Induction of labour in an out patient setting ?

(Extract from the Dr. Nalin Rodrigo Memorial Oration – June 2018)

M Goonewardene[a]

Introduction

Induction of labour (IOL) is carried out in women with intact membranes as well as in women with pre labour rupture of membranes (PLROM), if continuing the pregnancy is considered dangerous to the fetus or to the mother or to both, and there is no contraindication for a vaginal delivery. There are well known absolute and relative contraindications for IOL, and IOL should not be carried out if it is considered dangerous to the mother, to the fetus or to both.

In 2010, through a large, worldwide, multicentre study involving nearly 300,000 women, the World Health Organisation estimated that globally, approx. 10% of pregnant women undergo IOL. The estimate was lowest from Niger (1.4%) and the highest was from Sri Lanka 35.5%)[1]. Globally, IOL rates are steadily increasing due to many reasons, and in fact it has been suggested that a vast majority of women in the world will have IOL in the future, not only if it is obstetrically indicated but perhaps even when it is most convenient to them and / or their obstetrician, rather than awaiting spontaneous onset of labour (SOL). It has been reported that IOL without medical indication at term (37-40 weeks of gestation) could be associated with reduced odds of caesarean delivery (CD) among nulliparous women as well as multiparous women with a previous vaginal delivery, and with no increase of adverse maternal or neonatal outcomes other than hyperbilirubinemia at early-term gestational ages[2].Some obstetricians in North America have even recommend elective IOL for all women at 39 weeks' gestation rather than at 41 weeks gestation[3,4]. However, opposition to this has arisen from advocates of natural pregnancy and birth[5,6], especially because the recommendation is based primarily on a non increase of CD after IOL at 39 weeks' gestation and a possible increase of still births after 39 weeks' gestation[7], without taking into consideration all the other possible harms of unnecessary IOL. Although the odds of perinatal mortality were seen to reduce with elective IOL at each gestation between 37 and 41 completed weeks when compared with expectant management, elective IOL was observed to be also associated with increased admission to a neonatal unit at all gestations before 41 weeks[7]. The American College of Obstetricians and Gynaecologists too have not recommended elective induction for non obstetric reasons[8]. In a recent large multi center study involving more than 3000 women, carried out in the USA, Induction of labour at 39 weeks in low-risk nulliparous women resulted in a significantly lower frequency of caesarean delivery (CD) although it did not result in a significantly lower frequency of a composite adverse perinatal outcome[9].

[a] *Professor, Department of Obstetrics and Gynaecology,, International Medical University, Clinical Campus Seremban, Malaysia*

Correspondence: MG, e-mail: <indramalikrodrigo@imu.edu.my >

iD http://orcid.org/0000-0002-7899-7117

Competing interest: The author reports no conflict of interest

In a population based study carried out in France in 2010, involving about 14,680 women, there were about 13.9% of elective IOL and 47.3% of them were on the request of the women[10]. Therefore it has been suggested that even in the UK, elective IOL at term on maternal request should be an option which should be available to women[11], although the NICE Guidelines do not recommend this[14]. It is widely accepted that women should be involved in their care and that this includes decisions regarding IOL[1, 12-16]. It has been reported that a significant number of women who undergo IOL, as an inpatient in a hospital, may feel that they did not have adequate time and information to make an informed decision and actively participate in their IOL[13]. Some women prefer to have greater involvement and control over their management processes in a comfortable and supportive home environment. However, women who reside a signifi-cant distance away from their hospital may feel 'safer' in hospital and their preferences may vary according to the services available to them as well as their socio-demographic backgrounds[14-16].

Methods of Induction of labour

It is reported that IOL was first described by the 'Father of Medicine' himself (Hippocrates, *circa* 400 BC). What he described was mammary stimulation and mechanical dilation of the cervical canal. This was followed by artificial rupture of membranes (amniotomy), which was practiced by Soranus (*circa* AD 103)[17]. In 1909, Bell described the use of an extract from the pituitary for IOL[18], but it had serious side effects including rupture of the uterus. After Vincent du Vigneaud et al synthesized oxytocin in 1954[19], the intra venous infusion of synthetic oxytocin, mostly in combination with amniotomy, became the preferred method for IOL. Embrey and Mollison in 1967 described the supra cervical placement of a Foley catheter for ripening of the cervix to make it favourable for IOL[20] while Karim et al introduced the use of prostaglandins for IOL in 1968[21].

