RESULT

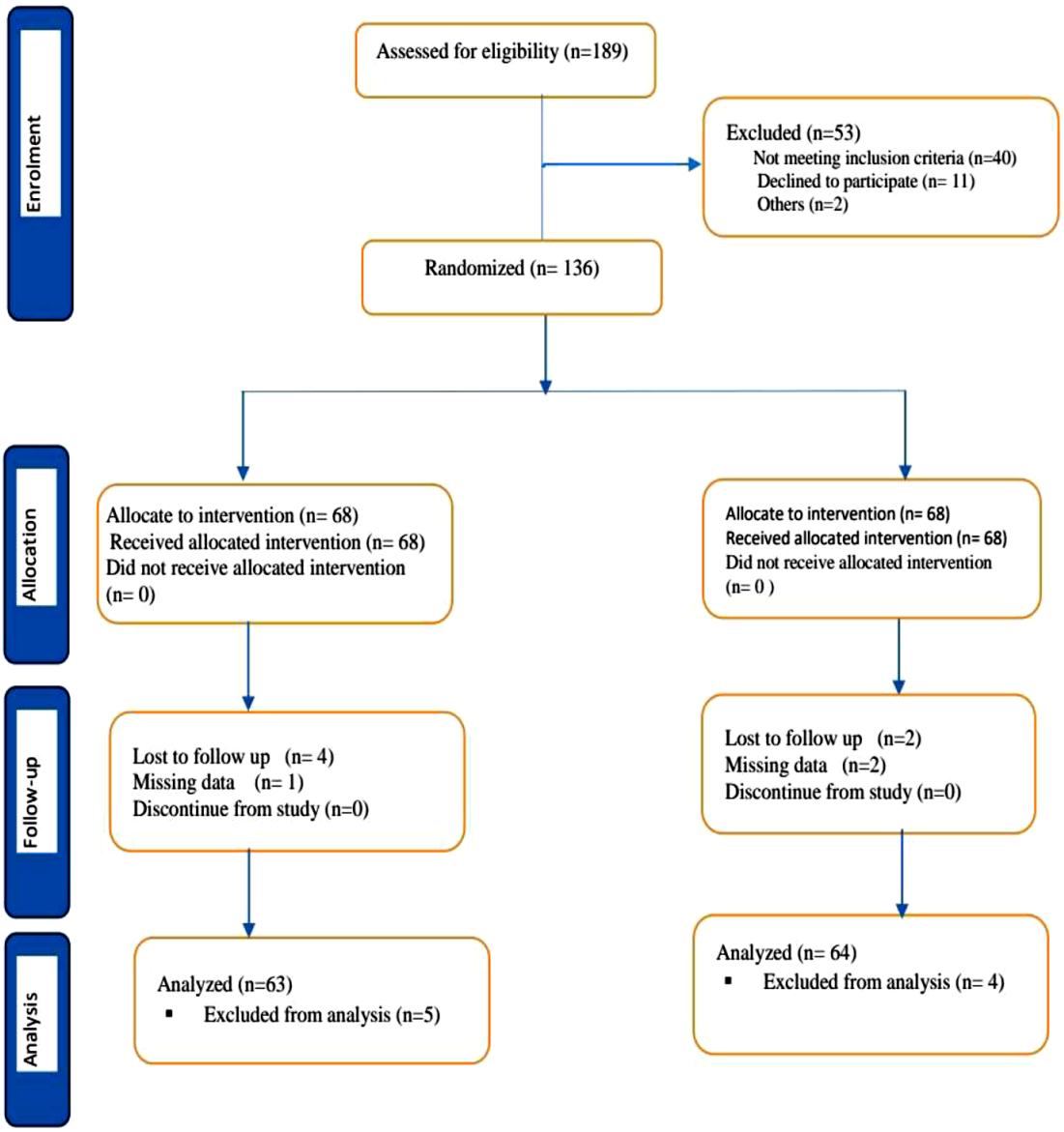

Figure I: CONSORT Flow chart for the study

This study was carried out between 28thMarch, to 18stAugust, 2023. A total of 189 women who had non-elective caesarean section during the study period were screened for eligibility, 136 eligible women who consented to participate were recruited and randomized into the study groups with 68 each into group A (Chlorhexidine group) and group B (Povidone-iodine group). Nine participants did not complete the study (3 left the hospital before collection of sample for lochia m/c/s while six were lost to follow up). The analysis was done as per protocol, so as to

assess the treatment's efficacy and safety while minimizing the impact of non-compliance or protocol violation.

