MANAGEMENT OF PRELABOUR RUPTURE OF MEMBRANES AT TERM: PROSTANGLANDINS OR OXYTOCIN FOR INDUCTION OF LABOUR IN UNFAVORABLE CERVIX?

BY

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A dissertation submitted in fulfilment of the requirement for the degree of Master of Obstetrics and Gynaecology

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ABSTRACT

This study was conducted to compare the outcome in between prostaglandins and oxytocin as methods of induction of labour in prelabour rupture of membranes with unfavorable cervix. This is a prospective randomized double blinded study carried out from 1st July 2012 to 30th June 2013 at Hospital Sultan Ismail Johor Bahru. A total of 148 women with singleton pregnancies at ≥ 37 weeks, no prior uterine scar, vertex presentation, reactive cardiotocogram (CTG) were randomly assigned to receive immediate induction of labour either by intravenous oxytocin infusion or vaginal prostaglandin E2. The primary outcomes were maternal and neonatal outcome. Data was analyzed using SPSS version 10.0 and p value of <0.05 was considered to be statistically significant. 148 patients were included in this study, 73 patients in prostaglandins arm, and 75 patients in oxytocin arm. The mean age was 27.8±4.9 years old and the mean gestational age was 38.7±1.2 weeks. Majority of them (73%) presented with PROM of less than 24 hours. Following induction of labour, 68% of them achieved vaginal delivery. In the oxytocin group, induction of labour to vaginal delivery interval (7.6±4.7 versus 16.5±14.8, p<0.001) and leaking liquor to delivery interval (19.1±11.8 versus 32.3±22.4, p<0.001) were significantly shorter than the PGE2 group. However caesarean delivery was found 3 times more (32.0% versus 9.6%, p=0.001) in the oxytocin group. The rate of neonatal infections (31.5% versus 8.0%, p<0.001) and NICU admission (38.4% versus 21.3%, p=0.023) were significantly lesser in the oxytocin group. In conclusion, neither oxytocin nor PGE2 was preferred as a method of induction of labour in patients with PROM at term with unfavourable cervix. The management of term PROM therefore needs to be individualized to achieve the best maternal and neonatal outcomes. Expectant management remains as an alternative option.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Master of Obstetrics and Gynaecology.

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Mokhtar Awang

Supervisor

I certify that I have read this study and that in my opinion it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Master of Obstetrics and Gynaecology.

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This dissertation was submitted to the Department of Obstetrics and Gynaecology and is accepted as a partial fulfilment of the requirements for the degree of Master of Obstetrics and Gynaecology

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DECLARATION

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CHAPTER ONE

INTRODUCTION

Pre-labour rupture of membranes (PROM) is a common antenatal problem that Obstetrician encounters in daily practice. It is most commonly defined as rupture of membranes before the onset of labour occurs at or beyond 37 weeks' gestation ("Practice bulletins," 2013). It occurs in approximately 8-10% of term pregnancies ("Practice bulletins," 2013; Alexander & Cox, 1996; Modena, Kaihura, & Fieni, 2004). In term PROM, more than 70% of women deliver within 24 hours and up to 85% of women give birth within 48 hours (Keirse, Ottervanger, & Smit, 1996). Though it is desirable, the risk of intrauterine infection increases with duration of membrane rupture ("Practice bulletins," 2013).

The clinical management of patients with term PROM especially in an unfavourable cervix remains controversial (Wagner, Chin, Peters, Drexler & Newman, 1989). As there is lack of clear evidence on optimal management of PROM at term, it is very much depends on local protocols which have shown to be varied from one to another. Management options include expectant management or induction of labour, either with oxytocin or dinoprostone (PGE2) (Mozurkewich, 2006). Expectant management is a reasonable option if there is no evidence of infection or fetal compromise. However patients need to be aware of morbidities associated with prolonged rupture of membranes which include fetal distress, cord prolapse and placental abruption apart from the risk of maternal and neonatal infections (Merenstein & Weisman, 1996).