Currently, a low dose of oral misoprostol (OM), a synthetic methyl analogue of prostaglandin E_1, has come to the fore front as a method for IOL[22-27], and there is also a concerted effort to identify the most convenient and cost effective method of cervical ripening and IOL, which could be safely adopted even in an outpatient setting[14-16, 27-32]. Since there is no clear demarcation between ripening of the cervix and SOL and because the former merges in to the latter in one continuous process, in clinical practice, most interventions used to ripen the cervix prior to IOL will lead

to IOL with stimulation of uterine muscle contractions, if used in increasing doses and frequency and for longer durations. This is exemplified by the insertion of a supra cervical Foley catheter. As it does not need intensive maternal or fetal monitoring, and has been shown to be safe and effective for IOL if kept in situ for four days, according to the currently available evidence, a supra cervical Foley catheter could be considered as an appropriate method for outpatient IOL[24,26, 28,29,31,32]. It has also been shown that IOL with the use of a supra cervical Foley catheter as an outpatient procedure is cost effective[32]. There is also an increased interest on the feasibility of telemonitoring of women in their homes itself, during pregnancy and labour[33-35]. Therefore outpatient IOL with low dose OM and telemonitoring of the mother and fetus may become a reality in the future.

Low dose oral misoprostol

Compared to vaginal misoprostol, low dose OM has been shown to be safer, with less risks of hyperstimulation, CD, delivery of babies with Apgar <7, and post partum haemorrhage, and also to be more effective than amniotomy with intravenous oxytocin, which can result in increased CD, especially if the cervix is 'not ripe'[22-25]. Regimens of 20-200 µg of OM given four to six hourly, and up to 12 doses of 50 µg over four days have been reported[22-26]. A starting dose of 20 µg of OM in solution, titrated against uterine contractions and administered hourly in increasing doses of up to 60 µg, is currently thought to be a safe, cost effective method for IOL[22-25], although more simplified regimens are needed[36]. The hourly dosing regimen has been calculated according to the pharmokinetics of OM where its half-life as well as the time taken to achieve peak serum concentrations has been estimated to vary from approximately 20-40 mins respectively[25,37]. Although doses of 20, 40 and 60 µg of OM are easily prepared by dissolving the commonly available 200 µg tablet in 200 ml of water, 25 µg tablets are also now available, and a more practical regimen of 50 µg administered four hourly, could be implemented[22,26,43,44]. This would be useful in settings with a heavy work load and lacking facilities for one to one nursing care and intensive fetal monitoring. The induction delivery interval (IDI) possibly being slightly longer after low dose OM should not be considered as a major draw-back. The fact that it is safer than vaginal misoprostol, results in less CD and is also effective with an 'unripe' cervix in contrast to amniotomy and intra venous infusions, indicate that it should be the preferred method for IOL now, unless a better method is found in the future[22-26]. The increased occurrence of

meconium stained liquor, without any associated evidence of neonatal asphyxia (risk of Apgar <7 is reduced with OM) suggests that the passage of meconium could be due to stimulation of the fetal gut by OM[23]. However, the maternal and fetal well-being need to be closely monitored when administering low dose OM. There are several advantages of low dose OM. These include: being more acceptable to women compared to vaginal or intravenous interventions, being easier to be administered, can be stored at room temperature (unlike vaginal dinoprostone), being cheaper and cost effective compared to vaginal dinoprostone, and being associated with lower CD rates.

Supra cervical Foley catheter

Although less effective than OM and vaginal misoprostol, vaginal dinoprostone, and amniotomy with oxytocin infusion, the placement of a supra cervical Foley catheter has the advantage of having the least risk of hyper stimulation[22,24]. The use of a larger volume of fluid (eg 60-80 ml) in the bulb of the Foley catheter has been shown to be associated with increased vaginal delivery in 24 hours (VD 24), although no significant differences in CD rates have been observed[38]. Although the supra cervical Foley catheter is often removed after 24 hours due to concerns of possible ascending infections, there does not appear to be a significant increase of adverse effects including chorioamnionitis associated with the insertion of a supra cervical Foley catheter for IOL[24,31,39,40]. Keeping the Foley catheter up to three days and four days has been shown to be safe and effective for IOL in Africa[41] and the Netherlands[26] respectively. A recent Systematic Review has shown that the risk of adverse effects during the period between insertion and expulsion of a supra cervical balloon catheter used for outpatient cervical ripening is low[31]. Furthermore it has been shown that outpatient cervical ripening with a supra cervical Foley catheter could potentially save almost € 1000/= per woman[32]. However, the Foley catheter should not be inserted in the presence of overt vaginal or cervical infection, and appropriate antiseptic measures and sterile procedures should be adopted during its insertion. The urinary channel of the Foley catheter should be closed off with a sterile cap and the catheter should be taped to the woman's thigh, applying gentle traction.

