

Single-Dose Antibiotic Prophylaxis in Women Undergoing Elective Caesarean Section

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Summary

This prospective, randomised, controlled trial was performed to evaluate the effectiveness of single-dose antibiotic prophylaxis in decreasing the infectious morbidity following elective caesarean section. Two hundred women undergoing elective caesarean section were randomly assigned to receive either 1.2 g of Augmentin intravenously, or no treatment, just before the start of their caesarean section. The two groups of women were comparable in terms of patient characteristics and operation variables. The overall postoperative morbidity rate was 19% in the Augmentin treated group versus 38% in the group that received no prophylaxis ($p < 0.01$). The incidence of wound sepsis was 3% in the Augmentin group versus 13% in the control group ($p < 0.01$). The incidence of febrile morbidity with no identifiable cause was 8% in the Augmentin group versus 18% in the control group ($p < 0.05$). The duration of hospital stay was significantly shorter in the Augmentin group ($p < 0.05$). A single-dose of prophylactic Augmentin significantly reduced the postoperative morbidity and duration of hospital stay in women who underwent elective caesarean sections.

Key Words: Caesarean section, Antibiotics, Prophylaxis

Introduction

Postoperative infection is an important cause of morbidity in women undergoing caesarean sections. The use of prophylactic antibiotics during caesarean section has been shown to be beneficial in reducing such morbidity¹. However, their role in the management of women undergoing elective caesarean section has been questioned, since the risk of postoperative infection in elective caesarean sections may not be as high as in emergency procedures^{2,3}.

Single-dose prophylactic antibiotics have been shown to be effective in reducing morbidity following elective caesarean sections in developing countries, where factors such as poor nutritional state, rapid turnover in operating rooms and relatively inexperienced surgeons, may contribute to a higher infection rate^{4,5}. However, their usefulness in countries where such factors are not prevalent, is uncertain.

Women undergoing elective caesarean sections in Malaysia may not be exposed to such factors which increase the risk of postoperative infection. Further, the effectiveness of single-dose antibiotic regimes in preventing postoperative morbidity has been questioned⁶. Thus, to determine the role of single-dose prophylactic antibiotics in elective caesarean sections in Malaysia, local studies are required.

This randomised controlled trial evaluates whether a single intravenous dose of Augmentin given preoperatively, is effective in preventing postoperative infectious morbidity in women undergoing elective caesarean sections at a teaching hospital in Kuala Lumpur. Augmentin® (SmithKline Beecham Pharmaceuticals) is a formulation of amoxicillin and the potent beta-lactamase inhibitor clavulanic acid. It was chosen because it is well tolerated, has a broad antimicrobial spectrum and has relatively few side effects⁷.

Materials and Methods

The study sample was recruited from women undergoing elective caesarean sections at the University Hospital, Kuala Lumpur, between September 1994 and

April 1995. Women were excluded from the study if they were allergic to penicillin, if they had evidence of an infection, if they had premature rupture of membranes, or if they were receiving antibiotics prior to the caesarean section. Verbal consent to participate

Table I
Characteristics of the two groups of women undergoing elective lower segment caesarean section

Characteristics	Augmentin (n = 100)	No antibiotics (n = 100)
Age (years)		
Mean (SD)	32.0 (4.7)	31.5 (5.1)
Parity		
Mean (SD)	1.4 (1.2)	1.6 (1.5)
Gestational age (weeks)		
Mean (SD)	38.3 (1.1)	38.2 (1.2)
Pre-operative maternal weight (kg)		
Mean (SD)	67.4 (12.1)	67.2 (13.0)
Maternal height (cm)		
Mean (SD)	152.9 (6.1)	153.9 (5.6)
Number of previous CS		
0	34	43
1	42	28
2	24	29
Indications for previous CS		
Two previous CS	24	29
Breech presentation	14	13
Other malpresentations	14	18
Placenta praevia	11	12
Cephalo-pelvic disproportion	21	15
Bad obstetric history	7	8
Others	9	5
Pre-operative WBC ($\times 10^9$)		
Mean (SD)	10.8 (2.7)	10.3 (2.5)
Pre-operative haemoglobin (g/dl)		
Mean (SD)	11.2 (1.2)	11.5 (1.2)

CS = caesarean section

WBC = white blood cell

There were no significant differences between the two groups for any of the characteristics.

in the study was obtained from all women recruited, and they were alternately allocated to either the antibiotic group or to the control group.

Preoperatively, the haemoglobin concentration, white cell count and urine microscopy were evaluated on all women. Women allocated to the study group were administered 1.2 g of Augmentin intravenously, either at the time general anaesthesia was induced, or after an epidural block was sited. Those women allocated to the control group received no antibiotics. The seniority of the surgeon, the type of incision made, the duration of the operation and the estimated blood loss for each operation were recorded.

Postoperatively, each woman was assessed daily for the presence of febrile morbidity and wound sepsis. Midstream urine culture, to exclude urinary tract infection, was routinely performed for all women on

the third postoperative day. Antibiotics were only prescribed for febrile morbidity developing or persisting after the first 24 hours postoperatively. The duration of postoperative hospital stay for each woman was noted.