On the other hand, active management leads to a shorter admission to onset of labour thus reducing the risk of intrauterine infection and neonatal intensive care unit admission (Dare, Middleton, Crowther, Flenady & Varatharaju, 2006; Hannah et al., 1996). Induction of labour also leads to shorter induction to delivery interval and shorter hospital stay with fewer digital examinations (Akyol, Mungun, Ünsal & Yüksel, 1999). And it is shown that most women preferred active management than expectant management (Hodnett et al., 1997).

Either prostaglandins E2 (PGE2) or oxytocin can be used when induction of labour is undertaken in nulliparous or multiparous women who have ruptured membranes, regardless of cervical status, as they are equally effective and safe (Rabl, Joura, Yücel & Egarter, 2002).

Induction of labour especially with intravenous oxytocin resulted in a slight lower risk of maternal infections (chorioamnionitis) and neonatal infections in comparison to intravaginal prostaglandins (Tan & Hannah, 2000). Therefore immediate oxytocin infusion is recommended by American College of Obstetrics and Gynecologists for induction of labour for those women with term PROM ("Practice bulletins," 2013). Induction of labour with intravenous oxytocin was also found more superior as it significantly shortens the time from induction to delivery and thus shorten the duration of hospital stay (Kunt et al., 2010; Güngördük et al., 2012).

With regards to caesarean section rates, neither oxytocin nor PGE2 has shown any significant differences between these two approaches (Dare, Middleton, Crowther, Flenady & Varatharaju, 2006; Tan & Hannah, 2000; Tan, Daud & Omar, 2009). However some authors concluded that induction of labour using oxytocin significantly increases the

rate of caesarean delivery in view of higher risk of induction failure (Güngördük et al., 2012; Ottervanger, Keirse, Smit & Holm 1996).

The aim of this randomized study was to compare the outcomes of two protocols - intravaginal prostaglandins versus oxytocin infusion for induction of labour in women with PROM at term and unfavorable cervix. Maternal and neonatal outcomes were assessed and compared. The research hypothesis is no difference in the maternal and neonatal outcome in between these two approaches.

CHAPTER TWO

LITERATURE REVIEW

Pre-labour rupture of the membranes (PROM) occurs in approximately 8% of term pregnancies and complicates 3% of pregnancies that have not reached 37 weeks of gestations ("Practice bulletins," 2013). Generally, PROM is defined as rupture of the membranes with leakage of amniotic fluid in the absence of uterine activity. Some defines PROM more specifically based on duration of latent period before onset of labour. For instance, according to South Australian Perinatal Practice Guidelines, PROM is defined as failure to establish in labour after a latent period of 4 hours following confirmed rupture of membranes (Department of Health, Government of South Australia, 2004). At term, it is shown in a large randomized trial that 95% of them gave birth within 28 hours of membrane rupture (Hannah et al., 1996).

Till now, the optimal management of term PROM remains controversial (Dare et al., 2006). Women with PROM at term (over 37 weeks) should be offered a choice of immediate induction of labour or expectant management.

Early studies suggested that immediate oxytocin induction of labour might reduce maternal and neonatal infections while increasing risk of caesarean section (Ottervanger et al., 1996; Duff et al., 1984). Later, a larger multicentre randomized controlled trial- TERMPROM Study proved that induction of labour with oxytocin or prostanglandin E2 and expectant management result in similar rates of neonatal infection and caesarean section (Hannah et al., 1996). In the similar trial, induction of labour with intravenous oxytocin results in a lower risk of maternal infection than does expectant

management (Hannah et al., 1996). In this trial also found that women in the induction group viewed induction of labour more positively and felt reassured. Immediate induction of labour with oxytocin was also found to be less costly (Gafni et al., 1997).

