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Methodology: This study was conducted in the department of Obstetrics and Gynaecology of Sacred Heart Hospital, Ikorodu. In this study, a total of 51 patients that met the inclusion criteria were recruited. Diagnosis of pPROM was strictly by gentle sterile speculum with evidence of either a gush of fluid from external cervical os or pool of liquor in the posterior fornix of the vagina in antenatal patients whose gestation ages were within the inclusion criteria. Statistical Package for Science Student (SPSS) version 21 was used in the analysis of data collected.

Keywords: amnioinfusion, pregnancy, reduced liquor, pPROM.

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Results: The mean age of the patients was 26.5 years while the gestational age group 26-29 weeks constituted 51% with the mean gestational age constituting 29.7 weeks. 13.7% of the patients recruited exhibited the indices of sepsis measured compared to 86.3% that did not exhibit any evidence of sepsis. Our study did not find any statistically significant relationship between transcervical route amnioinfusion and sepsis with the chi-square being 0.123 and the relative risk (RR) of 0.750 {95% CI 0.150 to

3.750}. Latency period was greatly increased in the test group compared to the control with a chi-square (X^2) of 0.000. Only one baby in the test group had asphyxia compared to 10 babies in the control arm of the study with X^2 of 0.003. There was a statistically significant relationship between birth weight at birth in the test group compared to the control group with a X^2 of 0.000. There was no maternal or neonatal death in this study.

Conclusion: Transcervical route amnioinfusion is as safe as the transabdominal route in carefully selected patients; this route is less invasive and cheaper compared to the transabdominal method and it will find usefulness in resource-constrained environments. It raises the liquor volume and prolongs latency period in patients thereby contributing to the improvement in neonatal outcome.

Keywords: amnioinfusion, pregnancy, reduced liquor, pprom.

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I. INTRODUCTION

Rupture of membranes is an integral part of the normal and abnormal labour process.¹ Preterm premature rupture of membranes (pPROM) is defined as the spontaneous rupture of the foetal membranes before the onset of labour.¹⁻⁴ Premature rupture of membranes (PROM) complicates approximately 10% of pregnancies,

with 3% of pregnant women having pPROM before 37 weeks of gestation.^{1,5} pPROM is more likely to occur in populations of lower socioeconomic status and complicates one-quarter to one-third of preterm births.⁵⁻⁷ It is a major cause of neonatal morbidity and mortality because these babies are born preterm.⁸ Presently pPROM can be classified into pre-viable pPROM this occurs before the age of viability⁹, pPROM remote from term this occurs from the age of viability to approximately 31 weeks, and pPROM near term that occurs approximately from 32 to 36 weeks of gestation¹.

Few clinical conditions in obstetrics are as challenging as pPROM remote from term.¹⁰ Management is influenced by gestational age and the presence of complicating factors, such as clinical infection, abruptio placentae, labour, or non-reassuring foetal status.¹¹ The aetiology is multifactorial.¹ It is hypothesized that a weakness in the foetal membranes occurs as a result of either a stretch or degradation of the extracellular matrix.¹² Other factors include ascending infection from the lower genital tract that serves a potential reservoir for bacteria that ultimately ascend into the cervix to cause inflammation and infection¹, history of cervical insufficiency, antepartum bleeding, multiple gestations, previous PROM or preterm labour, tobacco use, cervical cerclage, and amniocentesis⁸. However, most cases of preterm PROM occur in otherwise healthy women without identifiable risk factors.⁹

In recent years, different strategies had been tried to decrease neonatal morbidity and mortality rates resulting from pPROM.⁸ None of these strategies has proved to be consistently effective, reproducible, or applicable to most centres.⁸ Infusing physiologic solution into the amniotic cavity was suggested as a treatment modality to prolong the latency period and prevent complications that are associated with a reduction in amniotic fluid volume in cases of pPROM.^{13,14} The latency period is defined as the interval between rupture of membranes and onset of labour.¹⁵ Amnioinfusion (AI) entails infusion of normal saline or Ringer's lactate solution into the

uterine cavity to replace the lost amniotic fluid.¹⁶ Apart from prolonging the latency period there is some evidence to show that restoring amniotic fluid volume with saline or a similar fluid following pPROM may be beneficial for preterm babies (by preventing infection, lung hypoplasia and death) and mothers (by preventing endometritis after delivery).^{17,18}

Amnioinfusion can be carried out either through the abdominal route¹⁹ or cervical route^{20,21}. Since transabdominal amnioinfusion is carried out through a sterile field compared to the transcervical route it should theoretically be associated with less risk of infection, it is not without its own risk of complications like placenta abruption and chorioamnionitis.^{8,21}

The objective of this study was to determine the usefulness of transcervical AI in prolonging the latency period of pregnancies complicated by pPROM and improvement in maternal and neonatal outcome.

