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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.