Induction of labour is recently recommended for those women with PROM at 37 weeks of gestation or more if spontaneous labour does not occur near the time of presentation ("Practice bulletins," 2013). Another author recommended induction of labour only if spontaneous labour has not begun after 24 hours of PROM at term. Therefore timing of induction of labour still remains controversial. Induction of labour using oxytocin remains the method of choice as recommended by many well known guidelines ("Practice bulletins," 2013; "RANZCOG," 2010).

Induction of labour by oxytocin may decrease the risk of maternal and neonatal infection compared to expectant management, and does not appear to increase the rate of caesarean section (Tan & Hannah, 2000).

On the other hand, induction of labour with prostanglandins appears to decrease the risk of maternal infection and neonatal intensive care unit admission compared to expectant management, and similar to oxytocin, it does not appear to increase the rate of caesarean section (Tan & Hannah, 2002).

A meta-analysis of 12 randomized controlled trials showed that induction of labour in term PROM reduces the risk of maternal infectious morbidity and admission to neonatal care intensive unit without increasing obstetric interventions such as caesarean delivery and operative vaginal delivery (Dare et al., 2006). There was no difference in neonatal infection rates seen in both of the planned and expectant management groups (Dare et al., 2006).

In an earlier study conducted by Chua et al found that the use of PGE2 conferred no advantages over the use of intravenous oxytocin in obstetric and neonatal outcome (Chua et al., 1991). In another review comparing prostanglandins and oxytocin for induction of labour in women with PROM at term, it is shown that labour induced with prostanglandins appears to have a lower risk of epidural analgesia and fetal heart rate monitoring. However prostaglandins induction appears to have an increased risk of chorioamnionitis and neonatal infections in comparison to oxytocin (Tan & Hannah, 2000).

In a more recent randomized trial, the author concluded that oxytocin treatment seems to be more superior to vaginal admistration of prostanglandin E2 to induce labour in term pregnancies complicated with PROM and unfavourable cervices as it results in significantly shorter time from induction to delivery (Kunt et al., 2010). Similar outcome was seen in a randomized trial in Nepal (Rijal, Manandhar & Pradhan, 2012).

When PGE2 is used for induction of labour in term PROM, it is shown that it was successful and effective in more than 80% of cases with no apparent serious maternal or neonatal complications (Ben-Haroush et al., 2004). There was no significant difference in the rates of caesarean delivery, neonatal intensive care unit admissions or low Apgar score in either nulliparous or multiparous women when the labour was induced with PGE2 after PROM (Sobande & Albar, 2003).

In a local study conducted by Tan PC, it is shown that concurrent vaginal dinoprostone and intravenous oxytocin used for labour induction of term PROM neither expedite delivery nor improve women satisfaction (Tan et al., 2009). In contrast to the above study, in another study conducted recently in Turkey showed that the use of PGE2

followed by oxytocin infusion in term PROM led to a significantly higher numbers of women with vaginal delivery within 24 hours (Güngördük et al., 2012).

Prostanglandins E1 (misoprostol) is gaining increasing popularity as an alternative induction agent in patients with term PROM. It was shown to be equally efficacious in labour induction and demonstrates a similar fetal and maternal safety profile to prostaglandin E2 (Shetty, 2002; Crane, Buttler, Young & Hannah, 2006; Lin, Nuthalapaty, Carver, Case & Ramsey, 2005; Chaudhuri, Mitra, Banerjee, Biswas, & Bhattacharyya, 2011). However it is not licensed in Malaysia for induction of labour at term.

It is found that increasing number of digital examination, longer duration of active labour and meconium stained liquor were the most important risk factors for the development of clinical chorioamnionitis in women with PROM at term (Seaward et al., 1997). Strong predictors for caesareans section after PROM at term include nulliparity, long labour, previous caesarean delivery and epidural analgesia (Peleg et al., 1993). Prolonged rupture of membrane and chorioamnionitis are known risk factors for neonatal infection (Ladfors et al., 1998).

