Antimicrobial Use by The Department of Obstetrics and Gynecology of a Tertiary Care Hospital: Analysis for Rationality and other Aspects

Shah BK, Shah VN

Department of Pharmacology, M.P.Shah Medical College, Jamnagar.

OBJECTIVES – To study the antimicrobial use in obstetrics and gynecology with emphasis on its timing, frequency, dosage, route, duration, cost and rationality. METHODS – Case records of 453 patients admitted in the Department of Obstetrics and Gynecology from 1ST April 2002 to 31st May 2002 were analyzed using method of Gajjar¹ with some modifications. Rationality scores were assigned considering selected drugs, their duration, routes, dosages, frequency etc. Comparison was done with standard treatment protocol and unnecessary cost was derived by subtracting the cost of standard treatment from the cost of prescribed treatment. RESULTS – Antimicrobials were used in 431cases out of 453 giving an overall incidence of 95.14%. For further analysis of rationality, 340 cases meeting with inclusion criteria were used. Out of these 340 in 42 cases the prescriptions were found to be rational, in 112 semi-rational and in 186 irrational. Out of the total cost, 72% was found to be unnecessary. CONCLUSION –Antimicrobial use is very high and in many cases irrational. Apart from unnecessary cost this can increase chances of antimicrobial resistance.

Key words: antimicrobial use, rationality of antimicrobial use, perioperative prophylanis, cost of antimicrobial use

Introduction

The classical work of Burke² clearly established that the period during which infectious agents can enter inside the body is from the time of skin incision to the time of skin closure in any operation and this is the period during which an antimicrobial if present at the site in sufficient concentration can effectively prevent/reduce incidence of perioperative infection. Though this fact is well known for more than 40 years, postoperative use of antimicrobials is rampant and it not only adds to the financial burden of the hospital but also exposes the patients to the risk of adverse drug reactions and increases the chances of development of drug resistance.

The present study was designed to:

- study the perioperative antimicrobial use in the department of obstetrics and gynecology with emphasis on timing, frequency, dosage, route, duration of therapy, cost involved and rationality
- (2) study the use of antimicrobials during labor
- (3) understand and analyze the prescribing patterns for antimicrobials in other cases

Paper received on 09/02/04; accepted on 27/05/04

Correspondence:

Dr. B. K. Shah,

Head & Senior Professor, Department of Pharmacology M.P. Shah Medical College, Jamnagar.361008, (Gujarat) - Phone no: +91-288-2550204 Extn.-319 (O)

+91-288-2540131(Res.) Fax no.: +91-288-2540036

E-mail :viralshah_rational@yahoo.co.in

Material and Methods

Case records of patients admitted to obstetrics and gynecology department from 1st April 2002 to 31st May 2002 were collected and about 25% cases were selected for the study.

Details of each case were recorded in separate predesigned and pretested proforma. Any clinical evidence of infection was recorded separately.

Analysis for rationality was carried out by using the method of Phadke et al³ as modified by Gajjar¹. In short the method used a scoring system with a maximum of 30 points of which 20 were assigned for the main drug and 10 for the complementary drug. In each category half the points were given for the correctness of the drug decided on the basis of the recommendations of the standard textbooks of obstetrics and gynecology, pharmacology, and infectious diseases⁴⁷ and half the points were given for the correctness of the route, dose, frequency and duration of treatment. Negative points were *not* given for the use of unnecessary drugs. Further details of calculation were as under:

1. Correctness of the main drug:

-	first choice drug used	(100%)	10 Points
-	second choice drug used	(60%)	6 Points
-	third choice drug used	(30%)	3 Points
-	wrong drug used	(0%)	0 Points

2. Dose, duration etc.:

- Correct formulation, dose, frequency, duration, and route (100%) 10 Points
- Inadequate / excessive dose, duration or frequency (50%) 5 Points

The same method was used for the complementary drug. As mentioned previously, negative points were not given for the use of unnecessary drugs.

When complementary drug was not needed and hence not used, full 10 points were given. When no antimicrobials were needed and hence not prescribed, full 30 points were given.

Each prescription was thus assigned a score of 30 points and was graded as rational if it scored 20 points or more, semi-rational if it scored 10 to 19 points, and irrational if it scored less than 10.

Cost analysis:

For the analysis of cost, a standard treatment protocol for each operative procedure was decided on the basis of recommendations of the standard textbooks as mentioned previously, and cost for such treatment was worked out using lowest prices of a preparation as given in CIMS- APRIL 20028. Cost of the prescribed treatment was worked out similarly. Unnecessary cost is the difference between the cost of prescribed treatment and standard treatment.

