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Outcome of Induction of Labour Using 25μg Misoprostol in North Central Nigeria: A 5 - Year REVIEW.

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Abstract
Background: *Induction of labour is a very common procedure in obstetrics that is not without complications if proper patient selection is not followed.*
Material & Methods: *The aim of the study is to determine the incidence of Induction of Labour (IOL), indication and most importantly the outcome of labour when 25ug of misoprostol is used for IOL This was a retrospective study conducted from January 1, 2015 to December 31, 2019 at the University of Abuja Teaching Hospital Gwagwalada. A total of 264 parturient had IOL with misoprostol during the study period.*
Results: *The rate of induction of labour was 2.5%, the most common indication for induction of labour was prolonged pregnancy (43.9%). 50.4% of the parturients gave birth after a dose of 25ug of misoprostol. 81.8% of parturients had successful vaginal delivery while 18.2% had caesarean section due to failed IOL. The commonest maternal complication was perineal laceration. A total of 6 neonates died.*
Conclusion: *Induction of labour with 25ug of misoprostol was associated with a good foeto-maternal outcome however the need for careful patient selection prior to IOL cannot be overemphasized.*
Key Words: *Induction of labour, incidence, indications, maternal and fetal outcome*

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I. Introduction

Induction of labour is one of the most important and common interventions in obstetric practice.[1–3] Labour is induced when the maternal and fetal risk associated with continuing the pregnancy outweigh the risk of delivery.[2,4,5] Careful patient selection is critical for labour induction to succeed as failure means a resort to caesarean section, which tends to contribute to the current increase in the Caesarean section rate.[6,7]

Induction of labour is defined as the initiation of uterine contractions after the 28th week of gestation and before the onset of natural labour by medical and or surgical means for the purpose of normal delivery.[1] Over the past several decades, the incidence of labour induction has continued to rise with variations from region to region. Recent data indicate a percentage of induction of up to 35.5% in Sri Lanka, 24.5% in the United States and from 6.8% to 33% in Europe.[8–10] Induction of labour is underutilized in Africa at 4.4%, with an unmet need of 66.0- 80.2%. It accounts for 6.3% of deliveries in Nigeria.[11] A study in UATH done earlier revealed an induction rate of 14.3%.[12]

The indications for induction should be specific and justifiable. These indications are grouped into maternal and fetal indications. The maternal indications include; hypertensive disorders of pregnancy, abruption placentae, premature rupture of membranes, chorioamnionitis, polyhydramnios, diabetes mellitus and renal disease. Fetal indications include post-term, hemolytic disease, IUGR, unstable lie, fetal abnormality and IUFD.[1,2,4] Induction of labour is sometimes performed for social reasons in the absence of medical and obstetrics reasons.[13]

Labour can be induced via pharmacological and mechanical means. Pharmacological means involves the use of prostaglandins (PG E_1 –Misoprostol, PG E_2 –Dinoprostone) and use of oxytocin. Mechanical methods involve extraamniotic saline solution infusion, laminaria tent, the hygroscopic dilator, or extra-amniotic Foley catheter placement or cervical ripening balloon and amniotomy.[1,2,4] Prostaglandin E_1 analogue is the most common agent used in induction of labour in many places. It is given vaginally at a dose of 25µg every 4-6hours.[4,5] Oral administration of prostaglandins is not recommended at term because of gastrointestinal side effects.[2,4] In the past 100µg of Misoprostol was being used for nulliparous patients and 50µg for multiparous patients in the University of Abuja Teaching Hospital. This dosage was associated with increased risk of uterine rupture necessitating the use of 50µg for all paturients. Recently the WHO recommended dose of 25µg Misoprostol was adopted.

Induction of labour is associated with both maternal and fetal complications which include; uterine hyperstimulation and tachysystole, failure of induction, premature separation of the placenta, rupture of the uterus, laceration of the cervix, intrauterine infection, PPH, fetal distress leading to asphyxia and need for immediate care and admission of the newborn in the neonatal care unit.[1,4] This study was designed to assess the outcome of induction of labour using 25µg Misoprostol in our facility.

