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Ripening and dilatation of the unfavourable cervix for induction of labour by a double balloon device: experience with 250 cases

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Objective To determine the efficacy of the double balloon device (the Atad Ripener Device) in ripening and dilatation of the unfavourable cervix for induction of labour.

Methods Two hundred and fifty women with unfavourable cervices (Bishop score ≤ 4) underwent induction of labour with the Atad Ripener Device. Indications were pregnancy induced hypertension (n = 118), post-dates (n = 69), elective inductions (n = 23), other reasons including nonreassuring nonstress test, intrauterine growth retardation, previous caesarean section and diabetes mellitus (n = 40). The Atad Ripener Device was inserted into the cervix, the uterine balloon inflated in the internal os, and the cervico-vaginal balloon in the external os of the cervix (100 mL of normal saline to each balloon). Pressure produced by the inflated balloons caused gradual dilatation and effacement of the cervix. The Atad Ripener Device was removed 12 h after insertion, the cervix assessed again, and labour managed according to obstetrical criteria.

Results The Atad Ripener Device caused an increase in the Bishop score in all subgroups with a mean change of 4·6 (from 2·0 prior to induction to 6·6 upon removal of the Atad Ripener Device; $P < 0·05$). The mean time interval from insertion of the Atad Ripener Device to delivery was 18·9 h, and from removal to delivery was 6·9 h. Caesarean section was performed in 39/250 patients (16%), and the others had a normal vaginal delivery.

Conclusions 1. The double balloon device induces significant ripening and dilatation of the unfavourable cervix. 2. Induction of labour was successfully achieved following removal of the Atad Ripener Device. 3. Our caesarean section rate was low compared with rates reported for women with an unfavourable cervix induced by other methods.

INTRODUCTION

Induction of labour remains one of the therapeutic challenges in obstetrics. The success of induction depends on the cervical status at the start of the induction process[1]. Induction of labour in the presence of an unripe cervix results in a longer labour and a higher incidence of caesarean section and fetal asphyxia[2]. The use of intravenous infusion of oxytocin alone is associated with a prolonged induction period, a significant failure rate, and considerable discomfort to the woman[3,4]. Therefore various methods of cervical ripening have been developed to improve the chance of success of labour induction. Currently the most commonly used method is intravaginal application of prostaglandin E_2[5,6]. However, systemic absorption of this agent is common, resulting in nausea, vomiting and initiation of uterine contractions which may last for prolonged periods and leads to uterine hypertonicity and even placental abruption. This involves extra risk to the fetus which may already be compromised by the underlying reason for labour induction.

A newly developed double balloon device, the Atad Ripener Device, has been introduced to ripen the cervix by mechanical means without causing uterine contractions. We previously reported our experience with 50 cases and found this method of induction of labour to be effective and safe[7]. We now report our experience with 250 women with an unfavourable cervix undergoing induction of labour by the double balloon device for various indications. This is a descriptive report of our extended experience with this device. This study was intended to evaluate its usefulness in cervical ripening before initiating a comparative randomised study.

METHODS

Two hundred and fifty women with unfavourable cervices (Bishop score ≤ 4) underwent induction of

