RISK FACTORS FOR UNSUCCESSFUL INDUCTION OF LABOUR AT MOWBRAY MATERNITY HOSPITAL

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DECLARATION

I, **Dr Tsitukenina Ruffine Mfutila**, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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DEDICATION

This thesis is first dedicated to all women in Sub Saharan Africa who are at the mercy of a health system and who cannot afford an OBGYN specialist. You have been my actual university and the motive for pursuing and achieving this study.

Secondly, I dedicate this thesis to my beloved children Christopher Ngunda Matanda, Dave Mfutila Matanda, Micheal Nlanda Matanda, Offrael Nsimba Mawunsu, and Christelle Nlanda Nzonzo. Dear beloved children, you can achieve more than what I did in my life; only believe in yourself and trust the Lord.

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LIST OF ABBREVIATIONS

BMI	Body mass index
CD	Caesarean delivery
CS	Caesarean section
CTG	Cardiotocograph
FDA	Food and Drug Administration
GDM	Gestational diabetes mellitus
HIV/AIDS	Human immunodeficiency virus/Acquired immunodeficiency syndrome
HREC	Human research ethics committee
IGT	Impaired glucose tolerance
ICU	Intensive care unit
IOL	Induction of labour
IUGR	Intrauterine growth restriction
IUFD	Intra uterine fetal death
IV	Intravenous
LMIC	Low- and middle-income country
MMH	Mowbray Maternity Hospital
MOU	Midwife obstetric units
NICE	National Institute for Health and Care Excellence
NICU	Neonatal intensive care unit
PROM	Pre-labour rupture of membrane
PGE1	Prostaglandin E1
PGE2	Prostaglandin E2
SIOL	Successful induction of labour
USIOL	Unsuccessful induction of labour
UCT	University of Cape Town
WHO	World Health Organization

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ABSTRACT

BACKGROUND

Induction of labour (IOL) is a commonly performed obstetrical procedure. Over time, the rate of IOL has varied from region to region, with a progressive increase and almost doubling of the incidence in some developed countries.[1] According to the World Health Organization (WHO), IOL may account for up to 25% of all term deliveries in developed countries and account for only 4.4% of deliveries on average in African countries.[2] Major concerns associated with IOL are the potential for increased risk of emergency caesarean delivery (CD), iatrogenic prematurity and cost. The increasing IOL rates worldwide have resulted in debates on the cost benefit ratio of this procedure. There is no consensus on what constitutes unsuccessful IOL (USIOL). Some studies consider failure to achieve vaginal delivery as USIOL. Another view is that, since the purpose of IOL is to cause a non-labouring woman to go into labour, failure to achieve active labour should be the definition of USIOL. More accurate prediction of USIOL would provide useful information for the obstetrician and the women being counselled for IOL. For this study, unsuccessful IOL was defined as failure to achieve 5 cm cervical dilation (onset of active labour) despite IOL methods.

The main aim of this study was to identify factors associated with USIOL at the Mowbray Maternity Hospital (MMH), a regional referral hospital in Cape Town.

METHODS

This was a retrospective observational study**.** We identified women undergoing IOL in MMH labour wards between 01/01/2019 and 31/03/2019 and reviewed their medical records. Women having IOL with preterm gestations less than 34 weeks, with intra-uterine fetal death, with multiple pregnancy and prior caesarean delivery were excluded. Data was collected on background factors, indications for IOL, obstetric factors and outcomes. It was hypothesised that hypertension as the indication for IOL would be a significant risk factor for USIOL, and a sample size of 240 was estimated to be appropriate. Ethics approval was obtained from the Human Research Ethics Committee of the faculty of Health Sciences of the University of Cape Town (UCT).

RESULTS

Of the 240 women who commenced IOL during the study period, 223 were eligible for inclusion. SIOL (achieving active labour; ≥5 cm cervical dilatation) occurred for 169 (75.8%) women and USIOL occurred for 54 (24.2%).

The study revealed two factors statistically associated with USIOL: nulliparity, and low birthweight. In the USIOL group, 51.9% were nulliparous compared to 33.1% of SIOL (p=0.013). In the USIOL group, 18.5% of babies weighed less than 2.5 kgms compared to 8.3% in SIOL (p=0.006). Hypertension as an indication for IOL, as hypothesised in the sample size estimation, was not a determinant for USIOL. The most frequent indications for IOL were Prolonged pregnancy (31.8%), Hypertension (26%), Pre-labour rupture of membranes (13.5%), and 'Other' category (29%) which was a composite of several less common indications. There were no significant differences in IOL indications between SIOL and USIOL groups.

The USIOL group had a higher proportion of IOLs performed that were late preterm (34 to 36^{+6} weeks) compared to SIOL which correlates with the significantly lower birthweight in this group. Body Mass Index of the total study population was ≥ 30 kgms/m² (obesity) for 134 women (60%), yet this study did not show an association between body mass index and USIOL (p=0.864).

For the method of IOL, a higher proportion of the USIOL group had misoprostol (66.7%) compared to SIOL (58.6%); whereas a higher proportion of the SIOL group had intracervical catheter (40.2%) than the USIOL group (31.5%), but these differences were not statistically significant. The mean Induction to Delivery (I-D) intervals, was 18h43min for the whole study group; 18h19min for SIOL and 19h57min for USIOL. The caesarean delivery rate for the whole study group was 35%. By definition, it was 100% in the US IOL group. Of the 169 women with SIOL, 26 (15.4%) had emergency caesarean delivery, of which 46.1% were for an abnormal CTG, 34.6% for failure to progress into active labour, and 15.4% for an undiagnosed breech in labour. In the USIOL group, the majority of CD, 37 (68.5%) were performed for an abnormal CTG with only 14 (26%) being done for a truly failed IOL that did not progress into active labour despite receiving IOL methods. There were no major adverse maternal or perinatal outcomes in SIOL or USIOL groups, with 7 babies (3% of the whole study group) requiring admission to the neonatal unit.

DISCUSSION AND CONCLUSION

The study revealed two factors statistically associated with USIOL: nulliparity, and low birthweight. The higher proportion of low birthweight babies in the USIOL group, suggests undetected intrauterine growth restriction that may have been associated with the higher rate of CTG abnormalities in this group requiring CD, and/or the non-significant increase in the proportion of late preterm gestations. Hypertension, as hypothesised in the sample size estimation was not a risk factor for USIOL. The majority of women with USIOL had CD for an abnormal CTG during the process of IOL, rather than failure to progress into active labour, related possibly to high-risk fetuses or the IOL method employed.

Of note, the success rate for IOL was 75.8%, the overall CD rate of 35% in women commencing IOL was less than the average for MMH; and there were few maternal and perinatal complications. This information is valuable when counselling women for IOL at MMH.

CHAPTER ONE: INTRODUCTION

1.1. INTRODUCTION

Induction of labour (IOL) is a commonly performed obstetrical procedure. Over time, the rate of IOL has varied from region to region, with a progressive increase and almost doubling of the incidence in some developed countries.[1] According to the World Health Organization (WHO), IOL may account for up to 25% of all term deliveries in developed countries and accounts for only 4.4% of deliveries on average in African countries.[2] Recent data indicates induction rates of up to 35.5% in Sri Lanka,[3] 24.5% in the United States,[4] and an increase from 6.8 to 33% in Europe.[5]

The lower rates of IOL in Low- and Middle-income countries (LMICs) is probably accounted for by reduced access to maternity care services and resource constraints. The major concerns associated with induction of labour are the potential for increased risk of caesarean delivery (CD), iatrogenic prematurity and cost.[6] Emergency caesarean delivery when compared to simple vaginal delivery is in turn associated with a higher rate of excessive blood loss, postpartum infection and maternal mortality.

However, findings from the ARRIVE study[7] concluded that labour induction in low-risk nulliparous women resulted in a significantly lower frequency of caesarean delivery and hypertensive disorders of pregnancy than expectant management. They suggested that one caesarean delivery may be avoided for every 28 deliveries among low-risk nulliparous women for whom elective induction of labour at 39 weeks is planned.

There is no consensus on what constitutes failed or unsuccessful IOL (USIOL). There are several definitions employed in the literature in observational and randomised trials, which include failed entry into active labour,[8] failed vaginal delivery,[9] and failed labour after a certain number of ripening agents.[10] Thus, there is lack of standardisation even among randomised controlled trials.

USIOL remains a concern for health care professionals, and its accurate prediction would provide useful information for the obstetrician and inform the way patients are counselled about IOL.[11]

Some studies have found that the following are risk factors associated with USIOL: an unripe cervix, nulliparity, and obesity, with both studies defining “failure” as not achieving a vaginal delivery,[12.13] Hypertension has also been studied as a risk factor for

USIOL. A retrospective cohort study[14] on "Hypertension and patterns of induced labour at term" reported that women with a more chronic disease process such as chronic hypertension or superimposed pre-eclampsia required more time to progress through the first stage of labour.

1.2 JUSTIFICATION OF THE STUDY

At the Mowbray Maternity Hospital (MMH) in Cape Town, the success rate of IOL is not known and little is known about the risk factors associated with USIOL. Women commencing IOL may achieve active labour and have vaginal delivery with good outcomes, others may achieve active labour but require emergency Caesarean Delivery (CD) for fetal distress or obstructed labour; and another group will require a caesarean section for USIOL defined as not achieving active labour despite IOL methods. An exploratory review of the theatre register at MMH shows that at least 20 caesarean deliveries are performed per month for USIOL. This study aimed to assess the risk factors associated with USIOL at the Mowbray Maternity Hospital. This will enable the institution and the health care providers to have data when counselling women for IOL and could guide clinical decision making on IOL.

For this study, USIOL was defined as failure to achieve 5 cm cervical dilation (onset of active labour) despite IOL methods. This was the definition of active labour onset used in the Western Cape at the time the study was performed and illustrated in the partogram in the Maternity Case record. No time limit was prescribed since there is a practice in Metro West hospitals to give a day's break if initial attempts at non-urgent IOL do not cause labour, and then to recommence.

1.3 STUDY QUESTION

What are the risk factors for unsuccessful IOL at the Mowbray Maternity Hospital in Cape Town, South Africa?

1.4 AIMS OF THE STUDY

The overall aim is to identify the factors associated with unsuccessful IOL at the Mowbray Maternity Hospital, Cape Town.

1.5 SPECIFIC OBJECTIVES

1. To determine the proportion of IOLs at MMH that are unsuccessful using the definition described in Section 1.2
2. To determine the factors associated with unsuccessful IOL at the Mowbray Maternity Hospital, Cape Town
3. To determine the main indications for IOL at the Mowbray Maternity Hospital Cape Town.
4. To describe the IOL to delivery interval, the mode of delivery and maternal/fetal outcomes in all women commencing IOL.

CHAPTER TWO: LITERATURE REVIEW

2.1. INTRODUCTION

This chapter explores and presents a brief literature review related to the study objectives. The literature review includes five sections: a brief review of the different definitions of USIOL, the main indications for IOL, the risk factors associated with USIOL, the rates of CD for IOL, and the methods used for IOL.

2.2. UNSUCCESSFUL IOL: A BRIEF REVIEW OF DEFINITIONS

There is lack of standardisation of the definition of USIOL. Observational and randomised trials have used different definitions: failed entry into active labour,[8] failed vaginal delivery,[9] and failed labour after a certain number of ripening agents.[10]

A randomised multicentre trial[8] defined failed labour induction as a failure to enter active labour from the latent phase despite at least 12 hours of oxytocin after membrane rupture. In this study, a woman was considered to be in the latent phase of labour until her cervical dilation had progressed to 4 cm and was at least 90% effaced, or to 5 cm regardless of effacement.[8]

A successful labour induction was defined by Rouzy et al[9], as the proportion of women achieving vaginal delivery within 24 hours after treatment initiation.

Other authors argue that, since vaginal delivery is the main outcome for IOL, then caesarean delivery (CD) performed after commencing IOL constitutes an USIOL, even if it is due to other factors occurring during labour, and not linked to the process of IOL.[15]

The OPRA study[10] defined USIOL as failed cervical ripening after 2 or more consecutive doses of PGE2. This study compared clinical outcomes from outpatient versus inpatient cervical PGE2 ripening for low-risk labour induction. Ten out of 425 patients (2.3%) had failed ripening and required caesarean delivery.

