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Preoperative Versus Postoperative Vaginal Cleansing With Chlorhexidine Solution In Prevention Of Post-Cesarean Section Infectious Morbidity At A Teaching Hospital In Resource Poor Setting: A Randomized Trial.

Running head: Nnonyelu et al; Chlorhexidine vaginal cleansing

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ABSTRACT

Background: Maternal infectious morbidity is a common complication of cesarean delivery, especially in a poor resource setting like ours. This study was done in Ebonyi State over 5 months period. The State is inhabited mainly by rural farmers/petty traders, low Literacy, poverty with poor maternal health indices.

Objectives: To compare the effectiveness of preoperative vaginal cleansing with immediate postoperative vaginal cleansing with chlorhexidine solution in preventing post-cesarean infectious morbidities.

Method: Randomized trial involving 120 women who had elective or emergency cesarean sections at term, 60 in each group. Group 1 had preoperative while group 2 had postoperative vaginal cleansing. Research Randomizer software was used to generate 120 numbers. Sixty numbers were randomly generated from a pool of 120 numbers and were assigned to group 1 while the remaining 60 numbers were automatically assigned to group 2. Both groups received antibiotics and anterior abdominal wall scrubbing and monitored.

Result: About3.4% of group 1 had post-cesarean infection while 16.6% in group 2 had post-cesarean infection. This was significant (p= 0.015). No puerperal pyrexia noted in group 1 while group 2 had two.

Conclusion: Preoperative was more effective than postoperative vaginal cleansing with 1% chlorhexidine in reducing post-operative infectious morbidity post-cesarean section.

Keywords: Cesarean section, infection, chlorhexidine, preoperative, postoperative.

I. INTRODUCTION

Cesarean section is the commonest major surgical procedure performed by obstetricians worldwide[1]. The rate of cesarean section varies from country to country and within a country; a rate of 34% was reported in USA[2] while 30.7% rate was in Abakaliki, Southeast Nigeria[3]. Maternal infectious morbidity is a common complication of this procedure and is the third leading cause of death among pregnant women in Nigeria[4] and accounts for 15% of maternal death worldwide[5,6,7]. The incidence of postpartum maternal infectious morbidity is about 5 to 20 times higher in cesarean delivery compared to vaginal delivery[8,9,10]. Effort should be made to prevent postoperative infectious morbidities and mortality associated with cesarean delivery considering the increase in cesarean section rate. This is paramount especially in developing countries where post-operative infectious morbidities are commonest[6].

Endometritis is the second commonest cause of infectious morbidity after cesarean section, while surgical skin infection ranked first, and it is mainly due to ascending infections from the vagina[11]. It occurs in about 0.5 - 5% of cases following vaginal delivery[12]. However, endometritis occurs in 2 - 16% of patients after cesarean section with long term complications like endometrial adhesions, amenorrhea, tubal blockage and secondary infertility[13].The pathophysiology is usually polymicrobial with a significant proportion occurring as a result of ascending contamination from the cervicovaginal flora[3]. These organisms occasionally found in the vagina may ascend to the endometrium and operation site during caesarean delivery. Ascendingly, infections from the lower genital tract to the upper genital tract is perhaps the most important factor as other routes of infections are routinely prevented through surgical skin antisepsis, prophylactic antibiotics, hand washing with antiseptics and sterilization of surgical instruments.

other modalities include antibiotic prophylaxis, preoperative vaginal cleansing with povidone-iodine, preoperative shower with antiseptics, clip rather than shave pubic hairs, skin preparations with antiseptic agents, avoiding manual removal of the placenta and fetal membranes, avoiding closure of the skin with staples, and early removal of bladder catheters postoperatively[9,11,14,15,16]. Though antibiotic prophylaxis is the most popular among these modalities especially in low resource settings; its practice is still being challenged by resistance, efficacy, non-availability and cost[17]. Various preoperative antiseptics like benzalkonium chloride have all been tried with aim of reducing vaginal ascending infections[18].

Chlorhexidine is a topical safe, cheap and effective antiseptic for preoperative skin preparation and it exhibits a broad-based clinical activity against gram-positive, gram-negative and non-spore forming bacteria, yeast and selective lipid envelope viruses[3,19,20,21].