Table 1: Socio-demographic characteristics of study participants

Variable	Group A n=63(%)	Group B n =64(%)	Total n=127 (%)	χ^2/t	*P-value*
Age(years)					
18-19	2(3.2)	1 (1.6)	3 (2.4)	3.433	0.410
20-24	7 (11.1)	3 (4.7)	10 (7.9)		
25-30	31 (49.2)	36 (56.3)	67 (52.8)		
31-35	14 (22.2)	13 (20.3)	27 (21.3)		
>35	9 (14.3)	11 (17.2)	20 (15.7)		
Mean ± **SD**	28.90 ± 4.82	29.71 ± 4.51	29.31 ± 4.67	3.215^t	0.422
Parity					
0-1	33 (52.4)	37 (57.8)	70 (55.1)	0.818	0.764
2-4	28 (44.4)	24 (37.5)	52 (40.9)		
≥5	2 (3.2)	3 (4.7)	5 (3.9)		
Range	5 (5-0)	6 (6-0)	6 (6-0)		
Gestational Age(weeks)					
<37	11 (17.54	10 (15.6)	21 (16.5)	1.243	0.663
37- 42	50 (79.4)	53 (82.8)	103 (81.1)		
>42	2 (3.2)	1 (1.6)	3 (2.4)		
Mean ± SD	38.92 ± 2.07	38.77 ± 2.00	38.85 ± 2.03	0.381^t	0.827
Woman's Occupation					
Professional	9 (14.3)	12 (18.8)	21 (16.5)	0.443	0.931
Skilled	21 (33.3)	19 (29.7)	40 (31.5)		
Semi-skilled	19 (30.2)	20 (31.3)	39 (30.7)		
Unemployed	14 (22.2)	13 (20.3)	27 (21.3)		
Marital status					
Married	57 (90.5)	60 (93.8)	117 (92.1)	1.363	0.531
Single	5 (7.9)	3 (4.7)	8 (6.3)		
Divorced	0 (0.0)	1 (1.6)	1 (0.8)		
Widow	1 (1.6)	0 (0.0)	1 (0.8)		
Booking Status					
Booked	21 (33.3)	26 (40.6)	47 (37.0)	0.739	0.790
Unbooked	42 (66.7)	38 (59.4)	80 (63.0)		
Educational Status					
None	0 (0.0)	2 (3.1)	2 (1.6)	2.884	0.476
Primary	6 (9.5)	3 (4.7)	9 (7.1)		
Secondary	15 (23.8)	19 (29.7)	34 (26.8)		
Tertiary	42 (66.7)	40 (62.5)	82 (64.6)		

χ^2: chi square test; t: Independent Sample test

Table 1: Highlights the socio-demographic characteristics of the participants. The mean age of the participants in group A was 28.90 ± 4.82compared to 29 .71± 4.51 years for group B. The difference in the mean age was not statistically significant (p = 0.422). There was no statistically significant difference in the distribution of the participants by their parity (p=0.764) and the gestational age at delivery (p=0.827). Majority of the participants in group A had tertiary level of education 42 (66.7%), this is similar to the participants in the group B 40 (62.5%). There was no statistically significant difference in the distribution of the participants by their occupation (p=0.931). Also, 57 (90.5%) of participants in group A were married which is similar to 60 (93.8%) in group B; this was not statistically significant (p = 0.531). Most of the participants from both groups were unbooked; 42 (66.7%) for group A and 38 (59.4%) for group B; this was not statistically significant (p = 0.790). There was no statistically significant difference in the educational status of participants in the two groups **(**p = 0.476).