The following is a list of postoperative complications assessed in this study, together with the criteria used for their diagnosis.

1. Febrile morbidity – this was defined as febrile episodes of $> 38^{\circ}\text{C}$, occurring on two occasions, at least 4 hours apart, after the first 24 hours following the operation.
2. Wound sepsis – this was defined and graded as (a) erythema and/or induration (b) serous oozing (c) the presence of pus (d) wound dehiscence – when the wound gaped by more than 1 cm.
3. Urinary tract infection – this was diagnosed when

Table II
Operative variables in the two groups of women undergoing elective caesarean section

Variables	Augmentin (n = 100)	No antibiotics (n = 100)
Surgeon		
Medical Officer	93	90
Lecturer	1	4
Consultant	6	6
Anaesthetic		
General	61	55
Epidural	34	39
Spinal	5	6
Skin incision		
Pfannenstiel	73	75
Sub-umbilical midline	27	25
Estimated blood loss (ml)		
Mean (SD)	362 (177)	385 (209)
Duration of operation (min)		
Mean (SD)	50 (15)	52 (17)
Post-operative haemoglobin (g/dl)		
Mean (SD)	10.9 (1.2)	11.2 (1.5)

There were no significant differences between the two groups for any of the operative variables.

Table III
Maternal infections and duration of hospital stay in the two groups of women who underwent elective caesarean section

Maternal outcome	Augmentin (n = 100)	No treatment (n = 100)	Statistical significance
Febrile morbidity			p < 0.05
Cause unidentified	8	18	
Wound sepsis			p < 0.01
Erythema/induration	2	2	
Serous oozing	1	0	
Pus	0	2	
Dehiscence	0	9	
Urinary tract infection	8	7	p = NS
Endometritis	0	0	p = NS
Pneumonia	0	0	p = NS
Total number with morbidity	19 (19%)	38 (38%)	p < 0.01
Duration of hospital stay			p < 0.05
Mean (SD)	5.19 (0.7)	5.9 (2.8)	

the postoperative urine culture yielded a growth of more than 100,000 organisms per millilitre.

4. Endometritis – this was diagnosed when fever, uterine tenderness and foul smelling lochia were present.
5. Pneumonia – this was diagnosed on the basis of cough, fever and/or radiographic evidence of pulmonary consolidation.

When a woman developed more than one infectious complication, only the most severe was recorded. The T-test and Chi-square test were used to analyse the data, and this was performed using the Statistical/Data Analysis (STATA) Version 3 software.

Results

A total of 200 patients were recruited into the study. One hundred patients were allocated to the study group, and 100 patients were allocated to the control group. Both the study group and the control group were comparable in terms of patient characteristics and

operative variables as shown in Table I and Table II respectively. No adverse drug reactions were noted in any of the patients who were given Augmentin preoperatively.

The prevalence of infectious morbidity occurring in both groups of women following caesarean section is summarised in Table III. There was a significantly higher incidence of febrile morbidity in the group of patients who received no prophylactic antibiotic. The wound sepsis rate was also significantly higher in the group who received no prophylactic antibiotic. Postoperative morbidity occurred in a total of 38% of the women who received no prophylaxis, compared to only 19% in women who received prophylactic antibiotics. This reduction in the incidence of postoperative morbidity, when a single dose of Augmentin was given preoperatively, was statistically significant (p < 0.01).

The duration of hospital stay was also significantly shorter for women who received prophylactic antibiotics when compared to the women who did not receive prophylactic antibiotics (p < 0.05).

Discussion

Routine prescribing of prophylactic antibiotics is not without its disadvantages, and the possibility of anaphylaxis or other adverse effects should not be forgotten. The cost of widespread use of drugs, as well as the potential emergence of resistant strains of bacteria are other reasons to be sure that prophylactic antibiotics are really of value in reducing postoperative morbidity before their use becomes routine.

The effectiveness of prophylactic antibiotics in reducing postoperative morbidity in emergency caesarean sections in a local setting, has already been demonstrated⁸. Our study shows that prophylactic antibiotics significantly reduce the postoperative morbidity rate, as well as the duration of in-patient hospital stay, in women undergoing elective caesarean sections. It also shows that a single intravenous dose of Augmentin administered preoperatively, is sufficient to effect a significant reduction in the postoperative morbidity. Although a multiple-dose regimen may have been more effective in reducing the postoperative morbidity rate¹,

it is uncertain whether the cost effectiveness of such a regimen, when compared to a single-dose regimen, makes it a better choice. Further, single-dose regimens have the advantage of being easier to use and are less likely to cause adverse effects.

The high incidence of postoperative morbidity seen in the group who received no antibiotics is of concern, particularly when the rate of caesarean sections continues to rise⁹. Apart from minimising the number of unnecessary caesarean sections and ensuring optimal surgical technique, the introduction of routine antibiotic prophylaxis for both emergency and elective caesarean sections should help reduce this high rate of postoperative morbidity. Further studies are required however, to determine the best choice of antibiotics and the optimal dosage for prophylaxis in caesarean sections.

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