

Case-control study of the role of perineal application of an AC collagen/hyaluronic acid medical device on the maternal perineum at birth

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ABSTRACT

A 43-year-old woman was referred to our Department Perineal trauma (PT) following vaginal birth can be associated with short and long term morbidity. Aim of our research was to study the role of antenatal vulvo-vaginal and perineal application of a creamy medical device containing AC collagen and hyaluronic acid on the maternal perineum at birth. To this end seventy-two healthy pregnant women were approached and taught how perform the massage and apply the device, starting from the 28th gestational week up to delivery. Forty-seven of them completed the study and compared with controls. A lower incidence of PT and episiotomies and a shorter duration of 1st and 2nd stage of labor was observed in the study group. No significant differences when considering tears, intrapartum blood loss, instrumental deliveries. As such, women should be warned of the likely benefit of perineal massage and provided with information on how to massage.

Keywords: perineum, lacerations, episiotomy, collagen, birth, perineal massage, hyaluronic acid.

SOMMARIO

I traumi perineali (PT) dopo un parto vaginale possono essere associati a morbilità a breve e lungo termine. Scopo della nostra ricerca è stato quello di studiare l'effetto sul perineo dell'applicazione vulvo-vaginale e perineale di una crema contenente collagene AC e acido ialuronico. A tal fine 72 donne con gravidanza fisiologica sono state arruolate durante la 28ma settimana di gestazione. Ad esse è stato insegnato come eseguire il massaggio perineale per l'applicazione della crema dalla 28ma settimana di gravidanza fino al parto. Quarantasette donne hanno terminato lo studio e sono state confrontate con delle pazienti di controllo. Nel gruppo di studio abbiamo osservato una minore incidenza di PT e di episiotomie e una durata più breve del 1° e 2° stadio del travaglio. Nessuna differenza significativa se si considera le lacerazioni, la perdita ematica intraparto, parti operativi. Le donne dovrebbero essere informate dei benefici del massaggio perineale con una crema a base collagene e dovrebbero essere istruite su come effettuare il massaggio nel periodo antepartum.

INTRODUCTION

The female pelvic floor represents a region of the body whose anatomic structures must prevent incontinence and pelvic organ prolapse during the elevations in abdominal pressure and motions associated with daily physical activities; they must also permit urination and defecation and allow childbirth⁽¹⁾. The main components of the pelvic floor include i) the levator ani muscle, whose components are tonically contracted at rest and act to close the genital hiatus and provide a stable platform for the pelvic viscera; ii) the endopelvic fascia, connective-tissue network that envelops all organs of the pelvis and connects them to the supportive musculature and bones of the pelvis. This network holds vagina and uterus in their normal anatomical location and stabilizes the viscera to permit storage of urine and stool, coitus, parturition, and defecation⁽¹⁻²⁾.

The physiological changes occurring during pregnancy and the processes of childbirth have a detrimental effect on the structure and function of the muscles, nerves and fascial tissues, which may result in a wide range of symptoms including urinary or anal incontinence (**Table 1**)⁽³⁾. As gestation progresses, the pregnant uterus produce anatomical changes resulting in a wider opening of the bladder neck, increased bladder motility and changes in the collagen and connective tissues properties⁽⁴⁻⁶⁾. Nevertheless, the processes of vaginal delivery threaten the pelvic floor functions. During the stage of the 'crowning' of the baby's head, the widest part of the baby's head stretches the pelvic floor muscles, nerves and endopelvic fascia. It is likely that such stretching may contribute to PFD later in life (**Figure 1**). Magnetic Resonance Imaging analysis performed in primiparous and in nulliparous women showed a higher frequency of defects in the levator ani muscle in the first group (20% vs. 5%; 7). Pudendal nerve injury can occur in 80% of women following