Generally, there were no statistically significant differences in the socio-demographic characteristics of the participants in the two groups, this demonstrated an unbiased and well marched participant

Table 2: Obstetric parameters of study participants

Characteristics	Group A n=63 (%)	Group B n=64 (%)	Total n=127	χ^2/f	p-value
Previous CS					
Yes	17 (27.0)	20 (31.3)	37 (29.1)	11.452	0.163
No	46 (73.0)	44 (68.7)	90 (70.9)		
Women in labour before CS					
Yes	51 (80.9)	46 (71.9)	97 (76.4)	2.047	0.452
No	12 (19.1)	18 (28.1)	30 (23.6)		
State of fetal membrane before CS					
Intact	15(23.8)	13(20.3)	28 (22.1)	1.562	0.623
Ruptured	48 (76.2)	51 (79.7)	99 (77.9)		
Duration of memb. rupture before CS					
< 18 hours	40 (63.5)	41 (64.1)	81 (63.8)	1.468	0.680
≥ 18 hours	8 (12.7)	10 (15.6)	18 (14.1)		
No of digital vaginal examinations done					
0	3 (4.8)	2 (3.1)	5 (3.9)	1.582[f]	0.663
1 – 4	39 (61.9)	38 (59.4)	77(60.6)		
> 4	21 (32.3)	24(37.5)	45 (35.4)		
Duration of labour (hours)					
≤ 12	42 (66.6)	38 (59.4)	80 (63.0)	2.482	0.389
≥ 12	9 (14.3)	8 (12.5)	17 (13.4)		

χ^2: chi square test; f: Fisher's exact test

Table 2: Shows the obstetric parameters of the participants. Majority of the participants in both groups had no previous CS (group A: 46 (73.0%) and group B: 44 (68.7%) with p = 0.163. Most of the participants in both groups were in labour before decision to do CS; 51(80.9%) versus 46 (71.9%) with p = 0.452. Majority of the participants in both groups had rupture of fetal-membrane less than 18 hours before CS 40(63.5% versus 41 (64.1%); p = 0.680). Number of digital vaginal examinations done during labour was 1 to 4 among 39 (61.9%) for group A and 38 (59.4%) for group B, with p = 0.663. The duration of labour before CS was less than 12 hours for 42 (66.6%) in group A and 38 (59.4%) in group B; with p = 0.389. Over all, there were no statistically significant differences in the obstetric parameters of the participants in the two groups.

Table 3: Incidence of post caesarean section morbidity among the study groups

Variable	Group A n= 63 (%)	Group B n = 64 (%)	Total n=127(%)	f	*p* value
Post-op fever					
Yes	4 (6.3)	3 (4.7)	7 (5.5)	0.013	0.956
No	59(93.7)	61 (95.3)	120 (94.5)		
Clinical Endometritis					
Yes	1 (1.6)	2 (3.1)	3 (2.4)	0.014	0.641
No	62(98.4)	62 (96.9)	124 (100)		
Laboratory Endometritis					
Yes	2(3.2)	3(4.7)	5(3.9)	0.006	0.523
No	61(96.8)	61(95.3)	122(96.1)		

f: Fisher's exact test

Note: the pathogen cultured from lochia m/c/s/were polymicrobial; mainly *Staphylococcus aureus, Streptococcus spp, Escherichia coli and Klebsiella spp* and sensitive to clindamycin, gentamycin, amoxicillin/clavulanic acid, metronidazole and ceftriazone.

Table 3: Shows the incidence of post-caesarean endometritis among the study participants and between the two groups. The incidence of post-operative fever recorded were 7 (5.5%) among study participants, out of which in the group A, 4(6.3%) were recorded, while in group B 3(4.7%) were recorded, and the difference was not statistically significant (f = 0.013, p = 0.956). The total incidence of clinical endometritis among the participants were3 (2.4%), out of which 1(1.6%) occurred in group A, and 2 (3.1%) in group B, the difference was also not statistically significant (f= 0.014, p= 0.641). The total incidence of laboratory endometritis among participants were 5 (3.9%), out of which 2(3.2%) occurred in group A, and 3 (4.7%) in group B. The difference was also not statistically significant (f= 0.006, p = 0.523).

