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CLINICAL ARTICLE

An inflatable ergonomic 3-chamber fundal pressure belt to assist vaginal delivery

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ABSTRACT

Objective: To evaluate whether Baby-guard—a new medical device with an ergonomic 3-chamber inflatable abdominal belt—can reduce complications associated with vaginal delivery. *Methods:* A randomized controlled single-blind prospective study of 80 pregnant women delivering at term was conducted at San Giuseppe Hospital, Empoli, Italy. In the study group (n = 40), the abdominal belt was inflated to optimal therapeutic pressures. In the control group (n = 40), the abdominal belt was inflated to minimal, non-therapeutic pressures. Factors relating to maternal, fetal, and labor complications during vaginal delivery were evaluated. *Results:* Compared with the control group, women in the study group experienced a lower incidence of perineal and cervical lacerations ($P<0.001$); reduced use of the Kristeller maneuver ($P<0.001$); shorter duration of the second stage of labor ($P<0.001$); less psychologic and physical fatigue ($P<0.001$); fewer maternal requests for cesarean delivery during labor ($P<0.001$); fewer vacuum extractions ($P<0.01$); and fewer cesarean deliveries ($P<0.02$). No neonatal intensive care unit admissions were recorded in the study group versus 7 in the control group ($P<0.012$). *Conclusion:* Use of the ergonomic 3-chamber inflatable abdominal belt system reduced the incidence of risks associated with vaginal labor.
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1. Introduction

Ensuring the safety of vaginal delivery for both the pregnant woman and her offspring is a key aim among obstetricians, midwives, and clinical researchers. Complications following vaginal delivery may result in medico–legal issues and increased healthcare costs associated with the need for sanitary products.

Manual application of pressure on the uterus is a procedure currently used during the second stage of labor. Nevertheless, the use of this approach is controversial [1] and generally not documented or under-reported in medical records [1,2]. The Kristeller maneuver was first introduced in 1867 [3]. Although it consists of the operator gently placing a hand on the uterine fundus, which creates a longitudinal force toward a 30°–45° angle of the pelvis, thereby avoiding pressure on the spine of the mother, no clear definition of the maneuver and no indication for its use has been formally described [4]. Incorrect use of the fundal pressure maneuver concerned Kristeller as early as 1861. He stated that, if used incorrectly, this procedure might cause serious damage to mother and child; the uncorrected application of uncoordinated forces with uncontrolled force on the uterine fundus was judged as detrimental [3].

The Kristeller maneuver may be used in cases of non-reassuring fetal heart trace; operative delivery through vacuum extraction or forceps; cord prolapse; or fetal scalp sampling to assess base excess. However, its use in obstetrics is still controversial, owing to adverse maternal and fetal outcomes. The Kristeller maneuver cannot be measured in terms of pressure, which explains why it could potentially be very dangerous for a pregnant woman and/or the fetus. Indeed, use of the Kristeller maneuver is associated with an increased incidence of vaginal lacerations [5], hypotensive crisis, abdominal pain, respiratory distress syndrome, uterine rupture, rib fractures, and liver rupture [4].

Reported fetal injuries associated with the Kristeller maneuver include brachial plexus damage, homer and clavicle fracture, and thoracic spinal cord injuries [4,6,7]. Increased uterine fundal pressure caused by an operator leads to alterations in fetal cerebral blood flow [6,7], which have been associated with the development of cerebral palsy and asphyxia complications. Furthermore, increases in intracranial pressure can result in non-reassuring fetal heart tracings, compression of the umbilical cord, hypoxemia, and subgaleal hemorrhage [3]. Finally, use of the Kristeller maneuver during delivery can

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promote shoulder dystocia [8,9], particularly when associated with vacuum or forceps extraction procedures.

Given the potential limitations of the Kristeller maneuver, it seems clear that the development of a novel method to modulate uterine fundal pressure could be of help during labor [10,11]. The Baby-guard system (Cabel, Pistoia, Italy) is a new medical device engineered after studies of biomechanics and biophysics, following obstetric semiotics. Through its ergonomic 3-chamber inflatable abdominal belt, the Baby-guard system applies pressure on the uterine fundus during the second stage of labor toward the pelvic outlet.

