ANTIMICROBIAL PROPHYLAXIS FOR VAGINAL HYSTERECTOMY: COMPARISON OF TWO REGIMENS

G. MELE - G. GARGANO - P. GRECO - M. TARTAGNI
2nd Institute of Obstetrics and Gynecology - University of Bari (Italy)
(Head: Prof. R. Nappi)

Summary: A randomized trial has been performed to evaluate the efficacy of two antibiotic regimens as a prophylaxis for vaginal hysterectomy. The results, expecially in terms of microbiological characteristics of the local population, are then discussed.

INTRODUCTION

The administration of antimicrobial drugs to prevent infection after vaginal hysterectomy, although still a controversial matter in some institutions, has been recognized to be effective by the majority of gynaecological literature ([1, 2, 3]). Depending on the characteristics of the population studied, randomized trials have shown a ten-to-twenty fold reduction in postoperative morbidity with a repeated or single dose antibiotic regimen before surgery ([4, 5, 6]). An incidence of major pelvic infection of about 5% is expected after a single dose cephalosporin prophylaxis without significant inter-regimen difference ([7]).

Correctly randomized reports convincingly indicate that the administration of antibiotic at the time of vaginal hysterectomy did not significantly reduce the incidence of postoperative pelvic infection ([9, 10]). Many centres would also quote infection rates of 5 per cent or less without the use of prophylactic antibiotics. Symptomatic or asymptomatic urinary tract infections are reported in variable figures (2-40 per cent). Even though they do not affect the hospital stay, they approach a rate of 20-25 per cent in our population ([8]).

Based on these data, a trial study was carried out in order to assess the benefit of an associated antimicrobial regimen (Tobramycine + Cephamandale) versus the standard prophylactic treatment (cephaloridine).

MATERIAL AND METHODS

In order to investigate the results of the two regimens, some of the patients (104) undergoing vaginal hysterectomy with or without repair (from January 1983 to January 1985) were selected to fulfil the criteria of the study (no known allergy to antibiotics; no impairment in renal function; no recognizable present infection; no antibiotic treatment in the past 30 days). All the women gave informed consent before entering the study. They were divided into two groups according to the drugs and regimen employed:

Group A (58 patients): long term prophylaxis using cephaloridine (3 g daily, from the day of operation and for 5 days).

Group B (46 patients): short term prophylaxis with cephamandole (2 g before entering the theatre and five 1 g doses at hourly intervals) associated with tobramycine (150 mg soon after catheter removal, if performed 2 days after operation or 150 mg daily, in case of prolonged catheterism; starting 1 day after cephamandole suspension).

Either (A or B) regimen was administrated in an uneven way in order to reach an improved randomization. All the clinical records of each patient were included in files labelled according to an increasing number without any mention of the therapy. The same staff was alternatively performing the surgical procedures and following the postoperative period. The records were finally reviewed by a clinician (G. M.), who was unaware of the group assignment.

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Table 1. – *Preoperative factors compared in the two groups.*

	Group A (58 p.)	Group B (46 p.)
Hypertension	8	5
Diabetes	4	6
Cardiopathies	3	5
Liver disease	1	1
CNS disease	2	0
GI disease	4	2
Lung disease	1	2
Stress incontinence	4	0
Varicose veins	3	1
Previous surgery	1	9
	31/58 53.5% $\chi^2 = 2.69$	31/46 67.4% (NS)
Age	53.73±11.8	52.6±11.3
Parity	3.68±1.78	3.93±2.2
Duration of procedure (mins)	98.7±23.8	106.9±30.2
Duration of catheterism (hrs)	114.34±52.5	122.4±48.2
Pre-operative HB (g/dl)	13.31±1.9	13.1±1.9
Post-operative HB (g/dl, IV day)	11.95±1.6	12.0±1.4

The conventional criteria of definition for post-operative complications were taken into account:

1) Febrile morbidity (temperature rise above 38 °C in two separate controls, excluding the 1st day after operation).

2) Local infection (pelvic infiltrates).

3) Length of post-operative hospital stay (expressed as percentage of patients requiring more than the average 8 days permanence).