Every year there is need for 0.8 - 3.2 million cesarean deliveries in low income countries where 60% of the world's births occur while additional 4.0 - 6.2 million cesarean sections are performed in middle and high-income countries where 37.5% of the births occur[22]. Globally, cesarean section rate has been reported to be between 19.4% to over 50% across the countries and regions[5,6,8,23,24,25]. Puerperal infection is a broad term for any bacterial infection of the genital tract following delivery. It remains a major cause of maternal morbidity and mortality in both developed and low resource countries[9,10]. It is also a source of outbreak of nosocomial infections among other patients and healthcare staff[25]. It remains among the top five causes of pregnancy related maternal morbidity and mortality worldwide[26,27].

Although information about the role of preoperative vaginal preparations with chlorhexidine solution in reducing maternal infectious morbidity after cesarean delivery is available in the literatureincluding the center[28], it is not known if change in timing of the vaginal cleansing, that is, immediately after cesarean delivery will have any effect on post-cesarean infectious morbidity. This practice is not yet popular in our environment perhaps due to paucity of local studies on its practice. Considering the availability of chlorhexidine, cost, ease of application and tolerability, cleaning the vagina of women undergoing cesarean section with chlorhexidine solution may be a cost-effective way of reducing post-cesarean section infectious morbidities especially in our setting where morbidities and mortalities from infections are very high[6]. This study aimed to determine the most appropriate timing of this intervention in prevention of post-cesarean infectious morbidity.

II. MATERIALS AND METHOD

Ebonyi State is one of the five states in South-East Nigeria created in 1996. The State capital Abakaliki is the major urban settlement. The state is made up of 13 Local Government Areas, and three senatorial zones. Ebonyi State has a population of about 2.1 million people according to the 2006 census. The greater populations of the people of the state live in rural areas. Majority of the people are subsistent farmers, and petty traders. Literacy level is low and poverty is prevalent with poor maternal health indices. The study was carried out over a period of 5 months; from April to August, 2020 at the Teaching Hospital in Abakaliki the capital city of the state. It receives referrals from all parts of the state and neighboring states of Abia, Enugu, Benue, and Cross River. The cesarean section rate in hospital was 30.7%[3].

The study was carried out among consenting pregnant women at term who also consented for either elective or emergency cesarean section within the period of this study (inclusion criteria). The researcher explained the details of the study to the patient following decision for cesarean section before an informed consent was signed. The study was an equivalence randomized trial of the effectiveness of preoperative versus immediate postoperative vaginal cleansing with 1% chlorhexidine solution in prevention of post-cesarean maternal infectious morbidity. The exclusion criteria were, those that refusal consent, Antepartum hemorrhage, Cord prolapse, Fetal distress, Anemia in pregnancy, Women with fever/chorioamnionitis at presentation.

SAMPLE SIZE DETERMINATION

The minimum sample size was determined using the formula for calculating the sample size of a clinically equivalence randomized trial for dichotomous variables by Zhong[29].

$$N = 2 \times \left(\frac{z_{1-\frac{\alpha}{2}} + z_{1-\beta}}{\delta_0} \right)^2 \times p \times (1-p)$$

Where N = sample size per group, p = the response rate of standard treatment group, Z = standard normal deviate for a two-sided x, d_0 = a clinical accepted margin.

p= 0.237 (Tewfik H et al)

$\alpha = 0.05$

$\beta = 0.20$
$\delta_0 = 0.237$ (Tewfik H et al)
Substituting for;

$$N = 2 \times \frac{(1.96 + 0.845)^2}{0.237} \times 0.237(1 - 0.237)$$

$$N = 2 \times (11.835)^2 \times 0.237 \times 0.763$$

$$N = 2 \times 140.078 \times 0.237 \times 0.763$$

$N = 50.66$; approximately 51
Corrected for anticipated 10% attrition rate
$N =$ approximately 60
The sample size for each arm of the study was 60. Therefore, the total sample size was 120.