The aim of the present study was, therefore, to determine whether use of the Baby-guard system improves maternal and fetal outcomes during vaginal delivery.

2. Materials and methods

A randomized, controlled, single-blind prospective study of 80 nulliparous women undergoing vaginal delivery in the Obstetrics and Gynecology Unit, San Giuseppe Hospital, Empoli, Italy, from January 24 to March 24, 2011, was conducted.

The present study was performed according to the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; the Declaration of Helsinki regarding the standard operating procedures for clinical investigators; and the European Union requirements for clinical investigation of medical devices for human participants (BS EN ISO 14155–1:2009; UNI EN ISO 14155–2:2009; CE No. 1466 MDD). The study protocol was approved by the local ethics committee of the University of Florence and Empoli Hospital (No. 39.229; November 23, 2010). Participants received detailed information concerning the present study and its protocol; all participants provided written informed consent.

A flowchart of enrollment and randomization is depicted in Fig. 1. Inclusion criteria were active labor at term in primipara; maternal age 23–42 years; singleton pregnancy; and cephalic presentation of the fetus. Exclusion criteria were preterm delivery (gestational age <37 weeks); breech or transverse position of the fetus; gestational diabetes mellitus or pregnancy-induced hypertension; fetal macrosomia; placental abnormalities (low-lying placenta or placental abruption); uterine anatomic abnormalities; previous uterine scar; and fetal heart-rate anomalies at the time of enrollment (bradycardia, tachycardia, or prolonged variable decelerations).

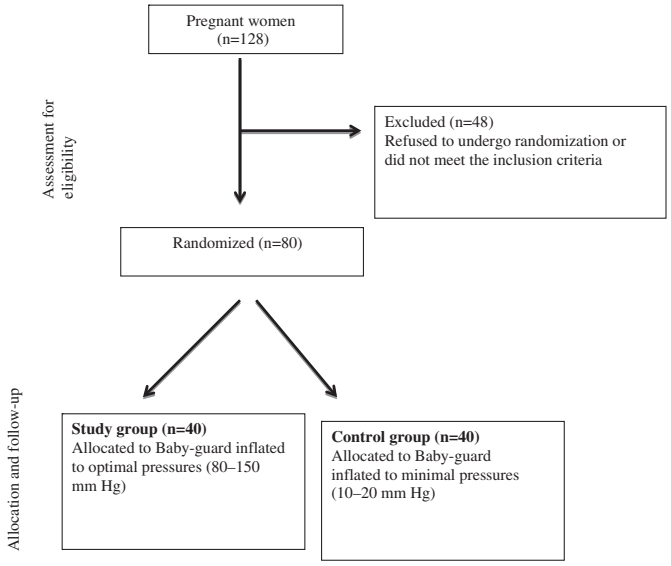

Fig. 1. Flowchart of the enrollment and randomization procedure.

The onset of the second stage of labor was defined as full cervical dilatation, as evaluated by digital examination. Eligible participants were assigned to 1 of 2 groups and randomization was performed using numbered envelopes during full dilatation of the cervix. Women allocated to the study group (n = 40) experienced optimal pressures (80–150 mm Hg) during inflation of the Baby-guard belt. The control group comprised 40 women in whom the Baby-guard belt was inflated with minimal pressures (10–20 mm Hg).

The manufacturers of Baby-guard provided all of the operative support without charge. As shown in Fig. 2, the Baby-guard system consists of a disposable ergonomic 3-chamber inflatable belt and a detector of electro-physiologic signals of myographic uterine activity from the maternal abdomen (i.e. fetal and maternal heart signals). The 3 chambers of the belt can be inflated individually in order to reposition the fetus. These chambers are filled according to the pressures set by the operator (midwife or clinician) and allow gentle positioning of the fetus in the correct position toward the pelvis. Once the correct fetal position has been attained, all 3 chambers are inflated synchronously during uterine contraction. The maternal and fetal heart monitoring unit comprises a medical touch-screen computer that records electro-physiologic signals collected by a medical signal amplifier deriving from the mother (uterine contractions and maternal heart rate) and the fetus (fetal heart rate). There is also the possibility to record Doppler parameters of the fetal heart from the cardiotocograph. All parameters and signals detected by the Baby-guard system can be stored on the computer hard drive, in line with the European Community rules on safety (UNI EN60601).

