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Induction of Labor at 39 Weeks versus Expecting Labour till 41 Weeks: Randomized Controlled Trial on Class I Obese Egyptian Women, with Mode of Delivery Being a Study Endpoint

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Abstract

Background: Maternal obesity is reported to be associated with increased incidence of gestational diabetes mellitus and hypertension. These cause failure of labour induction, leading to higher incidence of cesarean section (CS). The aim of this study was to assess which reduces CS rate, labor induction at 39 weeks or leaving women for spontaneous labor onset till 41 weeks. ***Methodology***: A randomized controlled trial was conducted in Ain Shams Maternity Hospital in Egypt from 2016 to 2018. Study population consisted of 200 term primigravida pregnant obese women delivered in Ain Shams Maternity Hospital. They were divided into two groups: Group A: induction of labor at 39 + 0 weeks (n = 100) by vaginal administration of 25 μg misoprostol (PGE1) every 6 hours for 5 doses; Group B: waiting spontaneous labor onset till 41 + 0 weeks (n = 100), and if no spontaneous labor occurred at 41 weeks, induction was performed in the same way. ***Results***: Induction (Group A) vs. waiting spontaneous labor (Group B) showed the followings, which were significant: CS: 22% vs 39%, p = 0.009; maternal birth injury: 4% vs 12%, p = 0.037; non-assisted vaginal deliveries: 93.6% vs 78.7%, p = 0.034; APGAR scores at 1 & 5 min: 7.6 ± 0.8 vs 7.3 ± 1.1 p = 0.038, 8.4 ± 1.0 vs 8.1 ± 1.3 p = 0.040, respectively; birth weight; 3.3 ± 0.1 vs 3.5 ± 0.2 kg, p < 0.001. The following did not show significance between Group A vs Group B but Group A showed lower incidence; postpartum hemorrhage: 3% vs 5%, blood transfusion: 1% vs 3%. ***Conclusion***: CS rate was significantly lower in women with induction of labor at 39 weeks than those waiting for spontaneous labor onset till 41 weeks in obese Egyptian pregnant women.

Keywords

Obesity, Induction, Cesarean Section, Vaginal, Delivery

1. Introduction

Obesity is clinically defined as is a medical condition in which accumulation of excess body fat to an extent may have a negative effect on health. Obesity is considered when the body mass index (BMI), a measurement obtained by dividing a person's weight by the square of the person's height, is over 30 kg/m^2; on the other hand, BMI is limited to be used as the only clinical diagnostic criterion for obesity. Obesity predisposes to cardiovascular disorders, type 2 Diabetes Mellitus (DM), hypertensive diseases and numerous other pathological issues [1] [2] [3] [4] [5].

Obese pregnant women are at risk of failed induction of labor due to related obstetric comorbidities, e.g. gestational diabetes, hypertension & fetal macrosomia. Maternal obesity is associated with prolonged pregnancy (≥41 gestational weeks), particularly with BMI of 35 kg/m^2 or higher [6] [7] [8] [9] [10].

Recent research studies reveal that labor in obese women does not follow exactly the usual process and timing of labor, particularly in the active phase of labor. Obese gestations take longer time to reach active 6 cm of dilation maybe due to decrease in the contractile capacity of the myometrium of obese women compared with non-obese women, without difference in the number of oxytocin receptors at term between both [11].

Presence of leptin and cholesterol in higher levels in obese women decreased contractility via decrease in the influx of calcium into uterine smooth muscle [11].

Obese pregnant women experience clinical and surgical complications before, during or after their cesarean sections, e.g. chorioamnionitis, deep venous thrombosis (DVT), postpartum hemorrhage, extensions of incisions, or visceral injury, wound infection. According to various research studies, neonates of obese gestations delivered by CS have more neonatal morbidity (RDS, TTN, antibiotic requirements, and/or NICU admission) than those delivered by vaginal route. On the other hand various research studies, revealed no statistical difference as regards neonatal morbidity and displayed no changes in cord blood pH, low Apgar scoring [12] [13] [14].

The aim of this study was to assess which reduces CS rate, labor induction at 39 weeks or leaving women for spontaneous labor onset till 41 weeks.

