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Full Length Research Paper

Pre-induction cervical ripening: A randomized controlled trial of vaginal dinoprostone gel vs double balloon catheter for induction of labour in nulliparous and multiparous women with unfavourable cervix

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The main aim of this study is to compare the efficacy and patient satisfaction of two methods of labour induction in terms of singleton pregnancies of both nulliparous and multiparous women with an unfavourable cervix. The primary outcome was caesarean section rates between groups. The study used Randomised Controlled trial. The population of nulliparous and multiparous women with an unfavourable cervix requiring induction at term is (n=251). Two study arms were used: double-balloon catheter (n=116) and Dinoprostone gel (n=130). Five women, who were eligible, declined intervention. Three women from Dinoprostone gel group and six from the double-balloon catheter group were excluded from analysis due to protocol violations. There is no significant difference in delivery outcomes or rates of caesarean section between the interventions. Induction with Dinoprostone gel resulted in significantly more uterine hyperstimulation with no increase neonatal morbidity. Overall there was no difference in patient's pain score or satisfaction between interventions regardless of parity. Labour induction with Dinoprostone gel or double-balloon catheter is equally efficacious and acceptable to women. We suggest that the method of induction should be dictated by clinicians' experience, facilities available and women's preference. Further evaluation of cost and neonatal outcomes are important ongoing research areas.

Key words: Induction of labour, double balloon catheter, mechanical ripening, prostaglandin, nulliparous, multiparous, unfavourable cervix.

INTRODUCTION

Induction of labour is one of the most commonly performed procedures in modern obstetric practice. Mealing et al. (2009), showed that in Australia the rate of induction of labour increased over the last decade with reported rates close to 30%.

The condition of the cervix prior to the onset of labour significantly impacts the course of labour. Cocks et al. (1955), showed that a cervix that is posterior, closed and firm is associated with longer duration of labour and higher rates of vaginal and operative delivery. Bueno et al. (2005), showed that the success of induction of labour, where a ripened cervix, defined as a Bishop's score >4, has been found to be a significant predictor of successful vaginal delivery within 24 hrs. The process of induction of labour first involves assessment of the cervix using the modified Bishop's score. If deemed unripe (Bishop's score ≤4) pre-induction ripening is undertaken.

As per NICE clinical guideline 70 (2008), the most common method of pre-induction cervical ripening is pharmacological, with the administration of prostaglandin

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E2 (PGE2) intravaginaly or intracervically. Rath et al. (1993), revealed that PGE2 work through increasing collagenase and proteinase activity within the cervix with a resultant fall in collagen concentration, allowing dilatation. Clinically, when compared to placebo or no treatment, induction of labour with PGE2 pre-ripening is more likely to result in cervical change and achievement of vaginal delivery within 24hrs. Importantly however, the use of prostaglandins in induction of labour is associated with an increased risk of uterine hyperstimulation and adverse effects on foetal heart rate. Thomas et al (2014), showed this does not appear to translate into serious neonatal morbidity or perinatal death, it remains of clinical concern.

Mechanical methods are also used in induction of labour, most commonly by the insertion of extra-amniotic transcervical single or double-balloon catheters. Lin et al. (2007), revealed this method generates change in cervical condition through both a direct mechanical dilatation and stretch induced of release of endogenous prostaglandins.

Gilson et al (1996) showed that induction of labour through mechanical methods have also been shown to increase the rates of vaginal delivery within 24hrs.when compared to no treatment.Several studies (Siddiqui, 2003; Jozwiak 2012) showed infection risk associated with mechanical induction of labour was initially of concern, howeverno significant increased risk of morbidity has been shown in large meta-analysis. Importantly the adverse events of uterine hyperstimulation occurring with the use of PGE2 is not seen with mechanical induction of labour.

Overall, the optimal method of cervical ripening remains unclear. Jozwiak et al (2012), showed in a recent meta-analysis that mechanical or vaginal PGE2 methods of cervical ripening did not significantly differ in the proportion of women achieving vaginal delivery within 24hrs or rates or caesarean section rate.