Another discourse about unsuccessful IOL is whether it should be linked to a specified time cut off for the procedure, at which stage a CD would be performed. In 2014, following the American College of Obstetricians and Gynaecologists (ACOG) and Society for Maternal-Fetal Medicine (SMFM) workshop on preventing the first caesarean delivery,[16] a joint ACOG/SMFM Obstetric Care Consensus document was released:

"Safe Prevention of the Primary Caesarean Delivery". This document recommended that before deeming an IOL to have failed, oxytocin should have been administered for at least 12 to 18 hours after membrane rupture. In situations where the maternal and fetal status allow, caesarean deliveries for failed induction of labour should be minimised by allowing longer durations of the latent phase (up to 24 hours since the initiation of the induction). Furthermore, a cervical dilatation of 6 cm was recommended to define active labour. Kawakita et al[17] used the 6 cm threshold to define entry into the active phase. Previous research has also shown that 96% of patients who reach 4 cm dilation ultimately reach 6 cm.[18]

It has been suggested that economic costs and bed availability relating to the duration of IOL should be taken into consideration when deciding on the definition of USIOL.[8] For example, integrated economic costs, in the context of resource constraints and high-pressure regarding bed availability and occupancy, could limit the time for allowing the process of IOL to continue; and thus define time limits for IOL.

The table below presents a summary of USIOL definitions reviewed from various studies. These studies have in common the inability to achieve active labour as the main outcome.

Table 1. Summary of reviews that define USIOL

(Table adapted from Banos N, Migliorelli F, Posadas E, Ferreri J & Palocio M. ***[15]****)*

Author	Year	Study	Main Outcome	Induction methods	Definition of unsuccessful IOL
Xenakis[19]	1993	Prospective observational	Unsuccessful IOL	Bishop's score; <7: PGE_2 3 mg/6 hrs Bishop's score >7: oxytocin infusion	Inability to achieve active phase of labour (cervical dilation ≤4 cm despite adequate exposure to cervical

					priming and oxytocin stimulation) after 15 hrs in primipara / 12 hrs in multipara
Roman[20]	2004	Prospective observational	Reaching active phase of labour	PGE_2, oxytocin + amniotomy	Inability to achieve active phase of labour (cervical dilatation ≤5 cm despite adequate uterine contraction activity)
Yang[21]	2004	Prospective observational	Reaching active phase of labour	Bishop's score <4: PGE_2 Bishop's score >4: oxytocin infusion	Inability to achieve active phase of labour (cervical dilation <4 cm despite regular contractions) after 48 hrs
Park[22]	2007	Prospective observational	Unsuccessful IOL	Bishop's score <4: PGE_2 × 9 hrs +	Inability to achieve active phase of labour

				oxytocin 12 hrs	(cervical dilatation of ≤4 cm within 12 hrs of initiating oxytocin) within 24 hrs of induction
Park[23]	2009	Prospective observational	Unsuccessful IOL	Bishop's score <4: PGE_2 × 9 hrs + oxytocin 12 hrs Bishop's score >4: oxytocin	Inability to achieve active phase of labour (cervical dilatation of ≤4 cm within 12 hrs of initiating oxytocin) or within 24 hrs of induction

2.3. THE MAIN INDICATIONS FOR IOL

A case series by Malende[24] conducted in a regional hospital in rural KwaZulu-Natal in South Africa in 2014 found that the three main indications for IOL were hypertensive disorder of pregnancy (43.6%), prolonged pregnancy (25.9%) and pre-labour rupture of membranes (14.7%). Similar results were found in a Pretoria study, conducted by Mbele.[25]

Internationally, there is a debate on whether IOL at term, without any medical indication, can be beneficial. The ARRIVE trial[7] has supported IOL in low-risk nulliparous women at 39 weeks without any medical indications for IOL. It showed strong evidence that IOL in low-risk nulliparous women resulted in a significantly lower frequency of caesarean

deliveries and hypertensive disorders of pregnancy compared to expectant management. The authors suggested that one caesarean delivery may be avoided for every 28 deliveries among low-risk nulliparous women who undergo elective IOL at 39 weeks. Currently this policy is not practised in the public sector in South Africa

Patients with gestational hypertension are usually induced at 38-40 weeks to reduce unfavourable fetal and maternal outcomes.[26] Pre-eclampsia may warrant earlier delivery at 34 weeks to avoid adverse feto-maternal complications associated with pre-eclampsia. Evidence from the Hypitat study[27] showed that induction of labour is associated with improved maternal outcome compared to expectant management and should be advised for women with mild hypertensive disease beyond 37 weeks gestation. This also correlates with findings from the ARRIVE study[7] where induction of labour in nulliparous women at 39 weeks resulted in a significantly reduced frequency of caesarean delivery and hypertensive disorders of pregnancy compared to expectant management.

A Cochrane review on IOL showed that the most common indication for IOL is prolonged pregnancy with frequency between 0.5 and 10%.[28] According to the American College of Obstetricians and Gynaecologists (ACOG),[29] IOL is recommended for women who are at 41 weeks of gestation or later, due to increased perinatal risks. The most serious associated problems with prolonged pregnancy are intrapartum related birth asphyxia, meconium aspiration, feto-pelvic disproportion and post maturity syndrome.

The 2016 Guidelines for Maternal Care in South Africa[30] recommends induction of labour beyond 41 weeks with certain gestation of the pregnancy. At 41 certain weeks of gestation, stretching and sweeping of the membranes is recommended and mothers must be referred from a clinic or community health centre to a district hospital for induction of labour within the next three days.

For women with pre-labour rupture of membrane (PROM) at term, it is usually accepted to induce labour to prevent fetal infection.[31] Expedited induction of labour after PROM reduces the risks of chorioamnionitis, endometritis, and admissions to a neonatal intensive care unit.

Systematic reviews by Mozurkewich and Wolf[32] and Dare et al[33] compared expedited induction of labour with conservative management for PROM. Expedited induction was defined as commencing between 2 and 12 hours after rupture of membranes.[32,33] Conservative or expectant management was usually defined as observation from 24 hours

to 4 days after rupture of membranes followed by induction if spontaneous labour did not result. Both systematic reviews found reduced incidence of chorioamnionitis and endometritis with expedited induction of labour compared with expectant management. Dare et al[33] found that a policy of expedited labour inductions reduced admissions to the NICU.

Other indications for induction of labour include suspected macrosomia, isolated oligohydramnios, and diabetes.

There is still controversy about IOL for suspected macrosomia. YW Cheng et al[34] compared women who had IOL at 39 weeks gestation with a neonatal birth weight of 4000 $\pm$ 125g with women who delivered (either induced or spontaneous labour) at 40, 41 or 42 weeks. They concluded that in the setting of known birth weight, it appears that IOL may reduce the risk of caesarean delivery. However, Mozurkewich et al[35] concluded that IOL does not improve outcomes in the setting of suspected fetal macrosomia.

There are discordant opinions about the need to induce labour in women with isolated oligohydramnios. A meta-analysis found empirical evidence that these women had a higher CD rate due to fetal heart abnormalities with lower Apgar scores, while there were no differences in fetal acidosis.[36] The above study had included high risk and preterm pregnancies. However, no retrospective studies of isolated oligohydramnios at term[37,38] demonstrated a difference in neonatal acidosis, perinatal death, or neonatal intensive care unit admissions from otherwise normal pregnancies with IOL for this indication[39].

A meta-analysis study carried out by Boulvain et al[40] found that diabetes was an important indication for IOL. Gestational diabetes mellitus (GDM) and impaired glucose tolerance (IGT) in pregnant women affect between 3 to 6% of all pregnancies, and both are associated with adverse perinatal complications.[41] The NICE guideline[42] recommends pregnant women with pre-existing diabetes and no other complications to have an elective birth by IOL, or by CD if indicated, between 37^{+0} weeks and 38^{+6} weeks of pregnancy, and that women with GDM give birth no later than 40^{+6} weeks.

Other studies had shown some evidence regarding IOL for other indications such as twin gestation, cholestasis of pregnancy, maternal cardiac disease and fetal gastroschisis[35]. Overall post-term pregnancy and hypertension remain the most frequent IOL indications in most series.

2.4. RISKS FACTORS ASSOCIATED WITH UNSUCCESSFUL IOL

IOL may account for up to 25% of all term deliveries in developed countries and for only 4.4% of deliveries on average in African countries as per WHO[2].

Various studies [28, 43-44] have documented many factors that predict both unsuccessful and successful IOL. Predictors of unsuccessful IOL include Bishop's score <6, nulliparity, gestational age >41 weeks, maternal age >30 years, pregnancy complicated by hypertension or pre-eclampsia, pre-labour rupture of membranes (PROM), isolated oligohydramnios, gestational diabetes or pre-existing diabetes, estimated fetal weight above 4 kgms, and body mass index (BMI) above 30[45]. Park[43] found that labour induction for PROM at term in nulliparous women with an unfavourable cervix was associated with longer duration of the second stage of labour and a higher risk of caesarean delivery for failure to progress in comparison to those with intact membranes. Wolfe, Rossi & Warshak[45] showed that women who had class III obesity (BMI > 40 kg/m^2) without having a prior vaginal delivery, as well as a macrosomic fetus were found to have an 80% rate of USIOL which is one of the highest reported rates of USIOL.

Socio-demographic and clinical factors have been explored in the literature as possible risk factors for USIOL. Studies reported that induction success declined as maternal age increased and gestational age approached 42 weeks.[46] There appears to be a linear relationship between maternal age and caesarean delivery rate, with increasing caesarean delivery rates with increasing maternal age.[47]

A study conducted by Admani et al[48] in Kenya at Kenyatta National Hospital found that multiparity is associated with SIOL. Furthermore, the likelihood of USIOL decreases in multiparous women as their uterine muscle is more easily stimulated to contract.[48] In South Africa, a study conducted in the Johannesburg Hospital by Basu and Jeketera[49] found that greater BMI and positive HIV status were both independently associated with USIOL. This study showed that 40% of the study population were obese. The HIV prevalence among antenatal women for the Western Cape Province was 17.9%[50] when our study was performed and it will be important to see if this is a risk factor for USIOL in our study, as it was in the Basu study.[49]

In their retrospective multicentre study, Kerbage et al[51] found that, in all class III obese patients who underwent IOL, 37.5% had a caesarean delivery.

The Bishop's score is used to assess the cervix at the start of induction of labour with a score of 6 or less indicating an unfavourable cervix and a score of 8 or more a favourable one.

A systematic meta-analysis done in Ethiopia by Melkie et al[52] found that an unfavourable Bishop's Score, intermediate Bishop's Score, and primiparity were significantly associated with failed induction. However, another systematic literature review of 40 articles done by Kolkman et al[53] concluded that the Bishop's score was a poor predictor for the outcome of induced labour at term and should not be used to decide whether to induce labour or not.

Different clinical models with scoring systems have been developed to predict the success of labour induction.

The only study done in South Africa by Mbele[25] regarding a scoring system showed that factors for unsuccessful IOL included primigravidity, pre-eclampsia, a low Bishop's score and intact membranes. Mbele, proposed his own scoring system with the aforementioned parameters (see Appendix 2). Mbele advised that a woman with a low composite score should be counselled about this and advised to have CD. Mbele[25] also concluded that the score must be tested prospectively on a new population to determine the real value of the score.

In 2018, Alavifard et al[54] internally validated a clinical prediction scoring model for SIOL using variables which included maternal demographic data, antenatal history, Bishop's score, maternal age, pre-pregnancy weight, pre-pregnancy BMI, weight at delivery, parity, and gestational age, to determine the likelihood of vaginal delivery. The main limitation of the study was the high proportion of missing data: they were unable to investigate the potential predictive value of four variables (cervical effacement, consistency, position, and fetal station) due to more than 10% of the values being missing.[54]

Levine et al[55] also developed a nomogram for predicting the probability of caesarean delivery after IOL with an unfavourable cervix. They found that maternal BMI at delivery, height, parity, gestational age ≥40 weeks at induction, and modified Bishop's score were independent risk factors for caesarean delivery. Using these factors, they developed and externally validated a model, and created an on-line tool that can be utilised to calculate

the likelihood of caesarean delivery for women undergoing induction with an unfavourable cervix. Limitation of the model was it could only be applied to women who met the same inclusion criteria as for the study and may not be generalisable to all other women.