2. Patients and Methods

A randomized controlled trial was conducted at Ain Shams University in the period from August 2016 and January 2018. Study population was 200 full term pregnant females with the following inclusion criteria were recruited in the

study: full term pregnant females: gestational age 39 weeks by reliable dates of 1st day of LMP (last menstrual period), primigravida, singleton, vertex, not in labor, with no fetal anomalies, BMI 30 - 34.9, no medical disorders with pregnancy (DM, Hypertension, preeclampsia) excluding those with multifetal gestation, BMI < 30, ≥ 35, multifetal gestation, congenital fetal malformations, preeclamptic gestations, Diabetic gestations, and any other medical disorders with pregnancy, previous uterine scar as myomectomy, macrosomic baby > 4 kg. All included women were subjected to the following at recruitment: An informed consent to participation after explaining the clinical study in simple form to the patient, full history was taken including: Personal history (Maternal age, weight, height). Obstetric history. Gravidity, Parity, Any associated complication during pregnancy. Menstrual history (Last menstrual period). Maternal medical history (Hypertension, Diabetes mellitus & Coagulopathies), past surgical history any previous surgeries as myomectomy, drug allergy. Examination: 1) General examination: a) Vital signs, b) Chest and heart examination; 2) Abdominal examination: a) Gestational age, b) Fetal weight, amount of liquor, fetal lie and presentation, fetal heart sounds, c) Uterine contractions and scar of previous surgeries. Investigations: CBC, Liver Function, Kidney function, one hour glucola test screening for gestational diabetes mellitus (GDM) (Drink a 50-gram glucose solution (non-fasting), with blood sugar measured 1 hour later. If the blood sugar level result is ≥130 mg/dL, then the screening test shows an increased risk for GDM). Schedule a 100-gram diagnostic OGTT to diagnose GDM (Drink a 100-gram diagnostic OGTT after you've been fasting for 8 or more hours).

The diagnosis of GDM is made when at least one or two (set by the institution) of the following blood sugar values (measured fasting and 1-hour, 2-hours, and 3-hours after the test) are met or exceeded using either of the criteria Fasting: (95 mg/dL, 1-hour: 180 mg/dL, 2-hour: 155 mg/dL, 3 hours 140 mg/dl), Prothrombin time (PT) and prothrombin concentration (PC) Obstetric ultrasound study: For assessment of gestational age, implantation site of the placenta and fetal weight, liquor, then the patients were randomized into 2 groups: group A: elective induction of labor at 39 + 0 weeks (n = 100 cases) by vaginal administration of 25 μg misoprostol (PGE1) every 6 hours for 5 doses. If failed cesarean section was performed, group B expectant management till 41 + 0 weeks (n = 100 cases), if no spontaneous labor at 41 weeks induction had been performed in the same previous way, if failed proceed to cesarean section, then assess which increased cesarean section rate as primary outcome either induction of labor at 39 + 0weeks or leaving women for spontaneous onset till 41 + 0 weeks, searching meanwhile for secondary outcomes as maternal injury, postpartum hemorrhage, blood transfusion, neonatal morbidities as APGAR score at one & five minutes, neonatal injury, NICU (neonatal ICU) admission & cord blood PH changes.

Uterine activity and fetal heart rate monitoring for 30 minutes after insertion of misoprostol and maintained when there are regular contractions. No uterine activity before misoprostol use.

When the women started to develop either uterine contractions ≥ 2 contrac-

tions/10 minutes or cervical effacement, misprostol doses stopped and augmentation by oxytocin (using infusion pump) or amniotomy after 4 hours after last misoprostol dose started till reaching efficient contractions (3 - 4 contractions/10 minutes).

Failed induction of labor is considered when it doesn't lead to uncomplicated vaginal delivery within 24 hours of oxytocin start, however no universal standard for failed induction, just give adequate time for cervical ripening and development of active labor phase before failed induction to be defined [15].

ACOG proposed failed induction with the following criteria: if no regular contractions (3 - 4 contractions every 10 minutes) and no cervical changes for at least 12 to 18 hours after oxytocin administration after membranes rupture or after 24 hours after oxytocin administration with intact membranes [15].

Time for cervical ripening is not included in length of induction of labor [15].