It is important to note that patient satisfaction with each method has seldom been addressed and nulliparous women have been over represented in previous study populations.

We conducted a randomized controlled trial comparing the efficacy of inducing labour with the use of double-balloon catheter versus PGE2 gel in both nulliparous and multiparous women. The primary outcome measure was the rate of caesarean section in each group. Secondary endpoints included induction to delivery interval and rates of obstetric and neonatal complications to assess harm and benefits of each intervention.Our study also addresses patient satisfaction between the two methods.

METHODS

Recruitment and randomisation

Women requiring induction of labour were recruited from the antenatal clinic of Royal Hobart Hospital, (RHH), Tasmania between September 2012 and May 2014 regardless of their parity.Ethics approval was obtained from the Health and Medical Human Research Ethics Committee, University of Tasmania.

Women were given written information about the trial andfor those who agreed to participate, informed consent was obtained prior to inclusion into the study. Once an indication for induction of labour was confirmed and consent obtained, subjects were randomly allocated to intervention groupsthrough sequential assignment of sealed opaque envelopes containing the treatment arm. The orders of the envelopes were randomly assigned. The nature of the interventionsmade blindingof subjects or clinicians unfeasible.

A modified Bishop's score was determined prior to induction by duty registrars or obstetricians and recorded on the study proforma.

The study included women who required induction of labour for any cause. Inclusion and exclusion criteria are listed in figure 1.

Intervention

Prostaglandin gel

PGE2 gel (ProstinE2, Pfizer Australia Pty Ltd.), 2mg for nulliparous women and 1mg for multiparous women,was placed in the posterior fornix as per institutional protocol. Dosingwas repeated six hourly to a maximum of three doses unless the Bishop's score was greater than six or onset of regular painful contractions <5 minutes apart. Withoutexception cardiotocographic (CTG)monitoring was performed for at least 30 minutes before and after administration.