In conclusion, a systematic review identified 14 models validated between 1966 and 2018 that uses maternal demographics, clinical findings and cervical characteristics as variables to predict the success of IOL.[56] The review concluded that no published model can be recommended for use to determine success of vaginal birth after labour induction due to limitations of all the models.[56]

2.5. RATES OF CAESAREAN DELIVERY FOR WOMEN UNDERGOING IOL

Several authors have argued that there is an increased rate of maternal and perinatal morbidity associated with IOL. This may be due to the underlying condition for which the IOL is performed or due to an associated increased CD rate from the procedure. Recently the notion that IOL increases CD rates has been challenged.[57] A Cochrane review concluded that CD rates and assisted vaginal delivery rates are not increased by IOL at term when a medical indication exists.[39] Evidence was presented showing that a policy of IOL at or beyond 41 weeks of gestation improves perinatal outcomes without increasing the CD rate.[58, 59] However, conflicting results concerning CD rates were reported for IOL at a gestation below 40-41 weeks.[60, 61]

Mbele[25], in his study on IOL in South Africa, found that 52.4% of patients had achieved vaginal delivery within 24 hours with a CD rate of 42.1%. Common indications for CD were fetal heart changes (22.8%) and unsuccessful induction (12.4%). The maternal morbidity rate was 6.9%. This included 33 primary postpartum haemorrhages (5.9%) nine abruptio placentae (1.6%) and 1 uterine rupture (0.2%). There was one maternal death following uterine rupture. Mbele[25] concluded that inductions of labour should only be performed for medical or obstetric indications and not because of patient or care provider preference.

A study conducted in Ethiopia[62] found a CD rate in induced women of 24%. Out of those who were delivered by CD, 25 (30.1%) were done for failed induction, other indications for CD were non-reassuring fetal heart rate pattern 41 (49.4%), cephalopelvic disproportion 14 (16.9%), intrapartum haemorrhage 2 (2.4%) and secondary labour arrest 1 (1.2%).

In other studies in women undergoing IOL, the CD rate increased 2-3-fold in medically uncomplicated nulliparous women at term undergoing IOL compared with spontaneous labour.[63]

In another study[64] comparing the efficacy and safety of 50 microgram intravaginal misoprostol every 4 hours compared to 0.5 mg of intracervical prostaglandin E_2 (dinoprostone) every 6 hours, the CD rate was 132 out of 537 (24.6%) for women randomised to misoprostol and 135 of 524 (25.8%) for those randomised to dinoprostone.

In a study[65] conducted on 138 women undergoing IOL for gestational hypertension at the Department of Obstetrics and Gynaecology, Liaquat University of Medical and Health Sciences Jamshoro for the period of one year from 1st January 2015 to 31st December 2015, delivery outcomes were as follows: normal vaginal delivery in 64.49% women, instrumental vaginal delivery in 7.2%, and emergency caesarean delivery in 28.3%. Of the 39 women having CD 30.76% had the CD for failed IOL, and 69.23% had the CD for maternal or fetal reasons.

In a study on IOL conducted by Ndovie[66] at New Somerset Hospital in Cape Town, the CD rate was 41.9%. The three main indications for CD were fetal heart changes (72%), failed induction of labour (21%) and cephalopelvic disproportion (7%).

A review of CD trends in Australia[67] suggested that increasing CD rates were related to changes in clinical decision making and women's preferences so that more women were opting for elective CS in preference to IOL.

In summary, different case series in different settings give different rates of CD for women having IOL. CD are done for failed IOL, poor progress in active labour and fetal heart abnormalities in the women being induced.

2.6. METHODS OF INDUCTION OF LABOUR

Three types of IOL methods are described, which include pharmacological, medical and surgical methods. All are outlined below.

1) Pharmacological methods

Misoprostol is a prostaglandin E1 analogue approved by the Food and Drug Administration (FDA) for the prevention and treatment of peptic ulcer disease in patients taking non-

steroidal anti-inflammatory drugs. It has also become an important drug in obstetric and gynaecologic practice because of its uterotonic and cervical ripening activity.[68] In contrast to other prostaglandin preparations, misoprostol does not require refrigeration or parenteral administration and it is also inexpensive. A Cochrane Pregnancy and Childbirth Group analysed 45 randomised trials of sound methodological quality, which collectively included more than 5400 women. The trials included in this meta-analysis compared vaginal misoprostol with placebo, oxytocin, prostaglandin E_2 (PGE2), or oral misoprostol. Vaginal misoprostol (25-100 mcg) was more effective than oxytocin or vaginal PGE2 at effecting vaginal delivery within 24 hours, without an increase in the frequency of uterine hyperstimulation associated with fetal heart rate changes.[69] Compared to induction of labour with oxytocin alone, induction with misoprostol was associated with an overall reduction in CD rates. However, CD rates were no different for women induced with misoprostol compared with women induced with PGE2.[70] In recent research[63] comparing different prostaglandins, low-dose oral misoprostol solution was associated with lower rates of CD, for both fetal heart rate abnormalities and poor progress in labour. All methods were generally safe, but the main complication of uterine hyper-stimulation was highest with high-dose vaginal misoprostol, and lowest in women induced with double-balloon catheter (two fluid-filled balloons either side of the cervix).

In a study[64] comparing the efficacy and safety of 50 microgram intravaginal misoprostol every 4 hours with dinoprostone 0.5 mg gel intracervically every 6 hours, it was noted that misoprostol was more effective than dinoprostone for labour induction. However, the significantly increased incidence of abnormal fetal heart rate tracings and the trend to increased CD for fetal distress in the misoprostol group was concerning. A prospective case-control study[70] conducted in Ranchi, comparing the effect of induction of labour with vaginal misoprostol versus PGE2 gel on the incidence of pathological cardiotocography tracings, also reported a higher incidence of CTG abnormalities in the misoprostol group. Misoprostol was associated with greater incidence of suspicious and pathological CTG tracing and tachysystole. These non-reassuring CTG findings were found to be associated with meconium-stained liquor, low Apgar scores at one minute, increased need for resuscitation and NICU admission, which are all parameters that indicate intrauterine fetal hypoxia.

A randomised controlled study conducted by Mackenzie[71] that compared PGE2 and placebo indicated a dramatic decline in the rate of USIOL and prolonged labour with use of prostaglandin. A Cochrane systematic review study[72] of PGE2 as a method for IOL also showed that the use of PGE2 reduced the failure of achieving vaginal delivery within a time limit of 24 hours when compared with the placebo. Other trials comparing PGE2 with a placebo find that the use of PGE2 reduces the need to use oxytocin. More conclusively, when compared with a placebo, PGE2 increased the rate of vaginal delivery within 24 hours. However, PGE2 as an IOL method, may increase uterine hyperstimulation and lead to fetal heart rate changes.

A study[73] that assessed the use of oxytocin alone as a method for IOL revealed that intravenous (IV) oxytocin in comparison with expectant management improved the likelihood of attaining vaginal delivery within 24 hours. Conversely, Oxytocin is less effective than PGE2 in achieving vaginal delivery in the next 24 hours; and is associated with a higher CD rate.

At MMH, misoprostol 25 microgram orally given twice 30 minutes apart as test doses, followed by 50 microgram 4 hourly orally is the preferred prostaglandin regimen for induction of labour. Patients are monitored for intensity of uterine contractions, signs of uterine hyperstimulation, CTG abnormalities 30 minutes before and after each dose of misoprostol.

2) Mechanical methods

The 2019 South African Society of Obstetricians and Gynaecologists (SASOG) Better Obs guidelines[74] suggested that membrane sweeping is an option to increase the chance of spontaneous labour. It recommended that membrane sweeping be offered prior to IOL in low-risk patients and patients should be informed about possible discomfort and/or vaginal bleeding from the procedure.

One study[75] found that the use of membrane sweeping was closely correlated with the probability of starting labour within 48 hours and correlated with a decreased risk of being undelivered within one week. However, the use of membrane sweeping as an IOL method was linked to more vaginal bleeding and maternal discomfort.[75]

Hazel[76] describes the use of intra cervical catheter/ Foley catheter as a method of IOL, and also argues that Foley catheter bulb induction can be used in women who previously

delivered by CS. The use of Foley bulb catheter is considered to be a mechanical method of IOL that enables SIOL with less risk of maternal and foetal complications.[76] Evidence[77] has been put forward that a Foley bulb catheter could be used without harm to ripen the cervix when a woman is considering a labour trial after CS. A study done by Owolabi, Kuti & Ogunlola[78] compared the safety and efficacy of intravaginal misoprostol and intracervical Foley's balloon catheter for pre-induction cervical ripening and labour induction. Patients requiring IOL with unfavourable Bishop's score (≤ 4) were randomised prospectively to receive either 50 mcg intravaginal misoprostol every 6 hrs for a maximum of two doses, or an intracervical Foley balloon catheter for 12 hrs followed by an intravenous oxytocin infusion. The two arms of the study were comparable with respect to maternal age, parity, gestational age, indication for induction, and initial Bishop's scores. There was significant change in the Bishop's score in the two groups (5.9 +/- 0.2 and 4.0 +/- 0.2, respectively, $p < 0.001$) but no inter group differences.

The intra cervical Foley bulb catheter is a method frequently used for IOL at MMH.

3) Surgical method

Amniotomy has been used in IOL. A study[79] found that the use of amniotomy and an oxytocin infusion is much more effective when compared with amniotomy alone, and within 24 hours most women achieve vaginal delivery.

There were concerns about amniotomy in women with HIV/AIDS and its use was reduced or stopped in facilities with high HIV prevalence, such as in South Africa. Previous studies[75] found an increase of perinatal HIV transmission in women with early amniotomy and prolonged labour after rupture of membranes.

However, the latest 2018 ACOG guideline on "Labor and delivery management of women with human immunodeficiency virus infection",[80] suggested that vaginal delivery is appropriate for HIV infected pregnant women on treatment with viral loads of 1000 copies/ml or less at/or near delivery. The guideline recommended these women to be managed in a similar manner to HIV uninfected women. In this case, the duration of rupture of membranes before delivery would not be considered as an independent risk factor for maternal-child transmission of HIV in women who are virally suppressed, and it would not be considered when deciding on the method of IOL or the route of delivery.

CHAPTER THREE: STUDY METHODOLOGY

3.1. STUDY DESIGN

This was a retrospective observational study**.** We identified all women retrospectively who had commenced an IOL in the Mowbray Maternity Hospital (MMH) labour ward between 1st of January 2019 and 31st March 2019, and reviewed their medical records.

3.2. STUDY SETTING

The study was carried out at MMH which forms part of the Metro West Maternity service in Cape Town. MMH is a secondary level hospital treating women with complicated pregnancies who are referred from the primary care level Midwife Obstetric Units (MOUs) of False Bay, Retreat, Hanover Park, Gugulethu and Mitchells Plain.

MMH refers women requiring tertiary hospital care to Groote Schuur hospital for sub-specialist attention, multidisciplinary care and other services, such as the intensive care unit (ICU), and interventional radiology.

MMH has a bed capacity of 62. There are 17 antenatal, 39 postnatal, and 6 high care beds. In addition, there are 8 labour and delivery beds and a 4-bed admissions suite. The Obstetric service at the hospital is staffed with 3 consultants, 5 registrars, 6 medical officers, and 4 interns.

3.3 STUDY POPULATION

The study population included all women who had commenced induction of labour at the Mowbray Maternity Hospital from January 2019 to March 2019.

3.4. INCLUSION AND EXCLUSION CRITERIA

3.4.1. Inclusion criteria

All women who commenced IOL at MMH with a singleton cephalic presentation pregnancy with a live fetus at a gestation of 34 weeks or greater, and with a previously unscarred uterus. Women who had intact membranes, and those who had pre-labour rupture of membranes were all included.

3.4.2. Exclusion criteria

Exclusion criteria included all women who went into spontaneous labour without IOL or who had elective CS. Women with intrauterine fetal death (IUFD), gestational age less than 34 weeks, previous caesarean section, suspected chorioamnionitis, and multiple pregnancy were also excluded.

