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Original Article

Transcervical double-balloon catheter as an alternative and salvage method for medical termination of pregnancy in midtrimester

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ABSTRACT

Objective: Termination of pregnancy in midtrimester can be performed surgically or medically. The aim of this study was to evaluate the medical methods, and the additional efficacy of using a transcervical double-balloon catheter in midtrimester termination.

Materials and methods: In this retrospective study, we included 167 pregnant women admitted during the period from January 1, 2011, to June 31, 2015, who were between 14 weeks and 28 weeks of gestation, and underwent intended termination of pregnancy at our center. Each of the 167 patients was allocated to either the cervical ripening balloon (CRB) group (with double-balloon catheter) or the non-CRB (without double-balloon catheter) group, by the choice or preference of the patient and her attending physician. Termination of pregnancy in the CRB group (72 patients) was conducted by placing a transcervical double-balloon catheter (COOK CRB), with both the uterine and vaginal balloons inflated with 30–80 mL of normal saline, and held in place for 12 hours, whereas in the non-CRB group (95 patients) vaginal and oral misoprostol alone were administered.

Results: There were no significant differences between the CRB and non-CRB groups with regard to induction-to-delivery time (23.1 hours vs. 21.1 hours) and successful abortion rate within 30 hours (80.0% vs. 83.7%). There were no severe complications in both groups.

Conclusion: There was no significant additional benefit of using a double-balloon catheter in midtrimester termination of pregnancy, although the technique was considered simple and generally well-tolerated. Placing a transcervical double-balloon catheter could be the primary method, or one of the alternative medical methods if the patient and/or obstetrician prefers no operation.

Introduction

In our practice of prenatal examination, we routinely suggest maternal serum screening for trisomy, and ultrasound examination performed in the first trimester helps to scan for fetal nuchal translucency [1]. Through these tests, many fetal abnormalities in chromosome and anatomy can be identified. After multidisciplinary consultation, some may decide to terminate the pregnancy due to lethal or severe fetal anomalies or poor postnatal outcome. There are also some other maternal indications for termination, such as newly diagnosed malignancy or unintended pregnancy. Sometimes the absence of fetal heart beat is incidentally detected during routine prenatal visits. Second trimester-induced abortion can be performed by surgical or medical means [2]. In general, medical methods of labor induction are not only less invasive, but also allow us to obtain fetal tissues that are largely intact. This allows for better pathologic evaluation to assist in definite diagnosis compared with the more destructive surgical methods [3].

Labor can be induced by mechanical methods, such as using intracervical Foley balloon catheters or hygroscopic dilators such as *Laminaria*, and by amniotomy. It can also be accomplished with the use of exogenously administered prostaglandins, such as misoprostol and dinoprostone. All these options ripen the cervix, thus softening and dilating the cervix in preparation for labor. At term pregnancy, we use dinoprostone vaginally and/or transcervical double-balloon catheter for labor induction with unripened cervix.

Currently, for midtrimester medical termination, prostaglandins have been widely used, because of their effects on both cervical ripening and uterine contraction [4]. Because the use of prostaglandins alone is usually painful and protracted, often taking more

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than 24 hours, many efforts have been made to shorten the induction-to-delivery interval.

In our experience, at term pregnancy, mechanical method with COOK cervical ripening balloon (CRB; Cook Medical, Cervical Ripening Balloon; Bloomington, Indiana, USA) catheter for cervical ripening and labor induction is safe and effective. It is a good choice for term or post-term induction of labor with unfavorable cervix (i.e., cervix with a low Bishop score), and we investigated its application in midtrimester termination. In a literature review, we did not find any published papers regarding the application of double-balloon catheter in the termination of pregnancy in the second trimester.

In this retrospective cohort study, we evaluated the efficacy of medical methods, specifically, the additional impact of using a transcervical double-balloon catheter [5], in comparison with vaginal and oral prostaglandins alone, in the termination of pregnancy in the second trimester.

Materials and methods

We retrospectively identified all women admitted to the National Taiwan University Hospital between January 1, 2011, and May 31, 2015, who were pregnant at 14–27 weeks of gestation, and underwent induction for termination of pregnancy due to various legal indications. The indications for termination of second-trimester pregnancy are presented in Table 1. Before the start of the induction process, all women had unfavorable cervical conditions and no signs or symptoms of labor. In other words, cases with preterm uterine contraction, vaginal bleeding, short cervical length, and preterm premature rupture of membranes were excluded.

All 167 patients were allocated to one of the two groups—the CRB group (with transcervical double-balloon catheter) or the non-CRB (without transcervical double-balloon catheter) group—by the preference of the patient and her attending physician.