The advantages of a supra cervical Foley catheter include: being a possible alternative for women who wish to have IOL at home, can be stored at room temperature (unlike vaginal dinoprostone), being cheaper than vaginal dinoprostone, having the least risk of uterine hyper stimulation and fetal heart rate changes, requiring less stringent need for maternal and fetal monitoring, requiring no further intervention until the Foley catheter falls out, being more suitable with a scarred uterus, being more suitable in women at risk of fetal compromise (eg Pre eclampsia & Fetal Growth Restriction), and having no evidence of increased risk of adverse events (eg. Chorioamnionitis).

Research on Oral Misoprostol versus the insertion of a supra cervical Foley catheter for ripening the cervix and induction of labour, carried out in a Teaching Hospital in Sri Lanka

Three RCTs have been carried out. Ethical approval for these studies was obtained from the Ethical Review Committee of the Faculty of Medicine, University of Ruhuna. Administrative approval was obtained from the Directors of the THMG during the periods of study. The RCTs were registered in the Sri Lanka Clinical Trials Register. Informed written consent was obtained from all the participants in all the RCT. In all three RCT, although the patients could not be blinded to the interventions, the investigators and the analysts of the results were blinded with regard to the intervention. Similar methods were used in all three RCT[42-43].

1) The first RCT was carried out in 2010/2011. The objective was to compare the effectiveness of the insertion of a supra cervical Foley catheter for 24 hrs versus two doses of OM 25 g four hours apart, in pre IOL cervical ripening, in postdated pregnancies. There were 156 consecutive women with uncomplicated singleton pregnancies having a vertex presentation and MBS < 6 at 40 weeks + 6 days of gestation, who were allocated by stratified (primip/multip) block randomization in a 1:1 ratio to receive either two doses of OM 25 µg, four hours apart (n=74) or a supra cervical Foley Catheter for 24 hrs (n=78). The MBS before and after the intervention was assessed in all participants by an investigator who was adequately trained and skilled in this procedure, and blind to the intervention. If the cervix was favourable, IOL was carried out with amniotomy and intravenous oxytocin infusion.

   Results: There were no significant differences in the distribution of parity, and the mean ages and the mean pre intervention MBS in the primigravidae and multigravidae, between the two study groups. There were no drop outs. There were significant

increases in mean MBS (ranging from 2.6-3.3 and 95% CI 1.7-4.1, p<0.001) after the inter-ventions in both groups. However there was no significant difference between the mean increases of MBS between the groups. In the primigravidae, the mean MBS after 24 hours was greater in the Foley catheter group compared to the OM group (6.9, 95% CI 6.3-7.5 vs 5.7, 95% CI 4.8-6.7, p<0.05). There were no significant differences in the proportions of primips and multips establishing SOL. More primips and multips had cervices favourable for IOL in the Foley catheter group compared to the OM group (p<0.05). There were no significant differences in the Induction Delivery Intervals (IDI) after IOL; successful vaginal delivery after IOL; and the CD rates between the groups. In the OM group there were no cases of uterine hyperstimulation, but two women complained of dyspepsia.

Conclusions: Insertion of a supra cervical Foley catheter for 24 hours was better than two doses of 25 g OM administered four hours apart, for pre IOL cervical ripening in post dated preg-nancies[42].

2) The second RCT was carried out in 2015/2016. The objective was to compare three doses of OM 50 µg four hourly versus a supra cervical Foley catheter for 24 hours, for pre-induction cervical ripening. This study involved 180 women who were allocated to receive three doses of OM 50 µg four hourly (n=91) or a supra cervical Foley catheter for 24 hours (n=89). MBS was reassessed at 41 weeks gestation. If MBS was >7, IOL was carried out with amniotomy and intravenous oxytocin infusion. If MBS was <7, cross over therapy was carried out with a supra cervical Foley catheter for OM group and vaginal prostaglandin E_2 for the Foley catheter group.