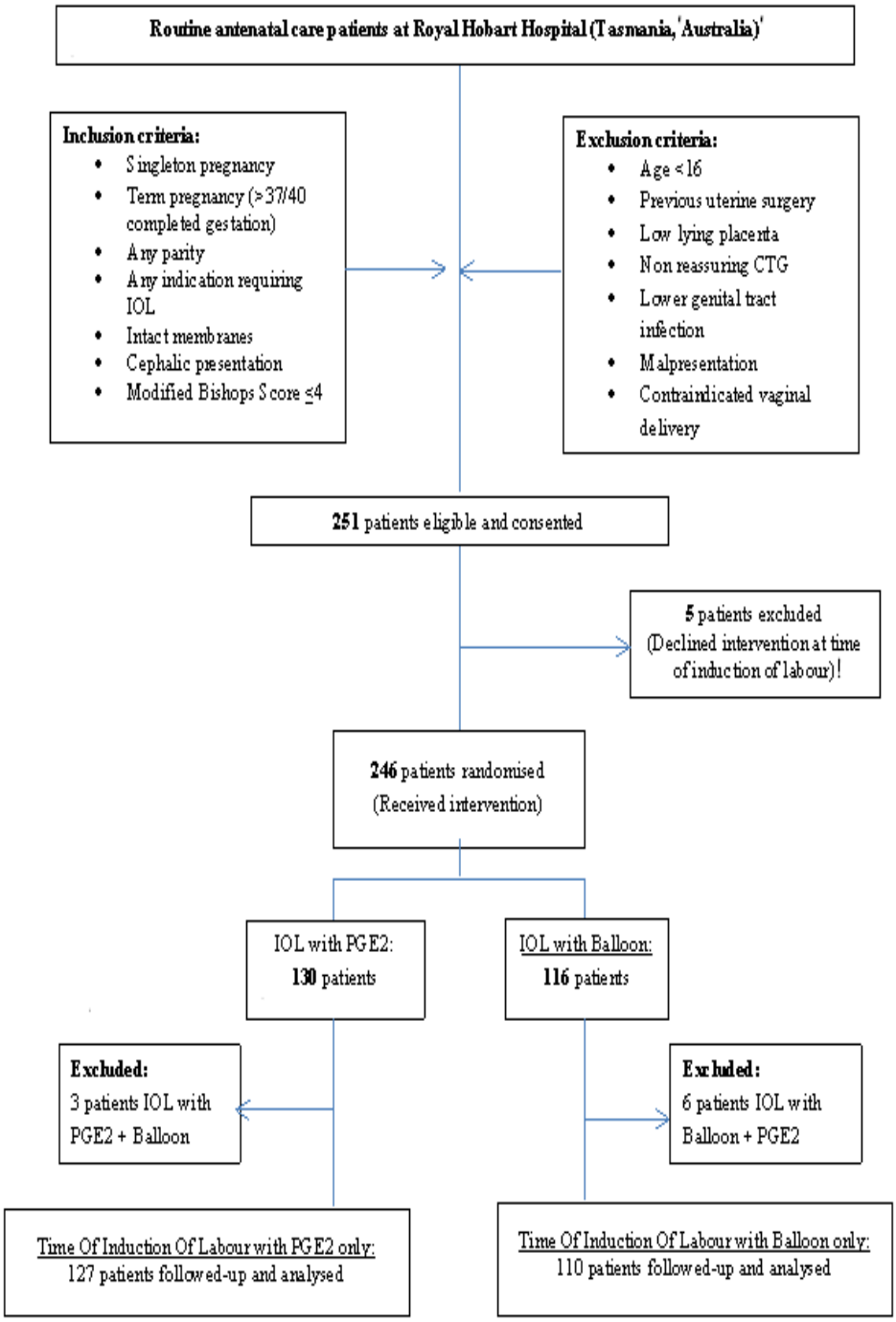
Double-balloon catheter

A double-balloon catheter (Cook Cervical Ripening Balloon 100% Silicone, Cook Ireland Ltd) was inserted through the cervix and each balloon inflated with 80mls of sterile water. The catheter was taped to the patient's thigh, free of tension, for patient comfort. The duty registrars inserted the catheter. The catheter was removed 12 hours after insertion if spontaneous expulsion had not occurred. As with PGE2 group, CTG monitoring was performed for at least 30 minutes before and after insertion.

Management of labour

Labour was managed by the attending midwives and obstetric registrars as per unit protocol. Amniotomy was performed at 3cm of cervical dilatation in women with spontaneous onset of labour, defined as the onset of strong regular contractions. In women not in labour, mem-

Figure 1. Recruitment and flow of patients with cervical ripening during study.



membranes were artificially rupturedonce the modified Bishop's Score was>6. Augmentation of labour was commenced if there is inadequate progress 2-4 hours after amniotomy. Oxytocin infusion was titrated to contractions and analgesia administered at maternal request.

Electronic foetal monitoring was used throughout labour and all CTGs were reviewed by the study investigators post-delivery. Uterine hyperstimulationwas defined as greater than 5 contractions in 10 minutes for two consecutive 10 minute periods or a contraction lasting at least 2 minutes as per National Institute for Health and Clinical

Table 1. Patient demographic data.

	Group		*P*-value
	Double Balloon (n = 110)	PGE_2 (n = 127)	
Age*	27 (18 - 43)	28 (16 - 44)	0.353
Gravidity (%)			
1	43 (39)	51 (40)	0.875
2	26 (24)	32 (25)	0.858
3+	41 (37)	44 (35)	0.749
Parity (%)			
0	63 (57)	69 (54)	0.643
1+	47 (43)	58 (46)	0.644
Gestational age*	39.5 (37.0 – 41.5)	40.2 (37.1 – 42.1)	0.037
GA < 37 weeks	0	0	
Indication for induction (%)			
Postdates	42 (38)	52 (41)	0.637
Diabetes mellitus	21 (19)	30 (24)	0.352
IUGR/SGA	22 (20)	9 (7)	0.033
Hypertensive disease	10 (9)	16 (13)	0.329
Other (various indications)	15 (14)	20 (15)	0.827
BMI*	28.1 (16.1 – 52.2)	28.8 (17.6 – 50)	0.483
Modified Bishop score (%)			
0 – 3	80 (73)	85 (67)	0.314
4 – 5	30 (27)	42 (33)	0.316

Values are n (%) unless indicated otherwise.
*Mean (range) therewere no significant difference between groups (P> 0.05). P value for Gestational age and IUGR (< 0.05) is not clinically significant.