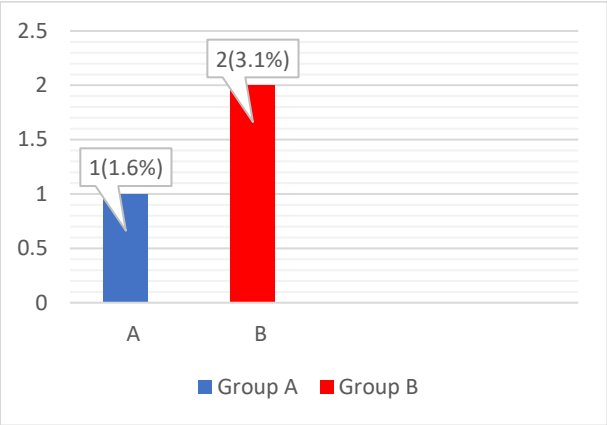

Figure IIA: Incidence of endometritis diagnosed by clinical method among study participants

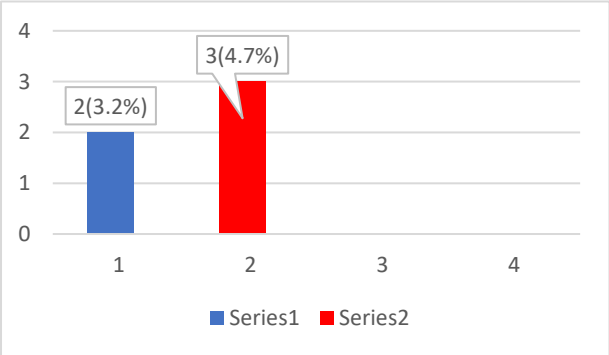

Figure IIB: Incidence of endometritis diagnosed by laboratory method among study participants

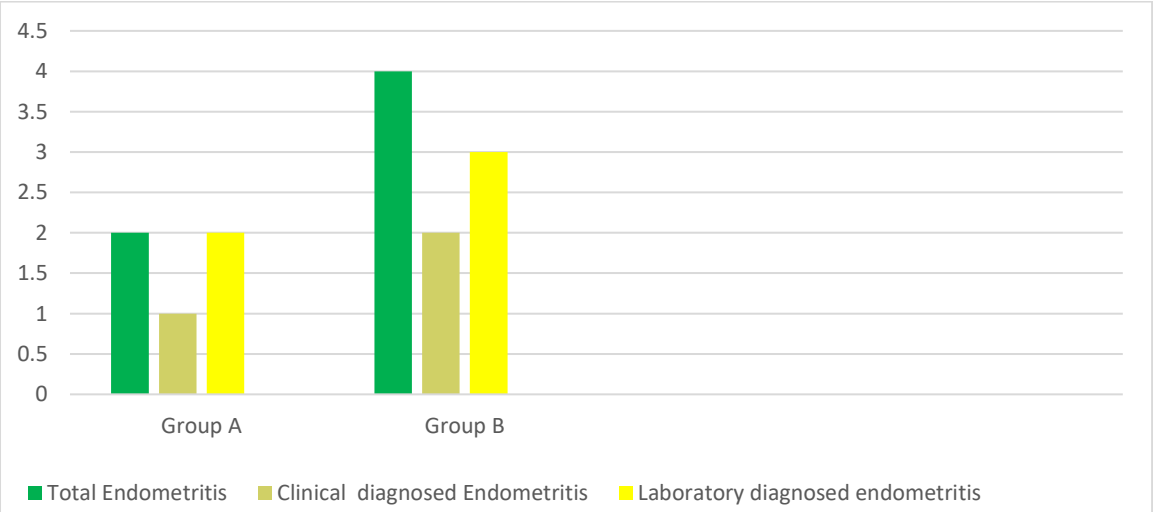

Figure IIC: Comparison of incidence of endometritis diagnosed by clinical and laboratory methods between the groups (A and B)

Figure II (A, B, C) highlighted the following:

From figure IIA, out of 63 participants in group A, 1(1.6%) was diagnosed with endometritis using clinical parameters, while out of 64 participants in group B, 2(3.1%) were diagnosed using clinical parameters. Therefore, out of 127 participants, the incidence of endometritis was 3 (2.4%) using clinical parameters.

From figure IIB, out of 63 participants in group A, 2(3.2%) were diagnosed with endometritis using laboratory parameters, while out of 64 participants in group B, 3(4.7%) were diagnosed using laboratory parameters. Therefore, out of 127 total participants, the incidence of endometritis was 5(3.9%) using laboratory parameters.

