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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).

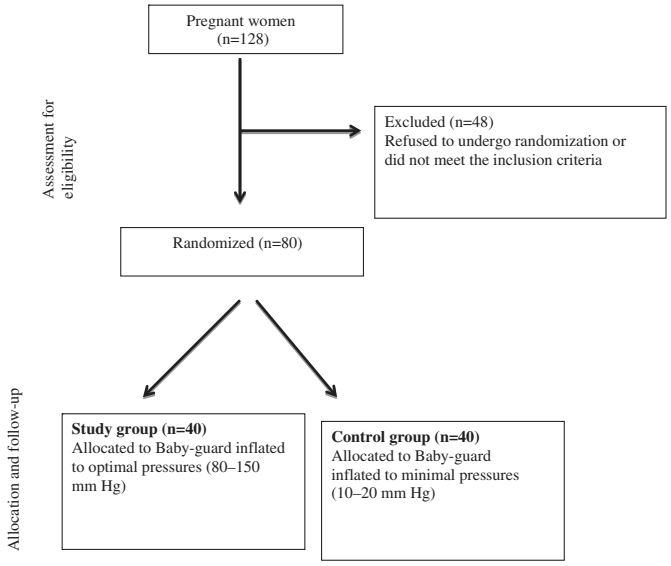

Fig. 1. Flowchart of the enrollment and randomization procedure.

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.