Excellence guideline.
Any CTG abnormalities during labour were recorded on the study proforma. In particular, persistent reduced variability, late decelerations and complicated variable decelerationswere considered suspicious and initiated foetal scalp blood monitoring. Subsequent management, including decision for operative delivery, was made in conjunction with the consultant obstetrician.
Failed induction was defined as an inability to rupture membranes 12 hours post insertion of a balloon catheter or three doses of PGE2. Cervical dilatation of <4 cm after 8 hour of strong spontaneous or augmented contractions was also included.

Data collection

Midwives, obstetric registrars and residents collectedrelevant labour and delivery data using a standard data proforma.Patient satisfaction was assessed though questionnaires distributed post-partum, prior to hospital discharge. The data was entered into a database that was reviewed monthly for completeness and accuracy by studyinvestigators.

Statistical Analysis

The primary outcome for this study wasa comparison of the rates of caesarean section. Secondary outcomes included evaluation ofdifferences in induction to delivery interval, adverse reactions to interventions and patient satisfaction.
Outcome data is presented in means with P values. The primary endpoint was analysed on an intention to treat basis using the t-sample tests (0.05 level of significance). Sample sizes of 125 women per group weresufficient to attain 80% power as described by Fritz and MacKinnon (2011). Continuous variables were compared between the groups using two sample t-tests. Patient satisfaction was compared using the Wilcoxon rank-sum test to account for the non-normal distribution. Exploratory subgroup analysis of multiparous and nulliparous study participants was also performed. Categorical variables were compared using proportion's test (for large and small as relevant). Time to delivery was analysed using

Table 2. Delivery outcomes and Neonatal outcomes.

	Group		*P*-value
	Double Balloon (n = 110)	**PGE_2 (n = 127)**	
Mode of delivery:			
Vaginal delivery	64 (59)	75 (59)	0.999
Assisted vaginal delivery	17 (15)	22 (17)	0.676
Caesarean section	29 (26)	30 (24)	0.723
Indication for caesarean section:			0.175
Failure to progress	15 (52)	9 (30)	
Obstructed labour	7 (24)	4 (13)	
Non Reassuring FHR pattern	4 (14)	13 (43)	
Cord prolapse	2 (7)	2 (7)	
Placental Abruption	1 (3)	1 (3)	
Failed Induction	0 (0)	1 (3)	
Indication for assisted vaginal delivery:			0.923
Prolonged second stage of labour	7 (41)	11 (50)	
Non-Reassuring FHR pattern	5 (29)	6 (27)	
Maternal Exhaustion	5 (29)	5 (23)	
Induction to delivery time*(hours)	21.87	19.53	0.011
Induction to active labour* (hours)	14.83	13.27	0.030
Length of labour* (hours)	7.11	5.87	0.025
Temperature in labour*	36.8	36.7	0.737
Pain on insertion of ripening device**	8	9	0.088
Pain during cervical ripening**	8	8	0.558
Overall satisfaction with induction of labour**	9	9	0.528
Fetal scalp blood sampling	3 (3)	4 (3)	0.901
Vaginal delivery <24 hours	51 (46)	60 (47)	0.894
Epidural	53 (48)	61 (48)	0.981
Antibiotics in labour	22 (20)	26 (20)	0.940
Blood loss at delivery:			
< 500 ml	91 (83)	102 (80)	0.554
500-1000 ml	15 (14)	17 (13)	0.822
> 1000ml	4 (4)	8 (6)	0.48
Birth weight (g)	3390 (1480 – 4780)	3600 (2300 – 5030)	0.006
Apgar <4 at 1 min	7 (6)	6 (5)	0.585
Apgar <7 at 5 min	3 (3)	2 (2)	0.571
Nursery admissions* **	29 (26)	14 (11)	0.003
Neonatal conditions	15 (14)	12 (9)	0.321
Fetal or congenital conditions	13 (12)	2 (2)	0.003
Mother unable to care for infant	1 (1)	0 (0)	0.490