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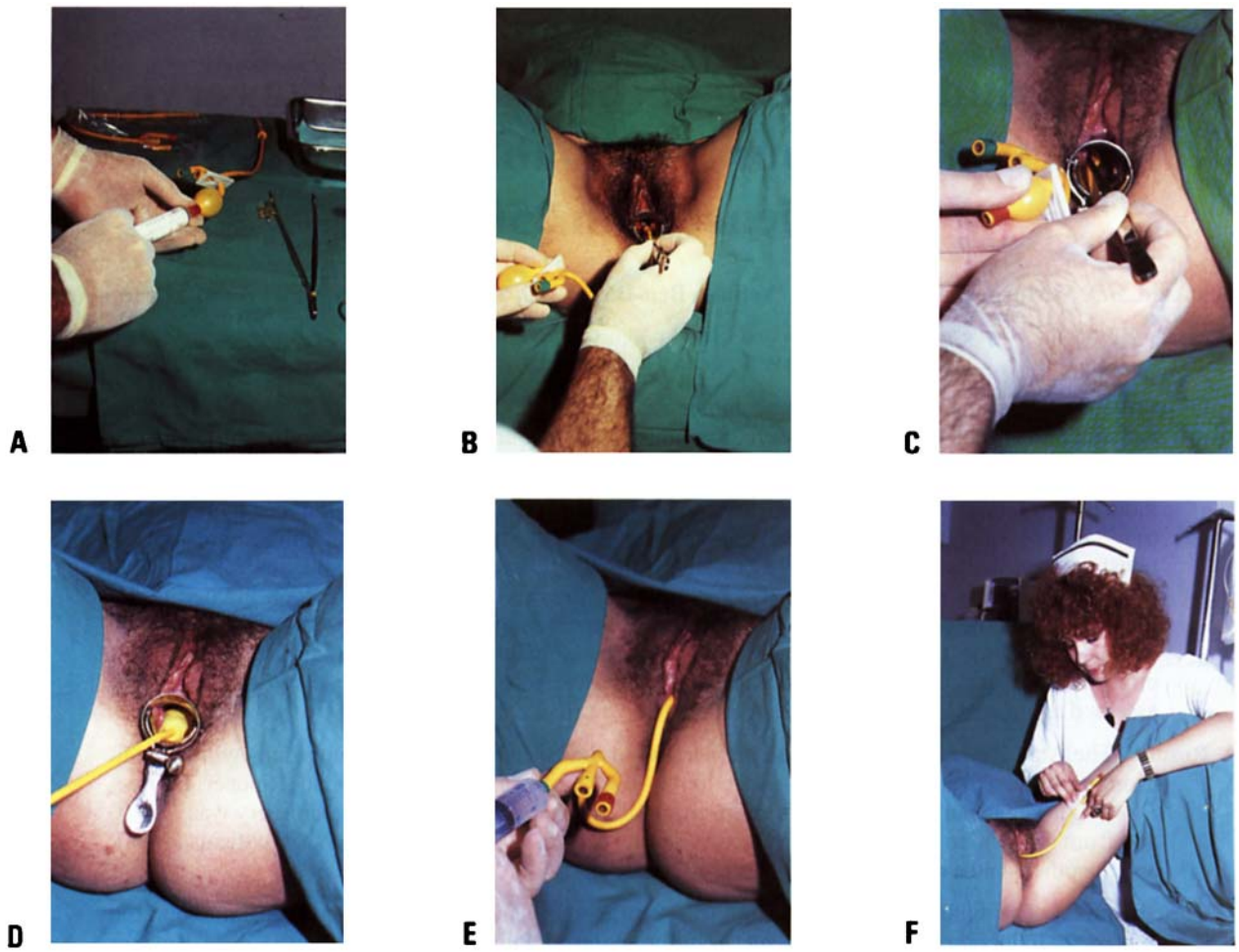

Fig. 1. Insertion technique: (A) Pre-inflation of the uterine valve arm; (B) Insertion of the device; (C) Inflation of the uterine balloon; (D) Inflation of the cervico-vaginal balloon; (E) Additional inflation of the balloons (100 mL each); (F) Device taped to the woman's leg.

labour with the double balloon device. Indications for labour induction were: pregnancy induced hypertension (n = 118), post-dates (n = 69), elective inductions (n = 23), and other reasons including non-reassuring nonstress test, intrauterine growth retardation, previous caesarean section and diabetes mellitus (n = 40). Inclusion criteria were singleton pregnancy, vertex presentation, the woman not in labour, Bishop score $\leq$ 4 points and intact membranes. We excluded patients with placenta praevia, acute fetal distress, two previous lower segment transverse or one classic caesarean section. When the decision was made to induce labour, we evaluated the cervix and determined the first Bishop score.

Insertion technique (Fig. 1)

With the woman in the lithotomy position a speculum was inserted to visualise the cervix. Before insertion, the uterine valve tip of the device was occluded and pre-loaded by 20 mL of saline. The ripener device was inserted into the cervix using long forceps until both balloons enter the cervical canal. At this stage, while holding the device in place, the occlusion system was removed to allow automatic inflation of the uterine balloon, or by applying some pressure on the pre-loaded uterine valve tip. The device was then pulled out until stopped by the uterine balloon covering the internal cervical os. The cervico-vaginal balloon located at the external os was inflated by injecting 20 mL of saline through the cervico-vaginal valve. At this stage the speculum was removed and both the uterine and the cervico-vaginal balloons were additionally inflated with alternate increments of 20 mL up to a total of 100 mL in each balloon. The device was taped to the woman's inner thigh. After completion of the device insertion, 30 min of external monitoring was performed. Afterwards the woman's activity was not restricted.

The device was inserted in most women in the evening (8 p.m.) and removed 12 h later (8 a.m.). Pressure produced by the inflated balloons caused

Table 1. Demographic data of the women in the study. Values are given as *n* (%) or mean [SD].

	Nulliparous	Multiparous	Total inductions
Patients	118 (47)	132 (53)	250 (100)
Maternal age (years)	24 [4·2]	28 [5·2]	26·1 [4·8]
Gestational age (weeks)	40·6 [1·1]	39·3 [1·4]	39·9 [1·3]

Table 3. Caesarean section rates. Values are given as *n*/*n* (%).

	Method successful*	Method failure†
No. of patients	229/250 (92)	21/250 (8)
No. of caesarean sections	29/229 (12·7)	10/21 (47·6)

*Final Bishop Score > 4; †Final Bishop Score ≤ 4.

Table 2. The change in Bishop score, insertion to delivery interval, and mode of delivery in 250 women induced by the double balloon ripener device. Values are given as mean [SD] or *n* (%) where appropriate. PIH = pregnancy induced hypertension.