This study was a non-blinded randomized trial. One hundred and twenty random numbers were generated using the software Research Randomizer®. Using this software, 60 numbers were randomly generated from a pool of 120 numbers and these numbers were assigned to group 1 (preoperative vaginal cleansing) while the remaining 60 numbers were automatically assigned to group 2 (immediate postoperative vaginal cleansing). These numbers were printed, cut into square shaped cards and thoroughly mixed in a brown envelope. All eligible women signed written informed consent form and received adequate information and education about the trial. Participants that met the inclusion criteria who had signed informed consent form picked one card from the brown envelope in the presence of any of the researcher/assistants. Each participant was allocated to the group based on the number picked. Group 1 received preoperative vaginal cleansing with 1% chlorhexidine while group 2 received postoperative vaginal cleansing with 1% chlorhexidine. Both groups received routine prophylactic antibiotics and abdominal scrub as per departmental protocol.

All the participants received prophylactic antibiotics (intravenous ceftriaxone 1gramme statim and intravenous metronidazole 500mg statim) 30 minutes before anesthesia and the routine anterior abdominal wall scrub with chlorhexidine and methylated spirit according to our departmental protocol. In group 1(preoperative vaginal cleansing group), just before anterior abdominal wall cleaning, two research assistants, one on each side, held the patient's legs in dorsal position after anesthesia had taken. Sterile gloves worn with three pieces of 4x4cm sterile gauze held with sponge holding forceps was soaked in 100ml 1% chlorhexidine solution in a sterile galipot. The thumb and index finger of the left hand were used to part the labia while the gauze soaked in 1% chlorhexidine solution was introduced into the vagina and used to cleanse the vagina within duration of 30 seconds starting from the vaginal apex to the introitus with attention to the anterior, posterior and lateral aspects of vagina. After vaginal cleansing, the sterile gloves were changed and routine abdominal scrub with chlorhexidine and methylated spirit was performed. In group 2 (immediate post-operative vaginal cleansing), while patient was still under anesthesia, the blood clots in the vagina were gently evacuated with gloved hand. This was followed by vaginal cleansing with three 4x4cm gauze pieces in a sponge holding forceps soaked in 100ml of 1% chlorhexidine solution in gallipot for each patient. The cleansing also lasted for 30 seconds and was done from the apex of the vagina to the introitus with attention to the anterior, posterior, and lateral aspects of vagina. All cesarean sections were lower segment cesarean section and were done by either consultant obstetrician or senior registrar. All uterine repairs were done with vicryl sutures. Anterior abdominal wall was repaired with vicryl 2 for rectus sheath and vicryl 2/0 for subcutaneous layer while skin closure was with subcuticular skin closure technique using vicryl 2/0. All participants received postoperative antibiotics: intravenous ceftriaxone 1g daily for 48 hours, intravenous metronidazole 500mg 8 hourly for 48 hours and thereafter, receive oral cefpodoxime 200mg 12 hourly for 5 days and oral metronidazole 400mg 8 hourly for 5 days, postoperative pain relief, fluid management and vital signs were monitored and these are according to the departmental protocol. Participants who developed fever within the period of admission had blood film for malaria parasite done to exclude malaria and urine microscopy, culture and sensitivity to exclude urinary tract infections as causes of fever. Information including socio-demographic data (age, social status[30], booking status), medical history (prior infection, anemia), obstetric history (parity, gestational age) status of fetal membranes (intact or ruptured), duration of labor, type of surgery (elective or emergency), and duration of hospital stay were obtained using the proforma. All patients were reviewed daily from the period of surgery to discharge for development of febrile morbidity, clinical diagnosis of endometritis and wound infection or breakdown.The evaluation was done daily during the ward rounds and at 2 weeks and 6 weeks respectively. Patients' clinical data including vital signs chart for temperature, pulse rate, respiratory rate and blood pressure were reviewed during admission and before discharge from hospital.Thosethat developedinfection were treated with different antibiotics according to sensitivity pattern and departmental protocol before discharge.

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Data was analyzed using Statistical Package for Social Science (SPSS) software (version 20, Chicago II, USA). Continuous variables were presented as means and standard deviation (Mean ± 2SD), while categorical variables were presented as numbers and percentages.

The student's t-test was used for comparison between groups for continuous variables while the chi-square was used to compare categorical variables. Relative risk and 95% confidence interval were calculated for outcome measures. p value < 0.05 was considered significant.