Values are n (%) or mean (range).
FHR.Foetal heart rate; PPH, postpartum haemorrhage.
*Mean (test statistic calculated using two sample t-test)
** Median (calculated using Wilcoxon rank sum test)
***Reasons for nursery admissions: neonatal conditions include birth trauma, asphyxia, respiratory, unstable temperature, jaundice requiring phototherapy; foetal conditions include growth restriction, congenital abnormalities; mother unable to care for infant because of admission to the Adult Special Care Unit.

Kaplan Meier curves. All analyses were conducted using the R Statistical Software (V.3.0.3).

RESULTS

A total of 251 eligible patients were consented and recruit-to the study. Five patients were excluded, declining randomized on the day of induction of labour. Overall, 246 patients were randomised with 130 women receiving PGE2 gel and 116 women the double-balloon catheter (Figure 1). There were 9 protocol violations. Three women in PGE2 group received double-balloon Catheter

Table 3. Adverse reactions.

	Group		P-value
	Double Balloon (n = 110)	**PGE_2 (n =127)**	
Any induction/intrapartum adverse event	7 (6)	24 (19)	<0.0001
Blood transfusion	6 (5)	7 (6)	<0.988
Ripening Device			
Unable to void	1 (1)		
Decreased balloon volume because of discomfort	4 (4)		
Device removed because of discomfort	1 (1)		
Uterine hyperstimulation		22(17)	
With normal FHR pattern		14 (11)	
With non-reassuring FHR pattern		8 (6)	
With non-reassuring FHR pattern		7 (6)	
Requiring delivery			
Abruptio placentae	2 (2)	2 (2)	0.861
Re-presentation to hospital after discharge	12 (11)	14 (11)	0.996
Emergency centre	8 (7)	7 (6)	0.582
Required inpatient care	4 (4)	7 (6)	0.547
Reason for re-presentation			0.052
Endometritis	10 (9)	7 (5)	
Episiotomy breakdown/infection	0 (0)	1 (1)	
Mastitis	0 (0)	2 (2)	
Wound infection	2 (17)	3 (2)	

FHR = fetal heart rate.
*≥ uterine contractions in 10 minutes for two consecutive 10-minute periods within 6 hours of insertion of mechanical ripening device or within 6 hours of insertion of individual PGE_2doses
******Percentages reported for those re-presenting to hospital
***Includes urinary tract infection, increased vaginal loss and infected perineum.

following PGE2 gel and 6 women received PGE2 following double-balloon Catheter. This was due to either unsuccessful cervical ripening or insertion difficulties (Figure 1).

Baseline characteristics of both groups were similar, including age, Body Mass Index (BMI) and parity. The mean gestational age was statistically higher in the PGE2 group; however this was clinically not significant. Overall indications for induction were also similar across interventions apart from more small for gestational age (SGA) or intra-uterine growth restriction (IUGR) inductions being performed with double balloon. Additionally, cervical status at time of induction did not differ across intervention groups (Table 1).

Delivery outcomes were similar across both interventions. Overall 24.9% of women undergoing induction of labour required caesarean section. Both intervention groups hadcomparable caesarean section rates of 26% with double-balloon catheter and 24% with the PGE2 gel. (P= 0.723; Table 2). There were no differences in therates of spontaneous vaginal delivery or assisted vaginal delivery between the interventions.

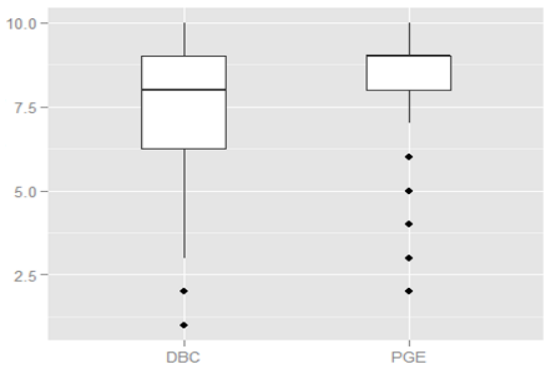
The time to induction and active length of labour weresignificantly shorter in the PGE2 group (P= 0.025) however, there was no difference in the rate of vaginal delivery at 24hrs (Table 2).