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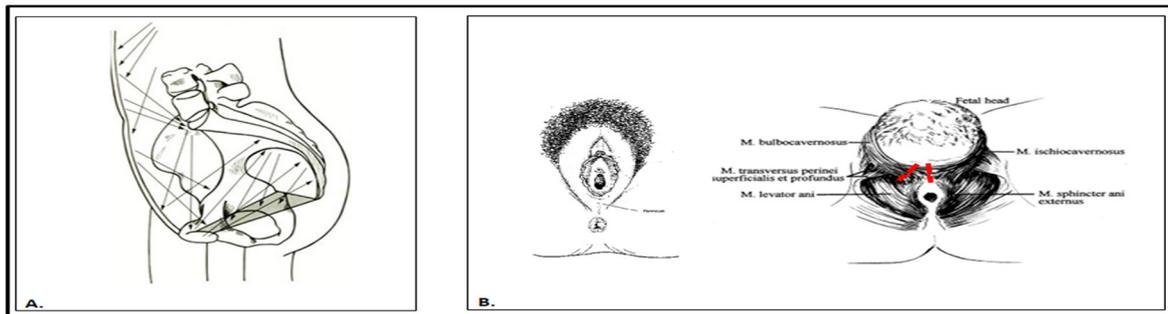


Figure 1

Pelvic floor changes during pregnancy and delivery. (A) Intra-abdominal pressure changes in pregnancy due to the increased volume and weight of the gravid uterus. The whole intra-abdominal pressure vector converge on the anterior area of pelvic floor (uro-genital hiatus) and pregnancy related compensations in biomechanics and structure of the spine. The increased size of uterus and fetus causes the occurrence of a backward compensation. The pelvis assumes a new angle to support the increased weight and volume. The center of gravity usually shifts forward. With a greater angle of pelvic inclination, a greater curvature of the lumbar spine results. (B) Pelvic floor muscles distention during vaginal delivery. Areas of midline and mediolateral episiotomies.

their first vaginal delivery⁽⁸⁻¹⁰⁾. Finally Dietz et al. by performing trans-perineal ultrasound scans demonstrated that up to one-third of women following vaginal delivery undergo avulsion/tearing of the endopelvic fascia and that such anatomical change is associated with postpartum stress urinary incontinence three months following delivery⁽¹¹⁻¹²⁾.

To date, different perineal techniques and interventions are being used to slow down the birth and allow the perineum to stretch slowly in order to prevent perineal injury⁽¹³⁾. Among these the antenatal exercises with the mechanical trainer EPI-NO[®], the intrapartum perineal massage (hands-on technique) and the local application of warm compresses are widely used by midwives and birth attendants⁽¹³⁻¹⁴⁾. Objective of our research was to study the possible role of antenatal perineal and vulvo-vaginal massage with a creamy medical device containing AC collagen and hyaluronic acid (Perilei Gravidanza[®]) on the maternal perineum at birth.

MATERIALS AND METHODS

Study design

Case-control study

Subjects investigated

This study was performed between May 2013 and July 2014 at the Department of Obstetrics and Gynecology, Policlinico A. Gemelli, Università Cattolica del Sacro Cuore, Rome, Italy. It was approved by the local institutional review board. Healthy pregnant women eligible for the study group were recruited mainly during antenatal outpatient clinic during their 28th week of

gestation.

Inclusion criteria included healthy pregnant women at 28 weeks gestation who were planned for a vaginal delivery at our institution. Exclusion criteria comprised a history of any vaginal surgical procedure, any vaginal infection, multiple gestation, use of a different perineal technique during the current pregnancy and communication difficulties (because of the difficulty to seek informed consent).

Participants were provided with background information regarding episiotomy and perineal trauma during vaginal delivery. After consent, the study coordinators instructed the women as to how to perform the perineal massage by providing them with written information about the technique of conducting perineal and vulvo-vaginal massage (**Figure 2**).

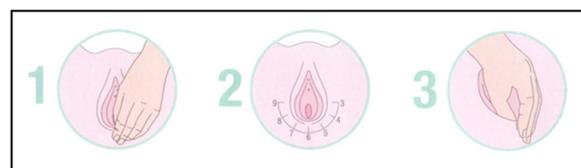


Figure 2.

Vulvo-vaginal and perineal massage technique. A uniform technique of conducting the perineal and vulvo-vaginal massage was provided through written information. Women were taught to apply a creamy medical device containing AC collagen and hyaluronic acid with their thumbs inside the vulvo-vaginal region and the posterior vagina (2–3 cm), and to gently press downwards and slide to both sides at the same time up to the anterior vulvar region. The stretching action was to be maintained until they felt a slight sensation of burning or tingling, at which point they were instructed to hold the pressure for 1 minute until the area turned slightly numb.