Protracted active phase defined when dilating less than 1 - 2 cm per hour when cervix dilatation more than 6 cm, while less than 6 cm still in latent phase, this needs reassessment for contractions, oxytocin titration [15].

Arrest of labor diagnosed only when cervix more than 6cm dilatation and no cervical changes for 4 or more hours despite adequate contractions or 6 or more hours with inadequate contractions. Cesarean section is the management [15].

Randomization: using computer random sequence by excel sheet divided into equal groups.

Allocation concealment: patients fulfilling inclusion and exclusion criteria were allocated into one of the two groups A and B by using consecutively numbered sealed opaque envelopes.

Blinding: staff members responsible for process of induction of labour by misoprostol were blinded to which group the women belonged either elective induction group at 39 weeks, or expectant management group till 41 weeks who failed to experience spontaneous labor.

Ethics: approved from the Ethical Committee of the Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University and fulfilling declaration of Helsinki ethical principles for medical research involving human subjects 2001.

Statistical methods

The collected research data were analyzed by usage of IBM SPSS statistics (Statistical Package for Social Sciences) software version 18.0, IBM Corp., Chicago, USA, 2009.

Descriptive statistics were performed for quantitative research data as mean ± SD (standard deviation) for quantitative normally distributed research data, whereas it was conducted for qualitative research data as number and percentage.

An inferential statistical analysis was performed for quantitative research variables by usage of independent t-test in cases of two independent groups. In qualitative research data, inferential analyses for independent variables were done using Chi square test for differences between proportions and Fisher's Exact test

for variables with small expected numbers. The level of significance was taken at P value < 0.050 is significant, otherwise is non-significant.

3. Results

Induction group had statistically significantly had less frequent CS (Induction vs spontaneous 22% vs 39% p value = 0.009), maternal injury (Induction vs spontaneous 4% vs 12% p value = 0.037), PPH (Induction vs spontaneous, 3% vs 5% p value = 0.721) and Blood transfusion (Induction vs spontaneous 1% vs 3% p value = 0.621) but statistically significantly had higher Non-assisted VD (Induction vs spontaneous 93.6% vs 78.7% p value = 0.034). Induction research group had statistically significantly higher APGAR 1 & 5 min scores (Induction vs spontaneous 7.6 ± 0.8 vs 7.3 ± 1.1 p value = 0.038, 8.4 ± 1.0 vs 8.1 ± 1.3 p value = 0.040, consecutively), but statistically significantly had lower neonatal weight (Induction vs spontaneous, 3.3 ± 0.1 vs 3.5 ± 0.2 Kg p value < 0.001).

In spontaneous research group, 9 (9.0%) cases reached 41 gestational weeks and required induction, amongst which 3 cases underwent cesarean section delivery due to failed induction (one case), fetal distress (one case) and failed progress (one case).

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4. Discussion

The current research study mainly focused on obstetric and neonatal clinical issues experienced by obese Egyptian women without medical disorders

The current research study revealed that induction research group had statistically significantly less frequent cesarean section deliveries (Induction vs spontaneous 22% vs 39% p value = 0.009), less liability for maternal injury (Induction vs spontaneous 4% vs 12% p value = 0.037), postpartum hemorrhage (Induction vs spontaneous, 3% vs 5% p value = 0.721) and Blood transfusion (Induction vs spontaneous 1% vs 3% p value = 0.621) on the other hand, induction research group had statistically significantly more frequent non-assisted vaginal deliveries (Induction vs spontaneous 93.6% vs 78.7% p value = 0.034). Induction research group had statistically significantly higher APGAR scores at 1 & 5 min (Induction vs spontaneous 7.6 ± 0.8 vs 7.3 ± 1.1 p value = 0.038, 8.4 ± 1.0 vs 8.1 ± 1.3 p value = 0.040, consecutively), however induction research group had statistically significantly lower neonatal weight (Induction vs spontaneous, 3.3 ± 0.1 vs 3.5 ± 0.2 Kg p value < 0.001).

Spontaneous group was more liable for neonatal injury in vaginal delivery in form of Erb's palsy & fracture humerous may be due to large fetal weight.