II. METHODOLOGY

This study was a prospective randomized-controlled study that spanned over a 12 month period starting from January 1st 2017 to December 31st 2017 in the Obstetrics and Gynaecology unit of Sacred Heart Hospital, Lantoro, Abeokuta in Ogun State. The hospital is a 300 bedded hospital with the Obstetrics and Gynaecology unit having 88 beds in various parts of the department. The hospital is the first hospital in Nigeria with clientele from the whole of the South-West of Nigeria as well as the Republic of Benin. The hospital engages in the training of postgraduate medical doctors in family medicine as well as nursing students.

Ethical approval was sought and obtained from the Ethical committee of the hospital. All consenting pregnant women who presented to the antenatal clinic and the antenatal or labour ward that met the inclusion criteria that included singleton foetus between 26 and 33 weeks, history of drainage of liquor, objective demonstration of

drainage of liquor by sterile speculum examination in addition to ultrasound diagnosis of amniotic fluid index (AFI) is ≤ 3.0 cm, cervical dilatation ≤ 4 cm, no sign of labour, and whose foetus was alive as confirmed by ultrasound scan were recruited into the study. However, patients that declined to participate, those with multiple foetuses, intrauterine foetal death as confirmed by ultrasound scan, cervical dilatation ≥ 4 cm, ultrasound diagnosis of amniotic fluid index ≥ 3.0 cm, lethal foetal congenital anomaly, no objective demonstration of drainage of liquor by a gentle speculum examination, and presence of chorioamnionitis were excluded from the study.

Designed proforma was used to obtain the necessary information that was relevant to the study.

Written informed consent was obtained from all pregnant women that met the inclusion criteria. The target populations were those between 26 and 33 weeks + 0 days; 26 weeks was selected as the lowest cutoff point, though the age of viability in our environment is 28 weeks, this was to increase the number of patients recruited.

The unit protocol for determining eligibility for this study started with ensuring that the gestational age was between 26 weeks and 33 weeks + 0 days, the history of drainage of liquor that must be confirmed by gentle sterile speculum in the antenatal ward or labour ward depending on where the recruitment took place. The AFI of ≤ 3.0 cm and foetal viability as determined by the ultrasound scan. All patients that were eligible had AI done twice weekly using the transcervical route and ultrasound scan for foetal wellbeing monitoring before delivery. As part of routine care management of the unit all patients with pPROM remote-from-term are routinely placed on erythromycin tablet 500mg three times daily as a form of prophylaxis unless otherwise stated, and antepartum intramuscular dexamethasone injection administration for foetal lung maturity. The eligible patients were not excluded from this care management.

The unit elected to carry out the AI using the transcervical route because it is easier, less invasive compared to the transabdominal route, there was no need for any special skill to carry out the procedure, and this did not constitute an additional cost for us. Maximum of 250ml of saline was instilled during each session of AI, this is to reduce triggering uterine contractions. Strict asepsis was observed during the procedure in order to reduce the risk of chorioamnionitis to the barest minimum. There were two arms to the study ie one arm had AI and the other arm was the expectant conservative arm. The two arms were matched for gestational age; this was done in order to assess if AI had any effect in prolonging the latency period thereby leading to an improvement in neonatal outcome.

SPSS version 21 was used in the analysis of data

Maternal outcome:

Final gestational age at delivery

Sepsis/endometritis

Need to change antibiotics from prophylaxis to treatment

Death

Neonatal outcome:

Birth weight

Apgar score

Antepartum foetal death

Neonatal death

III. RESULTS

During the period of study, the total delivery recorded in the Obstetrics Unit of the hospital was 1,699, pPROM complicated 139 of the patients; this gives an incidence of 8.2% in the hospital. 51 patients that met the inclusion criteria were recruited for this study. There was neither maternal death nor neonatal death amongst the studied population. The table.1 displayed the sociodemographic data of the patients recruited for this study; a total number of patients that met the inclusion criteria and recruited for the study was 51 and their gestational ages were between 26

and 33weeks + 0 days respectively. 33.3% of the patients were between the age range of 21 – 25years while only 3.9% were 36years and above. As part of the inclusion criteria for this study the gestational age of patients was from 26weeks to 33weeks, those within 26 - 29weeks constituted 51% and those within 30 – 33weeks were 49% respectively. 23.5% of the patients were nullipara while 3.9% were para4 and above. The patients in the upper socioeconomic class constituted 11.8%, the middle class constituted 64.7%, and the lower class were 23.3%. Table 2 shows the relationship between the two arms of the study group, the two arms were matched for gestational age and there was no statistically significant relationship between the two groups. Figure 1 shows the bar chart depicting the indices of sepsis in both mothers and their foetuses; the indices assessed included maternal pyrexia, maternal tachycardia, uterine tenderness, and foetal tachycardia. Those that had the indices of sepsis present were 7(13.7%) while those without these indices were 44(86.3%) respectively. Figure 2 shows the pie chart depicting those that had prophylactic and treatment with antibiotic respectively. Those that had antibiotic treatment were 10(19.6%) and the patients that had prophylactic antibiotic were 41(80.4%). Table 3 showed that there was no statistically significant relationship between transcervical amnioinfusion and risk for sepsis using the transcervical route with the X^2 of 0.123 and the relative risk (RR) being 0.750 {95% CI 0.150 to 3.750}. Table 4 shows the cross-tabulation between amnioinfusion and latency periods; there is a statistically significant relationship between amnioinfusion and latency period with the X^2 of 0.000. Table 5 shows the cross-tabulation between amnioinfusion and Apgar score of babies whose mothers had amnioinfusion and those that did not, there was also a statistically significant relationship with the X^2 of 0.003, as shown in this table also the Apgar was better in the babies whose mothers had amnioinfusion.

Table 6 showed the relationship between AI and weight of babies in the two arms of the study, the

babies in the test arm were heavier at delivery compared to the babies in the controlled arm with a statistically significant relationship between AI and weight.

Table 1: Sociodemographic characteristics of the population studied

Age(years)	Frequency	Percentage
≤20	11	21.6
21-25	17	33.3
26-30	18	15.7
31-35	13	25.5
≥36	2	3.9
Gestational age range(weeks)		
26-29	26	51
30-33	25	49
Parity		
0	12	23.5
1	18	35.3
2	15	29.4
3	4	7.8
≥4	2	3.9
Socioeconomic status		
Upper class	6	11.8
Middle class	33	64.7
Lower class	12	23.3