Results: At commencement, there were no significant differences in age, parity, body mass index and MBS between the two groups. There were no drop outs. Greater proportions established labour in both primigravidae (30% vs. 9%; Relative Risk (RR) =4.4, 95% CI 1.3-14.6; p=0.01) and multigravidae (44%.vs.16%; RR=4.3; 95% CI 1.6-11.8; p=0.003) before 41 weeks' gestation in OM group compared to the Foley catheter group. Among the multigravidae, the mean increase of MBS was greater in the OM group (3.1; 95% CI 2.4-4) compared to the Foley group (2.4; 95% CI 1.9-2.7, p=0.04). One primigravida and two multigravidae developed

hyper stimulation after OM. No significant differences were seen in the other maternal and perinatal outcomes.

Conclusions: Compared to a supra cervical Foley catheter for 24 hours, three doses of OM 50 µg four hourly was more effective for cervical ripening and even resulted in IOL[43].

3) The third RCT was carried out in 2016 / 2017. The objective was to compare the effectiveness of IOL with three doses OM 50 µg four hourly per day for 48 hours versus a supra cervical Foley catheter for 48 hours in women at 40 weeks + 5 days gestation. There were 144 women having MBS 5 at 40 weeks + 5 days gestation who were allocated to receive three doses of OM 50 µg given four hourly per day for 48 hours (n=72) or a supra cervical Foley catheter for 48 hours (n=72).

Results: At commencement, there were no significant differences in age, parity, body mass index and MBS between the two groups. There were no drop outs. Compared to a supra cervical Foley catheter, with OM, successful IOL was higher (RR 1.4, 95% CI 1.1-1.9, p=0.029), mean increase in MBS in those not in labour after 48 hours was greater (4.8, 95% CI 4.1-5.4 vs 4.1 95% CI 3.8-4.4, p=0.017), VD 24 was more (RR 4.2, 95% CI 1.8-9.6, p<0.001), IDI were shorter, more hyperstimulation and meconium stained liquor were seen, but no significant difference were seen in CD rates.

Conclusion: Three doses of OM 50 µg given four hourly per day for 48 hours was more effective than a supra cervical Foley catheter for 48 hours, for IOL[44].

Therefore in summary we concluded that: two doses of 25 g OM administered four hours apart, was inadequate and inferior to a supra cervical Foley catheter for pre induction cervical ripening in post dated pregnancies[42] compared to a supra cervical Foley catheter for 24 hours, three doses of OM 50 g four hourly was more effective for cervical ripening and even resulted in IOL[43], and three doses of OM 50 µg given four hourly per day for 48 hours was feasible and more effective than a supra cervical Foley catheter for 48 hours, for IOL[44].

Conclusions

As OM has been shown to be feasible and effective for IOL, it should be considered as an option for IOL

in Sri Lanka. As the trans cervical insertion of a supra cervical Foley catheter which could be kept *in situ* for 48 hours has been shown to be equally effective as OM for IOL, for low risk women staying close to their hospitals and preferring outpatient IOL, the insertion of a supra cervical Foley catheter appears to be a suitable option, while adopting suitable measures for the prevention / early detection and treatment of possible complications, which however have been shown to be minimal. When considering the current best available evidence, the common practice in several obstetric units in Sri Lanka, of removing the supra cervical Foley catheter after 24 hours, should be discouraged. In the Cochrane Review which included 34 studies with 5003 women, outpatient IOL was found to be feasible and effective, with a reduction in the need for interventions as well as shortened IDIs, and adverse events appeared to be rare[45]. Further research is needed to identify the safest, cost effective outpatient method of IOL which is preferred by women. In view of the availability of prostaglandins the MBS should be used only as a score to decide the modality of IOL and not to assess the favourability of the woman for IOL. In view of recent evidence, vaginal delivery in 24 hrs (VD24) should not be a criterion to assess "successful IOL" and CD for a "failed IOL" could be delayed up to four days, in the absence of any maternal or fetal complications. In the future, outpatient IOL with low dose OM and telemonitoring of the mother and fetus may become a reality.

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