There were significantly more adverse events in the PGE2 group (P <0.001) compared to the double-balloon catheter group (Table 3). Twenty-four patients experienced an adverse event in the PGE2 group. Seventeen percent, 22 women, experienced uterine hyperstimulation. Eight of these were associated witha non-reassuring FHR pattern, seven of whom required urgent caesarean sections (Table 3). No uterine hyperstimulation was seen in the double balloon group.Seven women experienced adverse reactions in the double-balloon group. Four women experienced discomfort with the double-balloon catheter and requested reduction of balloon volume. One women had voiding difficulty and requested catheter removal (Table 3).

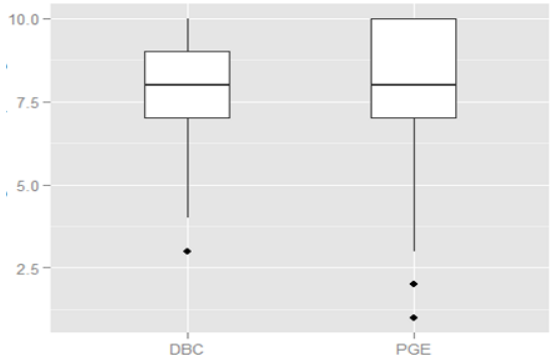
There were no differences in intra-partum analgesia use, maternal temperature or antibiotic use. Similarly post-partum blood loss or readmission postpartum did not differ.

On average 18% of neonates required admission to neonatal nursery or special care unit with significantly more admissions in the double-balloon catheter group; 26% versus 11%. (P= 0.003, Table 2). Reasons for nursery admissions were divided into neonatal conditions or foetal conditions. Neonatal conditions included birth trauma, asphyxia, respiratory difficulties, unstable

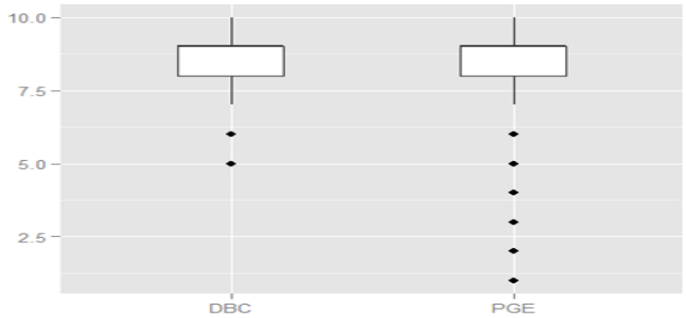
Figure 2. Patient pain and satisfaction scores with mode of induction. Box and Whisker plots for visual analogue score assessed prior to discharge from hospital.



A. Pain on Insertion of Ripening Device



B. Pain during Cervical Ripening



C. Overall satisfaction with Induction of Labour.

temperature and jaundice requiring phototherapy. Foetal conditions were defined as growth restriction or congenital abnormalities. The difference in nursery admissions between the two groups was primarily due to more foetal/congenital conditions seen in the double-balloon intervention group.

There was no difference in reported pain during insertion of ripening device/gel or during the cervical ripening process. Overall satisfaction with induction of labour was also similar between interventions with respective (p-values 0.088, 0.558, 0.528, Figure 2). Sub-group analysis was carried out separating nulliparous and multiparous women using similar endpoints. For the nulliparous women, 63 women received double-balloon catheter and69received PGE2 gel with comparable caesarean section rates of 29% and 32% respectively (Table 4). Induction to delivery time between the double balloon and PGE2 gel group was 23.4 vs. 21 hours, which approached statistical significance with P-value of 0.06. (Table 4. This difference was due to a significantly longer time to commencement of labour in the double balloon catheter group. Adverse events in nulliparous women during induction of labour or intrapartum were seen with both interventions. Two womeninduced with the double-balloon catheter requested balloon volume reduction due to discomfort. In the PEG2 intervention group 7patients experienced uterine hyper stimulation, 5 of whom required urgent delivery. Additionally 1 woman experienced placental abruption (Table 4).