The present study reports only the outcomes of delivery among the participants and their offspring. The Baby-guard system was used for less than 2 hours until delivery. The obstetrician, midwife, and participants were blind to whether the belt was inflated with sufficient pressure or not. During the second stage of labor, the operator inflated the ergonomic belt for 30 seconds at every contraction according to the pressures prescribed in the study protocol. Uterine fundal pressure through the inflatable belt was set at a 30°–40° angle to the spine toward the pelvic outlet, standardizing the force and surface area of application (980 cm^2). The frequency of inflation was limited to fewer than 6 times (each time for 30 seconds) for a total period of 20 minutes, followed by a pause of 10 minutes. All participants received standard management of the second stage of labor, which included fetal heart rate monitoring and care from the attending physician or midwife. Operative deliveries were performed when necessary.

Prepartum data collected from the delivery records included maternal age; race; parity; maternal body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters) at the time of delivery; and increases in body weight during pregnancy. Intrapartum data included gestational age at delivery; duration of the second stage of labor; use of intravenous oxytocin; episiotomy; cervical laceration; mild perineal lacerations (defined as 1–2 lacerations); severe perineal lacerations (defined as 3–4 lacerations); vacuum extraction; forceps delivery; and use of the Kristeller maneuver. Fetal weight was estimated by the combination of biparietal diameter, abdominal circumference, and femur length [10].

Outcome measures were the incidences of perineal and cervical lacerations; the use of the Kristeller maneuver; the incidence of vacuum extractions; the rate of cesarean delivery during labor; the duration of the second stage of labor; the degree of maternal psychologic and physical fatigue; the number of maternal requests for cesarean delivery during labor; and the number of admissions to the neonatal intensive care unit.

At the time of hospital discharge, the participants' satisfaction with the Baby-guard system was assessed by a questionnaire. The degree of psychologic and physical fatigue was recorded by a 10-point visual analog scale, where 0 was no discomfort and 10 was the highest level of discomfort. The women were also interviewed about the usefulness of the inflatable belt in assisting vaginal delivery.