3.5. DEFINITION OF UNSUCCESSFUL IOL

For this study, USIOL was defined as failure to achieve 5 cm cervical dilation (onset of active labour) despite IOL methods. No time limit was prescribed since there was a practice in Metro West hospitals to give a one-day break if initial attempts at non urgent IOL did not cause labour, and then recommence. The USIOL group was therefore expected to include women who failed to respond to methods of induction, and also those for whom the IOL was abandoned after commencement but before active labour due to an unforeseen emergency such as fetal distress.

3.6. IDENTIFICATION OF CASES/SUBJECTS

The antenatal clinic IOL booking diary, and the antenatal ward register were used to identify women in whom IOL was planned. The labour ward and theatre registers were then used to identify women for whom an IOL had been commenced, and their folders were retrieved from the Records Department.

3.7. DATA COLLECTION

A purpose designed data collection sheet, shown as Appendix 3, was used to retrospectively collect information on patient demographics, indication for IOL, gestational age at IOL, co-morbidity, HIV status, cervical assessment, method of induction, labour characteristics, time interval to onset of active labour (SIOL) and to delivery (SIOL and USIOL), mode of delivery, maternal outcome, and perinatal outcome.

3.8. SAMPLE SIZE AND STATISTICAL ANALYSIS

Power calculation

The study power calculation estimated that a required sample size of 240 patients undergoing IOL was required. This calculation was based on the hypothesis that Hypertension, which is a common indication for induction of labour (IOL), was a risk factor for USIOL at MMH. The literature supported a failure rate of IOL in the region of 33% for women being induced for hypertension. We assumed that the failure rate of IOL would be halved in women without hypertension, i.e. 15%. Using a 95% significance level we calculated the power of the study to be 90.9%. We therefore concluded that a sample size of 240 patients was suitable for this study. See the table below.

Table 2. Power for cross-sectional studies

	Input Data
Two sided-confidence interval (%)	95
Number of normotensive patients	120
Prevalence of unsuccessful IOL in hypertensive (%)	33
Number of hypertensive patients	120
Prevalence of unsuccessful IOL in normotensive (%)	15
Prevalence/Coverage Ratio	2.2
Prevalence Difference (%)[1]	18

Power based on:	
Normal approximation	90.9%
Normal approximation with continuity correction	88.03%

[1] Prevalence Difference = Prevalence in Exposed - Prevalence in Non-exposed.

Results from OpenEpi, Version 3, open-source calculator—PowerCross

The power calculation was thus based on the hypothesis that 33% of IOLs for Hypertension would be unsuccessful as defined by not achieving active labour (cervical dilatation of 5 cm). It was predicted that the required sample size of 240 patients commencing IOL, could be obtained within 2-3 months at MMH. It was recognised that, although approximately 240 women are booked monthly for IOL in the IOL booking diary, not all actually have an IOL commenced for various reasons such as spontaneous labour or an obstetric emergency, before the planned date for IOL. It was planned to identify consecutive women who were actually induced from the 1st of January 2019 and stop data collection when the sample size of 240 was achieved. This was done, but unfortunately, after reviewing the 240 files retrospectively, 17 needed to be excluded; but the researcher was now out of the country and unable to retrieve more folders due to restrictions imposed by the Covid-19 pandemic. This is mentioned further in the Results chapter and Discussion/Limitations of the study.

Statistical Analysis

The data was planned to be presented descriptively using tables and graphs with appropriate statistical information where applicable, for example, ranges, means, standard deviations, and others. The main dependent variable was USIOL as defined above. Possible risk factors for USIOL were identified and analysed in cross-tabulations and correlations. Pearson's Chi-square and t-tests were used for statistical analysis. A level of $p<0.05$ was used to indicate statistical significance.

3.9. ETHICAL CONSIDERATIONS

Ethical approval was obtained from the University of Cape Town's Human Research Ethics Committee (HREC). Prior to this, the study proposal was submitted to the University of Cape Town's Department of Obstetrics and Gynaecology for scientific review and approved.

Since this is a retrospective folder review, there was no need for individual patient consent.

Data for this study was anonymised and treated with confidentiality. The records of patients were identified by study numbers that the researcher allocated to each patient and linked

to the patient folder number. Completed Data sheets were kept in the researcher's office in a locked cabinet. Data collections sheets were anonymised without patient identifiers.

All information from data collection sheets was entered into the MS Excel database which was password protected by the researcher, and the password strictly accessed only by the researcher.

Before commencing the data collection, permission was sought from the Provincial Health Research Committee and the Mowbray Maternity Hospital to access and extract data from the hospital patients' folders and hospital registers.

CHAPTER FOUR: RESULTS

4.1 IDENTIFICATION OF CASES AND RATE OF USIOL

All women who had commenced an IOL at the Mowbray Maternity Hospital (MMH) from 1st of January 2019 to 31st March 2019 were identified retrospectively from the labour ward and theatre registers. The medical records of the first 240 women identified consecutively were retrieved and reviewed.

Of the 240 folders, 17 needed to be excluded according to the pre-defined exclusion criteria (intrauterine fetal death (IUFD), gestational age less than 34 weeks, previous caesarean section, suspected chorioamnionitis, and multiple pregnancy). Thus, the folders of 223 women were analysed.

Successful induction of labour, SIOL, (achieving active labour defined as 5 cm cervical dilatation) occurred for 169 (75.8%) women. Unsuccessful induction of labour, USIOL, (Active labour of 5cm cervical dilatation not achieved) occurred for 54 (24.2%). Demographic factors, indication for IOL, cervical status and method of IOL will be described for both SIOL and USIOL groups in sections 4.2 to 4.5 in order to establish possible risk factors for USIOL.

4.2 SOCIO-DEMOGRAPHIC AND BACKGROUND FACTORS

Maternal age and Parity

The mean age was 27.8 years (range 16 to 40) in the SIOL group and 27.1 years (range 14 to 41) in the USIOL group.

Table 3 shows the age distribution in each group; there was no significant difference between the 2 groups.

The median Parity was 1 in the SIOL group and 0 in the USIOL group.

There was a significant difference in parity distribution between the two groups with a higher proportion of primiparous women in the USIOL group.

Gestational age

The mean gestational age for the SIOL group was 39.6 weeks and 39.2 for USIOL and the distribution of gestational age between the two groups was not significantly different. However, there were more late preterm gestations in the USIOL group (18.5%) compared to 8.3% in the SIOL group. Although the difference was not statistically significant, it correlates with a later finding on low birth weight.

Table 3. Socio-demographic characteristics of study participants and success of IOL

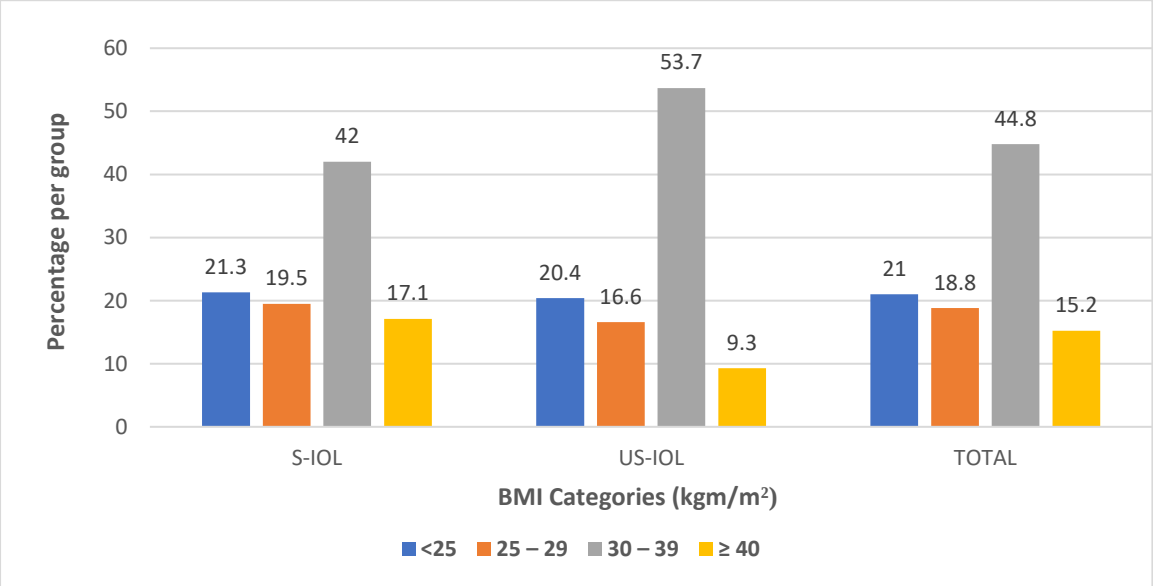
	Successful IOL (SIOL) N = 169	**Unsuccessful IOL (USIOL) N= 54**	**Total N= 223**	**P value**
Maternal age (years)				P= 0.429
<20	12 (7.1%)	5 (9.2%)	17 (7.6%)	
20 – 25	53 (31.3%)	17 (31.5%)	70 (31.4%)	
26 – 30	50 (29.6%)	19 (35.2%)	69 (31.0%)	
31 – 35	38 (22.5%)	6 (11.1%)	44 (19.7%)	
>35	16 (9.4%)	7 (13.0%)	23 (10.3%)	
Gestational age (weeks)				
<34	0 (0%)	0 (0%)	0 (0%)	
34 – 36.6	14 (8.3%)	10 (18.5%)	24 (%)	P = 0.106
37 – 40.6	97 (57.4%)	27 (50%)	124 (%)	
≥41	58 (34.3%)	17 (31.5%)	75 (%)	
Parity				
Para 0	56 (33.1%)	28 (51.9%)	84 (34.7%)	P = 0.013
Para 1 to 4	113 (66.9%)	26 (48.1%)	139 (62.3%)	
Para ≥5	0	0	0	
BMI (kgm/m^2)				
<25	36 (21.3%)	11(20.4%)	47 (21.0%)	P = 0.864
25 – 29	33 (19.5%)	9 (16.6%)	42 (18.8%)	
30 – 39	71 (42.0%)	29 (53.7%)	100 (44.8%)	
≥40	29 (17.1%)	5 (9.3%)	34 (15.2%)	
HIV status				
Negative	142 (84.0%)	41 (76.0%)	183 (82.0%)	P = 0.177

Positive	27 (16.0%)	13 (24.0%)	40 (18.0%)	

Body Mass Index

Table 3 and Figure 1 shows the BMI distribution of the patients in the two groups. Sixty percent (134 women) of the total study population were obese, with a BMI greater than 30 kgm/m². There was no significant difference between the SIOL and USIOL groups.

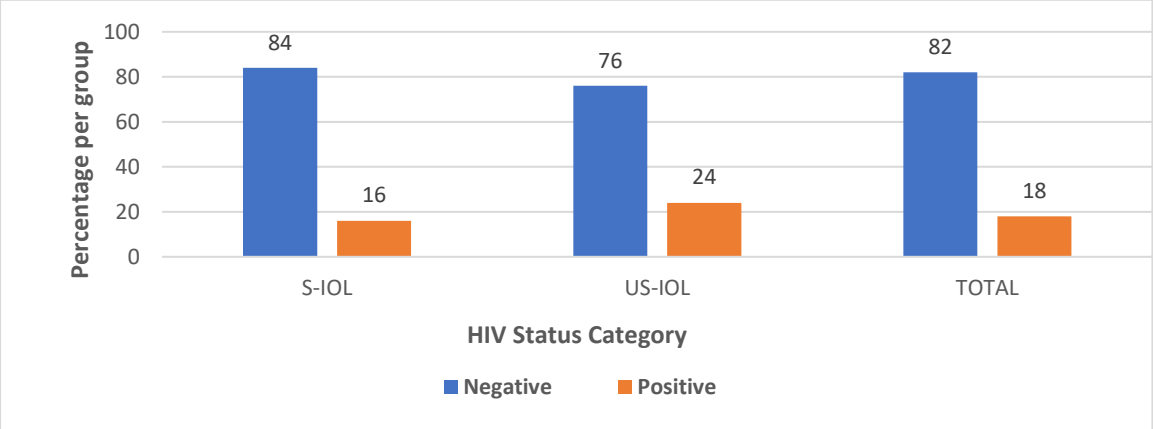
Figure 1. Distribution of BMI categories in the SIOL and USIOL groups



HIV status

Table 3 and Figure 2 shows the results of patients' HIV status. There were 40 women (18%) in the total study group who were HIV positive. Although the proportion who were HIV positive was higher in the USIOL group, the difference was not statistically significant.