Exclusion criteria:

Following cases were excluded from the study:

- 1. Cases which had clear evidence of infection at the time of admission with history of antimicrobial use in immediate preadmission period.
- 2. Cases in which information was incomplete, regarding the dose, duration, frequency of use etc.
- Cases in which it was not possible to decipher the handwritings or necessary information was not properly recorded.
- 4. One case of cesarean section for accidental hemorrhage was considered only for analysis of antimicrobial preference and for analysis of cases in which initial antimicrobial was changed. It was excluded from other considerations because the patient had died on the second day.

Results

A total of 1669 cases were admitted in the wards of obstetrics and gynecology department during the study period. Of these, 453 cases were available in the record

section at the time of study and the same were used for further analysis. Of the 453 cases, antimicrobials were used in 431 cases giving a figure of 95.41% for overall use of antimicrobials. Out of these 431 cases, 345 qualified for further analysis 86 were excluded due to various reasons as stated earlier.

Detailed break up of these 345 cases is given in Table I. It was observed that out of these 345 cases antimicrobials were not used in 15 cases only, an incidence of 4.34%.

Study of antimicrobial preference showed that ciprofloxacin was used maximally (60.90%) followed by ampicillin (54.54%) and metronidazole (39.69%). (Table II). Procedure wise preference appeared to be somewhat different with metronidazole (92.7%) topping the list in cases of lower segment cesarean section (LSCS), ciprofloxacin (97.4%) and metronidazole (94.8%) in cases of hysterectomy, and ampicillin (66.6%) in cases of normal delivery with episiotomy. Among the other drugs, gentamicin, cefotaxime, cephalexin and tetracycline were used with some frequency. Cefazolin, cefuroxime, cefotatan, clindamycin, doxycycline and benzyl penicillin were not used in any of the cases.

There were a number of cases in which initial antimicrobial was changed (Table III). The incidence was 45.5% in LSCS, 39.4% in evacuation and curettage (E and C), and 33.3% in hysterectomy. Similarly, a newer antimicrobial was added during therapy in 43.58% cases of hysterectomy, 35.2% cases of LSCS and 20% of miscellaneous cases.

Further analysis showed that minimum number of antimicrobials were used in cases of normal delivery without episiotomy and maximum in LSCS. It is noteworthy that three or more antimicrobials were used in 66 out of 69 cases of LSCS and 37 out of 39 cases of hysterectomy (Table IV).

Prescription of antimicrobials by generic name was found to be common (61.28%). Only brand names (no generic names) were used in 2 cases (0.62%).

Evidence of postoperative infection was 7.6% in cases of hysterectomy and 4.4% in LSCS.

For rationality scoring, we have used the method of Gajjar¹ with some modifications. As can be seen from Table V, a large number of prescriptions fall in the category of semi-rational or irrational, in spite of using more lenient method than the one used by Gajjar¹.

Obviously with the use of more number of antimicrobials

Table I. Distribution of cases

Procedure	Total number of cases	Number of cases in which antimicrobials were not used	Mean duration of antimicrobial therapy (Days)
Lower segment cesarean section	69	0	8.04
Hysterectomy	39	0	9
Episiotomy	123	4	,5
Normal delivery	23	6	5
Dilatation and Curettage	13	2	5
Evacuation and Curettage	39	0	5
Laparoscopic tubal ligation with or without termination of pregnancy (MTP)	24	3	5
Miscellaneous	15	0	6.44
Total	345 (100%)	15 (4.34%)	6.06

Table II. Antimicrobial preference (n=330)

Antimicrobial agents	Total no (%)
Ciprofloxin	201 (60.90%)
Ampicillin	180 (54.54%)
Metronidazole	131 (39.69%)
Gentamicin	81 (24.54%)
Cefotaxime	60 (18.18%)
Tetracycline	18 (5.45%)
Cephalexin	12 (3.63%)
Others	12 (3.63%)

Some patients had more than one antimicrobial

Table III. Number of cases in which initial antimicrobials were changed post-operatively or others added (n=345)

Antimicrobials changed n=97 (%)		Antimicrobials added n=46 (%)	
31	(45.5%)	24	(35.2%)
13	(33.3%)	17	(43.58%)
34	(27.6%)	2	(1.62%)
1	(4.34%)		-
1	(7.69%)		-
15	(39.4%)		-
	-		-
2	(13.3%)	3	(20%)
	n= 31 13 34 1 1 15	n=97 (%) 31 (45.5%) 13 (33.3%) 34 (27.6%) 1 (4.34%) 1 (7.69%) 15 (39.4%)	n=97 (%) 31 (45.5%) 24 13 (33.3%) 34 (27.6%) 2 (4.34%) 1 (7.69%) 15 (39.4%)