CHAPTER THREE

METHODOLOGY

This study was conducted at Hospital Sultan Ismail Johor Bahru for duration of 12 months, from 1st July 2012 till 30th June 2013. This hospital has 10,000 deliveries annually, since year 2010, with an average of 800 deliveries per month.

It was a prospective randomized study that included all women visited Pregnancy Assessment Centre (PAC) at Hospital Sultan Ismail with prelabour rupture of membrane at term during the stated duration. The sample size was calculated via PS 3.1.2 software (Dupont & Plummer, 1990). 72 women were required in each arm after setting significance at 5%, power at 80% and one-to-one recruitment ratio.

Inclusion criteria were singleton pregnancy, vertex presentation, no prior uterine scar, uncomplicated pregnancy, leaking with clear liquor and reactive cardiotocogram on admission. Samples were chosen from those patients who fulfill the inclusion criteria, presented to Pregnancy Assessment Centre (PAC) with leaking liquor prior to onset of labour at 37 weeks of gestations or more.

History of leaking liquor was then confirmed by a sterile speculum examination which shows pooling of liquor and positive reactions of Amnistix (nitrazine yellow) results in a blue / purple colour on contact. Once the diagnosis of PROM was made, it was then followed by a digital examination to determine the cervical score. Only those patients with confirmed diagnosis of PROM with unfavourable cervical score were included in the study. Unfavourable cervical score was defined as Bishop score of 6 or less (Tan, Valiapan, Tay & Omar, 2007; Bolnick, 2004; Christensen, 2006).

Informed consent was obtained from the subjects after thorough explanations of the study and its process being explained by the investigators. Identities of all patients participating in the study were kept confidential.

The women were randomised to receive either 3mg prostanglandin E2 (PGE2) every 6 hours to a maximum of 3 doses (1 cycle of treatment), or intravenous oxytocin infusion according to the hospital protocol. For women assigned to the induction with PGE2 group, PGE2 pessary was placed in the posterior vaginal fornix. CTG was performed 1 hour before and after insertion of PGE2 and the women were monitored for clinical signs of chorioamnionitis such as fever, foul smelling liquour, tender irritable uterus or fetal tachycardia. They were then reviewed 6 hours after the insertion of intravaginal PGE2 and subsequent dose of PGE2 was inserted if the cervical score was 6 or less. If the women did not go into active labour after 6 hours of third dose of PGE2 or cervical score remained 6 or less, then the case was considered failed induction. Once the cervical score was more than 6, they were sent to the labour room for intravenous oxytocin infusion.

Oxytocin infusion (5mU in 50mL of Ringer's lactate solution) was started at a rate of 2mU/min and increased 2mU/min every 30 minutes to aim for frequency of contractions of 4 in 10 minutes. The maximum allowable dose of oxytocin was 32mU/min. Oxytocin infusion was decreased or stopped when there was presence of 5 contractions or more in 10 minutes for 2 conservative 10 minutes period. Vaginal examination was performed every 4 hourly to assess progress of labour and liquor color. Intramuscular pethidine was used as obstetric analgesia.

Fetal heart rate and uterine activity were monitored continuously throughout labour. As indicated by the chemoprophylaxis guidelines of the hospital protocols, antibiotics were administered in case of PROM of 18 hours or more and body temperature of 37.5°C or more. The choice of antibiotic was intravenous ampicillin 1g and it was given every 6 hourly until delivery. All newborns were examined by paediatric team to assess for signs of sepsis and need for admission to neonatal intensive care unit (NICU).

A form was subsequently attached in patient's file so that the maternal and fetal outcome can be filled in. Assessment of maternal outcome included maternal infections (chorioamnionitis or endometritis), length of labour, induction to delivery interval, duration of induction of labour, caesarean section, operative vaginal birth, and postpartum hemorrhage (PPH). On the other hand, assessment of neonatal outcome included neonatal infections (presumed sepsis, congenital pneumonia, etc), Apgar score 7 or less at 1 minute, NICU admission, MAS and HIE.