From figure IIC, out of 63 participants in group A, 1(1.6%) was diagnosed with endometritis using clinical parameters, while 2(3.2%) were diagnosed using laboratory parameters, the total incidence of endometritis in group A was 2(3.2%) from both clinical and laboratory methods, while in group B, out of 64 participants, 2(3.1%) were diagnosed with endometritis using clinical parameters, while 3(4,7%) were diagnosed using laboratory parameters, the total incidence of endometritis in group B were 4(6.2%) from both clinical and laboratory methods. Therefore, the total incidence of endometritis from the two groups (A and B) was 6 (4.7%). There was 100% concordance in the clinically diagnosed endometritis with those diagnosed with laboratory method.

Table 4: Assessment for adverse effects of vaginal cleansing agents on study participants

Variables	Group A n=63 (%)	Group B n =64(%)	Total n =127(%)	f	p-value
Adverse reaction				1.849	0.137
Vaginal dryness	5 (7.9)	4(6.3)	9 (7.1)		
Burning sensation	2 (3.2)	3(4.7)	5 (3.9)		

f: Fisher's exact test

Note: There were no cases of vaginal itching, vaginal rash or vulva swelling among any of the participants in both groups

Table 4: Revealed the maternal side effects among study participants. Vaginal dryness occurred in 5(7.9%) of the participants in group A, and 4(6.3%) of the participants in group B while vulva burning sensation occurred in 2(3.2%) of the participants in group A, and 3(4.7%) of participants in group B. The incidence of vaginal dryness and vulva burning sensation between the two groups were not statistically significant (f= 1.849, p = 0.137). None of the participants in either group experienced vaginal itching, vaginal rashes, vaginal swelling or other adverse effects.

Table5: Fetal outcome across study groups

Fetal outcomes	Group A n=63 (%)	Group B n=64 (%)	Total n=127 (%)	χ^2/f	p-value
Apgar Score at first minute					
<7	12 (19.0)	10 (15.6)	22 (17.3)	6.233	0.234
≥7	51 (80.9)	54 (84.4)	105 (82.7)		
Apgar score at fifth minutes					
<7	2 (3.2)	1 (1.6)	3(2.4)	8.134[f]	0.136
≥7	61 (96.8)	63 (98.4)	124 (97.6)		
NICU Admission					
Yes	7 (11.1)	9 (14.1)	16 (12.6)	5.512	0.358
No	56 (88.9)	55 (85.9)	111 (87.4)		
Indications for NICU admission					
Respiratory distress syndrome	2 (3.2)	1 (1.6)	3 (2.4)	6.134[f]	0.324
HIE Stage 1	0 (0.0)	1 (1.6)	2 (1.6)		
HIE Stage 2	0 (0.0)	1 (1.6)	1 (0.8)		
HIE Stage 3	1 (1.6)	1 (1.6)	1 (0.8)		
Prematurity	2 (3.2)	1 (1.6)	3(2.4)		
Jaundice	1 (1.6)	2 (3.1)	3 (2.4)		
Observation	1(1.6)	2 (3.1)	3 (2.4)		
Final Neonatal Outcome					
Discharged home	62 (98.4)	62 (96.9)	124 (97.6)	3.069[f]	0.150
Dead	1 (1.6)	2 (3.1)	3 (2.4)		

χ^2: chi square test, f: Fisher's exact test, HIE: Hypoxic-ischemic encephalopathy

Table 5: Highlights the fetal outcomes among study participants. Two (2) participants in group A and one (1) in group B had babies with five minutes APGAR scores less than 7. Again, 12(19.0%) participants in group A and 10 (15.6%) in group B had babies with first minute APGAR scores less than 7. However, the differences in the APGAR scores at fifth minutes were not statistically significant between the two groups ($p = 0.136$). In addition, 7 (11.1%) babies of mothers in group A and 9 (14.1%) in group B were admitted into the NICU although the differences were not statistically significant ($p = 0.358$). Also, the indication for NICU admission were similar in both groups ($p = 0.324$). One neonate of the participants in group A, died on admission, while 2 neonates in group B suffered the same, however the difference in the final neonatal outcome was not statistically significant ($p = 0.150$). Finally, there were no statistically significant differences in the fetal outcome of participants between the two groups. The perinatal mortality rates were 0.02 per 1000 for group A and 0.03 per 1000 for group B.