As the proportion of women undergoing induction grows, there is a constant search for more efficacious ways to induce labour while maintaining fetal and maternal safety as well as patient satisfaction. Prostaglandins (PGE1-misoprostol and PGE2- dinoprostone) have been extensively studied and found to effective induction agents that increase vaginal delivery rates within 24 hours, decrease the need for oxytocin administration, and have no effect on the caesarean rate in women with an unscarred uterus.[14–16]

Misoprostol is a synthetic PGE1 analog and FDA-approved in an oral form (Cytotec®, Pfizer) for use as a gastric protectant in patients treated with NSAID's. Although not approved for induction of labour, the oral tablet had been extensively used off-label vaginally, orally, and sublingually since the 1980s for cervical ripening and labour induction.[14,15,17] Advantages of misoprostol over dinoprostone includes it's low cost, stability at room temperature, and accessibility, although some of the drawbacks include difficulty in dosing the tablet fragments accurately and the inability to discontinue the medication if uterine tachysystole or fetal heart rate tracing abnormalities arise.[18]

Hoffmeyr et al published one of the largest meta-analysis on induction of labour, including 121 randomized trials, of which 13 were double-blind, and found that compared with intracervical PGE2 and oxytocin, vaginal misoprostol in doses above 25ug every 4 hours was associated with fewer failures to achieve vaginal delivery within 24 hours and less need for oxytocin, although had a higher rate of uterine tachysystole with and without fetal heart rate changes. A 25ug tablet inserted vaginally every 24 hours had similar efficacy to intravaginal or intracervical dinoprostone (PGE2) with regard to delivery time.[15]

A systematic review compared mechanical methods (Foley catheter balloon) with locally applied prostaglandins (vaginal PGE2, cervical PGE2 and vaginal misoprostol). This systematic review included 27 randomized controlled trials that included 3532 participants. When compared with all locally applied prostaglandins (LAPG) combined there were no differences between mechanical methods and prostaglandins in caesarean deliveries, participants with cervices that were unfavourable or unchanged after 12 to 24 hours, maternal fevers, 5-minute Apgar scores less than 7, or admission of the neonate to a SCBU. Women who received LAPG were less likely to require oxytocin augmentation than those receiving mechanical methods but were more likely to experience excessive uterine activity defined as tachysystole, hypertonus, or hyperstimulation syndrome. There was significant heterogeneity noted for the outcomes of excessive uterine activity, vaginal delivery within 12-24hours and need for oxytocin augmentation.[19]

A systematic scoping review of quantitative studies of common indications for IOL using systematic reviews/meta-analysis, randomized control studies that compared maternal and neonatal outcomes for different modes or timing of birth supports IOL for women with post-term pregnancy, although the evidence was weak for the timing (41 versus 42weeks), and for women with hypertension/preeclampsia in terms of improved maternal outcomes. For women with preterm prelabour rupture of membrane (24-37weeks), high quality evidence supports expectant management rather than IOL/early birth. Evidence is weakly supportive for IOL in Women with term rupture of membranes. For all other indications there were conflicting findings and/or insufficient power to provide definitive evidence.[20]

Local studies in Nigeria have shown that misoprostol is a common prostaglandin E1 analogue used for induction of labour with appreciable outcome when proper patient selection, good preparation, as well as adequate feto-maternal monitoring are taken into consideration.[21–23]

A study in UATH by Dr Adebayo et al compared the use of 25ug and 50ug of misoprostol for IOL and showed that there was no significant difference between the effectiveness and safety of the two doses.[12]

This study was designed to assess the efficacy of 25ug of misoprostol for induction of labour, the fetal as well as the maternal complications associated with the use of 25ug of misoprostol. As more studies need to be done with a view for 25ug misoprostol being licenced for induction of labour.

Aim and Objective: To determine the incidence, indications and feto-maternal outcome of labour induction using 25µg Misoprostol at University of Abuja Teaching Hospital, Gwagwalada

II. Materials And Methods

This was a retrospective study of outcome of induction of labour using Misoprostol in 264 paturients at the University of Abuja Teaching Hospital Abuja between January 1, 2015 to December 31, 2019.