Figure 2. HIV status



4.3. INDICATIONS FOR IOL

The most frequent indications for IOL are shown in Table 4 and Figure 3, and were prolonged pregnancy (31.8%), hypertension (26%), pre-labour rupture of membranes (13.5%), and 'Other' category (29%) which was a composite of several less common indications shown in Table 5. The hypertension group was further subdivided into pre-eclampsia, gestational hypertension and chronic hypertension.

Although hypertension and the subcategory pre-eclampsia were more frequent indications for IOL in the USIOL group compared to SIOL, the differences were small and did not reach statistical significance. This refutes the study hypothesis on which the sample size was based, notably that USIOL would be more likely in women induced for hypertension.

For all the other major indications for IOL there were also no significant differences between the SIOL and USIOL groups.

Thus, no particular indication for IOL was identified as a risk factor for USIOL.

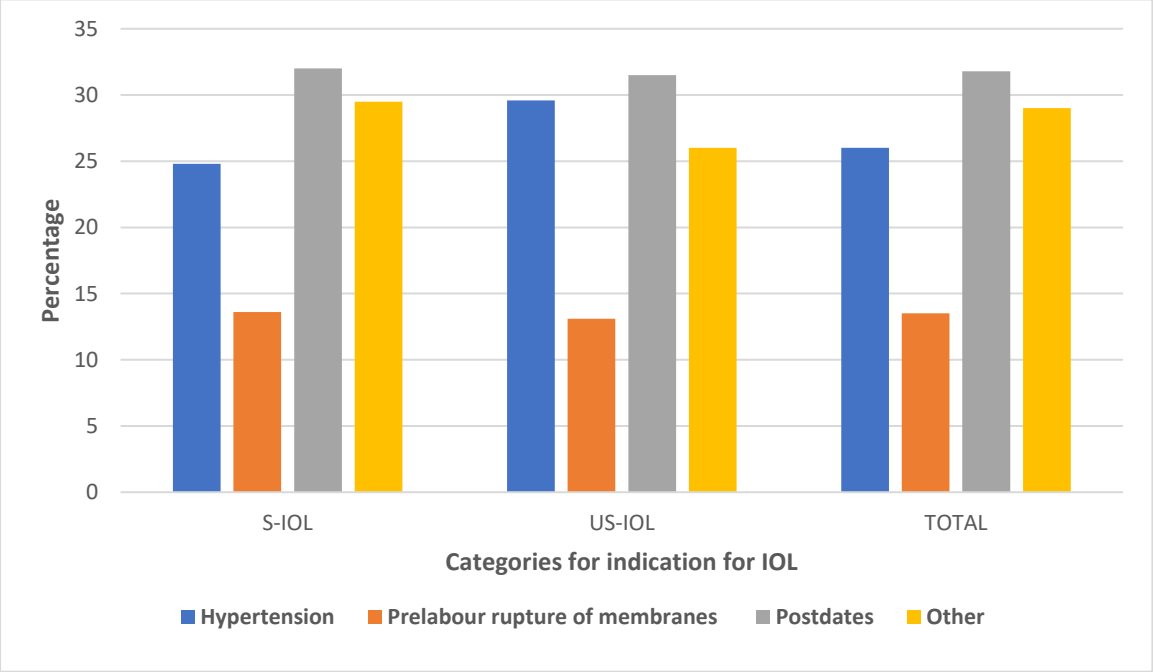
Table 4. Indications for IOL

Indication	**SIOL N=169 (%)**	**USIOL N= 54 (%)**	**Total N=223 (%)**	**Odds Ratio**	**P value**
Hypertension	42 (24.8%)	16 (29.6%)	58 (26%)	0.785	0.486
-Preeclampsia	*17 (40.8%)*	*8 (50%)*	*25 (43.1%)*	*0.680*	*0.512*
-Gestational hypertension	*11 (26.2%)*	*4 (25%)*	*15 (25.9%)*	*1.064*	*0.926*
-Chronic hypertension with and without superimposed PET	*14 (33.3%)*	*4 (25.0%)*	*18 (31.0%)*	*1.500*	*0.539*
Prelabour rupture of membranes	23 (13.6%)	7 (13.1%)	30 (13.5%)	1.057	0.903
Prolonged pregnancy	54 (32%)	17 (31.5%)	71 (31.8%)	1.022	0.948
Other	50 (29.5%)	14 (26 %)	64 (29 %)		

Table 5. Breakdown of 'other' category of indications for IOL

Indication	**SIOL N=50**	**USIOL N=14**	**Total N=64**
Antepartum Haemorrhage of unknown origin	4 (2.4%)	1 (1.9%)	5 (2.3%)
Intrauterine growth restriction	1 (0.6%)	2 (3.8%)	3 (1.3%)
Diabetes	12 (7.1%)	3 (5.7%)	15 (6.8%)
Fetal Macrosomia	4 (2.4%)	0	4 (1.8%)
Oligohydramnios	7 (4.1%)	1 (1.9%)	8 (3.6%)
Reduced fetal movements	4 (2.4%)	2 (3.8%)	6 (2.7%)
Non-Reassuring CTG	1 (0.6%)	0	1 (0.4%)
Prolonged latent phase of labour	4 (2.4%)	0	4 (1.8%)
Previous stillbirth	12 (7.1%)	5 (9.4%)	17 (7.7%)
Increased doppler resistance index	1 (0.6%)	0	1 (0.4%)

Figure 3. Indications for IOL



4.4. METHODS OF IOL

These are shown in Table 6 and Figure 4.

Although several women had more than one IOL method used, Table 6 describes the first method used for initiation of IOL. For the total study group, misoprostol was the most common first method used for IOL (60.5%), followed by intracervical bulb catheter (38.1 %). Only 1 woman had an amniotomy for IOL and 2 women had oxytocin for IOL. Of note, they may have had either of these for augmentation in active labour, but that data was not the subject of this study.

For the total group, 34 (15%) had membrane sweeping done before IOL; 26 (15.4%) of the SIOL group and 8 (14.8%) of the USIOL group. Only 13 (15%) of nulliparous women had cervical sweeping done; 8 (14.3%) of nulliparous women with SIOL and 5 (17.9%) of nulliparous women with USIOL.

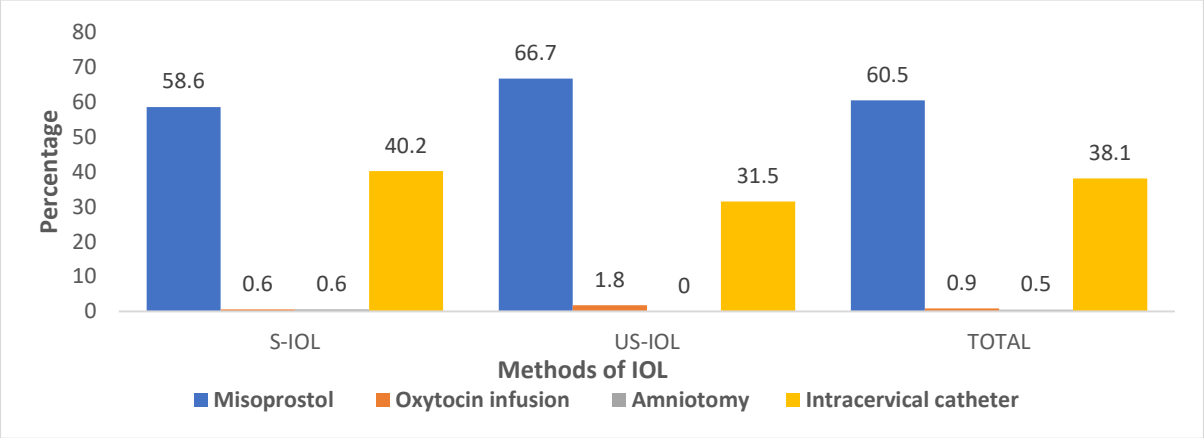
A higher proportion of the USIOL group had misoprostol (66.7%) compared to SIOL (58.6%); whereas a higher proportion of the SIOL group had an intracervical catheter (40.2%) when compared to the USIOL group (31.5%), but these differences were not statistically significant. There were 63 (28.2%) of women who had a combination of bulb catheter and misoprostol, 52 (30.8%) of SIOL and 11 (20.4%) of the USIOL group.

Oxytocin was only used as the first method in 1 woman. However, it was used for augmentation in 51 women, 12 (22.2%) of USIOL and 39 (23.1%) of the SIOL group. Choice of method may be explained by cervical status which is described in section 4.5.

Table 6. Initial method of IOL

	S-IOL N= 169 (%)	**US-IOL N= 54 (%)**	**Total N= 223 (%)**	**P value**
Misoprostol	99 (58.6%)	36 (66.7%)	135 (60.5%)	P = 0.511
Intracervical catheter	68 (40.2%)	17 (31.5%)	85 (38.1%)	
Oxytocin infusion	1 (0.6%)	1 (1.8%)	2 (0.9%)	
Amniotomy	1 (0.6%)	0 (0.0%)	1 (0.5%)	

Figure 4. Methods of IOL



4.5. STATUS OF MEMBRANES BEFORE IOL, INITIAL CERVICAL DILATATION AND CERVICAL LENGTH OF PATIENTS

Table 7 and Figure 5 show that for the total group, 85.6% of patients had intact membranes, 13% of patients had ruptured membranes with clear liquor and 0.9% had ruptured membranes with meconium. There was no significant difference between the SIOL and USIOL groups for membrane status (p=0.79).

Table 7 and Figure 6 show that for the whole group, 64.5% had a cervical dilatation of 0.5 cm or less, prior to commencing IOL. Although the proportion of women with a cervical dilatation of 0.5 cm or less was higher in the USIOL group (78%) compared to SIOL (60.4%), this was not statistically significant (p= 0.171).

Table 7 and Figure 7 show that 85.2% of the whole group had a cervical length of 0.5 to 2 cm, but there was no significant difference between SIOL and USIOL groups (p= 0.326).

Table 7. Status of membranes before IOL, initial cervical dilatation and cervical length before commencing IOL

	Successful IOL N= 169 (%)	**Unsuccessful IOL N= 54 (%)**	**Total N= 223 (%)**	**P value**
Status of membranes				

Intact Clear liquor Meconium stained liquor Blood stained liquor	145 (85.80%) 22 (13.02%) 1 (0.59%) 1(0.59%)	46 (85.19%) 7 (12.96%) 1(1.85%) 0 (0.00%)	191 (85.6%) 29 (13%) 2 (0.90%) 1 (0.45%)	P = 0.790
Initial cervical dilatation ≤ 0.5 cm 1-2 cm ≥ 3 cm Not recorded	 102 (60.4%) 51 (30.2%) 7 (4.1%) 9 (5.3%)	 42 (78%) 7 (12%) 1 (2%) 4 (7.4%)	 144 (64.5%) 58 (26%) 8 (3.6%) 13 (5.8%)	 P=0.171
Initial cervical length 0 (fully effaced) 0.5-2cm ≥3 cm Not recorded	 1 (0.6%) 145 (85.7%) 14 (8.3%) 9 (5.3%)	 1 (1.8%) 45 (83.3) 3 (5.5) 5 (9.2)	 2 (0.9%) 190 (85.2%) 17 (7.6%) 14 (6.3%)	 P=0.326

