Factors associated with successful induction of labor

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ABSTRACT

الأهداف: تحديد معدل تحفيز المخاض والأسباب الشائعة لذلك والعوامل المرتبطة بنجاح تحفيز المخاض ونتائجها.

الطريقة: أجريت هذه الدراسة في مستشفى الملك خالد الجامعي التابع لجامعة الملك سعود، الرياض، المملكة العربية السعودية، واستمرت خلال الفترة من ابريل 2010م إلى مارس 2011م. شملت الدراسة جميع النساء الحوامل الذين أُدخلوا بغرض تحفيز الولادة حيث تمت مقارنة خصائص اللواتي وُلدن ولادة طبيعية (نجاح تحفيز المخاض) باللواتي وُلدن ولادة قيصرية. لقد قمنا بإجراء تحليل الانحدار اللوجستي متعدد المتغيرات لتقييم العوامل المرتبطة بنجاح تحفيز المخاض.

النتائج: لقد خضعت 564 امرأة خلال فترة الدراسة لتحفيز المخاض حيث كان معدل تحفيز المخاض 16%، وقد تحققت الولادة المهبلية في 472 (84%) من النساء. وأشارت نتائج الدراسة إلى أن أكثر الأسباب لتحفيز المخاض قد كانت كالتالي: تأخر موعد الولادة المتوقعة في 174 (31%)، وداء السكري في 131 (23.2%) من المشاركات في الدراسة. ولقد كانت الخصائص التي من شأنها زيادة معدل الولادة القيصرية كالتالي: عدم وجود أي ولادة سابقة (OR: 1.58, 95% CI: 1.09–2.320, p=0.01)، وارتفاع متوسط مؤشر كتلة الجسم للأم (p=0.01). لقد كان معدل أبغار (APGAR score) لمواليد النساء اللواتي خضعن لتحفيز المخاض أعلى بشكل ملحوظ (p=0.04)، كما كان معدل حموضة الدم في الحبل السري عند الولادة أكثر من أو يساوي 7.1 أعلى بشكل ملحوظ (p=0.02) من مواليد المجموعة الأخرى. ولم يكن هناك اختلاف في معدل النزف بعد الولادة، والولادة القيصرية، وتمزق الرحم بين النساء اللاتي خضعن لتحفيز المخاض واللواتي وُلدن بدون تحفيز.

خاتمة: أظهرت هذه الدراسة بأن عدم وجود ولادة سابقة ووزن الأم هي المحددات الرئيسية لنتائج تحفيز الولادة. ولهذا فإن اختيار حالات تحفيز الولادة هو أمر حيوي لتحقيق نتائج مماثلة للولادة الطبيعية.

Objectives: To evaluate the prevalence, indications, and factors associated with successful induction of labor (IOL), and maternal and neonatal outcomes.

Methods: All women booked for IOL at King Khalid University Hospital, King Saud University, Riyadh, Kingdom of Saudi Arabia from April 2010 to March 2011 were included. The characteristics of women who had successful IOL were compared to those who delivered by cesarean section (CS). A multivariable logistic regression analysis was performed to evaluate the factors associated with successful IOL.

Results: During the study period, 564 women had IOL. The prevalence rate of IOL was 16%. Vaginal delivery was achieved in 472 (84%) women. The most common indications for IOL were post-term pregnancy in 174 (31%), and diabetes mellitus in 131 (23.2%) of the participants. Maternal characteristics associated with risk of CS were nulliparity (odds ratio: 1.58; 95% confidence interval: 1.09-2.320; p=0.01), and high maternal body mass index (p=0.01). Neonates of women with successful IOL had significantly higher APGAR scores (p=0.04), and more frequent pH ≥7.1 at delivery (p=0.02). There was no difference in the rate of post-partum hemorrhage, CS, or ruptured uterus between the women who had IOL, and those who went into spontaneous labor.

Conclusion: Nulliparity and maternal weight are the main determinants of the outcome of IOL. Case selection for IOL is vital for achieving outcomes similar to spontaneous labor.