ETHICAL ISSUES

Ethical approval was obtained from the Research and Ethics Committee of the Teaching Hospital. Participants were educated and counselled on the research. Participation was optional and only women who gave written consent were recruited into the study and were given the option to opt out any time if they do not wish to continue. Chlorhexidine solution was free for the participants and the post-operative investigation costs were born by the researchers. Those that developed complication were managed according to departmental protocol free.

Patient's participation in this study was strictly confidential. The information collected and the results were kept private and used only for the study. They were also assured that refusal of consent will not affect their management in the hospital.

III. RESULTS

Fig. 1 showed the flow diagram of patients through the study.

One hundred and forty-three were assessed, 21 did not meet the criteria while 2 declined consent. One hundred and twenty-two were randomized, 60 participants to each arm. All participants received the intervention and there was no drop-out or loss to follow up.

Table 1 shows the socio-demographic characteristics of the study participants in both groups. The baseline maternal characteristics were similar in both groups. Majority of the participants were multiparous 70(58.33%) and booked 83(69.17%) and of low socioeconomic class.

Table 2 shows no statistically significant clinical difference among the two groups.

Table 3 showed statistically significant difference between the two groups 1 and 2, 2 to 10 respectively. p= 0.015 (RR 5.00, 95%CI 1.14-21.86). other parameters were similar in both groups.

Table 4. There was no statistically significant difference in both groups in terms of membrane status at presentation.

Table 5 showed that booking and ante-natal clinic attendance as well as elective cesarean section is a good way of preventing post cesarean infectious morbidity among women.

IV. DISCUSSION

Many studies had examined preoperative vaginal cleansing with antiseptic solution before cesarean section and its efficacy in reducing postoperative infectious morbidity[28,31,32,33], but there is little or no study on the effectiveness of vaginal cleansing immediately after caesarean delivery when the patient is still in the theatre. This study compared the effectiveness of preoperative versus postoperative vaginal cleansing with 1% chlorhexidine solution in reduction of post-cesarean maternal infectious morbidity such as endometritis, wound infection and pyrexia. This study showed statistically significant reduction in the incidence of post-cesarean maternal infectious morbidity among women who had preoperative vaginal cleansing with chlorhexidine solution compared to women who had immediate post-cesarean vaginal cleansing with chlorhexidine solution. The infectious morbidities were more in group 2; endometritis, wound infection, and pyrexia. This may be because the vagina harbors a lot of micro-organisms which can ascend during cesarean section leading to post-operative infectious morbidities. Cleaning the vagina with chlorhexidine which has broad spectrum anti-microbial action before the surgery will reduce to the barest minimum the organisms in the vagina that may ascend and cause post-operative infectious morbidity. The prophylactic antibiotic given may not take care of the organisms in the vagina at the time of surgery. This result is similar to previous studies[32,33,34,35,36].

In our study, the incidence of wound infection was less in group 1 compared to group 2 but this was not statistically. This is similar to some previous reports[31,33,35] but differs from the reports of those that used povidone-iodine[32,34,37]. This may be as a result of rapid action of chlorhexidine.

Post-cesarean infectious morbidity occurred more in the postoperative vaginal cleansing group than in the preoperative vaginal cleansing group among women with already ruptured fetal membranes. However, there was no statistically significant difference in each of the individual post-cesarean maternal infectious morbidity (endometritis, wound infection and pyrexia) between the two arms. Preoperative vaginal cleansing with chlorhexidine is more likely to reduce the microbial load in the lower genital tract occasioned by rupture of membranes, hence reducing inoculation to the raw placental bed and surgical wound. The short onset of action of chlorhexidine after application postoperatively, may have accounted for this reduction not being statistically significant. The small sample size may have contributed to this.

Similarly, among women who had emergency cesarean section, there was no statistically significant reduction in incidence of post-cesarean endometritis, wound infection and pyrexia between the two arms. This finding may also be partly due to the above reason.

Among women who were un-booked, there was no statistically significant difference in the incidence of post-cesarean endometritis, wound infection and pyrexia between the two arms. Also, the above reasons might be responsible for this observation.