Table IV. Prevalence of antimicrobial polytherapy (n=345)

Procedure(cases)	Total no of antimicrobials						
(number of cases)]	0 n=15	1 n=46	2 n=69	3 n=61	4 or more n=54		
Lower segment cewsarean section (69)	0	0	3	26	40		
Hysterectomy (39)	0	0	2	27	10		
Episiotomy (123)	4	78	37	4	0		
Normal delivery (23)	6	16	1	•0	0		
Dilatation and Curettage (13)	2	10	1	0			
Evacuation and Curettage (39) •	0	21	17	1	0		
Laparoscopic tubal ligation with or without termination of pregnancy (MTP) (24)	3	16	4	1	0		
Miscellaneous (15)	0	5	4	2	4		

Table V. Rationality score (n=340)

Procedure(cases)	Modified average Score	Rational prescriptions	Semi-rational prescriptions	Irrational prescriptions	
Lower segment cesarean secton (68	3) 12.8	0	59	9	
Hysterectomy(39)	14.39	0	28	11	
Episiotomy(123)	0.97	4	0	119	
Normal delivery(23)	7.8	6	0	17	
Dilatation and curettage (13)	4.6	2	0	11	
Evacuation and curettage (38)	17.21	21	17	0	
Laparoscopic tubal ligation with or without termination of pregnancy (MTP) (24)	10.4	9	5	10	
Miscellaneous(12)	5.25	0	3	9	
Total(340)	_	42	112	186	

Table VI. Average number of antimicrobials and total as well as unnecessary cost

Procedure(cases)	Average number of ntimicrobials (Range)	Cost (Rupees) Total (Average)		Unnecessary cost (Rupees) Total (Average)	
Lower segment cesarean segment (6	8) 3.75 (2-5)	28520.56	(419.42)	19401.76 (285.32)	
Hysterectomy(39)	3.42 (2-6)	14190.93	(363.87)	8498.1 (217.9)	
Episiotomy(123)	1.33 (0-3)	7448.88	(60.56)	7448.88 (60.56)	
Normal delivery(23)	0.76 (0-2)	701.5	(30.5)	701.5 (30.5)	
Dilatation and curettage (13)	0.1 (0-2)	488.8	(37.6)	488.8 (37.6)	
Evacuation and curettage (38)	1.48 (1-3)	1667.44	(43.88)	1439.44 (37.88)	
Laparoscopic tubal ligation termination of pregnancy without (MTP) (24)	1.125 (0-3)	1283.28	(53.47)	969.6 (40.4)	
Miscellaneous(12)	2.43 (1-6)	3200.16	(266.68)	2464.8 (205.4)	
Total	1.91	57501.55	(169.42)	41412.88 (121.80)	

A sum of Rs 41412.88 was spent unnecessarily among these 340 cases.

and longer duration of therapy, the overall cost increased. At least about Rs. 41412.88 were spent unnecessarily in 2 months on these 340 patients – amounting to about 72% of expenditure (Table VI).

Maximum and minimum average unnecessary expense was Rs. 285.32 for each case of LSCS and Rs. 30.50 for each case of normal delivery.

Discussion

A striking feature of our study was the use of antimicrobials in 95% or more of the admitted patients which appears to be very high by any type of comparisons with reports from other institutions in the country^{9,10}.

Another striking feature of our study is the duration for which the antimicrobials were prescribed. Since in majority of the cases under study the use was for prophylaxis against postoperative wound infection, administration of more than one dose or continuation of therapy for more than 24 hours is not justified. Mean duration of antimicrobial therapy is 6.06 days in our study. Other Indian studies report 5.26 days¹¹ and 3.24 days¹⁰ as mean duration of prophylactic antimicrobial therapy in obstetrics and gynecology.

Mean number of antimicrobials used was 1.91 for all cases, 3.75 for LSCS cases and 3.42 for hysterectomy cases.

The instances of changing antimicrobials or adding the newer ones were also quite high.

Informal discussion with treating clinicians indicated that there is an ingrained fear in their minds about possibility of a severe postoperative (or postpartum) infection if antimicrobials are not used. Various reasons that were put forth during such discussions included –

- a) inadequate/ improper aseptic precautions,
- b) perineal region remains colonized by a plethora of infecting organisms,
- c) unhygienic habits of patients and hospital staff,
- d) consequences of infection may be quite serious,
- e) likelihood of acquiring infection is high in hospital environment,
- and f) overall attitude conveyed that antimicrobials are panacea for all ills.