Study Design: Retrospective study

Study Location: The University of Abuja Teaching Hospital is one of the tertiary Hospitals in the Federal Capital Territory located in Gwagwalada area council. It's geographical coordinates are 8^0 56' 29'' North and

7^0 5' 31'' East. The hospital serves the surrounding environs of kogi, Nassarawa, Niger and Kaduna States. Attendance to the Hospital is by self presentation, and referral from public and private hospitals.

Sample Size: 264 patients

Procedure: Socio-demographic and Clinical data were obtained from labour, postnatal and theatre records. The information obtained were coded and transferred into a profoma designed for the study. There were 264 parturients who had induction of labour with Misoprostol during the Study period. The data was analyzed using simple percentages.

III. Results

The total number of deliveries during the study period of 5 years was 10416 out of which 264 had induction of labour for various reasons. The rate of induction of labour was 2.5%. Table 1 shows the maternal characteristics of the women who had induction of labour at UATH. Their ages ranged from 17 to 40 years with a mean age of 30.2 years. Majority 105/264 was between the ages of 30-34 years. One hundred and thirteen (42.8%) were primigravidae, 138(52.3%) were multiparous while 13(4.9%) were grandmultiparous. Majority of the women 215(81.4%) were induced at term, 49(18.6%) were induced before term. Two hundred and eight (78.8%) had unfavourable Bishop Score while 56(21.2%) had favourable Bishop Score.

Table 1 Maternal characteristics

	N	%
Age (years)		
<20	4	1.5
20-24	23	8.7
25-29	88	33.3
30-34	105	39.8
35-39	38	14.4
>40	6	2.3
Parity		
0	113	42.8
1-4	138	52.3
≥5	13	4.9
Gestational age		
28-36	49	18.6
$37\text{-}41^{+6}$	215	81.4
Bishop score		
0-4	208	78.8
5-8	56	21.2

The most common indications for induction of labour in this study were postdated/prolonged pregnancy 116(43.9%), followed by hypertensive disorders of pregnancy 67(25.4%), IUFD 42(15.9%) and PROM at term 27(10.3%). This is shown in table II below.

TableII: Indicaton for induction of labour

Indication for induction	N	%
Post date	116	43.9
Hypertensive disorders	67	25.4
IUFD	42	15.9
PROM at term	27	10.3
Others*	12	4.5
Total	264	100

*Others IUGR, congenital anomaly and GDM at term.

Table III below shows that majority of patients went into labour 133(50.4%) following administration of a dose of 25µg of misoprostol, 96(36.4%) after two doses, 21(7.9%) after 3 doses and 14(5.3%) after 4 doses. The maximum doses used were 4.

Table III: Number of Doses of 25µg Misoprostol used

	N	%
No of doses		
1	133	50.4
2	96	36.4
3	21	7.9
4	14	5.3

Table IV overleaf shows that 216(81.8%) had successful induction of labour which led to vaginal delivery while 48(18.2%) had failed induction leading to caesarean section. The highest indication for failed induction of labour was fetal distress 25(52.1%) and CPD 23(47.9%). Adverse maternal events was as follows perineal laceration was the commonest complication 14(56%), PPH 8(32%), uterine hyperstimulation 2(8%) and uterine rupture 1(4%). There were no cases of infection and uterine tachysystole

Table IV: Maternal Outcome

	N	%
Mode of delivery		
SVD	216	81.8
C/S	48	18.2
Indication for C/S		
CPD	23	47.9
Foetal distress	25	52.1
Maternal complications		
Ruptured uterus	1	4
PPH	8	32
Perineal laceration	14	56
Uterine hyperstimulation	2	8

Table V shows the fetal outcome. Two hundred and thirteen (80.7%) were alive and 51(19.3%) were dead this included those that presented with IUFD, fresh stillbirth due to hypertensive disorders, congenital anomalies and early neonatal death. Neonates with Apgar score less than 7 at 1 and 5 minutes were 32(15%) while 181(85%) had Apgar score greater than 7 at 1 and 5 minute. Twenty- two patients were admitted into the neonatal intensive care unit 19(86.4%) were alive and 3(13.6%) died subsequently. The reasons for admission were birth asphyxia 15(68.2%) and sepsis 7(31.8%).

