. This establishes Pentaphyte - P - 5 as a useful broad spectrum antimicrobial agent.

CONCLUSION

This closely observed study comprising fifty .ve patients has established the role of capsule Pentaphyte - P - 5 for chemoprophylaxis. It has helped us prove the anti microbial properties of Bombay Hospital Journal, Vol. 45, No. 4, 2003 595 Pentaphyte - P - 5. It can thus be recommended as a wide spectrum prophylactic anti - microbial agent. It is cheap and does not require expensive imported raw materials for its production. It has the convenience of single drug, oral route, simple dosage schedule as against multiple antimicrobials required to be used parenterally. It has no side effects of GIT irritation and this ensures good patient

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