4) Urinary tract infection (positive midstream urine culture 4 days after antibiotic suspension).

The Chi-squadre tests was used in order to verify any statistical difference in the results.

RESULTS

As shown in table 1, the two groups were comparable when matched for preoperative factors predisposing to infection. Two of the postoperative parameters (febrile morbility, local infection) were also distributed without any statistical difference, whereas the average hospital stay was significantly shorter in group B (table 2). Urinary tract infections were twice as frequent in group A versus the Cephamandole + Tobramycine treated group (table 3).

DISCUSSION

These results are comparable, in terms of major pelvic infections, to those mentioned in Literature. Febrile morbility is a difficult parameter to be compared, since some Authors would not consider as a complication a rise in temperature with no physical sign of infection ([7]).

Since the significative bias related to patient selection in various series (social class, premenopausal or postmenopausal, preoperative risk factors such as diabetes, anemia), it could easily be concluded that the choice employing or not an antimicrobial prophylaxis could be left to any single institution.

Urinary tract infection rate does not dictate per se the necessity for prophylaxis, since an outpatient treatment is usually sufficient without altering the hospital stay. Besides some factors related to different surgical attitudes (length of cathe-

Table 2. – *Infection-related post-operative complications.*

	Group A	Group B
Febrile morbidity	9/58 15.5% $\chi^2 = 0.27$	8/46 17.4% (NS)
Local infection	2/58 3.5% $\chi^2 = 0.56$	2/46 4.3% (NS)
Post-operative hospital stay (longer than 8 days)	31/58 53.5% $\chi^2 = 4.64$	14/46 30.4% (<0.05)

Table 3. – *Positive midstream urine cultures and microbiological milieu recovered.*

Group A	Group B
1 –	1 –
2 –	2 –
3 + Pseudomonas	3 –
4 –	4 –
5 + Pseudomonas	5 + Proteus
6 –	6 + E. Coli
7 –	7 –
8 –	8 + E. Coli
9 –	9 + Klebsiella
10 + Klebsiella	10 –
11 + Klebsiella	11 –
12 –	12 –
13 –	13 –
14 –	14 –
15 –	15 –
16 + E. Coli	16 –
17 –	17 –
18 –	18 –
19 + Pseudomonas	19 –
20 + E. Coli	20 –
21 –	21 –
22 + Proteus	22 –
23 –	23 –
24 + Pseudomonas	24 –
25 –	25 –
26 + E. Coli	26 –
27 –	27 –
28 + Proteus	28 –
29 –	29 –
30 + Piocianeo (20/58)	30 –
31 –	31 –
32 –	32 + E. Coli
33 –	33 –
34 + Klebsiella (34.5%)	34 –
35 –	35 + E. Coli
36 + Proteus	36 –
37 –	37 –
38 + Klebsiella	38 –
39 –	39 + Pseudomonas
40 –	40 –
41 –	41 –
42 –	42 –
43 –	43 –
44 + E. Coli	44 –
45 –	45 –
46 + Pseudomonas	46 –
47 –	
48 + Klebsiella	
49 –	
50 –	
51 + Proteus	
52 –	
53 –	
54 –	
55 –	
56 –	
57 + Proteus	
58 –	
Infected number of patients	
20/58 34.5%	7/46 15.29%
$\chi^2 = 4.00$ (>0.05)	

terism), it does reflect the risk of infection for a given population.

A relative increase in anaerobic bacteria has been shown from culture collected either from the endocervix or the infection sites in patients who developed complications ([7]). Since there is not enough evidence the same Authors stated that the presence of these bacteria alone does not dictate a necessity for prophylaxis. Each institution should ideally be aware of a microbiological milieu predisposing to infection of the operative site. Therefore more randomized trial are necessary before defining the real cost-benefit ratio of any antimicrobial prophylaxis.

It is interesting to observe the difference in the bacterial strains cultured in the two subgroups of our study.

Whether these results represent a real clinical difference and perhaps " risk factor " for infection or whether they are purely iatrogenic interference, it is now under investigation on a larger number of patients.

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