Different methods of termination of second trimester pregnancy with scarred uterus at Mansoura University Hospitals

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Abstract

Objective: To describe different methods used in termination of second trimester pregnancy in those with previous uterine scare(s) and compare their efficacy and safety at a tertiary care center.

Patients and Methods: a prospective, randomizedcontrolled comparative trial conducted at Mansoura University Hospitals, Egypt during February 2018 through March 2019 and involved 105 healthy pregnant women at 14-28 weeks of gestation diagnosed to have missed abortion or intrauterine fetal death with a previous one or more caesarean delivery (CD). They divided into 3 equal groups, GI; received misoprostolalone for termination of pregnancy via either vaginal or sublingual routes as 400 μg / 6 hours for pregnancy at 14- 20 weeks; 200 μg / 6 hours for pregnancy at 20 -25 weeks or 100 μg / 6hours at 26 -27 weeks; G (II) for whom a Foley's catheter was inserted under complete aseptic precautions, passed beyond the internal os then its balloon inflated by 20-30 ml normal saline for pregnancy at 14 - 20 weeks; 40-50 ml for pregnancy at 20 - 27 weeks and its position was confirmed by TAS then oxytocin infusion was commenced after the catheter expulsion, GIII; involved women who received a combination of Foley's catheter inserted intracervical and a misoprostol dose 200 μg for pregnancy from 14-20 weeks or 100 μg for those between 20-27 weeks that was dissolved in 30 ml saline and injected intrauterine through the catheter lumen. Any of the previous method continued for 24 hours otherwise the fetus comes out earlier. All patients in the three groups received oxytocin infusion 20 units in 500 ml normal saline after fetal expulsion to avoid placental retention and post-abortive bleeding.The primary outcome was induction-to-abortion interval (IAI) plus the mean time (SD) needed for complete uterine evacuation.

Results: The patients' characteristics and baseline data for the three groups including the age, weight, gravidity, parity, duration of pregnancy, number of previous scar(s) showed no significant difference ($p > 0.05$).Studying the mean (SD) of IAI/hourtogether with data observed after starting treatment and postoperative complications recorded a significant difference among the three groups as regard IAI (being shortest in GIII;11.6 ±2.6, longest in GII; 17.3 ±3.4 and in between for GI;15.9 ±3.4 respectively; $P< 0.001$), the success rate (100% for GIII, 91.4 % for GI and 85.7% for GII, p 0.02) and the occurrence of diarrhea being lowest in GII (no cases), highest in GI (5 cases) in compare to 1 case only recorded in GIII (P0.024). On the other hand, insignificant difference among the study groups was observed as regard the mean (SD) of time/minutes needed for placenta expulsion after the fetal descent being 31.09 ± 5.01, 27.8 ± 7.61 and 26.57 ± 12.17 for the three groupsrespectively, the occurrence of post induction nausea and vomiting, fever or post-evacuation bleeding ($p> 0.05$). Somecases

needed MVA after placental expulsion (6 cases in GI, 7 cases in GII and 4 in GIII) but again with no significant difference.

Conclusion:Combined use of misoprostol and Foley's catheter for termination of mid-trimester pregnancy with previous uterine scar(s) is found more superior than the use of either method alone regarding the success rate and shorter duration with minimal non serious complications and side effects.

Keywords: mid-trimester, pregnancy, termination.

Introduction

Second trimester, mid-trimester pregnancy, is defined as the period of gestation between 13 to 28 weeks and is commonly subdivided into early ranging from 13-20 weeks and late from 20-28 weeks gestation [1,2]. The Termination of pregnancy by induced abortion is practiced worldwide, 22 % of pregnancies, but the majority of this terminations, nearly 90 %, takes place in the first trimester [3]. Now the universal prenatal screening programs have led to an increase in the diagnosis of congenital malformations and consequently gradual increase in the second trimester pregnancy termination [4].

Essentially pregnancy termination in cases with prior cesarean delivery become an increasingly common situation facing obstetricians due to progressive increase in the rate and incidence of cesarean births [5]. Despite various mechanical and pharmacological methods listed in the literature for termination of such pregnancy but the safety and efficacy of every method are the main factors governing its choice [5.].