Table V: Fetal Outcome

	N	%
Foetal outcome		
Alive	213	80.7
Dead	51	19.3
Apgar scores at 1 and 5 minute		
< 7	32	15
> 7	181	85
SCBU admission		
Yes	22	10.3
No	191	89.7
Eventual SCBU admission		
Alive	19	86.4
Dead	3	13.6
Reason for admission		
Birth asphyxia	15	68.2
Presumed sepsis	7	31.8

IV. Discussion

The IOL rate of 2.5% found in this study is lower than the 6.6% and 6.5% that were seen in Maiduguri North-eastern Nigeria and Bayelsa of Niger Delta region.[24,25] However it was similar to 2.35% and 3.6% reported in Kano and Sokoto respectively.[23,26] These figures are low compared to reports from developed world like United States where rates of 24.5% were seen. The reasons for lower induction of labour was attributed to the cost and inconvenience of hospital admission, the belief that the procedure was painful and result to caesarean section if unsuccessful and poor record keeping of hospital information could have attributed to this.

The commonest indication for induction of labour was postdate pregnancy in 43.9% and hypertensive disorder 25.4%. This is similar to some studies in Nigeria.[22,23,26–29] Induction of labour after 40 weeks is justified to reduce perinatal mortality, which increases after this period due to reduction in the function of an ageing placenta. Most of the indications for induction of labour were medically indicated as there were no reasons to induce labour on social grounds. However, induction of labour for social reasons accounted for 5-10% of cases particularly in some developed nations.[30]

The success rate for induction of labour in this study was 81.8%. this was similar to 83.5% reported in Kano but lower but lower than 85% and 90.4% from studies in Bayelsa and Benin city.[24,31] The study in Benin was possibly high because it considered only term pregnancies while other studies were unselective. Majority of

patients 86.8% required between 1 and 2 doses of 25µg of misoprostol this is similar to 85% requiring between 1 and 2 doses of 50µg misoprostol from a study by Lawani et al in Cross River State.[13]

The study revealed that 18.2% of patients had caesarean section due to unsuccessful IOL. This is similar to studies in Jos 17.8% but lower than studies seen in Sokoto 22.5% and Lagos 32.3%.[22,23,28] The reasons for the caesarean section included failed induction where labour failed to establish despite the use of maximum doses of 25µg misoprostol, fetal distress and cephalopelvic disproportion. Caesarean section becomes unavoidable under such situations. There is therefore the need for proper and adequate counseling with good patient pre-assessment before labour is induced.

The maternal complications in this study included perineal laceration. Primary post partum haemorrhage ruptured uterus and uterine hyperstimulation. These complications were also seen in some studies.[24,29,32] There were 2 maternal mortalities due to primary post partum haemorrhage and an underlying retroviral disease giving a case fatality rate of 0.9%. Though IOL is not without risk there is need to reinforce the safety of the procedure when there is a clear indication.

The eventual neonatal outcome shows that there were 85% of neonates with good Apgar scores and out of the 22 admitted in to the NICU, 3 eventually died. Thus IOL is still of immense benefit when the risk of continuing the pregnancy outweighs the risk of delivery.

V. Conclusion

The main indications for induction of labour in this study were postdated pregnancy and hypertensive disorders. Labour induction was mostly achieved following the use of a single dose of 25µg of misoprostol with associated good fetal outcome. Therefore the need to carefully select patients for induction of labour is very vital. The induction rate in this study was quite low compared to other studies thus it is important for the institution to convert to digital means of keeping medical records to avoid loss of vital patient information from the manual means currently being practiced though there is a high aversion to caesarean section in our environment which lead to delay in patient presentation when they are scheduled for an elective IOL.

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