Our findings support findings from the Swedish Medical Birth Registry, in which excessive maternal weight was correlated with significantly reduced risk

of third- or fourth-degree laceration (maternal injury) within singleton vaginal birth in obese women. Interestingly this inverse correlation could be partially attributable to thicker soft connective tissues in obese cases, which could have a protective effect against deep levels of laceration, most cases of pregnant obese women deliver by CS due to fetal macrsomia [7] [16] [17].

Mcintyre *et al.* research group displayed a raised clinical risk of neonatal respiratory distress syndrome in obese mothers in Australia. In a previously conducted research study increased rates of labor induction failure and requirement of cesarean delivery existed within 3.9% of obese class I and II females and 5.7% of females in class III obesity. Similarly in another research study this rate was 20.2% and 24.2%, consecutively [5] [10].

These studies differ from present one that it either compared different classes of obesity as regards induction of labour or assessed the efficacy of induction of labour in obese women to establish vaginal delivery or compare induction of labour versus expectant management without specifying the gestational age of pregnant obeses women.

Pickens CMG study was done retrospective by depending on prepregnancy BMI not during pregnancy found that elective induction at 39 weeks yield less cesarean delivery rates than expectantly managed group at 40 weeks, but the difference at 41 weeks was not statistically significant. In contrast the risk of operative vaginal delivery increased among elective induced group, as compared to expectantly managed. Also lower incidence of postpartum hemorrhage, severe perineal lacerations, unplanned surgical procedure, uterine rupture, admission to an intensive care unit (ICU), maternal sepsis, and endometritis, lower rates of neonatal ICU admission among labour induction group at 39 weeks rather that expectantly managed, these go with our study, but this study didn't address specific class of obesity [18].

These facts express the need for specific labor induction protocols doses & timing that are more likely to result in a successful vaginal delivery in Obese women cases.

Positive points in this study is comparing the timing of termination of pregnancy if it correlates with the mode of delivery or not? Finding that elective Induction at 39 weeks is better than leaving obese women for Spontaneous onset till 41 weeks. This may be attributed to increased fetal growth and more fetal weight or may be women underwent expectant management of low bishop score.

Restrictions in our current research study involve various issues in which Pre pregnancy BMI was not available and fat distribution was not considered (e.g gynecoid and android type of obesity), study not involving whose BMI > 35, those of medical disorders as diabetes mellitus, involved Egyptian women only. Research didn't address Bishop score as criteria; favorable cervix (Bishop > 6) as non favorable ones as regards success of induction.

Optimizing maternal Weight indices before gestation is crucial and could aid in prevention of clinical maternal and neonatal morbidities (**Table 1** & **Figure 1**).