Medical termination of second trimester pregnancy, mainly by misoprostol (PGE1)use, offers a high possibility for improving access and relative safety owing to its simplicity in compare to surgical techniques butmight be complicated by uterine hyperstimulation and subsequent rupture especially in women with previous scars [6, 7, 8]. The use of intracervical extra-amniotic Foley's catheter placement is another procedure used for mechanical cervical ripeningand stimulating endogenous release of prostaglandins and cytokines that make the cervix inducible and eases the process of termination [9,10, 11]. Some stated the combination of Foley's catheter for mechanical induction and cervical preparation withmisoprostol simultaneously gave shorter induction-to-abortion intervals [12,13] despite some others have failed to state this difference [14]

This study was thoughtto describe different methods used in termination of second trimester pregnancy in those with previous uterine scare comparing their efficacy and safety profile at tertiary care center.

Patients and methods

This study is a prospective randomized clinical comparative study conducted at Department of Obstetrics and Gynecology, Mansoura University Hospitals, Egypt, from February 2018 to march 2019. Local institutional research board approval for the study was obtained with IRB number [MS/17.12.124] together with a written and verbal informed consent from all the participant after clearly explaining the nature of the study, health benefits, possible side effects and expected complications. Therefore, the study was performed in accordance with the ethical standards laid down with the Helsinki Declaration at 1975, as revised in 1983and its later amendments. The total number of patients recruited and met to participate were 200 but only 105 patients had the study inclusion and allocated to participate.Inclusion criteria comprised patient's age ranged between 20-43 years, gestational age from 14- 28 weeks as calculated according to either sure due date of last normal menstrual period or reliable first trimester sonography or TAS at the time of admission, had a scarred uterus, one or more lower segment caesarean delivery (CD) scars, and were entitled for second trimester pregnancy termination due to either intrauterine fetal death (IUFD) or fetal congenital anomalies incompatible with life. Exclusion criteria involved gestational age less than 13 weeks or more than 28 weeks, patient with low lying placenta, history of previous rupture uterus as well as those who diagnosed to have bleeding tendency or preterm premature rupture of membranes. One hundred and five women were allocated and randomized using closed envelope method into 3 equal groups. Group (I) who received misoprostol alone (prostaglandin E1 analog, Cytotec® 200 micrograms imported and distributed by Pfizer Inc, Egypt))for termination of pregnancy via either vaginal or sublingual routes with the dosage based on gestational age as following: from 14 weeks up to 20 weeks; 400 μg / 6 hours, from 21 weeks up to 25 weeks; 200 μg / 6 hours, then at 26 -27