In multiparous women, 47 received a double-balloon catheter and 58 women received PGE2 gel. Caesarean section rates were 23% and 14% (P value= 0.20)Regardless of intervention multiparous women who were induced had a lower caesarean section rate than nulliparous women undergoing induction (Table 4).

In multiparous women, 5 patients in double-balloon catheter and 16 in the PGE2 groups experienced adverse events. (Table 4) Specifically, 15 patients experienced uterine hyperstimulation, 2 of whom required urgent delivery. One woman experienced placental abruption in the PGE2 group. In the double-balloon catheter group 2 women requested balloon volume reduction due to discomfort and 1 woman was unable to void and requested catheter removal. Two women in this group experienced placental abruption. (Table 4).

There was no significant difference in patient pain and satisfaction score with mode of induction of labour between nulliparous or multiparous women (Table 4).

DISCUSSION

Our study was undertaken to compare the efficacy, safety and patient satisfaction of two commonly used methods

Table 4. Delivery outcome, Neonatal outcomes and adverse outcomes for nulliparous and multiparous women.

	Nulliparous			Multiparous		
	DBC (n =63)	**PGE_2 (n =69)**	**P value**	**DBC (n =47)**	**PGE_2 (n = 58)**	**P value**
Mode of delivery:						
Vaginal delivery	28 (44)	28 (41)	0.65	36 (77)	47 (81)	0.56
Assisted vaginal delivery	17 (27)	19 (27)	0.94	-	3 (5)	0.11
Caesarean section	18 (29)	22 (32)	0.68	11 (23)	8 (14)	0.20
Indication for caesarean section:						
Failure to progress	10 (55)	7 (32)		5 (46)	2 (25)	
Obstructed labour	6 (33)	4 (18)		1 (9)	-	
Non Reassuring FHR pattern	1 (6)	11 (50)		3 (27)	2 (25)	
Cord prolapse	1(6)	-		1 (9)	2 (25)	
Placental Abruption	-	-		1 (9)	1 (12)	
Failed Induction	-	-		0 (0)	1 (13)	
Indication for assisted vaginal delivery:						
Prolonged second stage of labour	7 (42)	10 (53)		-	2 (67)	
Non-Reassuring FHR pattern	5(29)	4(21)		-	1 (33)	
Maternal Exhaustion	5 (29)	5 (26)		-	-	
Induction to delivery time*(hours)	23.4	21	0.06	19.9	17.8	0.09
Induction to active labour* (hours)	15.0	13.6	0.13	14.6	12.9	0.12
Length of labour* (hours)	8.4	7.4	0.17	5.4	4.0	0.06
Blood loss at delivery:						
< 500 ml	49 (78)	52 (75)		42 (89)	50 (86)	
500-1000 ml	11 (17)	9 (13)		4 (9)	8 (14)	
> 1000ml	3 (5)	8 (12)		1 (2)	-	
Induction/intrapartum adverse event	2 (3)	8 (12)		5 (11)	16 (28)	
Blood transfusion	4 (6)	7 (10)		2 (4)	-	
Ripening Device (n)						
Unable to void	0	-		1	-	
Decreased balloon volume because of discomfort	2	-		2	-	
Device removed because of discomfort	0	-		1	-	
Uterine hyperstimulation (n)		7		15		
With normal FHR pattern **	-	2		-	12	
With non-reassuring FHR pattern **	-	5		-	3	
With non-reassuring FHR pattern requiring delivery**	-	5		-	2	
Abruptio placentae	0 (0)	1 (1)		2 (4)	1 (2)	

Values are n (%).
* Mean (p values calculates using two sample t-test) FHR= fetal heart rate
**≥5 uterine contractions in 10 minutes for two consecutive 10-minute periods within 6 hours of insertion of mechanical ripening deviceor within 6 hours of insertion of individual PGE2 doses.

of induction of labour. Several studies (Atad J, 1996; Pennel C, 2009; Prager M, 2008 and Yuen P, 1996) compared the efficacy, safety and patient satisfaction of these two methods of induction but, these studies are small or restricted to nulliparous women, and weincluded 237 subjects, both nulliparous and multiparous women. With almost 50% multiparous women in each intervention group, our study population was representative and well powered.