Figure 5. Status of membranes before IOL

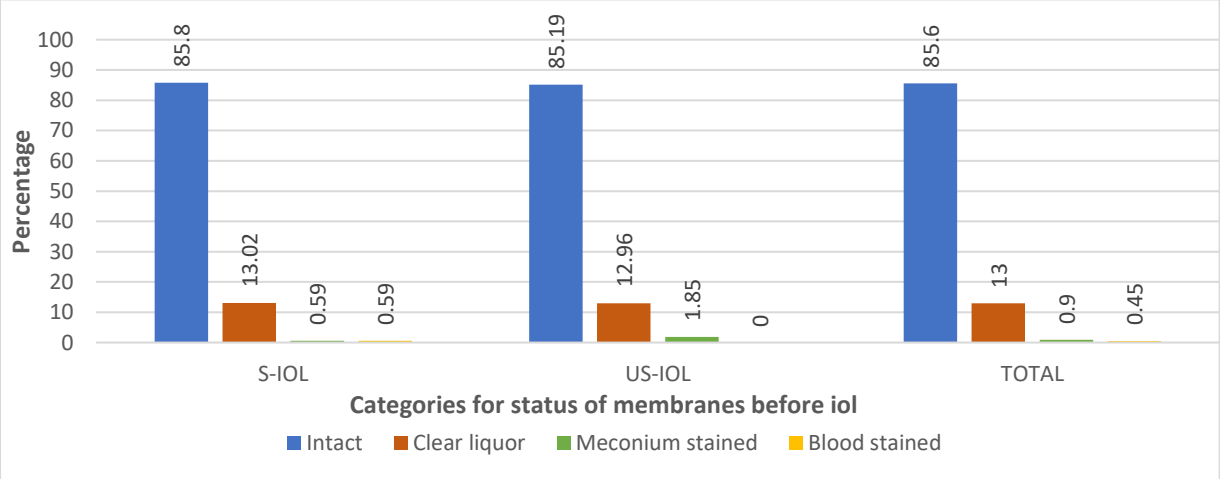


Figure 6. Initial cervical dilatation

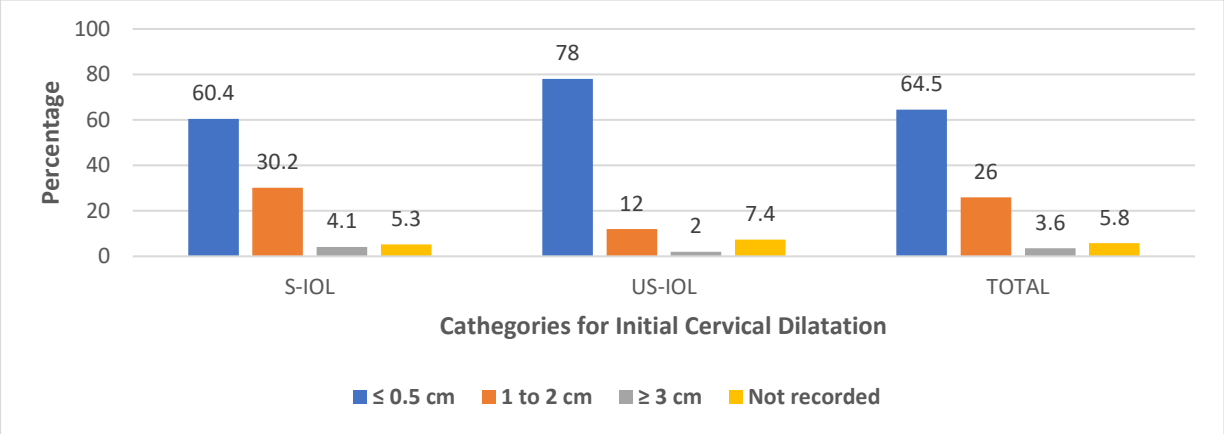
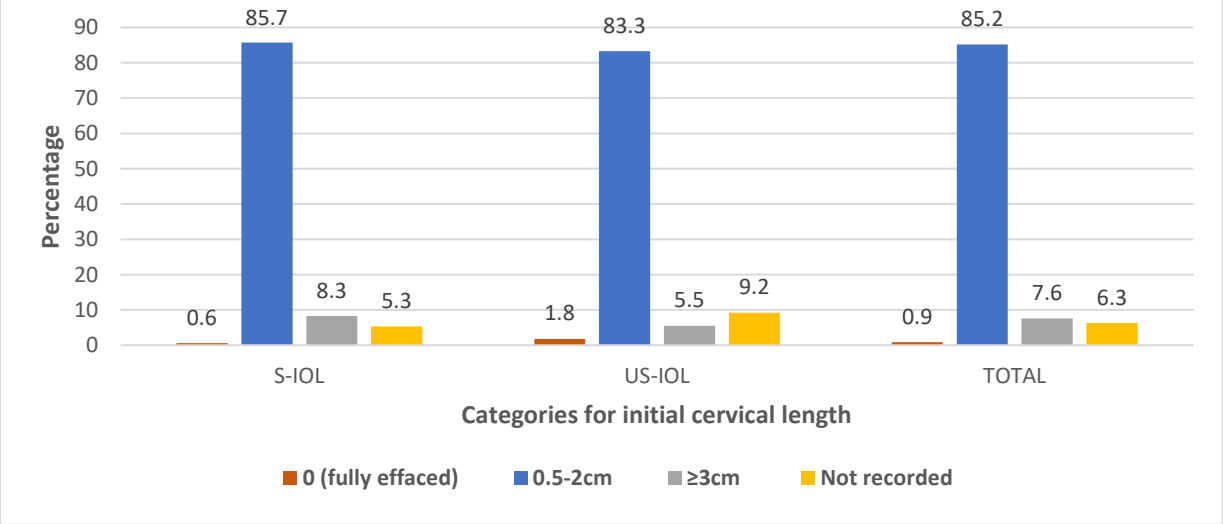


Figure 7. Initial cervical length



The results in Sections 4.2 to 4.5 address objective 2, and show that at MMH, nulliparity was identified as a risk factor for USIOL. There were more late preterm gestations in the USIOL group (18.5%) compared to the SIOL group (8.3%), but this was not statistically significant. Other factors such as age, BMI, HIV status, indication for IOL, method of IOL, cervical and membrane status at onset of IOL were not significantly associated with an USIOL.

4.6. IOL TO DELIVERY INTERVAL

These are shown in Table 8 and Figure 8. The mean induction to delivery (I-D) interval for the whole study group was 18h37min (range of 1h32min to 68h27min). It tended to be shorter for the SIOL group with a mean of 18h11min (range of 1h50min to

58h48min), compared to the US IOL which had a mean of 19h57min (range of 1h32min to 68h27min).

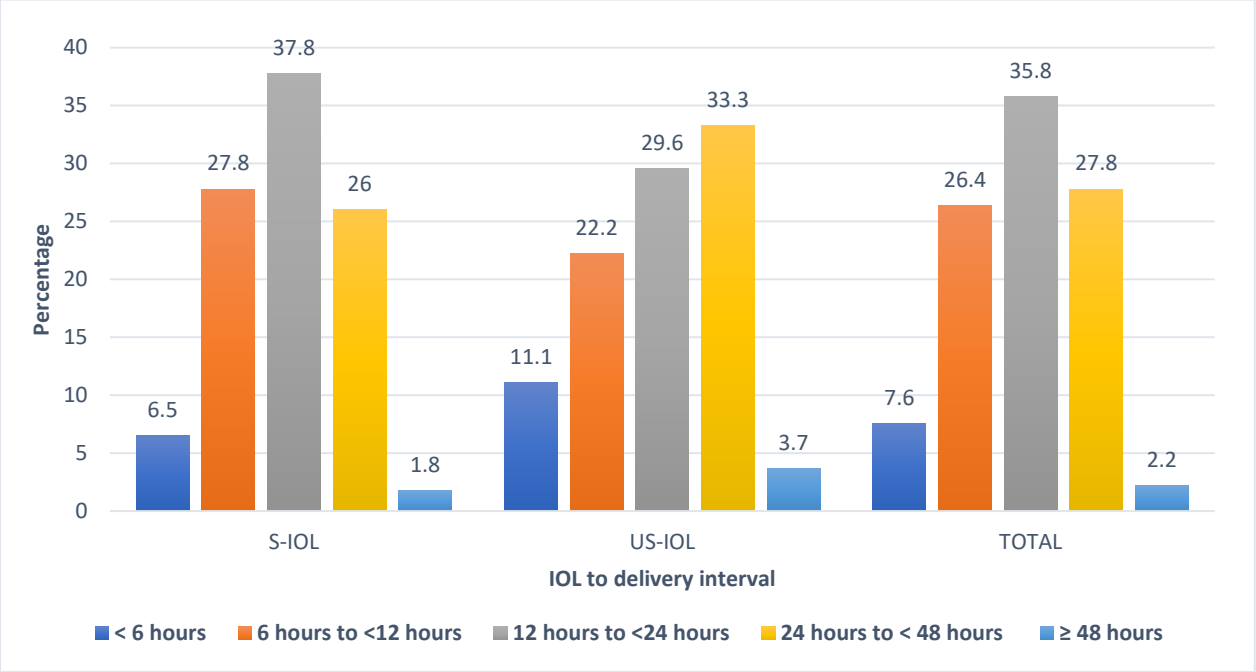
For the total study group, 7.6% had an I-D interval of less than 6 hours, 26.4% of 6 to <12 hours, and 30% of ≥ 24hours. A higher proportion of women with USIOL were in the last category.

The longer I-D intervals may be partly explained by the practise of giving women with a non-urgent IOL a rest day in between IOL attempts which was also documented in Table 8; 5.8 % of the whole group had a rest day with 3.6% in the SIOL group and 13% in the USIOL group**.** Non-urgent indications included prolonged pregnancy and gestational aproteinuric hypertension. IOLs deemed urgent included pre-eclampsia, antepartum haemorrhage and severe intrauterine growth restriction (IUGR).

Table 8. IOL to delivery interval

	S-IOL N= 169 (%)	**US-IOL N= 54 (%)**	**Total N= 223 (%)**
< 6 hours	11 (6.5%)	6 (11.1%)	17 (7.6 %)
6 hours to <12 hours	47 (27.8%)	12 (22.2%)	59 (26.4 %)
12 hours to <24 hours	64 (37.8 %)	16 (29.6%)	80 (35.8 %)
24 hours to <48 hours	44 (26%)	18 (33.3%)	62 (27.8 %
≥ 48 hours	3 (1.8%)	2 (3.7%)	5 (2.2 %)
One day Rest time between IOL attempts	6 (3.6%)	7 (13%)	13 (5.8%)

Figure 8. IOL to delivery interval



The mean induction to active labour (I-A) interval for the SIOL group was 15h47min (range of 1h45min to 57h15min). In this group, 5 patients did not have the time they achieved active labour recorded. They were found fully dilated and all delivered vaginally. By definition, this parameter (I-A) did not apply to the USIOL group.

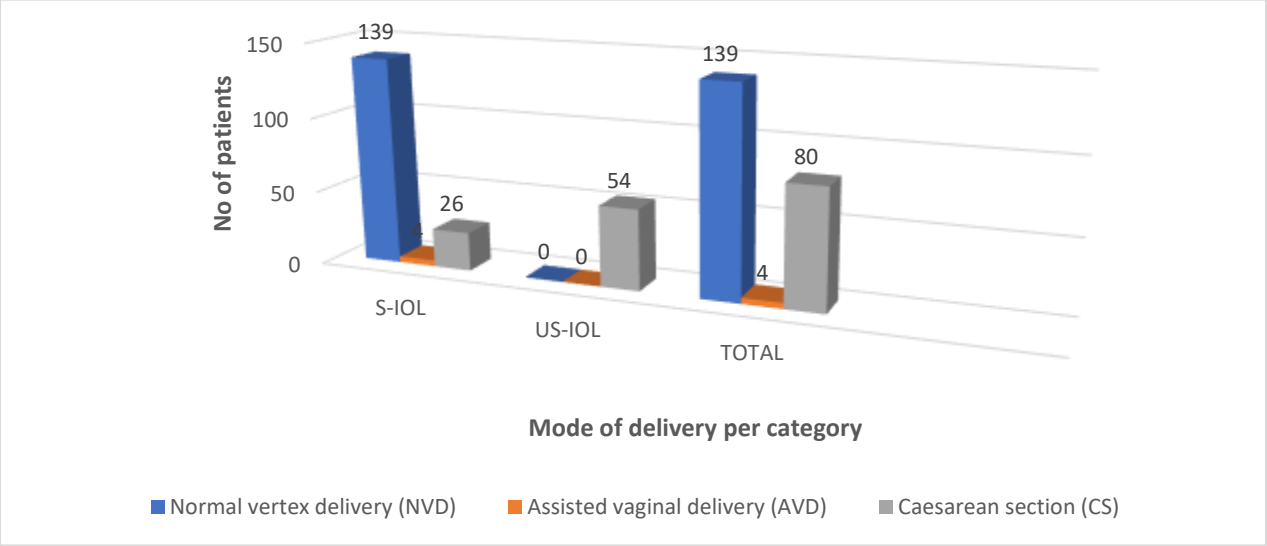
4.7. MODE OF DELIVERY

Table 9 and Figure 9 show that the caesarean delivery rate was 35 % for the whole study group. By definition, it was 100% in the USIOL group. Of the 169 women with SIOL, 26 (15.4%) required an emergency caesarean delivery in active labour.