Table 2: Gestational age against amnioinfusion

		Amnioinfusion		X^2
		yes	No	
GA	26-29	14	12	0.494
	30-33	11	14	
Total		25	26	

Table 3: Risk for sepsis against AI through the vaginal route

	Risk for sepsis		X^2
	Yes	No	
Amnioinfusi on Yes	3	22	0.123
No	4	22	
Total	7	44	

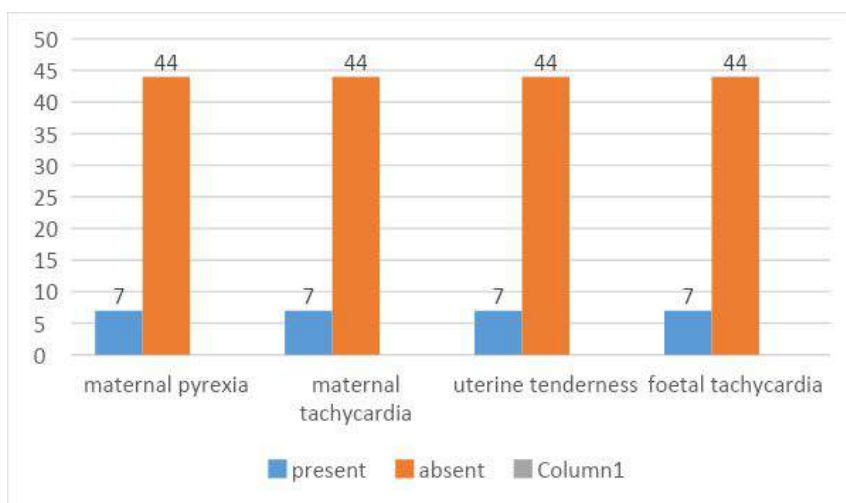


Figure 1: Indices of sepsis in mothers and fetuses

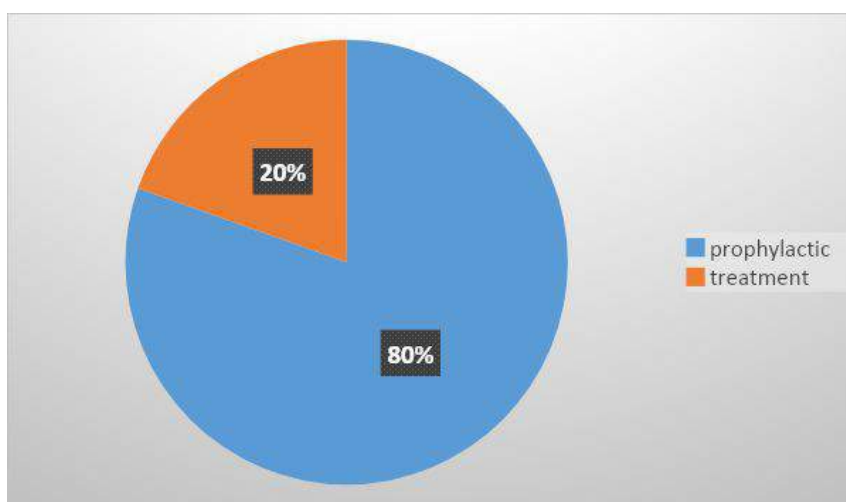


Figure 2: Prophylactic and treatment with antibiotics

Table 4: Relationship between amnioinfusion and latency period

		Latency period			X ²
		<7days	<14days	>14 – 21	
Amnioinfusion	Yes	2	8	15	0.000
	No	16	5	5	

Table 5: Relationship between amnioinfusion and APGAR scores

		APGAR		X ²
		No asphyxia	Asphyxia	
Amnioinfusion				
Yes		24	1	0.003
No		16	10	

Table 6: Relationship between amnioinfusion and weight of babies at delivery

		Weight				X ²
		<900g	900-1500g	1501-2000g	>2000g	
Amnioinfusion	Yes	0	5	15	5	0.000
	No	11	10	4	1	
Total		11	15	19	6	

IV. DISCUSSION

Preterm premature rupture of membranes is one of the leading causes of perinatal morbidity and mortality. Methods to improve neonatal outcome include amnioinfusion; this can be carried out through the transabdominal or vaginal route. None of these methods is devoid of complications. Drainage of liquor triggers labour irrespective of the gestational age, the labour could be spontaneous or iatrogenic. Preterm labour is associated with neonatal morbidity and/or mortality. The volume of residual amniotic fluid is associated with prolongation of latency period and improvement in perinatal outcome.²³The aim of this study was to determine the usefulness of prophylactic transcervical AI in patients with pPROM between gestational age of 26 and <34weeks in prolonging latency period, and in reducing morbidities associated with preterm delivery.

Theoretically, there is the risk of the possibility of sepsis associated with transcervical AI^{8,21}, this was not found to be so in our study evidenced by the non-statistically significant relationship between the route chosen for this study and risk for sepsis. The indices for sepsis assessed revealed very few of the participants exhibiting such; only 10 (19.6%) out of the total number of patients recruited needed complete antibiotic treatment. The import of this finding is that with proper patient selection and under strict asepsis AI can be carried out using the transvaginal route as well with minimal risk of sepsis.

The latency period in the intervention group was also found to be prolonged compared to the

control group; this finding was consistent with findings in Cochrane review by Hofmeyr et al¹⁷, van Teeffelen et al¹⁸, Fatima et al²³, Gazetti et al²⁴, and Qazi et al²⁵. Apgar scores of the babies were significantly improved with only one baby being asphyxiated compared to 10 babies in the control arm. This procedure also had a positive influence on the weight of these babies though this was not found to be so in the Cochrane review carried out by Hofmeyr et al¹⁷. This stands to reason since the increase in latency will translate into a longer duration of pregnancy and ultimately increase in birth weight. During the period of this study, no perinatal death was recorded this high survival rate is comparable with the high survival rate found by Locatelli et al²⁶ as well as Hofmeyr et al¹⁷ where a high survival rate of 92% and 87.3% respectively were recorded in patients that had amnioinfusion compared to the control group.

In conclusion, in carefully selected patients and observing strict asepsis transcervical AI is as safe as transabdominal route AI. This route ie transcervical AI is less invasive compared to transabdominal route AI and it will definitely find usefulness in the resource-constraint environment thereby contributing to the reduction on neonatal morbidity and mortality.

Conflict of interest:

The authors have none.

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