Chorioamnionitis is defined as temperature of 38°C or more accompanied by maternal or fetal tachycardia (>160 beats/min), uterine tenderness, malodorous amniotic fluid discharge, and/or maternal leucocytosis (white cell count >15,000 cell/min) (Webb, 1967). Postpartum endometritis is defined as temperature of 38°C or more accompanied by uterine tenderness and/or purulent or foul smelling lochia beyond the first 24 hours after delivery. Postpartum hemorrhage is defined as a blood loss of 500 mls or more within 24 hours after birth (Tuncalp, Souza & Gulmezoglu, 2013).

Failed induction of labour is defined as failure to progress to active phase of labour after administration of oxytocin for 12 hours following membrane rupture or labour has not begun after 1 cycle of PGE2 administration (Rouse et al., 2011). Neonatal sepsis is

defined as infection in an infant 28 days of life or younger, manifested by systemic signs of infection and confirmed with at least one of the following: a positive culture of blood, cerebrospinal fluid, urine, tracheal aspirate, or lung tissue; a positive Gram's stain of cerebrospinal fluid; a positive antigen-detection test with blood, cerebrospinal fluid, or urine; a chest radiograph compatible with pneumonia; or a histologic diagnosis of pneumonia (Edwards & Baker, 2004).

The data obtained was analysed using the Statistical Package for the Social Sciences (SPSS) version 20.0. Basic descriptive statistics and frequency calculations were performed on all the variables. Apart from mean, standard deviation, percentage, Pearson's Chi-square test was used to analyse the categorical data and student T test was used to analyze continuous variables. P value of < 0.05 represented statistically significance.

CHAPTER FOUR

RESULTS & FINDINGS

During the duration of 12 months from 1st July 2012 to 30 June 2013, a total of 150 pregnant women were recruited. However two subjects in the prostanglandin E2 (PGE2) group were excluded from the study because they were found to have group B Streptococcal infection. Therefore, there were 73 subjects in the PGE2 group and 75 subjects in the oxytocin group.

Table 4.1 Demographic characteristics of the women in the PGE2 and oxytocin groups

Demographic characteristics	**PGE2 (n=73)**	**Oxytocin (n=75)**	**P value**
Maternal age (years)	27.5±5.1	28.0±4.7	0.551
Gestational age (weeks)	38.5±1.2	38.8±1.2	0.223
Ethnics			0.404
-Malay	58 (79.5)	54 (72.0)	
-Chinese	8 (11.0)	9 (12.0)	
-Indian	1 (1.4)	5 (6.7)	
-Others	6 (8.8)	7 (9.3)	
Parity			0.031
-0	48 (65.8)	61 (81.3)	
-1-4	25 (34.2)	14 (18.7)	

*Data are presented as mean ± standard deviation or n (%)

The demographic characteristics of the study population are summarized in Table 1. Mean maternal age was 27.8±4.9 years old and mean gestational age was 38.7±1.2 weeks. There was no significant difference among the ethnicity in between these two groups. However the majority of the respondents were Malays (75.7%). It was noted that more nulliparous women in the oxytocin group as compared to multiparous women (81.3% versus 18.7%, p=0.031).

Table 4.2 Pre-induction characteristics in between PGE2 and oxytocin groups

Pre-induction characteristics	**PGE2 (n=73)**	**Oxytocin (n=75)**	**P value**
Duration of leaking (hours)			0.001
-≤24 hours	44 (60.3)	64 (85.3)	
->24 hours	29 (39.7)	11 (14.7)	
Pre-induction Bishop Score	2.8±1.7	4.4±0.8	<0.001

*Data are presented as mean ± standard deviation or n (%)

Pre-induction characteristics of the study population are shown in Table 4.2. Most of them (73.0%) presented with leaking liquor with duration of 24 hours or less.