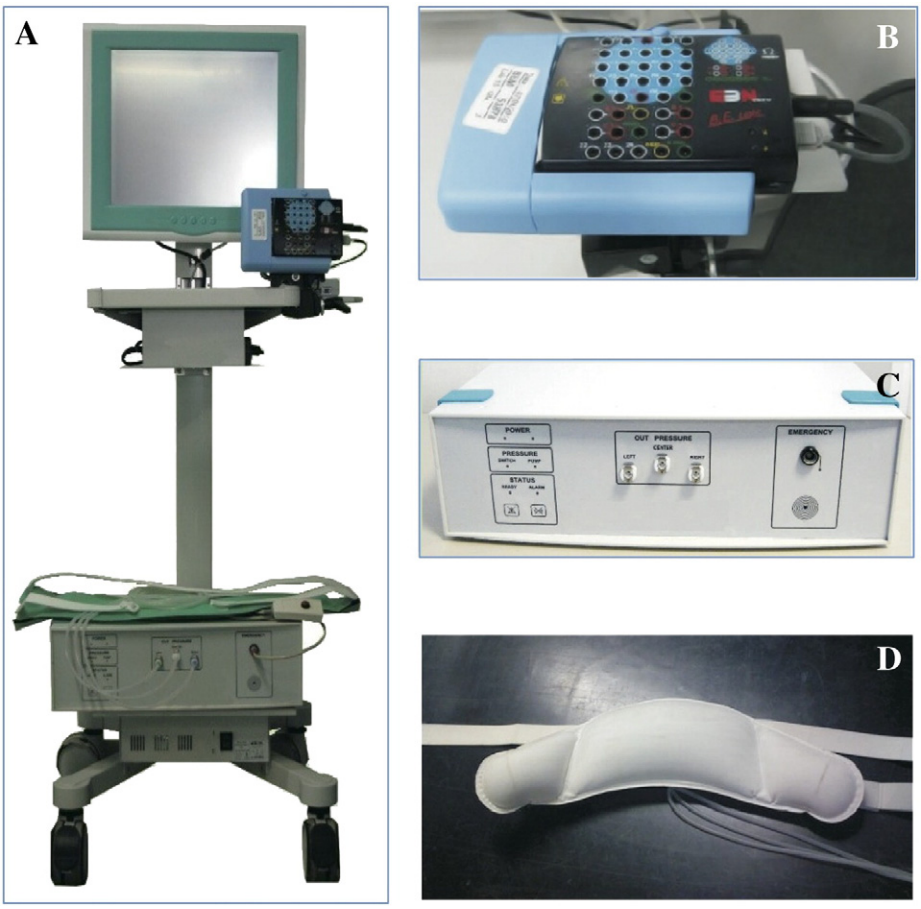

Fig. 2. Baby-guard composition. (A) The Baby-guard device with (B) the equipment for fetal heart-rate monitoring, (C) the pump for the belt, and (D) the belt.

Data were analyzed using STATA version 5 (StataCorp, College Station, TX, USA) and expressed as mean ± standard deviation or as number (percentage). To test whether differences between the 2 groups were statistically significant, the sample size was calculated a priori. To do this, a primary endpoint was first identified (incidence of perineal–cervical lacerations). The sample size ($n > 62$ participants for 2 groups) was obtained using a 2-tailed test (α level of 0.05 and 90% of statistical power [1-β]) to detect a statistically significant reduction from 50% to 10% or less with respect the primary endpoint. Consequently, randomization of 40 pregnant women to each group was deemed necessary after exclusions owing to refusal or withdrawal [11]. Comparisons of proportions and means between groups (study group versus control group) were performed using the χ^2 test (or the Fisher exact test, if suitable) and an independent t test, respectively. $P<0.05$ was considered statistically significant.

3. Results

Table 1 shows the clinical characteristics of the participants. No significant differences between the study and control groups were observed with respect to maternal age, gestational age at delivery, maternal BMI, body weight change during pregnancy, and indications for admission. Compared with the control group, the study group demonstrated a lower incidence of perineal lacerations ($P<0.001$); absence of use of the Kristeller maneuver ($P<0.001$); shorter duration of the second stage of labor (37.9 ± 22.56 minutes versus 111.37 ± 35.10 minutes; $P<0.001$); lower incidence of vacuum extractions ($P<0.01$); and lack of cesarean delivery during labor ($P<0.02$). With regard to fetal outcomes, no significant differences were observed between the 2 groups for birth weight, Apgar score, and sex. By contrast, the number of neonatal intensive care unit admissions was lower in the study group than in the control group (0 versus 7; $P=0.012$).

Table 1
Clinical characteristics of the participants (n = 80).[a]

Characteristic	Study group (n = 40)	Control group (n = 40)	*P* value
Maternal age, y	30.975 ± 5.166	31.475 ± 4.218	0.8
Gestational age at delivery	39.52 ± 1.2	39.67 ± 1.2	0.9
Maternal BMI	25.2 ± 6.4	26.4 ± 6.8	0.3
Body weight change, kg	12.40 ± 3.11	12.12 ± 3.93	0.4
Indications for admission			
Rupture of membranes	15 (37.5)	13 (32.5)	0.8
Onset of labor	25 (62.5)	27 (67.5)	0.9
Duration of second stage of labor, min	37.90 ± 22.56	111.37 ± 35.10	<0.001
Cervical lacerations	0 (0.0)	1 (2.5)	0.7
Mild perineal lacerations	1 (2.5)	15 (37.5)	<0.001
Severe perineal lacerations	2 (5.0)	16 (40.0)	<0.001
Kristeller Maneuver	0 (0.0)	27 (67.5)	<0.001
Operative deliveries			
Cesarean delivery	0 (0.0)	5 (12.5)	<0.02
Vacuum extraction	4 (10.0)	12 (30.0)	<0.01
Neonatal birth weight, g	3234.75 ± 456.85	3291.50 ± 430.90	0.7
Neonatal sex			
Male	16 (40.0)	20 (50.0)	0.8
Female	24 (60.0)	20 (50.0)	0.9
Apgar score, 1 min	8.850 ± 0.921	8.775 ± 0.831	0.9
Apgar score, 5 min	9.575 ± 0.813	9.575 ± 0.675	0.7
NICU recovery	0 (0.0)	7 (17.5)	<0.012