Under such circumstances, it is not surprising that

overall scoring for rationality could not reach, for any of the procedures, the desired score of 20 points, which is considered rational use. Individual prescriptions in some of the cases were found to be rational but the overall scenario remained quite disappointing.

An important aspect of perioperative antimicrobial prophylaxis is timing of administration because adequate antimicrobial concentration during entire period of operation assures better prophylaxis and administration after 3 hours of incision is shown to be ineffective in preventing infection. This important point could not be properly evaluated in this study as it was a retrospective study and all the cases under study did not have a proper record of time of administration of prophylactic drug as well as the precise time of initiation of operative procedure. However, available general information indicated that in almost all cases, preprocedure dose of the antimicrobial was administered.

As far as preference of antimicrobials was concerned two major factors viz., availability of free drugs from hospital supply and availability in oral formulation for postoperative administration appeared to be governing the choice. Ciprofloxacin, ampicillin and metronidazole, therefore, topped the list. Cefazolin was not available in hospital supply, hence was not used even in a single case. A number of Indian studies have recorded a high level of use of ampicillin, metronidazole, gentamicin, cefazolin and ciprofloxacin for gynecological/ surgical prophylaxis⁹⁻¹¹.

Overall impression gathered from informal discussions with clinicians is that there is probably lack of awareness about suitability of using benzyl penicllin / doxycycline in selected cases. A fear of anaphylaxis with penicillin also seems to be an important reason for its non-use.

Total cost of antimicrobials used in our study population amounted to Rs. 57,501.55 and of this Rs. 41,412.88 (72%) was unnecessary cost. Moss et al¹² reported that only 7% antibiotics prescribed for conventional surgical prophylaxis fulfilled all the criteria used to assess the suitability of choice. Srishyla¹³ has reported that antimicrobial prophylaxis is being continued beyond 72 hours in 48% of cases. Goyal¹⁰ reported an extended period of prophylaxis with an unnecessary cost of 65% of the total antimicrobial cost in obstetric and gynecological cases.

Some encouraging points noted in the present study are the relatively low rates of postoperative infection and use of antimicrobials predominantly by generic names.

References

- 1. Gajjar BM. Evaluation and comparison of prescribing pattern of physicians from the institute and private sector for rational drug therapy [dissertation]. *Vallabh Vidyanagar*(Guj.). *Sardar Patel Univ.*1999.
- 2. Burke JF. The effective period of preventive antibiotic action in experimental incision and dermal lesions. *Surgery* 1961;50:161-8.
- 3. Phadke A, Fernandes A, Sharda L et al eds. A study of supply and use of pharmaceuticals in Satara district. *The Foundation for Research in Community Health, Pune.* 1995.
- 4. Cunningham FG, MacDonald PC, Grant MD et al eds. William's Obstetrics. 20th ed. New Jersey. Prentice Hall International.1997.
- Hager WD. Postopertive infections: Prevention and management. In: Rock JA, Thompson JD eds. TeLinde's Operative Gynecology. 8th ed. New York. Lippincott-Raven. 1997: 233-43.
- 6. Chambers HF, Sande MA. Antimicrobial agents general considerations. In: Hardman JG, Limbird LE, eds. Goodman & Gillman's The Pharmacological Basis of Therapeutics. 10th ed. New York. McGraw Hill. 2001: 1143-70.

- 7. Kernodle DS, Kaiser AB. Postoperative intections and antimicrobial prophylaxis. In: Mendell GL, Bennet JE, Dolin R eds. *Principles and practice of infectious diseases*. 4th ed. New York. Churchill Livingstone. 1995; 2742-56.
- 8. CIMS-Current Index of Medical Specialities *Banglore*. *Medimedia Health Pot. Ltd. April* 2002.
- Srishyla MV, Nagarani MA, Vekantraman BV. Drug utilization of antimicrobials in the in-patient setting of a tertiary hospital. Ind J Pharmacol 1994;26:282-7.
- 10. Goyal R. Antimicrobial utilization by four departments of a tertiary care hospital in rural setting [dissertation]. *Vallabh Vidyanagar(Guj.) Sardar Patel Univ.*2002.
- 11. Uppal R, Gupta S, Shobha G et al. Drug utilization of antimicrobials in caesarian section. *J Obstet Gynecol Ind* 1991;41:346-9.
- 12. Moss F, McNicol MW, McSwiggan DA et al. Survey of antibiotic prescribing in a district general hospital. I. Pattern of use. *Lancet* 1981;2:349–32.
- 13. Srishyla MV, Nagarani MA, Damodar S et al. A preliminary audit of practice. Antibacterial prophylaxis in general surgery in Indian hospital setting. *Ind J Physiol Pharmacol* 1994;38:207-10.