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Induction of labor (IOL) has become one of the most common interventions in modern obstetrics. Innovations in diagnostic and screening methods in obstetrics led to the early detection of maternal and fetal conditions, which indicate artificial termination of pregnancy before the onset of spontaneous labor. Induction of labor is frequently used to avoid serious complications to the mother or the fetus, arising from conditions, such as: pre-eclampsia; pre-term rupture of the membranes (PROM); intrauterine growth restriction (IUGR); and post-term pregnancy. Nevertheless, IOL may result in undesirable effects, such as increased cesarean section (CS) rates, post-partum hemorrhage (PPH), and fetal distress,[1] therefore, it should only be considered when the benefits to the mother and her fetus outweighs the risks of waiting for spontaneous onset of labor. Moreover, IOL, as a medical intervention, increases the cost of medical care compared to spontaneous labor,[2] and such excess cost can be justified, if the indication for IOL alleviate a risk to the mother or the fetus, who should otherwise be delivered by CS. Like many other obstetrics population statistics, and similar to many Middle Eastern countries, the national rate of IOL in the Kingdom of Saudi Arabia (KSA) is not known. However, knowledge of the determinants of IOL at King Khalid University Hospital (KKUH) may be employed as a foundation for a database to monitor rates, and outcome of IOL for the hospital and similar hospitals in the country. The objectives of this study is to evaluate the prevalence of labor induction, indications, factors associated with successful IOL, and maternal and perinatal outcomes in KKUH.

Methods. This study is a hospital-based prospective cohort study of obstetric patients booked for induction of labor at the Obstetrics and Gynecology Department (OGD) in KKUH, King Saud University, Riyadh, KSA. This study was carried out from April 2010 to March 2011. The OGD has a capacity of 126 in-patient bed, and a total of 3000-4000 deliveries per annum. The CS rate (emergency and elective) is 20%. The participants in this study are women who were admitted for IOL, and consented to participate in the study. The OGD follows a clinical pathway for IOL (**Figure 1**), and does not provide services for elective IOL. The IOL is with prostaglandin E2 (PGE2) vaginal tablets 3 mg (Dinoprostone; UpJohn Ltd, London, UK) commences in the morning of admission, the modified Bishop score is recorded at the initiation of induction, and if the Bishop score was 6 or more, labor was induced with amniotomy, and if uterine contractions were not established within 2 hours of amniotomy, labor was augmented with oxytocin. For participants with Bishop score less than 6, vaginal PGE2 tablet was inserted into the posterior vaginal fornix, while a non-stress test was performed for one hour (30 minutes before, and 30 minutes after the insertion of PGE2 tablet). The patient was reassessed 6 hours after the initial PGE2 insertion, and depending on the response of the cervix as indicated by the Bishop score, another dose of PGE2 was inserted.[3] The procedure was repeated every 6 hours until regular contraction starts, or the cervix was favorable for amniotomy. The maximum dose of PGE2 allowed was 3 tablets. Participants with a history of one previous CS were induced by insertion of Foley's catheter balloon filled with 30 ml of distilled water in the cervical canal.

Data were collected prospectively using a pre-designed data collection sheet from all women admitted for IOL. The inclusion criteria were gestation age 24

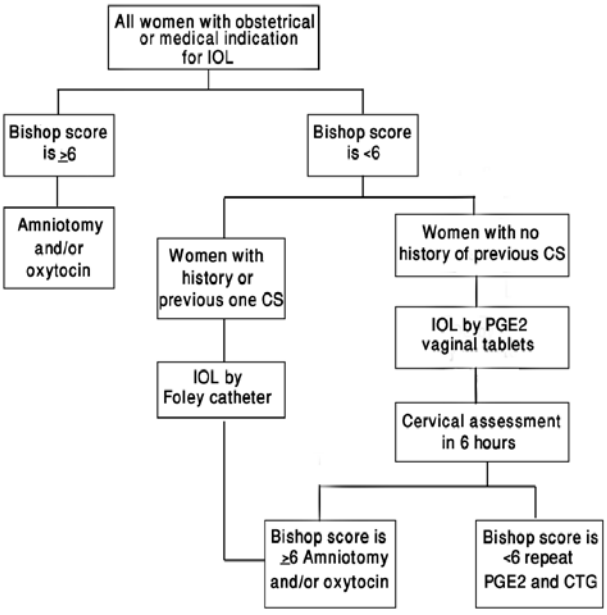

Figure 1 - Pathway for induction of labor in the Obstetrics and Gynecology Department in King Khalid University Hospital, Riyadh, Kingdom of Saudi Arabia. IOL - induction of labor, CS - Cesarian section, PGE2 - prostaglandin E2, CTG - cardio-tocogram