Maternal outcomes of the study population are as shown in Table 4.3. The time from induction of labour to vaginal delivery (7.6±4.7 versus 16.5±14.8, p<0.001) and the time from leaking of liquor to delivery (19.1±11.8 versus 32.3±22.4, p<0.001) were significantly shorter in the oxytocin group than in the PGE2 group.

Caesarean delivery was significantly increased (p=0.001) whereas spontaneous vaginal delivery (p=0.011) was significantly reduced in the oxytocin group. The

indications for caesarean delivery were mainly failure to progress, failed induction of labour and fetal distress.

Table 4.3 Maternal outcome in between the PGE2 and oxytocin group

Maternal outcome	**PGE2 (n=73)**	**Oxytocin (n=75)**	**P value**
Induction to vaginal delivery interval (hour)	16.5±14.8	7.6±4.7	<0.001
PROM to delivery interval (hour)	32.3±22.4	19.1±11.8	<0.001
Maternal fever during labour	2 (2.7)	6 (8.0)	0.276
Intrapartum antibiotics	54 (74.0)	53 (70.7)	0.653
Mode of delivery			
-Spontaneous vaginal delivery	57 (78.1)	44 (58.7)	0.011
-Caesarean delivery	7 (9.6)	24 (32.0)	0.001
-Operative vaginal delivery	9 (12.3)	7 (9.3)	0.557
Indications for caesarean delivery			
-Fetal distress	0	8	
-Failed induction	4	6	
-Failure to progress	3	10	
EBL during delivery (ml)	375.3±65.7	402.7±134.8	0.121
Postpartum hemorrhage (EBL 500mL or more)	7 (9.6)	11 (14.7)	0.345

*Data are presented as mean ± standard deviation or n (%)

The neonatal outcomes are as listed in Table 4.4. The rates of Apgar score 7 or less at 1 minute (p=0.617), MAS (p=0.242) and HIE (p=0.242) were not statistically different in between the study groups. The rates of neonatal infection (31.5% versus 8.0%, p<0.001) and NICU admission (38.4% versus 21.3%, p=0.023) were found to be significantly higher in the PGE2 group in comparison to the oxytocin group.

Table 4.4 Neonatal outcomes in between the PGE2 and oxytocin group

Neonatal outcome	**PGE2 (n=73)**	**Oxytocin (n=75)**	**P value**
Mean birth weight (kg)	2.939±0.41	2.977±0.43	0.587
Apgar score 7 or less at 1 minute	2 (2.7)	1 (1.3)	0.617
Neonatal infection/sepsis	23 (31.5)	6 (8.0)	<0.001
NICU admission	28 (38.4)	16 (21.3)	0.023
MAS	2 (2.7)	0 (0.0)	0.242
HIE	2 (2.7)	0 (0.0)	0.242

*Data are presented as mean ± standard deviation or n (%)

Table 4.5 Subgroup analysis by parity

Subgroup analysis by parity	**PGE2 (n=73)**	**Oxytocin (n=75)**	**P value**
Parity 0	n=48	n=61	
Mode of delivery			
-Spontaneous vaginal delivery	34	34	0.106
-Caesarean delivery	5	20	0.006
-Operative vaginal delivery	9	7	0.287
Parity 1-4	n=25	n=14	
Mode of delivery			
-Spontaneous vaginal delivery	23	10	0.088
-Caesarean delivery	2	4	0.088
-Operative vaginal delivery	0	0	-

*Data are presented as mean ± standard deviation or n (%)

Table 4.5 shows subgroup analysis of mode of delivery by parity. Further analysis according to parity found that there was statistically significant difference in mode of delivery especially caesarean delivery in between nulliparous and multiparous women with term PROM. Caesarean delivery is found to be statistically higher in nulliparous women in the oxytocin group (p=0.020).