Our analysis showed that overall there is no difference in efficacy of induction of labour using double-balloon catheter or PGE2 gel as reflected by the comparable caesarean section and instrumental delivery rates between the intervention groups. This is consistent with the results seen in the Cochrane meta-analysis of mechanical methods for induction of labour conducted by Jozwiak et al (2012).

The study data also showed that there was a trend towards higher rates of caesarean section in multiparous women being induced by double-balloon catheter. This was not statistically significant given the small sample size and further research into explore this potential association is needed.

Of statistical significance the induction to delivery interval was longer in the double-balloon group 21.9 hrs.vs. 19.6 hrs. (P Value = 0.011). Overall this translates to around an hour's difference in onset of active labour between interventions. This is not clinically significant as the overall rates of vaginal delivery at less than 24 hrs.are similar across both interventions. Induction with PGE2 resulted in a larger number of adverse events, primarily uterine hyperstimulation. Thomas et al (2014) revealed that uterine hyperstimulation is a well described complication of this method of labour induction and may potentially translate to poor neonatal outcomes.

Pennell et al showed that uterine hyperstimulation secondary to PGE2 induction was associated with neonatal academia with a median arterial cord blood pH of 7.26. We did not analyse umbilical artery blood gases instead clinical measures of Apgar scores and nursery admissions were used as markers of neonatal morbidity. We found no difference in the Apgar scores between the two interventions; however an increase in neonatal nursery admissions was seen in the double-balloon catheter group.

Admissions in the catheter group were primarily for foetal conditions including growth restriction and congenital abnormalities, rather than a neonatal condition secondary to labour complications. This is further supported by the finding of a significantly lower mean birth-weight of neonates being induced by double balloon catheter.

It is likely the differences in neonatal morbidity between intervention groups is secondary to selection bias as there were significantly more inductions for IUGR/SGA randomly assigned to the double-balloon intervention. (Table 1).

Adverse events in the double-balloon catheter group centred around pain and discomfort. Despite this there was no difference in reported pain scores, epidural rates or overall patient satisfaction between the interventions. Atad et al. (1996) have demonstrated higher pain scores with insertion of double balloon catheter than PGE2 gel. It is important to note that pain perception is highly subjective and the applicability of this result, especially in the context of conflicting data, must be interpreted with caution and with the woman's preference in mind.

Overall we found there is no significant difference between the two methods of induction of labour in terms of delivery outcomes, safety or patient satisfaction, thus it is up to clinicians discretion in conjunction with patient preferences to select a suitable method for induction of labour.

CONCLUSION

Induction with PGE2 gel or double-balloon catheter is equally efficacious and acceptable to women, although there is a trend towards higher rates of operative delivery in multiparous women being induced with a double balloon catheter. There is a higher risk of uterine hyperstimulation with the use of PGE2; although it does not translate to increased neonatal morbidity it did necessitate emergency operative delivery in some instances. We suggest that the method of induction used should be dictated by clinician experience and facilities available in conjunction with women's' preferences. Further evaluation of cost and neonatal outcomes are important ongoing research areas.

Disclosure of interests

The authors are financially independent from the funding bodies and have no potential conflict of interest.

Contribution to authorship

PM conceived and designed the study, prepared the protocol, implemented the intervention, collected and interpreted the data and contributed to writing of the article. AR collaborated with interpretation of data and preparation and revision of the article. BL collaborated with the study design, reviewed protocol and supervised the project. All authors approved the final version.

Details of ethics approval

Approval by the Ethics Committee of the University of Tasmania, Hobart, Tasmania (Registration Number H0012439).

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