Table 6: Details of the caesarean section among the study participants

Variables	Group A n=63 (%)	Group B n =64(%)	t/f	p-value
Duration of surgery (hours)				
Mean ± SD	1.42 ±0.47	1.39 ± 0.41	7.112[t]	0.174
Range	1 (2 – 1)	1 (2 – 1)		
Type of Anaesthesia				
Regional	61(96.8)	63 (98.4)	2.435[f]	0.672
General	2 (3.2)	1 (1.6)		
Estimated blood loss (ml)				
<1000	60 (95.2)	62 (96.9)	8.324[f]	0.165
> 1000	3 (4.8)	2 (3.1)		
Mean ± SD	541.58 ±103.55	558.94±108.64	2.522[t]	0.698
Range	650 (1100-450)	580(1050-470)		
Intra-operative blood transfusion				
Yes	2 (3.2)	1 (1.6)	5.313[f]	0.246
No	61 (96.8)	63 (98.4)		

t: Independent Sample t-test, f: Fisher's exact test

Table 6: Shows details of caesarean section in the index pregnancy among study participants. The mean duration of surgery for group A was (1. 42± 0.47) hours, while in the group B it was (1.39 ± 0.41) hours. The difference was not statistically significant (t= 7.122, p = 0.174). Although majority of the participants in both groups had regional anaesthesia; 61(96.8%) and 63(98.4%), this was statistically similar (f=2.435, p=0.672). Again, 3, (4.8%) in group A and 2, (3.1%) in group B had blood loss at delivery>1000ml; but, the observed difference was not statistically significant (t=2.522, p=0.698). Two (2) had intra-operative blood transfusion represented (3.2%) in group A, and 1(1.6%) in group B, the difference was not also statistically significant (f = 5.313, p = 0.246). Generally, there were no statistically significant differences in the details of caesarean section of participants between the two groups.

Table 7: Regression analysis of risk factors for post-caesarean endometritis

Variables	Coefficient	SE	OR	95% CI	p-value
BMI (Kg/m^2)					
< 30	17.909	21.252	1.668	0.022 – 0.165	0.744
> 30	2.812	0.983	3.444	0.065 – 3.050	0.529
Number of Vaginal Examinations					
0	-14.488	1.100	0.107	2.909 – 8.413	0.821
< 4	-15.284	0.531	2.302	-8.125 – 6.520	0.651
> 4	-16.423	0.524	5.372	7.372 – 13.37	0.531
State of fetal membrane					
Membrane intact	0.875	0.878	0.417	0.075 – 2.331	0.319
Ruptured < 18 hours	0.120	0.723	2.887	0.215 – 3.656	0.243
Ruptured > 18 hours	0.457	0.853	8.638	0.563 – 5.721	0.022
Pre-operative fever					
Yes	2.909	11.252	5.668	0.022 – 0.165	0.044
No	1.909	1.252	0.668	0.022 – 0.265	0.744
Duration of labour before CS					
$\leq$ 12 hours	-1.405	0.926	0.245	0.04 – 1.51	0.229
$\geq$ 12 hours	-0.850	0.744	2.427	0.10 – 1.84	0.125
Appearance of liquor					
Clear	1.432	1.876	0.474	0.837 – 5.37	0.073
Meconium stained	0.645	1.652	4.907	0.075 – 48.55	0.054
Blood stained	0.606	1.635	8.833	0.074 – 45.20	0.018

OR: Odd Ratio; CI: Confidence Interval

Table 7: Shows simple logistic regression analysis of risk factors for endometritis between the two groups. Membranes rupture greater than 18 hours before labour, pre-operative maternal fever and blood stained liquor were the variables that showed a significant association with endometritis (with; OR=8.638, 95% CI=0.563-5.721, p=0.022), (OR=5.668, 95% CI= 0.022-0.165, p=0.044,), (and, OR=8.833, 95% CI=0.074-45.20, P=0.018) respectively. Study participants with morbid obesity (BMI >30), Intra-partum vaginal examination greater than 4 times, membrane rupture greater than 18 hours before labour, pre-operative maternal fever, meconium stained and blood stained liquor had increased odds ratio for association with endometritis as shown in table 7. However, the association between: morbid obesity (BMI >30), intrapartum vaginal examination greater than 4 times, and meconium stained liquor with endometritis were not statistically significant; with P values; 0.529, 0.531, and 0.054 respectively.