On admission, we took all the patients' complete medical histories and collected data on previous obstetrical examinations. Cases with cardiac diseases, glaucoma, and asthmatics were excluded from the study. Abdominal ultrasound was performed for diagnosis of intrauterine fetal demise.

In the non-CRB group (96 patients), we administered misoprostol (100 mg) vaginally Q6H for two doses, followed by oral misoprostol (200 mg) in repeated doses at 4-hour intervals until effective uterine contractions and cervical dilatation were achieved.

The induction of termination in the CRB group (71 patients) was performed by inserting a double-balloon catheter (COOK CRB) at the cervix, and inflating the uterine and cervical balloons with 30–80 mL of normal saline. The catheter was held in place for 12 hours. The catheter has three-way valves: a uterine valve marked as “U,” a vaginal valve marked as “V,” and a middle valve connected to the tip of the catheter. Patients were placed in the lithotomy position and the cervix was exposed through a bivalve speculum. The catheter was inserted through the cervix until both balloons had passed it. The uterine balloon was inflated with 20 mL of saline through the “U” valve, and then the catheter was drawn out until the uterine balloon was engaged by the internal cervical os. The vaginal balloon is then inflated with 20 mL of saline via the “V” valve. Both balloons were further inflated to a total volume of 30–80 mL each, according to the gestational age, and the catheter was taped to the patient's inner thigh. Double-balloon catheter was kept in place with two expanded balloons for 8 hours and, if the catheter did not expulse, vaginal balloon was deflated and traction performed with a 500-mL weighted bag of fluid for 4 hours, and then the CRB catheter is removed. If the delivery did not occur, vaginal and oral misoprostol were given as in the non-CRB group. As soon as the catheter was expelled, PV examination was performed immediately to re-evaluate the state of the cervix.

Oxytocin infusion, dosed as 10 units in 500 mL Ringer solution, with an infusion rate of 8–40 mL/h, was used in both groups to augment labor, when necessary. To compare the efficacy of different methods, the primary outcome was induction-to-delivery interval. In addition, the success rate within 30 hours was analyzed. If there was inadequate progress at around 30 hours, the patient and her doctor would discuss the potential of further intervention, including the reinsertion of another transcervical CRB, *Laminaria*, Foley catheter, dilatation and extraction, or hysterotomy. If any of the salvage intervention was adopted, we defined the case as a failed case. Cumulative abortion rates were calculated by the number aborted at the specific time divided by total number excluding failed cases.

Data were analyzed with the standard methods for the calculation of means and standard deviations. One-way analysis of variance was used to evaluate group differences in maternal age, gestational age, time from induction to delivery, and white cell count (WBC) before induction of labor. We excluded the WBC data in one case of newly diagnosed maternal acute myeloid leukemia. In addition, Chi-square test was used to compare the differences in nulliparity, fetal death, and success rate within 30 hours. Life table analysis was used to compare the cumulative abortion rates among groups. Severe complications, including uterine rupture, major bleeding, or high fever, if presented, were recorded. We followed the principles outlined in the Declaration of Helsinki.

Results

Demographic profiles

Patients' profiles according to termination methods are presented in Table 2. In summary, the CRB and non-CRB groups have similar profiles in maternal age, percentage of nulliparity, and WBC before induction of labor. However, the mean gestational age in the

Table 1
The indications for second-trimester pregnancy termination.

Indication	*n* (%)
Fetal death	51 (30.1)
Fetal structural and/or chromosomal anomaly	101 (60.5)
Maternal indications	
Severe pre-eclampsia	1 (0.6)
Malignancy	1 (0.6)
Teratogenic drug exposure	2 (1.2)
Sexual assault	1 (0.6)
Human immunodeficiency virus infection	3 (1.8)
Unintended[a]	7 (4.2)
Total	167 (100)

[a] Gestational ages of seven unintended pregnancies: 15 weeks, 16 weeks, 16 weeks, 17 weeks, 18 weeks, 19 weeks, and 19 weeks.

Table 2
Demographic profiles of the patients.

	CRB	Non-CRB	*p*
Age, mean ± SD[a]	33.7 ± 0.6	33.3 ± 0.6	0.697
Gestational age (wk), mean ± SD[a]	20.1 ± 0.4	16.8 ± 0.2	<0.001*
Nulliparous, *n* (%)[b]	33 (46.5)	51 (53.1)	0.396
Fetal demise, *n* (%)[b]	18 (26.8)	33 (34.4)	0.408
White cell count (k/μL), mean ± SD[a]	9.24 ± 0.27	9.38 ± 0.32	0.380

CRB = cervical ripening balloon; SD = standard deviation.
*Significant.
[a] One-way analysis of variance.
[b] Chi-square test.