Among women with intact membranes, elective cesarean section and those that were booked, preoperative versus postoperative vaginal cleansing with chlorhexidine solution did not show any statistically significant difference for development of post-cesarean maternal infectious morbidity between the two groups, thus booking and elective cesarean section reduces post-operative morbidity. In conclusion, Preoperative vaginal cleansing was more effective in reducing post-cesarean infectious morbidity than postoperative vaginal cleansing with chlorhexidine solution and should be done, but if missed, immediate post-operative cleansing is not a bad idea.

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CONFLICT OF INTEREST

None declared by any of the authors

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FIG. 1 The flow diagram of patients through the study.
One hundred and forty-three were assessed, 21 did not meet the criteria while 2 declined consent. One hundred and twenty-two were randomized, 60 participants to each arm. All participants received the intervention and there was no drop-out or loss to follow up.

FIGURE AND TABLES

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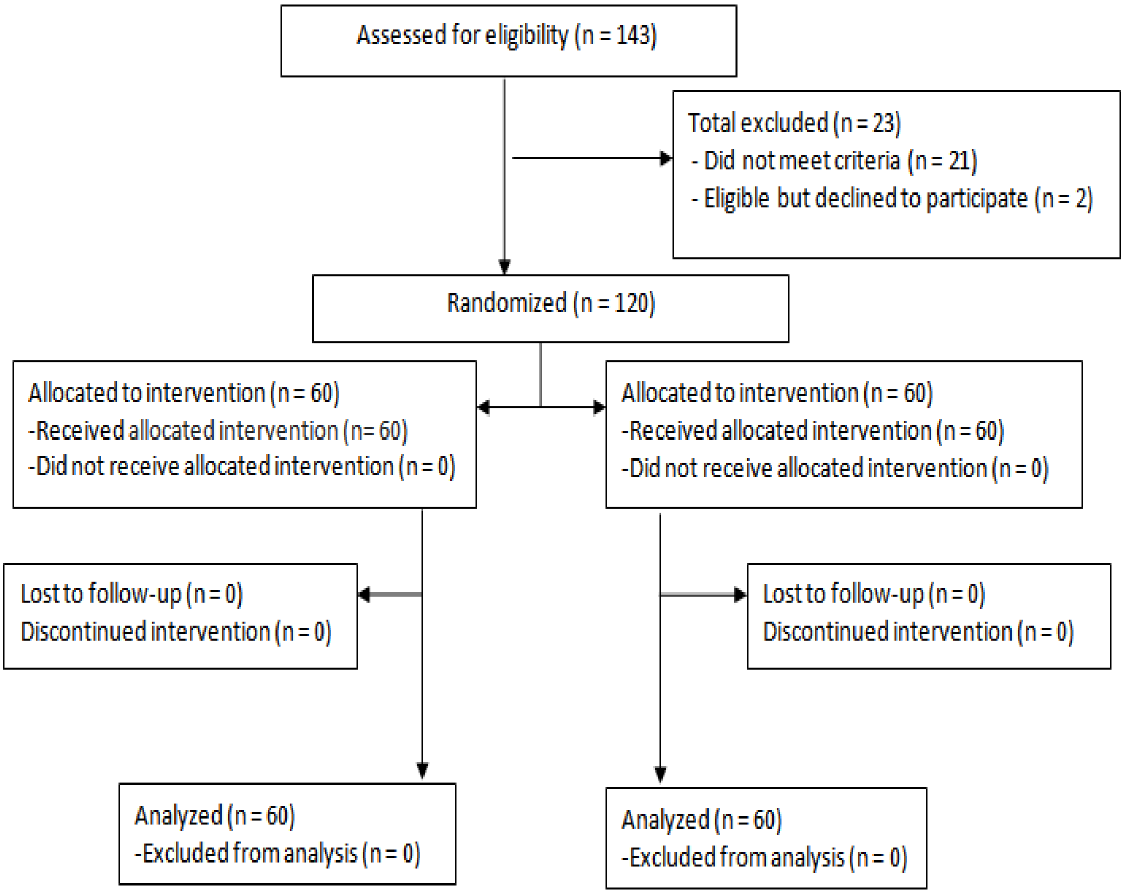