Membrane rupture greater than 18 hours and blood stained liquor had the highest odds ratio among the variables considered, (OR= 8.638 and OR= 8.833respectively).

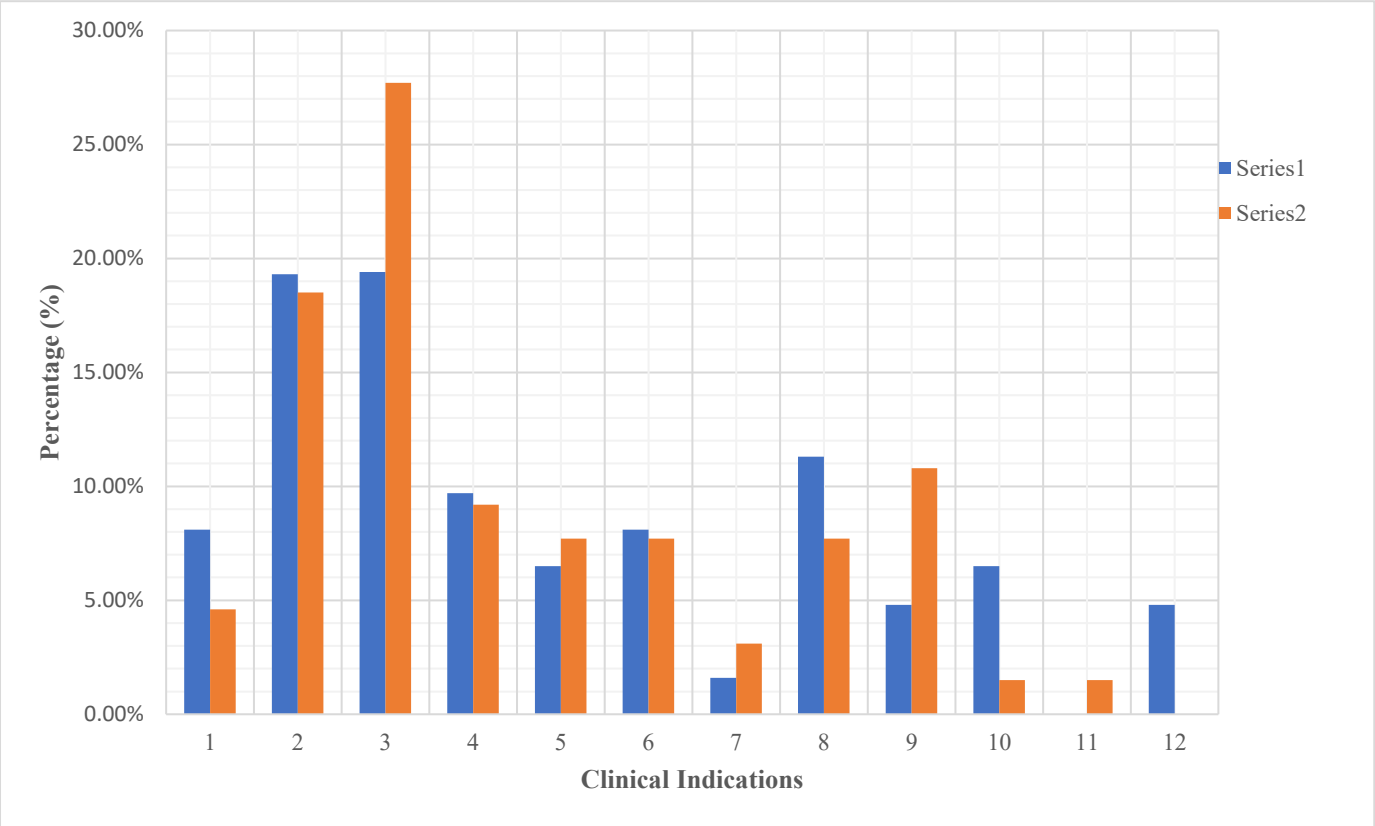

Figure III: The clinical indication for CS among the study participants

Figure III: Shows the clinical indications for CS among the participants in the two groups, the two commonest indications were hypertensive disease in pregnancy;13 (20.6%) vs. 15(23.4%) and failed induction of labour;10(15.9%) vs. 11(17.2%), for groups A and B respectively.