Table 3
Outcomes.

	CRB	Non-CRB	*p*
Induction-to-delivery time (h), mean ± SD[a]	23.1 ± 1.7	21.1 ± 1.5	0.393
Success rate at 30 h, *n* (%)[b]	52 (80.0)	69 (83.7)	0.624
Fetal weight (g), mean ± SD[a]	367.7 ± 32.6	147.6 ± 13.8	<0.001*
Failed case, *n* (%)[c]	6 (8.5)	13 (13.5)	0.248
Severe complications[d]	0	0	

CRB = cervical ripening balloon; SD = standard deviation.
*Significant.
[a] One-way analysis of variance.
[b] Chi-square test.
[c] Failed: salvage intervention was used, including reinsertion of another transcervical CRB, *Laminaria* or Foley catheter, dilatation and extraction, or hysterotomy.
[d] Severe complications include uterine rupture, major bleeding, or high fever.

CRB group (20.1 weeks) is much larger than in the non-CRB group (16.8 weeks).

Outcomes

There were no significant differences between the CRB and non-CRB groups with regards to induction-to-delivery time (mean, 23.1 hours vs. 21.1 hours) and success rate within 30 hours (80.0% vs. 83.7%; Table 3). There were 19 failed cases, which were unsuccessful after the primary intervention at 30 hours (Table 4), and six of them were in the CRB group and 13 were in the non-CRB group. As much as 14/19 (73.7%) of the primary unsuccessful attempts were able to achieve termination after the placement of a transcervical Foley catheter, or a second-time CRB insertion. Two cases ended up receiving dilatation and evacuation procedure, and three cases underwent hysterotomy. Besides, the mean fetal weight in the CRB group (367 g) was significantly larger than in the non-CRB group (146 g), which might be related to the larger mean gestational age. No severe complications in both groups were recorded, including uterine rupture, major bleeding, or high fever.

Discussion

This study excluded patients with preterm uterine contraction, vaginal bleeding, short cervical length, and preterm premature rupture of membranes. The women enrolled in our retrospective study were pregnant between 14 weeks and 28 weeks of gestational age, undergoing intended termination for various legal indications. Of the total 167 women enrolled, 60.5% received termination due to fetal structural and/or chromosomal anomaly, 30.5% was due to intrauterine fetal demise, and less than 9% was for other maternal indications. WBCs obtained before induction of labor were similar between the two groups, showing no significant difference in baseline condition in terms of systemic inflammation [6]. There is a considerable amount of controversies on the topic of optimal method for midtrimester termination, that is, the safest measure that is not only efficient, but also produces the fewest number of complications, the least amount of stress for the patients, and the most cost-effective. Complication rate appears to increase with a prolongation of the induction-to-abortion interval.

Prostaglandins are widely applied to labor induction with a relatively fair efficacy and acceptable adverse effects [7]. To shorten the induction-to-abortion interval, we hypothesized that the insertion of transcervical double-balloon catheter might be synergic to the effect of prostaglandins [8]. The practice of traction with a COOK CRB catheter is usually applied to term or post-term induction of labor for unfavorable cervix (i.e., cervix with a low Bishop score) [9], and in this study, we evaluated its application in midtrimester termination of pregnancy in comparison with that of vaginal and oral misoprostol. The patients in the CRB group had to pay an extra US $100 for the use of COOK CRB catheter.

Reported risk factors for prolonged induction-to-abortion interval or increased failure rate were older age, nulliparity, advanced gestational age, and the presence of fetal heartbeat [10]. We analyzed all these characteristics in the two groups, and found no significant differences in maternal age, the percentage of nulliparity, and fetal demise. However, the mean gestational age in the CRB group (20.1 weeks) was much older than in the non-CRB group (16.8 weeks), and the mean fetal weight in the CRB group (367 g) was significantly larger than in the non-CRB group (146 g).

There were no significant differences between the CRB and non-CRB groups with regards to mean induction-to-delivery time (23.1 hours vs. 21.1 hours). Successful abortion rate within 30 hours in the CRB and non-CRB groups (80.0% vs. 83.7%) also revealed no significant difference. Besides, in both groups, more than 90% of patients achieved abortion within 48 hours (data not shown).

Table 4
Failed cases.