TABLES

Table 1: Socio-demographic characteristics of participants

Variables	Preoperative (n = 60)	Postoperative (n = 60)	X^2	p-value
Marital status				
Single	0(0%)	2(3.3%)		
Married	60(100%)	58(96.7%)	2.02*	0.10
Ethnicity				
Igbo	60(100%)	59(98.3%)		
Yoruba	0(0%)	1(1.7%)	1.00*	0.32
Booking status				
Booked	34(56.7%)	36(60.0%)		
Unbooked	26(43.3%)	24(40.0%)	0.14	0.71
Parity				
0	10(16.7%)	19(31.7%)		
1 - 4	45(75.0%)	38(63.3%)		
≥5	5(8.3%)	3(5.0%)	3.88*	0.15
Social class				
1	7(11.7%)	9(15.0%)		
2	9(15.0%)	10(15.7%)		
3	9(15.0%)	8(13.3%)		
4	15(25.0%)	16(26.7%)		
5	20(33.3%)	17(28.3%)	0.64	0.96
Elective cesarean section	22(36.7%)	19(31.7%)		
Emergency cesarean section	38(63.3%)	41(68.3%)	0.33	0.70

*Fisher's exact

Table 2: Clinical characteristics of participants

Variables	Preoperative	Postoperative	p-value	t
Mean age(years)	29.7±7.2	28.60±6.2	0.91	1.21
Gestational age (weeks)	37.8±1.3	37.8±1.6	0.50	0.06
Membranes rupture duration(hours)	10.16±4.5	11.06±4.9	0.43	0.74
Labor duration(hours)	13.13±6.9	12.2±7.2	0.85	0.52
Hospital stay(days)	6.9±1.7	8.2±2.3	0.06	-3.49

Table 3: Infectious morbidity rate between the groups

Outcome variables	Preoperative	Postoperative	p-value	RR/95%CI
Total infectious morbidity	2 (3.4%)	10 (16.6%)	0.015	5.00(1.14-21.86)
Endometritis	1 (1.7%)	3 (5.0%)	0.620	0.33(0.04-3.12)
Wound infection	1 (1.7%)	5 (8.3%)	0.207	0.20(0.02-1.66)
Pyrexia	0 (0%)	2 (3.3%)	0.496	0.42(0.01-1.89)

Table 4: Incidence of post-cesarean maternal infectious morbidity among women stratified by membranes status

Variables	Preoperative	Postoperative	p-value	RR/95%CI
Membranes intact	**n = 29**	**n =31**		
Endometritis	0(0%)	0(0%)	1	1
Wound infection	0(0%)	1(3.2%)	0.516	0.41(0.40-2.57)
Pyrexia	0(0%)	0(0%)	1	1
Membranes ruptured	**n = 31**	**n = 29**		
Endometritis	1(3.2%)	3(10.3%)	0.612	0.33(0.04-3.03)
Wound infection	1(3.2%)	4(13.8%)	0.188	0.23(0.03-1.97)
Pyrexia	0(0%)	2(6.9%)	0.492	0.42(0.41-2.73)

Table 5: The incidence of post-cesarean infectious morbidity between women who had elective and emergency cesarean section based on booking status

Variables	Preoperative	Postoperative	p-value	RR/95%CI
Type of surgery				
Elective cesarean section	**n =21**	**n = 19**		
Endometritis	0(0%)	0(0%)	1	1
Wound infection	0(0%)	0(0%)	1	1
Pyrexia	0(0%)	0(0%)	1	1
Emergency cesarean section	**n =39**	**n =41**		
Endometritis	1(2.6%)	3(7.3%)	0.615	0.35(0.04-3.23)
Wound infection	1(2.6%)	5(12.2%)	0.202	0.21(0.03-1.72)
Pyrexia	0(0%)	2(4.9%)	0.494	0.37(0.37-2.06)
Booking status: Booked	**n = 34**	**n = 36**		
Endometritis	0(0%)	0(0%)	1	1
Wound infection	0(0%)	1(2.8%)	0.514	0.41(0.40-2.53)
Pyrexia	0(0%)	0(0%)	1	1
Un-booked	**n = 26**	**n = 24**		
Endometritis	1(3.8%)	3(12.5%)	0.339	0.31(0.03-2.76)
Wound infection	1(3.8%)	4(16.7%)	0.173	0.22(0.03-1.84)
Pyrexia	0(0%)	2(8.3%)	0.225	0.20(0.19-1.35)