	First Bishop score	Second Bishop score	Insertion–delivery interval (h)	Mode of delivery	
				Vaginal	Caesarean section
PIH (*n* = 118)	1·8	6·3*	19·4	104 (87)	14 (13)
Post-dates (*n* = 69)	2·2	6·8*	20·2	54 (78)	15 (22)
Elective (*n* = 23)	2·3	7·1*	16·3	20 (86)	3 (14)
Others (*n* = 40)	2·4	6·9*	17·2	33 (83)	7 (17)
TOTAL (*n* = 250)	2·0 [0·9]	6·6 [1·5]*	18·9 [6·1]	211 (84)	39 (16)

*Second Bishop > first Bishop; $P < 0.05$

gradual dilatation and effacement of the cervix. Following removal of the device, the cervix was assessed for a second Bishop score by the same investigator. In all women where the Bishop score was ≥ 5, induction of labour was resumed using artificial rupture of the membranes and/or intravenous administration of oxytocin. Afterwards labour was managed according to obstetric criteria. A nonparametric statistical test (Mann-Whitney *U* test) was used to evaluate the changes in the Bishop score. Results are presented as mean [SD] and $P < 0.05$ was considered significant.

RESULTS

A total of 250 women with an unfavourable cervix who underwent induction of labour were included in this study. Of these, 118 (47%) were nulliparous and 132 (53%) were multiparous. Demographic data according to parity are presented in Table 1. Overall, the mean change in Bishop score in the nulliparous group was 4·7 ($P < 0.05$). The mean change in Bishop score in the multiparous women was 5·0 ($P < 0.05$). Cervical ripening (second Bishop score > 4) was achieved in 229/250 women (92%): 107/118 in the nulliparous group (91%) and 122/132 in the multiparous group (92%).

The change in Bishop score following induction of labour with Atad Ripener Device, the insertion–delivery interval, and caesarean section rate according to indication for induction are presented in Table 2. The Atad Ripener Device caused an increase in the Bishop score in all subgroups with a mean change of 4·6 ($P < 0.05$). The mean time interval from insertion of the Atad Ripener Device to delivery was 18·9 h, and from removal to delivery was 6·9 h. Caesarean section was performed in 39/250 women (16%); the others had normal vaginal delivery. Table 3 provides a separate analysis for women who had caesarean section. The indications for caesarean section included arrest of dilatation/descent, prolonged second stage of labour, and fetal distress.

Eighteen women (7·2%) went into active labour before removal of the Atad Ripener Device (< 12 h from insertion). The Atad Ripener Device actually led to delivery within 12 h without any additional intervention in 11 women (4·4%), some of whom had either spontaneous expulsion of the Atad Ripener Device or rupture of the membranes. In all women in whom the Atad Ripener Device was spontaneously expelled, the cervical dilatation at that time was > 4 cm. In these patients contractions started spontaneously probably as a results of stretching of the cervix (Ferguson effect).

DISCUSSION

The Atad Ripener Device induced significant ripening and dilatation of the unfavourable cervix in 229 (92%) of our patients. Vaginal delivery was achieved within a mean of 6·9 h following removal of the Atad Ripener Device in 211 women (84%). The Atad Ripener Device did not cause discomfort such as that caused by pharmaceutical methods of labour induction[8]. The method is safe and well tolerated by most women who can remain mobile while the Atad Ripener Device is in place. Our caesarean section rate was low (16%) compared with rates reported in the literature (> 30%) for women induced with an unfavourable cervix[9].

The Atad Ripener Device was successfully used with all indications for induction (pregnancy-induced hypertension, postdate pregnancies, fetal growth retardation, previous caesarean sections, diabetes mellitus and elective inductions). This nonpharmaceutical method is especially advantageous in patients where prolonged uterine contractions are best avoided, such as those with placental insufficiency, intrauterine growth retardation, oligohydramnios, and previous caesarean sections.

The mechanism of action of this device may be by two ways. Gradual mechanical cervical dilatation is achieved by the pressure applied on both the external and internal os due to the inflated balloons. The cervical pressure of the internal uterine balloon may cause release of endogenous prostaglandins from the adjacent decidua[10].

The use of a single balloon device such as a Foley catheter has been reported by several investigators[11,12]. Traction of the catheter by the women's leg involves a certain degree of discomfort. The advantage of the Atad Ripener Device is that it is held in place and the dilator vector is applied by the two balloons inflated on both sides of the cervix, avoiding the need for traction. Moreover, the mean increase in Bishop score was lower with the Foley catheter than that achieved by the Atad Ripener Device (1·22 *versus* 4·6, respectively) and the failure rate in these reports is much higher than ours, 20% *versus* 8%, respectively[11,12].

The high success rate of and the low caesarean section rate make it particularly appealing. A randomised controlled trial is necessary in order to give a reliable comparison of caesarean section rate, length of labour, and cervical ripening. The current study is mainly a descriptive report of our experience in a large number of women as compared with published data.

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