Briefly, the women were taught to apply a creamy medical device containing AC collagen and hyaluronic acid (Perilei Gravidanza® cream, ©Angelini Acraf S.p.A, Italy) with their thumbs inside the vagina (2–3 cm), and to gently press downwards and slide to both sides at the same time. The stretching action was to be maintained until they felt a slight sensation of burning or tingling, at which point they were instructed to hold the pressure for 1 minute until the area turned slightly numb. The women were asked to continue the massage back and forth over the posterior distal half of the vagina for 10 minutes. They were asked to begin this perineal and vulvo-vaginal massage starting from their 28th week of gestation once a day for the first week and then once a day on alternate days until delivery. In order to improve and reinforce compliance and for any questions that might arise, a weekly telephone call to all participants was made by a study coordinator throughout the study period.

All participants were instructed not to reveal to the attending staff during labor whether they performed perineal massage during gestation. Attending midwives and physicians were asked not to inquire about possible use of antenatal perineal massage. No perineal massage during the second stage of labor while the vertex was in the crowning position was performed by the midwives. Midwives were instructed not to perform systematic episiotomy.

For each participant, upon arrival to the delivery unit in active labor, data regarding the following primary outcomes were added to the medical file: perineal damage, episiotomy performance. The duration of first and second stage of labor, the method of delivery (i.e., instrumental vs. spontaneous), the intrapartum blood loss were registered as secondary outcome. For all participants the following additional parameters were also evaluated: gestational age at delivery labor, fetal birth weight, use of epidural analgesia during delivery. The medical files were filled out immediately postpartum by the midwives assisting in the delivery.

Perineal outcomes were categorized into the following: intact perineum; lacerations of the perineum; first, second, third and fourth-degree tears; performance of an episiotomy. Laceration was defined as a perineal tear or bruise not requiring suturing.

Women delivered by emergent cesarean section were excluded from the study.

Statistical analysis

All analyses were performed with the use

of SPSS v.16.0 software. Continuous variables were expressed as mean + SD or median and interquartile range as appropriate. Wilcoxon Mann-Whitney test was used for statistical analysis. Statistical significance was accepted at $p < 0.05$.

RESULTS

A total of 72 patients (49 primigravid and 24 secondigravid) were approached for this study. Forty-seven patients (31 primigravid and 16 secondigravid) completed the study. A total of 25 women were excluded because an urgent cesarean section occurred during the course of labor (16 women, 64%) or because of delivery at a different hospital (2 women, 8%), preterm delivery (mean gestational age of 29 weeks; 2 women, 8%), stillbirth (1 woman, 4%), poor adherence (3 patients, 12%), or loss at the follow-up (1 woman, 4%). The 47 patients in the study group were compared with 47 controls matched for age, BMI, parity, use of epidural analgesia during labor (Figure 3).

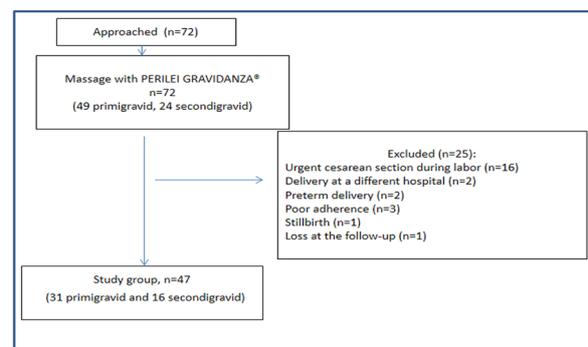


Figure 3
Perineal massage trial profile.

Most (n=42) of the women in the control group were recruited in the delivery room prior to delivery and after verifying no prior use of massage during the current pregnancy. Mean maternal age was 31.42±4.1 years in the study group and 32.1±3.8 in the control group. When considering gestational age at delivery and fetal birth weight, no significant differences were observed in the groups (mean 39.2±1.5 and mean 39.4±3 weeks, respectively). Other baseline demographic characteristics were similar between the two groups (Table 2). Our surveillance telephone calls revealed that 81.3% of the women performed the massage more than two-thirds of the time, 14.48% between a third to two-thirds and 4.22% less than a third of the time.

We found a significant difference in the rate of intact perineum in the massage group as compared with the control group (14.1% vs. 2.1%, $P < 0.05$). While no significant differences in the rate of tears/lacerations was observed (31.9% vs 27.6%, $p = 0.390$), the rates of episiotomy were significantly lower in the study group (51.1% vs. 70.2%, $p < 0.05$; Table 3). No difference was found between the groups when considering the amount of intrapartum blood loss ($p = 0.497$) and the number of vacuum deliveries ($p = 0.13$). On the contrary a significantly reduction in the duration of the first and second stage of labor was observed (Figure 4).