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weeks or more, singleton pregnancy, and cephalic presentation irrespective of the fetal viability. Women with multiple pregnancies were excluded from this study. The maternal variables assessed were; age, height and weight at admission, parity, gestation age at IOL, indication for IOL, method of IOL, Bishop score at the commencement of IOL, and outcome of IOL including mode of delivery. The neonatal characteristics included birth weight and Apgar score at one, and 5 minutes after delivery. Maternal body mass index (BMI) was calculated based on maternal height and weight measurements provided at admission. Term delivery was defined as reaching 37-41+2 weeks (259-289 days), while pre-term birth was defined as any birth before 37 completed weeks (259 days) of gestation, and post-term pregnancy was defined as delivery on, or after 290 days (41+3 weeks) of gestation, as calculated from the last menstrual period, and confirmed by ultrasound scanning. The main outcome measure was the mode of delivery. We considered IOL to be successful in women who delivered vaginally (spontaneous and instrumental) as opposed to those delivered by CS. Further analysis was carried out to investigate the maternal and the fetal characteristics, which were associated with successful IOL, by comparing participants who delivered vaginally with those who delivered by CS. To assess complication rates associated with IOL, we compared the prevalence of PPH, ruptured uterus, and emergency CS between the women who had IOL, and those who had spontaneous labor during the same study period. Ethical approval was sought and granted before commencing the study from the institutional ethics review board of KKUH. The prevalence rate of IOL and the total number of deliveries for the study period was described, then the success rate in achieving vaginal delivery was calculated. To assess the general characteristics of the women and their pregnancies as predictors of outcome, data from women who had successful IOL were compared to the women who were delivered by CS.

Crude odds ratio (OR) and their respective 95% confidence intervals (95% CI) were estimated, adjusted OR were calculated using multiple logistic regression models. We compared the mean using the Student t-test for continuous variables, and Chi square test for categorical variables. A $p<0.05$ was considered statistically significant. Data were analyzed using the Statistical Package for Social Sciences version 17 (SPSS Inc., Chicago, IL, USA).

Results. The total number of deliveries during the study period was 3522, of which 573 underwent IOL, and 564 met the inclusion criteria. The prevalence rate of IOL was 16%. Of the 564 participants, 472 (84%) women had IOL, 419 (74.3%) had spontaneous vaginal delivery, and 53 (9.4%) had instrumental delivery. The demographic characteristics of the participants in this study are shown on **Table 1**. The most common indication for IOL was post-term pregnancy accounting for 174 (31%) cases followed by gestational and pre-

Table 1 - Demographic and baseline characteristics of the study population in King Khalid University Hospital, Riyadh, Kingdom of Saudi Arabia.

Characteristics	n	(%)
Maternal age, mean ± SD	29.0 ± 6.397	
Parity		
Nullipara	200	(35.5)
Multipara	364	(64.5)
Gestational age, mean ± SD	39.0 ± 2.099	
Previous CS delivery	36	(6.7)
PIH	30	(5.3)
Route of delivery		
Normal	419	(74.3)
Ventouse assisted	50	(8.9)
Forceps assisted	3	(0.5)
Cesarian section	90	(16.0)
Bishop score	3.26 ± 2.28	
Birth weight	3.06 ± 0.54	
Method of induction		
PGE2	489	(86.7)
Others	75	(13.3)

Data are expressed as mean ± standard deviation (SD), CS - Cesarian section, PIH - pregnancy induced hypertension, PGE2 - prostaglandin E2

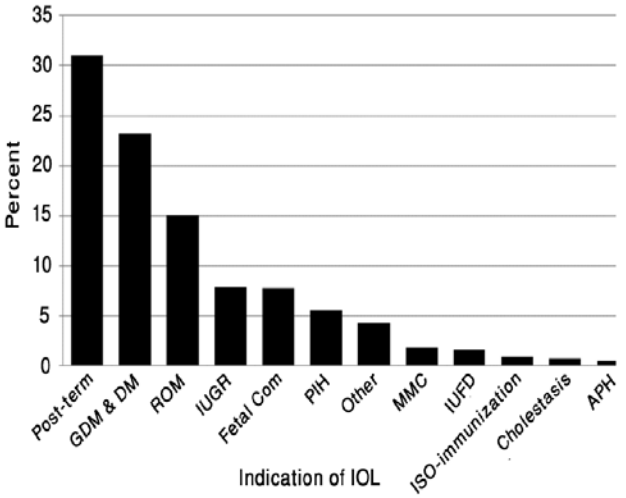

Figure 2 - Indications for induction of labor (IOL). GDM = gestational diabetes, DM = diabetes mellitus, ROM = rupture of membranes, IUGR = intra-uterine growth restriction, Fetal com = fetal compromise, PIH = pregnancy induced hypertension, MMC = maternal medical condition, IUFD = intrauterine fetal death, ISO immunization = Rhesus iso-immunization, APH= ante-partum hemorrhage

Table 2 - Maternal and fetal characteristics in relation to the outcome of induction of labor (IOL) in the Obstetrics and Gynecology Department in King Khalid University Hospital, Riyadh, Kingdom of Saudi Arabia.