Table 9. Mode of delivery

	S-IOL N= 169 (%)	**US-IOL N= 54 (%)**	**Total N= 223 (%)**
Normal vertex delivery (NVD)	139 (82.2%)	0 (0.00)	139 (62.3%)
Assisted vaginal delivery (AVD)	4 (2.4%)	0 (0.00)	4 (1.8%)
Caesarean delivery (CD)	26 (15.4%)	54 (100%)	80 (35 %)

Figure 9. Mode of delivery



4.8. DETAILS OF CAESAREAN DELIVERIES

All the CD were emergencies. For the total study group, 61.2% were performed for a CTG abnormality, 17.5% for failed IOL, 11.3% for failure to progress in active labour, and 8.7% for malpresentation detected after IOL was commenced (Table10).

Table 10. Details of caesarean deliveries

	S-IOL N= 26 (%)	**US- IOL N= 54 (%)**	**Total N= 80 (%)**
Timing of CD			
Before active labour	0 (0 %)	54 (100 %)	54 (67.5%)
During active labour	22 (84.6 %)	0 (0 %)	22 (27.5 %)
During second stage labour	4 (15.4 %)	0 (0%)	4 (5 %)
Indication for CD			
Suspicious CTG	3 (11.5 %)	11 (20.4 %)	14 (17.5 %)
Pathological CTG	9 (34.6 %)	26 (48.1 %)	35 (43.7 %)
Failed IOL	0	14 (26%)	14 (17.5%)
Failure to progress	9 (34.6 %)	0	9 (11.3%)
Breech	4 (15.4 %)	3 (5.5 %)	7 (8.7 %)
Failed instrumental delivery	1 (3.84 %)	0	1 (1.2 %)

For the SIOL group 84.6% of CDs were done in active labour and 15.4% in the second stage; with 46.1% for an abnormal CTG, 34.6% for failure to progress in active labour, and 15.4% for a breech presentation detected in labour. In the USIOL group the majority, 37 (68.5%) were done for an abnormal CTG during the IOL process, with only 14 (26%) being done for an IOL that did not progress into active labour despite receiving IOL methods. Even in the USIOL group there were 3 (5.5%) done for a malpresentation detected after IOL was commenced.

4.9. PERINATAL OUTCOMES

For the total study group, the majority (83.4%) of babies born were in the 2500 to <4000 gms weight category with 10.7% <2500gms and 5.8% >4000gms (Table 11). There was a significant difference in birthweights between the two groups with a higher proportion of low birthweight (less than 2500gms) in the USIOL group (18.5%) compared to 8.3% in the SIOL group (p=0.006).

For the total study group, 5-minute Apgar scores were ≥7 in 98.7% of babies, and 7 babies (3%) required admission to the neonatal unit. These parameters were similar for the SIOL and USIOL groups.

Table 11. Perinatal outcomes

	Successful IOL N= 169 (%)	**Unsuccessful IOL N= 54 (%)**	**Total N= 223 (%)**	**P value**
Birth weight				
<2500 gms	14 (8.3%)	10 (18.5%)	24 (10.7%)	P=0.006
2500 to < 4000 gms	144 (85.2%)	42 (77.8%)	186 (83.4%)	
≥ 4000 gms	11 (6.5%)	2 (3.7%)	13 (5.8%)	
Apgar score at 5 mins				
< 5	0	0	0	
5 to 7	3 (1.8%)	0	3 (1.3%)	
≥ 7	166 (98.2%)	54 (100%)	220 (98.7%)	
Admission to NICU	6 (3.6%)	1 (2%)	7 (3%)	

4.10 MATERNAL COMPLICATIONS

Maternal complications occurred for 30 women (13.4%) of the total study group and are shown in Table 12. Some women had more than one complication. The numbers of complications were too small to compare between the two groups, but they appeared similar, apart from a slight increase in puerperal sepsis and tachycardia in the USIOL group.

Table 12. Maternal complications

Maternal complications	**SIOL N= 169 (%)**	**USIOL N= 54 (%)**	**Total N= 223 (%)**
None	150 (88.7%)	46 (85.2%)	196 (87.8%)
Puerperal sepsis	6 (3.5%)	4 (7.4%)	10 (4.5%)
Postpartum haemorrhage	8 (4.7%)	2 (3.7%)	10 (4.5%)
Anaemia	4 (2.4%)	0 (0.0%)	4 (1.8%)
Unexplained tachycardia	2 (1.2%)	2 (3.7%)	4 (1.8%)
Pyrexia in labour	1 (0.6%)	0 (0.0%)	1 (0.4%)
Third degree perineal tear	1 (0.6%)	0 (0.0%)	1 (0.4%)

CHAPTER FIVE: DISCUSSION

5.1 SUMMARY OF RESULTS

The sample size of 240 was not achieved due to an unanticipated number of exclusions. Of the 223 cases eligible for inclusion in the study, SIOL (achieving active labour ≥5 cm cervical dilatation) occurred for 169 (75.8%) patients and USIOL occurred for 54 (24.2%). The overall CD rate in women commencing IOL was 35% (less than the average for MMH); and there were few maternal and perinatal complications. The most frequent indications for IOL were prolonged pregnancy, hypertension, pre-labour rupture of membranes and 'other' category which was a composite of several less common indications There were no significant differences in IOL indications between SIOL and USIOL groups; thus, the hypothesis that hypertension would be a risk factor for USIOL was not proven.

The following risk factors for USIOL were identified; nulliparity, and low birthweight. Other factors such as maternal age, BMI, HIV status, indication for IOL, hypertension, method of IOL, cervical and membrane status at IOL were not significantly associated with an USIOL. The majority of women with USIOL had a CD for an abnormal CTG rather than true failure to progress, related possibly to high-risk fetuses and the IOL method employed. These results will now be discussed in more detail.

5.2 PROPORTION OF UNSUCCESSFUL IOLS AT MMH

The USIOL rate of 24.2% is comparable to the rate found in similar studies conducted in other counties; Ghana (27%),[81] Northwest Ethiopia (24.4 %)[82] and Southwest Ethiopia (21%).[83]

The rate of USIOL at MMH must be interpreted in the context of the study population which does not include tertiary patients who are not managed at MMH. Women with eclampsia, gestational diabetes on medication, morbid obesity, preeclampsia with severe features and gestational age <34weeks are not induced at MMH but managed at the tertiary hospital, Groote Schuur.

The USIOL rate found in our study, together with the CD rate of 35% in women commencing IOL, is a useful statistic to quote to women when counselling them about IOL.

5.3 EXPLORATION OF FACTORS POTENTIALLY ASSOCIATED WITH USIOL AT THE MOWBRAY MATERNITY HOSPITAL

5.3.1. Socio-Demographic and Background factors

Maternal age. In our study, advancing maternal age was not found to be associated with USIOL, unlike in some other studies. A study in Ethiopia concluded that women older than 30 years were 3.7 times more likely to have failed IOL than women with age less than or equal to 30years.[82]

This could be explained by our study population having different characteristics in that MMH serves women with secondary level complications and high-risk women with medical disorders, morbid obesity and diabetes, which may be associated with advanced maternal age, are managed at the tertiary hospital.

Maternal parity. Significantly more women (51.9%) in the USIOL group were nulliparous compared to 33.1 % for the SIOL group with the likelihood of having USIOL being increased by more than one-thirds in nulliparous women compared to multiparous women. This study finding is also supported by other studies such as one conducted at Kenyatta National Hospital in Kenya in 2016 by Admani, Wanyoike & Odawa[48] which concluded that multiparity was a major predictor for successful induction of labour. Another study by Debele et al[84] also found that maternal nulliparity was an important determining factor for USIOL with nulliparous mothers being 1.9 times more likely to have a failed IOL. These data concur with perceptions and observations by obstetricians and midwives that the parous uterus is more sensitive to IOL methods.

Gestational age Considering the distribution of gestational age categories for women having IOL, our study found there was no statistically significant association between gestational age and risk factor for USIOL (P=0.16). However, it is noted that the USIOL group had a higher proportion of IOLs performed that were late preterm (34 to 36^{+6} weeks) compared to SIOL which correlates with the significantly lower birthweight in the USIOL group. Other studies have found different associations with GA. A

studyconducted in Ethiopia by Hurissa showed an association between advanced GA and USIOL.[85]

Body Mass Index. This study shows, alarmingly, that 134 women (60%) of the total study population were obese with BMI ≥30 kgm/m², which is high compared to other studies in SA, such as the one conducted by Basu and Jeketera in the Johannesburg Hospital which found 44.0 % of patients were obese[49].

In a retrospective multicentre study by Kerbage and Senat[51], in all class III obese patients (≥40kgms/ m²) who underwent IOL, 37.5% delivered by caesarean section.

However, our study did not show an association between body mass and USIOL (p=0.864). Of note, although MMH does manage women with mild, moderate and severe obesity (30 to 49 kgms/m²), all those with BMI >50 are referred to tertiary care; and they could be the group that have an association with USIOL.

HIV status. For the total study population, 183 (82 %) patients were HIV negative, and 40 (18%) patients were positive. The 2012 South Africa National Antenatal Sentinel HIV & Herpes Simplex Type-2 Prevalence Survey shows that the national estimated HIV prevalence among antenatal women was 29.5%, whilst the HIV prevalence among antenatal women for the Western Cape Province was 16.9%[50]. From this study, there was no significant association between the patient's HIV status and USIOL. The use of early amniotomy for IOL and augmentation was discontinued at MMH when the HIV epidemic started in South Africa and before HIV testing was routine. This was in order to reduce mother to child transmission of the HI virus, and this policy has been continued for both HIV positive and negative women. Thus, the approach to IOL does not differ according to HIV status.

5.3.2 Clinical Indications for IOL at MMH in USIOL and SIOL groups

This study found that the three most frequent indications for IOL were prolonged pregnancy (31.8%), hypertension (26%), and pre-labour rupture of membranes (13.5%). Less frequent indications were grouped into a fourth category, 'Other' (29%). The above-mentioned indications were similar to the findings reported by Malende and Mbele in their studies on IOL in South Africa[24, 25].

Although hypertension and particularly the subcategory pre-eclampsia were more frequent indications for IOL in the USIOL group compared to SIOL, the differences were small and did not reach statistical significance. This refutes the study hypothesis on which the sample size was based, notably that USIOL would be more likely in women induced for hypertension.

In this study, for all the other major indications for IOL there was no significant difference between the SIOL and USIOL groups, therefore no particular indication for IOL was identified as a risk factor for USIOL. This could be influenced by the referral policies in Metro West whereby MMH refers all high-risk women with eclampsia, and early onset pre-eclampsia (<34weeks) with severe features, to the tertiary hospital. These could all be subgroups with greater risk of USIOL.

5.3.3 Cervical status and Methods of IOL in USIOL compared to SIOL

Cervical status. Bishop's score could not be calculated since all the parameters for the Bishop's score were not recorded in most of the files reviewed. Thus, cervical dilatation and length were the only parameters of the Bishop's score which could be assessed. This study found that cervical status at the onset of IOL did not influence the success of IOL.

A systematic literature review of 40 articles done by Kolkman et al[53] concluded that the Bishop's score was a poor predictor for the outcome of induced labour at term and should not be used to decide whether to induce labour or not. On the contrary, a systematic review and meta-analysis carried out in Ethiopia by Melkie et al[52] found that unfavourable Bishop's Score, intermediate Bishop's Score, and nulliparity were significantly associated with failed induction of labour.

Method of IOL. A higher proportion of the USIOL group had misoprostol (66.7%) compared to SIOL (58.6%); whereas a higher proportion of the SIOL group had an intracervical bulb catheter (40.2%) when compared to the USIOL group (31.5%), but these differences were not statistically significant. It is possible that the use of misoprostol as a primary IOL method was the reason why such a high proportion of USIOL required CD due to an abnormal CTG. Misoprostol induction is more likely to be associated with uterine hyperstimulation than intracervical bulb catheter. Choice of IOL method was probably related to cervical status but may also have been provider dependent.