weeks; 100 µg / 6hours. Group (II) for whom a Foley's catheter (16F silicon coated foley's catheter manufactured by Ultra for medical products Co) was inserted under complete aseptic precautions in minor operative room with no sedation where Cusco's speculum was inserted after sterilization of the vulva and vagina by iodine betadine then a 16F foley's catheter tip is passed beyond internal osand the balloon was inflated by normal saline depending on gestational age as following; from 14 weeks up to 20 weeks; the balloon was filled by 20-30 ml, from 20 weeks up to 27 weeks; the balloon was filled by 40-50 ml, then traction was applied on Foley's catheter as much as the patient can withstand then tapped to patient's upper inner thigh to facilitate their mobility and the position of the catheter balloon was confirmed by transabdominalultrasound (Chison model ECO 5, PIN 95-0016-01, Chison medical technologies co. Ltd. Shanghai International Holding Corp. GmbH(Europe), Eiffestrasse 80, 20537 Hamburg, Germany). Oxytocin infusion (Oxytocin ® 10 I.U. Ampoules, Minapharm, Egypt)as 10 units in 500 ml normal saline started after the catheter expulsion occurred in this group. Group (III) involved women who received a combination of misoprostol with Foley's catheter as follows: the catheter is inserted as described before and then after applying traction upon it, misoprostol dose (200 µg for pregnancy from 14-20 weeks or 100 µg for those between 20-27 weeks) was dissolved by putting it in a 50 ml syringe containing 30 ml normal saline then injected intrauterine through the catheter lumen and tapped into the inside of the patients' upper thigh and the tip of catheter was then closed. All patients in the three groups received oxytocin infusion 20 units in 500 ml normal saline after expulsion of the fetus to avoid placental retention and post-evacuation hemorrhage. Failure of induction by any of the three methods was determined as no uterine activity or change in cervical parameters after 24 hours from start of the procedure. In such situations, the procedure may be extended for extra 24 hours or terminated by hysterotomy or dilatation and evacuation (D&E). Incomplete evacuation that need for manual vacuum aspiration (MVA) for retained parts of the placenta or membranes in any case was considered when intrauterine remnants exceeds 2 cm by vaginal ultrasonography (by the same machine described before) after finishing oxytocin infusion. The primary outcomes: success to achieve complete uterine evacuation with the placenta and membranes with proposed method, induction-to-abortion interval whilst secondary outcomes included drug induced side effects mainly fever, nausea, vomiting, diarrhea, lower abdominal pain and/or bleeding or method dependent complications as rupture uterus, infection, retained parts of the placenta and post-abortive hemorrhage. Basic demographic data was collected from all patients in the three groups including detailed history involving the age, height, weight, gravidity, parity, gestational age, methods of previous parities, types and numbers of uterine scars, history of previous termination of pregnancy, indication for termination of this pregnancy and gestational age at the time of termination, previous uterine surgeries. Thorough clinical examination including general examination for exclusion of contraindications for prostaglandins and vaginal examination for cervical dilatation, effacement and position. Transabdominal ultrasound was done to confirm gestational age, IUFD, congenital malformation, amniotic fluid and to approve placental localization.

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 17 for Windows® (SPSS Inc, Chicago, IL, USA). Qualitative data was presented as number and percent. Comparison between groups was done by Chi-Square test. Quantitative data was presented as mean ± SD. F-test (One Way Anova) was used to compare between more than two groups. $P < 0.05$ was considered to be statistically significant.

Results

The study cohort involved 105 participants in 3 equal groups. The basic demographic data including the age, weight, gravidity, parity, gestational age together with history of uterine section scar(s) are presented in table (1) with non-recorded any significant differences among the three groups of these variables ($p > 0.05$), table (1).

Table (2) shows the mean ± SD of IAI/hour together with data observed after starting treatment

and postoperative complications if any. There was a significant difference among the three groups as regard IAI being shortest in combined treatment group [GIII], longest in foley's catheter group [GII] and in between for misoprostol only dependent group [GI] (11.6 ±2.6, 17.3 ±3.4 and 15.9 ±3.4 respectively) (P< 0.001). As regard the time needed for placental expulsion after the fetal descent, there is no significant difference recorded among the 3 groups as the time needed for GI patients is 31.09 ± 5.01 minutes while it is 27.8 ± 7.61 and 26.57 ± 12.17 for GII and GIII respectively (P = 0.45) despite some cases needed manual vacuum aspiration (MVA) in all groups, 6 cases in G!; 7 cases in GII and 4 in GIII, table (2). The success rate of complete uterine evacuation after 24 hours of initiating the method recorded 100% for patients in GIII compared to 91.4 %for GI and 85.7% for GIIpatients (p 0.02), table 2. In cases where failed evacuation occurred after 24 hours, for GI, 1 case needed hysterotomy to terminate pregnancy and 2 cases succeed to evacuate with prolongation of the procedure for 24 hours more meanwhile for GII cases, 3 cases evacuated after prolongation for 1 day more, 2 cases needed dilatation and evacuation (D&E) and 1 case needed hysterotomy. Again, complications after induction and post evacuation are recorded in table (2); there is a significant difference regarding the occurrence of diarrhea being lowest in GII (no cases), highest in GI (5 cases) in compare to 1 case only recorded in GIII, P (0.024), table (2). Similarly, the occurrence of post induction nausea and vomiting, fever or post-evacuation bleeding shows insignificant difference among the three study groups; (p> 0.05), table (2).