Characteristics	Vaginal delivery n (%)	Cesarean section n (%)	OR	(95% confidence interval)	*P*-value
Maternal age, <35 years	328 (74.4)	62 (72.9)	1.07	(0.64-1.8)	0.78
Parity, nullipara	183 (38.6)	47 (52.2)	1.58	(1.09-2.32)	0.01
Gestation age, 37+ weeks	384 (83.5)	68 (79.1)	0.79	(0.49-1.25)	0.32
Post term, 41+ weeks	140 (30.4)	31 (36.0)	1.25	(0.78-2.02)	0.35
Maternal diabetes as indication for IOL	114 (24.1)	17 (18.9)	0.735	(0.417-1.29)	0.28
Body mass index at term, kg/m^2	32.56 ± 6.09	34.22 ± 6.05			0.01
Bishop score <5	325 (68.7)	67 (74.4)	1.32	(0.79-2.21)	0.31
Cervical dilatation <2	349 (75.2)	72 (80.9)	1.39	(0.79-2.47)	0.25
Birth weight					
4,000+ g	24 (5.1)	7 (7.8)	1.55	(0.59-3.95)	0.32
<2,500	57 (12.2)	17 (18.9)	1.68	(0.88-3.15)	0.09

existing diabetes mellitus, which we grouped together as one indication, and was observed in 131 (23.2%) of the participants. The third most common indication for IOL was PROM accounting for 84 (15%) of the cases. Other indications are shown in **Figure 2**. The PGE2 was used for IOL in 489 (86.7%) of the participants, while oxytocin as the primary method for IOL was used in 56 (9.9%), and Foley's catheter balloon was used in 20 (3.5%) participants (all had a history of one previous CS). The characteristics and comparison between the participants who achieved vaginal delivery and those who delivered by CS is shown in **Table 2**. Nulliparous women had raised odds of CS compared with multiparous women, and this was statistically significant (OR: 1.58, 95% CI: 1.09-2.320, p=0.01). The mean admission BMI in the successful induction group was significantly lower than the mean BMI in the failed induction group (32.5 versus 34 kg/m^2, p=0.01). The outcome of IOL was also analyzed according to the gestational age at the time of induction. Gestational age of 37 weeks or more had raised odds of vaginal birth when compared to women with gestational age less than 37 weeks. Although this was not statistically significant (p=0.32), there is a suggestion that higher gestational age may be associated with a higher probability of vaginal birth among women in whom labor had been induced. Women who had a baby weighing less than 4,000 g had raised odds of vaginal birth compared to women with a baby weighing 4,000 g or more (OR: 1.55, 95% CI: 0.59-3.95). Although it was not statistically significant (p=0.32), there is a suggestion that lower birth weight may be associated with a higher probability of vaginal birth in women in undergoing IOL. There was no association between maternal age and successful IOL (OR: 1.07, 95% CI: 0.64-1.8), as well as no association was found between Bishop score more than 5 and successful IOL (OR: 1.32, 95% CI: 0.79-2.21). Infants of mothers who had successful IOL had significantly higher Apgar score at 5 minutes of birth (p=0.04), and more frequent pH≥7.1 (p=0.02). A multivariable logistic regression analysis was performed to evaluate each of the above factors as an independent predictor of successful IOL. Prior vaginal delivery and lower maternal BMI were associated independently with an increased likelihood of successful induction of labor, and nulliparous women were more likely to undergo CS (OR: 2.59, 95% CI: 1.51-4.46). With each increase in the BMI by one unit, the patient was more likely to need CS after IOL (OR: 1.06, 95% CI: 1.018-1.105). The total number of women who presented in spontaneous labor during the study period was 2661, of which 448 had emergency CS. There were 13 cases of PPH in the IOL group, and 67 in the spontaneous labor group, however, no evidence of association between IOL and PPH was found (p=0.77). There was one woman with ruptured uterus in the IOL group, one woman in the spontaneous labor group, and both women had previous CS, however, the difference in the prevalence of ruptured uterus between the 2 groups was not statistically significant (p=0.23). The emergency CS rate in the IOL group was 16%, which is comparable to that in the spontaneous labor group (16.8%).