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); NICU, neonatal intensive care unit.
[a] Values are given as mean ± standard deviation or number (percentage).

Table 2
Patients' satisfaction with the ergonomic inflatable 3-chamber belt.[a]

Parameter	Study group (n = 40)	Control group (n = 40)	*P* value
Psychologic fatigue, cm[b]	2.32 ± 1.77	9.25 ± 1.33	<0.001
Physical fatigue, cm[b]	2.40 ± 1.51	8.88 ± 1.27	<0.001
Perceived usefulness of the belt	39 (97.5)	1 (2.5)	<0.001
Requests for cesarean delivery during the second phase of labor	6 (15.0)	30 (75.0)	<0.001

[a] Values are given as mean ± standard deviation or number (percentage).
[b] Evaluated by scoring the degree of psychologic and physical fatigue marking a 10-cm visual analog scale from 0 (minimal) to 10 (optimal).

Data related to the participants' satisfaction with the Baby-guard system are presented in Table 2. Based on the postpartum questionnaire, most of the women in the study group reported positively about their experiences of psychologic and physical fatigue, as well as their general degree of satisfaction with Baby-guard. Indeed, women in the study group experienced significantly lower psychologic fatigue than women in the control group (2.32 ± 1.77 cm versus 9.25 ± 1.33 cm; $P<0.001$). A similar result was obtained for physical fatigue (2.40 ± 1.51 cm versus 8.88 ± 1.27 cm; $P<0.001$). Moreover, when participants were asked about the usefulness of the inflatable belt in assisting vaginal delivery, 39 women in the study group versus 1 woman in the control group judged the Baby-guard system as helpful ($P<0.001$). Finally, a higher number of maternal requests for cesarean delivery during the second phase of labor was recorded in the control group than in the study group (30 versus 6; $P<0.001$).

4. Discussion

The Kristeller maneuver is generally used to increase uterine forces and intrauterine pressure during the second stage of labor, although clinical complications may arise when using this approach. Several reports on the Kristeller maneuver describe pressure being performed by the physician on the maternal abdomen, and exerting downward pressure, or leaning across the abdomen and placing the forearm at the height of the fundus [12]. This manual maneuver is potentially dangerous both for pregnant women and for the fetus or newborn. By contrast, the net effect exerted by the Baby-guard system in the present study was to obviate this practice of manual pushing by substituting with the application of controlled fundal pressure in the direction of the pelvic outlet during spontaneous uterine contractions in the second stage of labor. As early as 1861, Kristeller registered concern regarding the incorrect use of the fundal pressure maneuver [3].

In the present study, it was shown that using the Baby-guard system improves natural vaginal delivery. The positive effect observed during the second phase of labor may be ascribed to the surface area of application of uterine fundal pressure, by means of the 3-chambered inflatable belt [13]. Therefore, by aiding maternal pushing and shortening the duration of the second stage of labor, the Baby-guard system may prevent maternal fatigue and exhaustion, as suggested by the findings of the present study. Both psychologic fatigue and physical fatigue were significantly lower among women in whom the Baby-guard system was used at optimal pressures than in those women in whom the belt was inflated to minimal pressures. In addition, the findings of the present study suggest that the use of Baby-guard reduces perineal lacerations, fundal pressure, vacuum extraction use, and maternal requests for cesarean delivery during labor.

In conclusion, the present study indicates that the Baby-guard system could offer several advantages during vaginal delivery, reducing risks [11,14–16] associated with a prolonged second stage of labor and decreasing the need for operative interventions.

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Conflict of interest

The authors have no conflicts of interest.

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