Discussion

The main findingof the study results confirmed that the second trimester termination of pregnancy is bestfound when a combination of misoprostol and intrauterine catheterwas used despite the three methods are apparently safe with no evident morbidities threatening the patients' life recorded. Nowadays termination of the second trimester abortionappeared riskier than the first owing mainly to the increasing rate of CD. Henceforward; the pharmacologic management seems to be an appealing method despite there is no clear information on the safety profile of any termination technique, as no method is risk free, particularlyin settings of prior uterine surgery and moreover, the technique used for second trimester termination is probably influenced by physician's opinion and expertise than objective outcome data [7, 15].The synthetic prostaglandins have largely replaced other techniques for pregnancy termination chiefly in the second trimester because of its efficacy, safety, cost, easy-to-use and easy-to-store properties [8]. On the other hand; some authors reported a higher incidence of life-threateninguterine rupture and major hemorrhage in women with prior caesarean scar(s) as compared to those with unscarred uteri following various techniques of mid-trimester pregnancy terminationand this increases dramatically almost many times, up to 11% in some researches, among those with a history of two or more CD [16-19]. Thispushed some others to state that misoprostol dosage of 100 μg should not be exceeded in patients with a history of CD due to the risk of uterine rupture [20].This discrepancy among different results published make us to prepare for judicious use of prostaglandin for abortion induction in our patients as the dose protocol is changed according the gestational age being higher in early second trimester, 400μgwhen the uterus is small and there is a difficulty in initiating uterine contraction and inducibility of the cervix, and lowest at the end of this gestational period, 100 μg when the uterus is supposed to have more receptors for prostaglandins and oxytocics with favorability for induction. In our study, cases used prostaglandin analogue (misoprostol) only as a method for pregnancy termination, had the success rate for initiation of uterine contraction and expulsion of the fetusof 91.4 % for GI(32/35), 2 cases evacuated after prolongation for 24 hours more and one case evacuated by hysterotomy. Of all patients in this group; 6 cases were subjected for MVA to remove some placental remnants.Our results, as regard this efficacy and safety are found slightly better than those proved by Rezk et al. 2014 [14], 87%success rate, and Naguib et al. [21], 90% success rate as well as Ranjan et al, 2016 [22] who proved 82% success rate in patients using misoprostol only for pregnancy termination at a similar gestational age.

Considering the Foley's catheter induction method, it has been used successfully for induction of second trimester missed abortionespeciallywhen

traction is correctly and properly applied [23, 24]. This actually is proved in our study where the success rate documented was 85.7%(30/35). Two of failed cases to expel the fetus in this group evacuated actually after prolongation for 1 day more, 2 cases needed dilatation and evacuation (D&E) meanwhile 1 case only needed hysterotomy. This method appeared inferior to misoprostol only method (GI) as this time needed to evacuate the uterus was longer and more cases needed MVA, 7 cases vs 6 respectively, the same findings also stated by some authors [14, 21, 26].Contrary to this; Sciscione et al. 2004 [25] stated that the Foley's catheter appears to be superior to prostaglandins for pre-induction cervical ripening being exerting its effect by disrupting the integrity of amnion-chorion, separating chorion from the decidua hence releasing local prostaglandin and cytokines. As regard the combined method treatment; our results proved that it is the most effective and with relative safety compared to other methods. It had the shortest IAI (11.66 ± 2.63 hours, $p < 0.001$)and the highest success rate (100%, p 0.02) and consequently considered the best one used. Thiscomes in accordance with results observed in many studies[13, 14, 15, 25, 27, 28]. However, some other studies disagree with our results regarding this short IAI asthey reported insignificant difference between patients used combined treatment and misoprostol only treatment, moreover, they describeda significant increase in IAI in those usingcombined methods than in misoprostol only and considered Foley's catheter use had shorter duration [29].Also; some authors [22] reported less effectiveness and success rate, being 90%, of the combined method than ours.