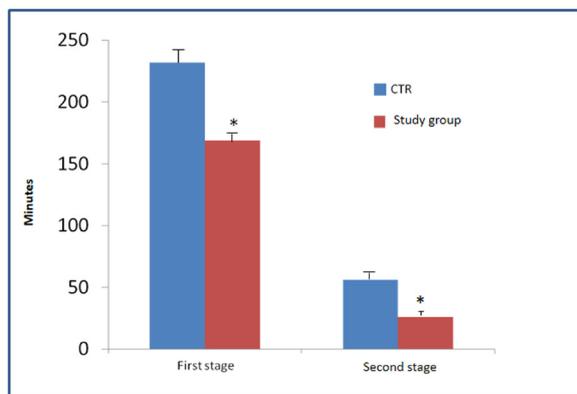


Figure 4
Secondary outcome. Duration of the first and second stage of labour. CTR: control group. * $p < 0.05$.

Almost 90% of the women in the massage group stated that they would perform perineal massage during their next pregnancy.

Table 1
Symptoms of pelvic floor dysfunction

Lower urinary tract
• Urinary incontinence
• Urgency and frequency
• Slow or intermittent stream and straining
• Feeling of incomplete emptying
Bowel
• Obstructed defecation
• Functional constipation
• Faecal incontinence
• Rectal/anal prolapse
Vagina
• Pelvic organ prolapse
Pain
• Chronic pelvic pain
• Pelvic pain syndrome
Sexual function
• Dyspareunia (painful sexual intercourse)
• Orgasmic dysfunction

Table 2
Baseline characteristic of the study and control population

Parameter	Perilei Gravidanza Massage (study group n=47)	Control (n=47)	p
Primigravid (n)	31	31	
Secondigravid (n)	16	16	
Age (years; mean \pm SD)	31.42 \pm 4.1	32.1 \pm 3.8	ns
BMI (kg/m ²) median (range)	24 (20-24)	23 (19-24)	ns
Gestational age at delivery (wk) (mean \pm SD)	39.2 \pm 1.5	39.4 \pm 3	ns
Mean Birth weight (gr, mean \pm SD)	3250 \pm 250	3330 \pm 150	ns
Use of epidural block (%; n ^o of doses)	70%; 2 \pm 1	68%; 2 \pm 2	ns

Table 3
Primary and secondary outcomes

Outcomes	Study group	Control
	Primary outcomes	
	n ^o (%)	n ^o %
Intact perineum	7 (14.8)*	1 (2.1)
Tears (total)	15 (31.9)	13 (27.6)
First degree/laceration	10	6
Second degree	5	5
Third-fourth degree	0	2
Episiotomy	25 (53.1)*	33 (70.2)
	Secondary outcomes	
Intrapartum blood loss (cc; mean \pm SD)	245 \pm 30	223 \pm 40
Vacuum deliveries	0	4

* $p < 0.05$

DISCUSSION

The results of the present case-control study showed a higher prevalence of deliveries with intact perineum in patients performing antenatal perineal and vulvo-vaginal massage with a creamy medical device containing AC collagen and hyaluronic acid (Perilei Gravidanza®) compared to patients no performing massage, possibly suggesting a protective perineal effect of the procedure. Even though we could not find a statistically significant benefit regarding the rates of all categories of perineal tears, the perineal massage group showed a significant lower rate of episiotomies, which explains the reason why the antenatal perineal and vulvo-vaginal massage with the medical device is in relation with increased rate of deliveries with intact perineum. A slight non-significant reduction in third-fourth degree perineal tears and vacuum deliveries was observed in the massage group. However it is not possible to draw a clear-cut conclusion based on these trends since a larger sample would be needed. When considering the secondary outcomes, no significant difference was observed in the intrapartum blood loss. Surprisingly we observed a significantly reduced duration of the first and the second stage of labor.