Case	Age (y)	GA (wk)	Indication	Pregnant history	Primary method	Salvage method/ delivery mode
CRB						
1	47	14	Fetal death	G3P2	CRB	D&E
2	32	14	Trisomy 13	G2P0A1	CRB	D&E
3	45	17	Trisomy 9 mosaicism	G5P2A2	CRB	CRB, then Foley
4	37	14	Omphalocele	G3P1A1	CRB	Foley
5	35	17	47XXY	G1P0	CRB	CRB, then CRB
6	31	14	Acrania	G2P1	CRB	CRB, then Foley
Non-CRB						
1	41	19	Fetal death	G3P0A2	Misoprostol	Hysterotomy
2	45	17	Trisomy 18	G1P0	Misoprostol	Hysterotomy
3	39	18	Active HIV infection	G5P3A1	Misoprostol	CRB
4	32	19	Trisomy 21	G3P0A2	Misoprostol	Hysterotomy
5	36	19	Down syndrome	G2P1	Misoprostol	Foley
6	35	15	Multiple structural anomaly	G2P1	Misoprostol	Foley
7	32	14	Fetal thalassemia major	G3P1A1	Misoprostol	Foley
8	37	14	Fetal death	G2P0A1	Misoprostol	Foley
9	16	15	Unintended	G1P0	Misoprostol	Foley
10	28	15	Multiple structural anomaly	G1P0	Misoprostol	CRB
11	29	14	Multiple structural anomaly	G1P0	Misoprostol	CRB
12	38	16	Down syndrome	G2P1	Misoprostol	CRB
13	33	20	Fetal death	G1P0	Misoprostol	CRB

CRB = cervical ripening balloon; D&E = dilatation and evacuation; GA = gestational age; HIV = human immunodeficiency virus.

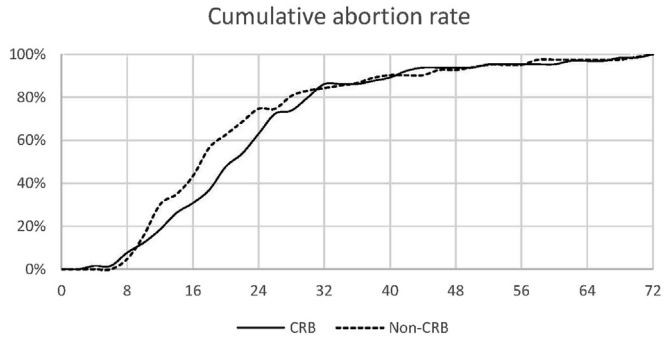

Figure 1. Cumulative abortion rates in two groups with time. CRB = cervical ripening balloon.

Yapar et al [3] found no significant difference in the cumulative abortion rates between an induction-to-abortion interval of 30 hours and 48 hours among groups, and hypothesized that when a patient fails to abort at 30 hours after the primary termination methods, it may be useful to try alternative methods as opposed to further waiting. As can be seen in Figure 1, the curves of the cumulative abortion rates of the two groups noticeably crossed near the "30 hours" mark, which is compatible with the previous finding. We also found that of the 19 cases that failed to abort after primary CRB or non-CRB intervention at around 30 hours, 14 eventually achieved termination after placement of a transcervical Foley catheter, or a second-time CRB insertion. This suggests transcervical double-balloon catheter as a salvage treatment if there is prolonged induction-to-abortion interval after 30 hours.

Adverse effects of misoprostol are well-known, and include diarrhea, nausea, vomiting, dizziness, headache, fever, and chills. However, we found that sometimes there was an added level of anxiety and discomfort in patients receiving transcervical catheter insertion. Concerning the inevitable extra expense that comes with COOK CRB, we should use it as a salvage method, not as a primary way for induction of labor in midtrimester termination.

Moreover, in second-trimester termination of pregnancy, misoprostol and COOK CRB are both off-label use. Misoprostol is authorized only in peptic ulcer disease, and COOK CRB in induction of labor for unfavorable cervix for "term" pregnancy.

There were some limitations in this retrospective study, especially the demographic difference in gestational age. In our current practice, the vaginal and uterine balloons were inflated to 40 mL for gestational age between 14 weeks and 16 weeks; 50 mL was used for 17–20 weeks, 60 mL for 21–24 weeks, and 70 mL for 25–28 weeks. This is based on the assumption that larger gestational tissues are associated with a larger gestational age, and hence require greater balloon volumes for cervical dilatation and ripening. Finally, balloon sizes used in the CRB group in this study were inconsistent.

In conclusion, there was no significant change of termination time when using a transcervical double-balloon catheter in the termination of pregnancy in the second trimester as a primary method versus vaginal and oral misoprostol alone, although the technique was simple and generally well-tolerated. Placing a transcervical double-balloon catheter could be the primary method, or one of the alternative medical methods if the patient and/or obstetrician prefers no operation.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

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