Investigating the complications associated with different treatments used for our patients, we found that there are more cases of diarrhea for misoprostol only users, 5 cases compared to no cases for Foley's catheter usersand only 1 case for those used both methods (p 0.024). Also, higher incidence of nausea and vomiting for patients using prostaglandin only, 8.6% vs 5.7% in patients of combined group, only 2.9% for those used Foley's catheter. These findings come similarto results found by other authors (15, 26, 29). Fever, being a side effect of misoprostol and not due to infection, was also found higher in patients used misoprostol only, 8.6% vs 2.9% in those used the combined method while no fever reported in foley's catheter group. To this findings, similar results wereproved in a study by Ercan et al., 2015 [13]. Some of our cases in all groups experienced some post-abortive bleeding but not massive or associated with the need for blood transfusion. Surprisingto us it was reported higher (8.6%) in misoprostol dependent group vs 5.7% in combined treatment group whilst only 2.9% in foley's catheter using group. These results are in accordance to those proved by Ranjan et al 2016 [22].

From the results obtained in our study, we recommend a combination of misoprostol and foley's catheter to be the best method for second trimester pregnancy termination in patients with previous CD but infact, our study has some drawbacks being one center study and the decreased number of the patients involved in each group compared to a large number of caesarean deliveries at a tertiary care center like ours. Form this aspect the authors recommend large scale studies to be investigated and published as multicentric study involving larger number of patients.

Conclusions: there are different methods available for second trimester termination of pregnancy with scarred uterus but a combination of misoprostol and Foley's catheter is considered as the most effective being have the shortest duration needed for induction beside minimal complications with negligible and accepted side effects.

Conflict of interest:the authors affirm any conflict of interest.

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Table [1]: patients 's demographic data in the studied groups.

Variables	G (I) (n = 35)	G (II) (n = 35)	Group (III)	P
Age	28.43 ± 6.08	27.49 ± 5.93	28.6 ± 6.62	0.723
Weight	79.74 ± 10.67	85.77 ± 11.6	78.37 ± 10.38	0.13
Gravidity	3.4 ± 1.74	3.49 ± 1.63	3.29 ± 1.36	0.869
Parity	1.69 ± 0.9	1.83 ± 1.1	1.94 ± 0.97	0.556
Gestationalage	18.86 ± 3.84	18.74 ± 3.86	19.09 ± 3.58	0.927
Number of LSCS **1 LSCS** **2 LSCS** **3 LSCS** **4 LSCS**	 20 (57.1) 10 (28.6) 5 (14.3) 0	 20 (57.1) 9 (25.7) 4 (11.4) 2 (5.7)	 17 (48.6) 12 (34.3) 4 (11.4) 2 (5.7)	0.819

Data presented as number (%), mean +SD, $p < 0.05$ was set significant.
Abbreviations: LSCS, lower segment caesarean section.

Table [2]: operative and postoperative data for the studied groups.

Variables	Group (I)	Group (II)	Group (III)	P
IAI (hours)	15.94 ± 3.4	17.33 ± 3.42	11.66 ± 2.63	<0.001*
Intervalfor PE/minutes	31.09 ± 5.01	27.8 ± 7.61	26.57 ± 12.17	0.450
Evacuation: Complete Incomplete	 26 (81.25) 6 (18.75)	 23 (76.67) 7 (23.33)	 31 (88.57) 4 (11.42)	0.442
The success rate:	32/35 (91.4)	30/35 (85.7)	35/35 (100)	0.02*
Complications: N&V Fever Diarrhea Bleeding	 3 (8.6) 3 (8.6) 5 (14.3) 3 (8.6)	 1 (2.9) 0 (0) 0 (0) 1 (2.9)	 2 (5.8) 1 (2.9) 1 (2.9) 2 (5.8)	 0.588 0.162 0.024* 0.588

Data presented in numbers (%), means ± SD, P <0.05 wasset significant (*).
Abbreviations:IAI; induction abortion interval, PE, placental expulsion, N&V; nausea and vomiting.