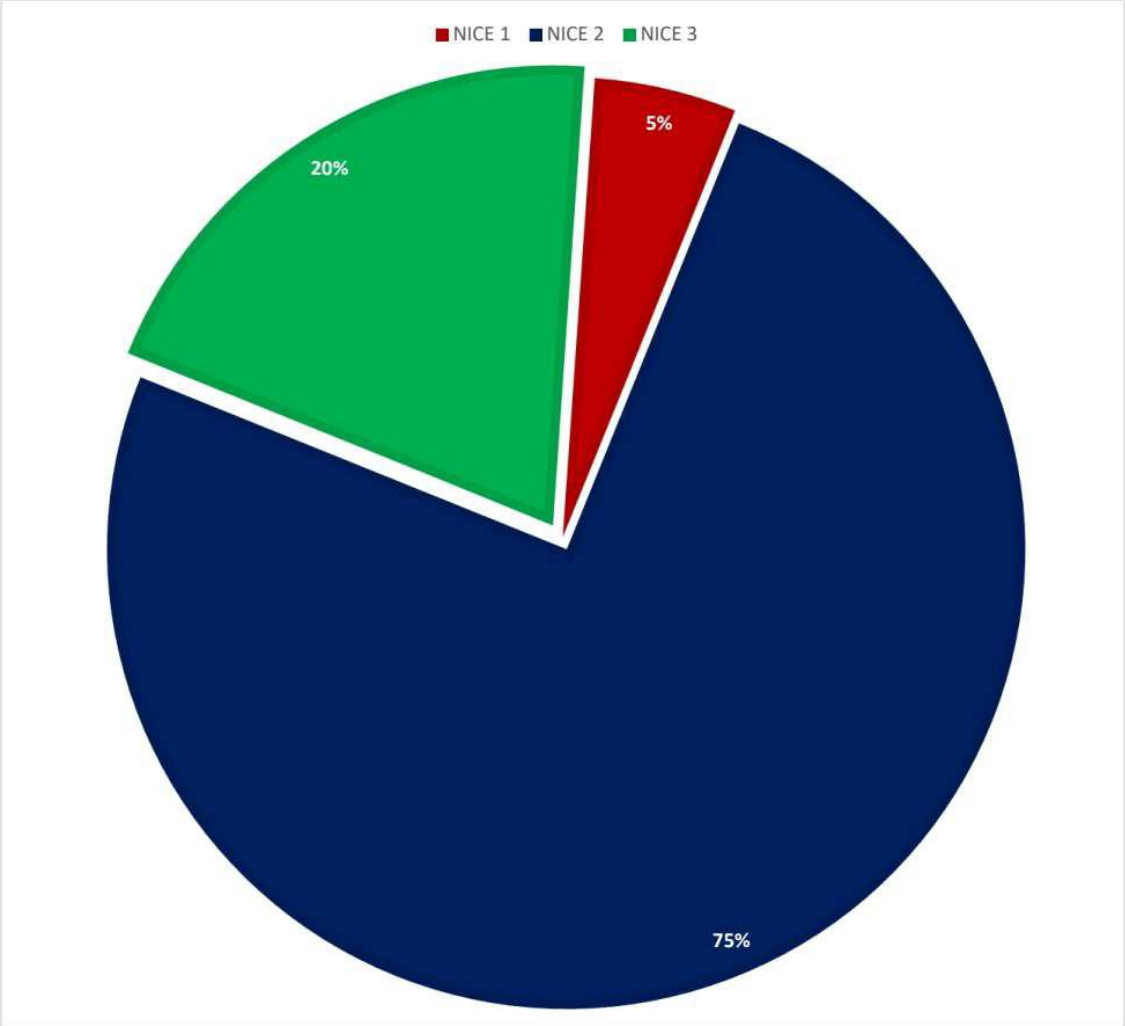

Figure IV: Category of Caesarean section by NICE

Figure IV highlights the classification of caesarean section by NICE into; category I, II and III. Majority of the indication for the caesarean section was category II; (96 [75%]), followed by category III; (25 [20%]) and category I (6 [5%]) respectively.