Discussion. This study showed that the prevalence rate of IOL in KKUH is 16%. This is less than that reported for the developed countries, which is between

20 and 33%, however, it is more than that reported for Latin American countries of 11.4%.[4-6] This lower IOL rate, compared to the developed countries can be explained by the OGD policy of inducing labor for obstetrical or medical indications only, and excluding elective IOL from their protocol. On the other hand, higher rate of labor induction compared to Latin American countries is explained by the low threshold for CS in these countries leading to a rate of 33%[7] compared to 20% for the OGD in KKUH. The most common indication for labor induction in this study was post-term pregnancy, which is similar to other studies.[4,8] Labor induction for post-term pregnancy may be associated with reduced perinatal mortality when compared to expectant management and antenatal surveillance.[9] A unique indication for IOL in this cohort is the large number of women induced due to pre-existing or gestational diabetes, which accounted for 23% of the total cohort. Diabetes is one of the most common public health problems in Saudi community,[10] with an estimated adult prevalence rate of 23.7%[11].The IOL in women with diabetes in pregnancy was found to reduce fetal macrosomia[12] and many maternal and fetal complications, such as increase rate of CS and shoulder dystocia.[13] Similar to other studies, PROM was the third most common indication for IOL in this study.[4,14]

The success rate of IOL in this study was 84%, and is comparable to that reported by other studies,[4,15] however, it is more than that reported by Guerra et al[5] for IOL in Latin American countries. This difference might be due to the predominant use of PGE2 for ripping the cervix in this cohort, which was used in 86.7% of the cases, while it was used in only 10% of the cases in Latin American countries. Multiple regression analysis indicated that nulliparity and increased BMI independently increased the risk of failed IOL. Moreover, a birth weight of 4 kg or more, and gestation age of less than 37 weeks both increased the odds for CS. Similar results were found by other investigators.[16,17] However, unlike the findings by Pevzner et al[16] the maternal age and Bishop score were not predictive of the outcome of IOL in this study.

Nulliparity was found by other investigators to be a risk factor for CS in women undergoing IOL,[18] similarly maternal overweight and obesity, as well as fetal macrosomia are associated with many adverse pregnancy outcomes including an increase risk of CS birth.[13,19] Despite the wide use of Bishop Score to decide on the need for cervical ripping, the score was found by many studies to be of a poor predictive power for the outcome of IOL with recommendations for replacement of the score, by ultrasound assessment of the cervix as a better predictor of IOL outcome, and pre-induction need of cervical ripening.[20,21] The strain exerted by the operative delivery on the infants of the mother who delivered by CS compared to those delivered vaginally in this cohort is reflected on the lower Apgar scores, and lower cord blood pH at delivery. It is noteworthy that the rate of maternal complications for the induction group was similar to the rate of complications in the women who presented in spontaneous labor, and delivered in the department during the same study period including a similar rate of emergency CS. This result could be attributed to the successful selection policy of women for IOL, and the avoidance of elective IOL for non-medical reasons with its known associated risks of maternal and perinatal adverse outcomes, and the use of PGE2 to ripen the cervix as confirmed by other studies.[22,23]

We believe that the strength of this study is based on its prospective design. The results of the study gave an insight to the reproductive health services in one of the leading health institution in KSA, in addition it provided information on the outcomes of a common obstetrical intervention, which is IOL. Such information is vital, considering the paucity of data on reproductive health and obstetrical practice in the Middle East. However, we are aware of the limitation of this study including that it is from one center only, which limits its generalizability.

In conclusion, nulliparity and maternal weight are the main determinants of the outcome of IOL. Case selection for IOL is vital for achieving outcomes similar to spontaneous labor in respect to the rate of complications and risk of CS. The results of this study gave valuable information on one of the most common intervention in the obstetrics practice, which is linked to maternal and perinatal morbidities and mortalities, and to the rate of CS deliveries. Future research should be directed to conducting a multicenter study of similar objectives to provide national data set for evaluating and monitoring this important intervention, and provide information for health services provision. We believe the development of national evidence-based clinical practice guidelines is a pivotal step to avoid the misuse of IOL for non-medical reasons.

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