Previous studies about the role of perineal massage in preventing the perineal trauma did not reach a definite consensus on this matter. By studying a population of 531 primiparous women, Bodner-Adler et al. could not find a significant benefit of the perineal massage with respect to the incidence of perineal trauma⁽¹⁵⁾. A further case-controlled trial by Elad Mei-dan et al. concluded that the antepartum perineal massage, from the 34th week of pregnancy up to delivery, had neither a protective nor a detrimental significant effect on overall spontaneous tears, episiotomy rates and intact perineum rates⁽¹⁶⁾. On the contrary Labrecque et al. observed an absolute increase of 9% in intact perineum in primigravid women randomized to perform antenatal perineal massage (4% vs 15%; $P=0.001$; 17). They also reported a positive correlation with the duration of treatment showing that women who practiced perineal massage on less than one third, one third to two thirds, and more than two thirds of the assigned days had an intact perineum in 20%, 23%, and 28% of cases, respectively. Finally, a recent Cochrane, including four trials (2,497 women), reported that antenatal digital perineal massage is associated with an overall reduction in the incidence of trauma requiring suturing (risk ratio, RR, 0.91; 95% confidence interval, CI 0.86-0.96),

and of episiotomy (RR 0.84; 95% CI 0.74-0.95; 18).

In line with these results, our findings support the role of perineal massage started from the 28th gestational week in reducing the episiotomy rate and increasing the number of deliveries with intact perineum. In addition, in our study, we recommended women to perform the massage in the anterior vulvo-vaginal region and to locally apply a specific medical device (perineal cream). This device contains AC collagen and hyaluronic acid which, through the massage, can penetrate deeply the vulvo-vaginal and perineal mucosa. It is possible that such a cream, through the positive action of collagen and hyaluronic acid on perineal skin and pelvic floor muscles tropism, improves the elasticity of perineal tissues. One previous trial demonstrated that hyaluronidase injections in the perineum during labor are associated with perineal relaxation and likelihood of an intact perineum, thus suggesting a positive role of hyaluronic acid during perineal distension⁽¹⁹⁾. However, hyaluronidase is not of common use and, also, it requires to be locally delivered through injections. On the contrary in our study we used a cream locally applied through a less invasive procedure, even though during a longer-lasting period.

In our research, we observed a significantly reduced rate of episiotomies in the study group. According to the initial consideration of episiotomy as a protective procedure against perineal lacerations⁽²⁰⁾, it could be supposed a higher frequency of spontaneous lacerations/tears. On the contrary no statistically significant differences were observed in the incidence of any category of tears. In addition, no third-fourth degree lacerations were observed in the study group, although the limited number of patients could not reach a significant result. Episiotomy was initially considered a procedure used to prevent lacerations and perineal tears. A recent review reported that (i) there is no evidence of a protective effect of routine midline/mediolateral episiotomy on pelvic floor anatomy and function and (ii) routine mediolateral episiotomy does not reduce or prevent the rate of urinary or anal incontinence and anal sphincter lacerations⁽²⁰⁾. Furthermore, in the recent years, several reports showed a reduction in pelvic floor strength and increased perineal pain and dyspareunia as a consequence of episiotomy⁽²⁰⁻²⁴⁾. Based on the observed lower episiotomy rate, our findings are encouraging toward the consideration of the perineal and vulvo-vaginal massage with a medical device containing AC collagen and

hyaluronic acid as useful tool to prevent the perineal trauma and the consequent reduction of the strength of the pelvic floor. In our study we did not investigate the degree of post-partum perineal pain and the presence of dyspareunia, nevertheless the reduction of episiotomies might suggest a possible preventive effect.

Another unexpected finding of the study was the significant reduction of the duration of the first and second stage of labor. We are not able to explain such observation: possibly the perineal massage can increase a woman's confidence in her body's ability to stretch and open for her baby by relaxing more during labor.

It is important to note the some aspects may have affected the results of our study: since the women voluntarily chose to participate to the study, our trial was not randomized. This fact surely enhanced the compliance during pregnancy in the study group, nevertheless the

perineal outcome was not favorably influenced. Furthermore we included secondigravid women, a fact that may have influenced the perineal distension; in order to overcome this bias, women were matched with secondigravid controls.

In conclusion antenatal digital perineal massage with creamy medical device (AC collagen and hyaluronic acid containing cream) is linked to a reduced rate of perineal trauma (mainly episiotomies) at birth, and is generally well accepted by women⁽²⁵⁾. As such, women should be warned of the likely benefit of perineal massage and provided with information on how to massage.

DECLARATION OF INTEREST

None of the authors report declarations of interest with the subject matter or materials discussed in the manuscript.

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