A recent research study[63] comparing prostaglandins, found that low-dose oral misoprostol solution was associated with lower rates of caesarean delivery, for both fetal heart rate abnormalities and poor progress in labour, compared to the vaginal route. All methods were generally safe, but the main complication of uterine hyperstimulation was highest with high-dose vaginal misoprostol, and lowest in women induced with double-balloon catheter (two fluid-filled balloons either side of the cervix).

In another study[64] comparing the efficacy and safety of 50 microgram intravaginal misoprostol every 4 hours, with 0.5 mg of intracervical PGE2 gel (dinoprostone) every 6 hours, it was noted that misoprostol was more efficacious than dinoprostone for labour induction. However, the significantly increased incidence of abnormal fetal heart rate tracings and the trend in increased deliveries for fetal distress with misoprostol dosing of 50 microgram every 4 hours were of concern. MMH uses a low dose oral 50 microgram misoprostol regimen which is closely monitored. However, given the relatively high rates of emergency CD for CTG abnormalities in women undergoing IOL observed in this study, increasing the use of Foley bulb catheter IOLs and reducing the number being induced with misoprostol, would be advantageous.

5.4. DESCRIPTION OF IOL TO DELIVERY INTERVAL, IOL TO ACTIVE LABOUR INTERVAL, THE MODE OF DELIVERY AND MATERNAL/FETAL OUTCOMES IN ALL WOMEN COMMENCING IOL

Description of IOL to delivery interval. The findings for the mean Induction to Delivery (I-D) intervals for the whole study group was 18h37min (range of 1h32min to 68h27min). It tended to be shorter for the SIOL group with a mean of 18h11min (range of 1h50min to 58h48min) SIOL group, compared to the USIOL which had a mean of 19h57min (range of 1h32min to 68h27min).

The longer I-D intervals may be partly explained by the practice of giving women a rest day in between IOL attempts which happened for 5.8 % of the whole group. Of note a higher proportion (13%) of the USIOL group had a rest day compared to 3.6% of SIOL. This shows that the USIOL group responded less well to the first attempt of IOL methods, and also that attempts to achieve active labour were pursued.

These I-D intervals appear to reflect a relatively long time required to affect delivery in women undergoing IOL, and need to be explained to women being counselled for IOL. It also has implications for bed occupancy and patient flow into labour wards. This study did not ascertain women's perceptions of the IOL process, but this would be an important area for future research.

IOL to active phase of labour interval. The mean induction to active labour (I-A) interval for the SIOL group was 15h47min (range of 1h45min to 57h15min). In this group, 5 patients did not have the time they achieved active labour recorded. They were found fully dilated and all delivered vaginally.

Mode of delivery in women having IOL

One of the aims of induction of labour is to achieve a successful vaginal delivery, even though some authors suggest that IOL exposes women to higher risk of a CD than spontaneous labour.[66]

The caesarean delivery rate for all women undergoing IOL was 35 % for the whole study group, and by definition, all were emergency CD. It was obviously 100% in the US IOL group. Of the 169 women with SIOL, 26 (15.4%) required an emergency Caesarean section.

Malende[24] in his IOL study found that 59.8% of patients had vaginal delivery compared to 40.2 % of patients who had CD delivery. The author further found an increase in the CD rate with increasing duration of IOL, although the CD rate for inductions taking longer than 48 hours did not increase above the rate for inductions taking between 24 and 48 hours.

The finding of the CD rate of 35% found in our study is in keeping with several other studies[70]. However, a study in Ethiopia had a CS rate of 24 % among induced women[28].

Interestingly the overall CD rate for MMH in 2019 was over 50% which is actually higher than that for women undergoing IOL in our study. The high overall CS rate at MMH may be explained by the fact that it only does complicated obstetric deliveries and low risk vaginal deliveries are performed at satellite MOUs. Thus, if the whole catchment population is considered the CD rate at MMH would be less than 30%.

Other studies show differing findings on CD rates in women undergoing IOL, with one study showing that the CD rate increases nearly 2-3-fold in medically uncomplicated

nulliparous women at term undergoing IOL compared with spontaneous labour.[86] Conversely, the ARRIVE study found reduced CD rates with elective IOL at 39 weeks.[7]

Another study[65] conducted on labour induction for gestational hypertension showed that the emergency CD rate was 28.3%. Of these CD, 30.8% were due to failed induction and 69.2% for feto-maternal indications. Uncontrolled hypertension was observed in 16.7% of all cases without specification of whether it was more prevalent in the CD group.

Our finding of a CD rate of 35 % in women undergoing IOL is a useful observation when counselling women for IOL, who may have fears or misconceptions about CD rates in IOL.

All the CD in our study were emergencies, elective CD obviously being an exclusion factor. CTG abnormalities were the most frequent indication for CD (61.2%) followed by failed IOL (17.5%), failure to progress in active labour (11.3%) and malpresentation detected after IOL was commenced (8.7%). Malpresentation is an exclusion criterion for IOL at MMH and the study. However, these cases were induced having been assessed to be cephalic presentation prior to IOL. This was a concerning finding and reflects poor initial assessment of women prior to IOL at MMH.

The CD rate of our study and associated factors are comparable to the CD rate in a study on IOL conducted by Ndovie[66] at New Somerset Hospital in Cape Town. In the Ndovie study, the CS rate was 41.9% and the three main indications for CS were fetal heart changes (72%), followed by failed induction of labour (21%) and cephalopelvic disproportion (7%). In comparing our study findings with Ndovie, it appears that MMH had a higher rate of pathological CTG (43.7%) in women undergoing IOL, compared to 18.8 % at New Somerset Hospital.

The high rate of CD at MMH for abnormal CTGs is interesting and was a more frequent indication for CD than failure to progress to active labour despite IOL methods used. This could reflect that the fetuses of mothers being induced have placental insufficiency and are at risk of hypoxia as the reason for which they are being induced. It also indicates that more attention is needed to the methods of IOL employed, and reducing reliance on misoprostol in favour of intracervical bulb catheters, although as mentioned earlier, relatively low dose oral regimens are used. The study did not explore the interpretation of CTGs and whether all these CD were really indicated.

Perinatal Outcomes

In this study, for the total study group, the majority (83.4%) of babies born were in the 2500 to <4000 gms weight category with 10.7% <2500gms and 5.8% >4000gms. There was a significant difference in birthweights between the two groups, with a higher proportion of lower birthweights in the USIOL group, suggesting undetected intrauterine growth restriction that could have been associated with the higher rate of CTG abnormalities in this group requiring caesarean section. It also may be related to a non-significant increase in the proportion of preterm deliveries in the USIOL. The possibility of incorrect dating must also be considered. For the total study group, 5-minute Apgar scores were ≥7 in 98.7% of babies, and 7 babies (3%) required admission to the neonatal unit. These parameters were similar for the SIOL and USIOL groups. The above finding supports the Ndovie[66] study which showed similar low admission rates into the neonatal unit. The relatively low rate of poor perinatal outcomes in this study in women having IOL is reassuring.

Maternal complication

Maternal complications occurred for 30 women (13.4%) of the total study group. Some women had more than one complication. The number of complications was too small to compare the two groups, but they appeared similar.

5.5 STUDY LIMITATIONS

The sample size was not achieved due to an unexpected number of exclusions and the researcher having been unable to return to SA for further data collection due to Covid travel restrictions. Also, the study was powered to detect a difference in hypertension as the indication for IOL between USIOL and SIOL groups but was likely to be underpowered for other parameters which could have reached significance with a larger sample size.

The study was performed at a regional/secondary level hospital which did not manage women with severe early onset pre-eclampsia, morbid obesity or GDM requiring treatment who were all referred to tertiary level. Thus, the results cannot be generalisable to a whole obstetric population.

The retrospective study design limited the information that could be obtained. For example, it was not possible to engage with women about their experiences of IOL; this could be the subject of future research.

5.6 RECOMMENDATIONS ARISING FROM THE RESEARCH

Several different data sources were used to identify women who commenced IOL; for example, the booking diary in the antenatal clinic, ward registers and delivery registers. It is suggested that a single database is developed for ongoing audit of IOL indications, practices and outcomes at MMH. This would enable observation of trends in response to new practices and policies; and allow for future research on IOL at MMH.

In addition, improved assessment of women prior to IOL would be important to prevent inadvertent IOL of a malpresentation.

CONCLUSION

The success rate for IOL was 75.8%, the overall CD rate in IOL women was 35% (less than the average for MMH); and there were few maternal and perinatal complications. This information is valuable when counselling women for IOL at MMH. The most frequent indications for IOL were prolonged pregnancy, hypertension, pre-labour rupture of membranes and 'other' category which was a composite of several less common indications, with no differences between SIOL and USIOL groups.

In terms of the main study aim, our study revealed two associations with USIOL: nulliparity, and low birthweight. Hypertension, as hypothesised in the sample size estimation, was not a risk factor for USIOL. The majority of women with USIOL had CD for an abnormal CTG during the IOL process, rather than failure to progress into active labour, related possibly to high-risk fetuses and the IOL method employed.

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APPENDICES

APPENDIX 1: BISHOP'S SCORE

Score	Dilation (cm)	Position of cervix	Length (cm)	Station (-3 to +3)	Cervical consistency
0	Closed	posterior	>4	-3	Firm
1	1-2	Mid position	3-4	-2	Medium
2	3-4	anterior	1-2	-1, 0	Soft
3	5-6		<1	+1, +2	

Score ≤5: unfavourable cervix

Score 6-7: not definitively predicting whether induction will be successful

Score ≥8: spontaneous vaginal delivery more likely and augmentation or induction may be unnecessary

APPENDIX 2: MBELE SCORE

Parameters	0	1	2	3
Parity	Primiparous	Multiparous		
Pre-eclampsia	yes		no	
Rupture of membranes	no		yes	
Bishop score	≤ 3		4-6	≥7

Scores	positive predictive values for successful IOL
0 to 2	16 – 31%
3 to 5	48 – 63%
6 to 8	68 – 89%

APPENDIX 3: DATA COLLECTION SHEET

1. **Demographic data**

- Age
- Parity before delivery
- Gestational age at delivery in weeks:
- BMI
- Booked: yes =1, no =2
- HIV status: positive =1, negative=2, unknown=0

2. **Indications for IOL**

- Hypertension =1, Preeclampsia =1.1, Gestational hypertension =1.2, Chronic hypertension =1.3
- Pre-labour rupture of membranes=2
- Prolonged pregnancy =3
- Unexplained antepartum haemorrhage = 4
- Placental insufficiency/intrauterine growth restriction =5
- Diabetes mellitus =6
- Suspected macrosomia =7
- Isolated oligohydramnios =8
- Antepartum haemorrhage of unknown origin =9
- Reduced foetal movements at term =10
- Suspect macrosomia =11

3. **Bishop score**

- ≥5 =1
- 6-7 =2
- >8 =3

- Not done =4

4. Method of IOL

- Oral misoprostol =1
- Amniotomy =2
- Pitocin infusion =3
- Intracervical catheter =4
- Prostaglandin E_2 =5
- Combination= 6

5. Active labour (dilatation ≥5cm)

- Achieved =1
- not achieved =2
- Duration interval from starting induction to active labour:
- Duration interval from starting induction to delivery:

6. Mode of delivery

- NVD =1
- assisted vaginal delivery =2
- CD =3

7. Indications for c section

- Fetal distress =1; before active labour =1.1
  During active labour=1.2
  During second stage =1.3
- Unsuccessful IOL =2
- Prolonged active labour =3
- Prolonged second stage =4

8. Maternal adverse outcomes:

- Hyperstimulation =1

-Ruptured uterus =2

-Cord prolapse =3

- 3rd degree tear =4

- Postpartum haemorrhage =5

- Puerperal sepsis =6

9. **Fetal outcomes:**

- Gestational age at delivery
- Birth weight
- Apgar score at 5 minutes ≥7 =1, <7 =2
- Neonatal resuscitation: yes=1, no=2
- Admission to NICU: yes=1, no=2
- Intrapartum stillbirth: yes =1, no=2
- Early Neonatal death: yes =1, no =2
- Late neonatal death: yes =1, no =2