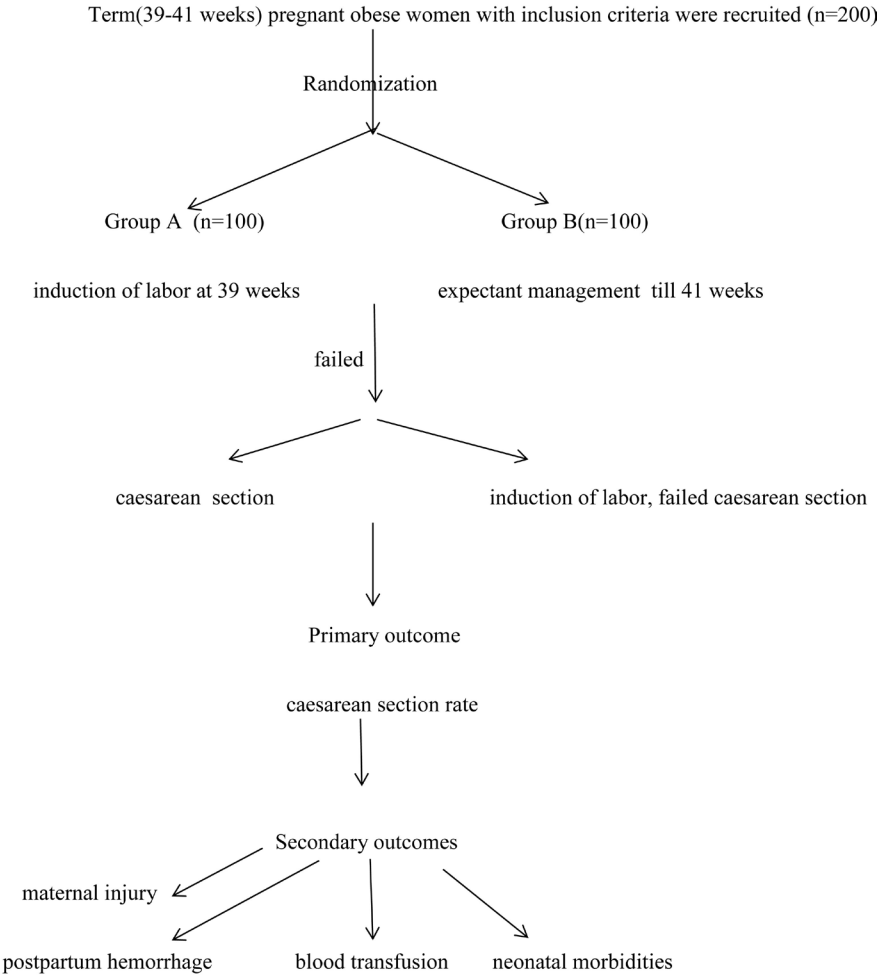

Figure 1. CONSORT 2010 flow diagram showing the recruitment and handling of the study population during the course of the study.

Table 1. Comparison between the studied groups.

Variables		Induction	Spontaneous	P	RR (95% CI)
Age (years)		27.4 ± 2.8	26.9 ± 2.8	^0.309	
BMI (kg/m^2)		32.7 ± 0.9	32.7 ± 0.8	^0.792	
Induction (tracing)		-	9 (9.0%)	-	-
GA at delivery		39	39.8 ± 0.7	-	-
Mode of delivery	CS	22 (22.0%)	39 (39.0%)	#0.009*	0.56 (0.36 - 0.88)
	VD	78 (78.0%)	61 (61.0%)		
Indications of CS (in CS only)	Fetal distress	9 (40.9%)	7 (17.9%)	§0.045*	-
	Failed progress	11 (50.0%)	31 (79.5%)		
	Failed induction	2 (9.1%)	1 (2.6%)		
Types of VD (in VD only)	Non-assisted	73 (93.6%)	48 (78.7%)	§0.034*	-
	Ventose	4 (5.1%)	9 (14.8%)		
	Forceps	1 (1.3%)	4 (6.6%)		

Continued

Maternal injury (perineal trauma)	4 (4.0%)	12 (12.0%)	#0.037*	0.33 (0.11 - 1.00)
PPH	3 (3.0%)	5 (5.0%)	#0.721*	0.60 (0.12 - 2.44)
Blood transfusion	1 (1.0%)	3 (3.0%)	#0.621*	0.33 (0.04 - 3.15)
Neonatal weight (kg)	3.3 ± 0.1	3.5 ± 0.2	^<0.001*	-
APGAR1	7.6 ± 0.8	7.3 ± 1.1	^0.038*	-
APGAR5	8.4 ± 1.0	8.1 ± 1.3	^0.040*	-
Neonatal injury	0 (0.0%)	2 (2.0%)	§0.497	-
NICU admission	5 (5.0%)	12 (12.0%)	§0.076	0.42 (0.15 - 1.14)
PH < 7.00	2 (2.0%)	4 (4.0%)	§0.683	0.50 (0.09 - 2.67)
Lactate > 6.0	1 (1.0%)	5 (5.0%)	§0.212	0.20 (0.02 - 1.68)

^Independent t-test, #Chi square test, §Fisher's Exact test, *Significant.

5. Conclusion

Waiting for spontaneous onset of labor after 39 gestational weeks is statistically correlated with higher maternal cesarean section delivery rates within obese Egyptian gestations. However future research should consider various classes of obesity and cases with obesity and co-existing medical disorders.

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Compliance with Ethical Standards

Disclosure statement: No potential conflict of interest was reported by the authors.

Informed consent: Informed consent was obtained from all participants in the study.

Ethical approval: All procedures performed in studies were approved with ethical standards of the Ethical committee of the department of obstetrics and gynecology faculty of medicine, Ain Shams University.

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