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Effects of Episioguide – a 60° Mediolateral Episiotomy Guide Device – on Post Suture Episiotomy Angle: A randomized controlled trial

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ABSTRACT

Objectives: To compare the post-suture episiotomy angle between groups on which the Episioguide – a 60° mediolateral episiotomy (MLE) guide device was used and not used in the performance of MLE.

Materials and Methods: This prospective randomized controlled trial was conducted at the HRH Princess Maha Chakri Sirindhorn Medical Center, Nakhon Nayok, Thailand. Eligible women were randomized into two groups, the first group was women who had a MLE using the Episioguide and the second group was women who had a conventional MLE. The primary outcome was a comparison of the rates of post-suture episiotomy angle in the safe zone (30°-60°) between the groups.

Results: One-hundred and twelve eligible pregnant women were recruited, of whom 88 underwent randomization, 44 each in the Episioguide and conventional MLE groups. The procedures using the Episioguide had a significantly higher rate of a post-suture episiotomy angle in the desired 30°-60° range (relative risk (RR) 1.526, 95% confidence interval (CI) 1.023-2.277, p = 0.032), and there was a statistically significant difference in mean post suture angle between the two groups, 34.636° ± 9.445° in the Episioguide group and 27.614° ± 9.267° in the standard procedure group (mean difference 7.022, 95%CI 3.057-10.988, p = 0.001).

Conclusion: Using the Episioguide to perform a MLE achieved a significantly higher rate of post-suture episiotomy angle in the safe zone compared with conventional MLE.

Keywords: episiotomy, episioguide, angle of incision, obstetrical anal sphincter injuries (OASIS), post-suture angle.

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ผลของการใช้เครื่องมือช่วยตัดฝีเย็บ Episioguide ในการตัดฝีเย็บชนิด mediolateral episiotomy ต่อมุมหลังเย็บแผลฝีเย็บ: การทดลองแบบสุ่มและมีกลุ่มควบคุม

ชัชศรัณย์ ธนพงษ์พิบูล, เมสิตา สุขสมานวงศ์

บทคัดย่อ

วัตถุประสงค์: *เพื่อเปรียบเทียบมุมหลังการเย็บซ่อมฝีเย็บในมารดาที่ได้รับการตัดฝีเย็บชนิด mediolateral episiotomy (MLE) ด้วยการใช้เครื่องมือ Episioguide กับมารดาที่ไม่ได้ใช้เครื่องมือช่วยตัดฝีเย็บ*

วัสดุและวิธีการ: *การศึกษานี้เป็นการศึกษาแบบสุ่มซึ่งเก็บข้อมูลที่โรงพยาบาลศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดา ฯ สยามบรมราชกุมารี จังหวัดนครนายก โดยทำการแบ่งกลุ่มมารดาเป็น 2 กลุ่ม ได้แก่ กลุ่มที่ได้รับการตัดฝีเย็บแบบ MLE ด้วยการใช้ Episioguide และกลุ่มที่ไม่ได้ใช้เครื่องมือช่วย และทำการเปรียบเทียบมุมฝีเย็บหลังการเย็บซ่อมที่อยู่ในระยะปลอดภัย คือ ช่วง 30 ถึง 60 องศาในแต่ละกลุ่ม*

ผลการศึกษา: *มารดาตั้งครรภ์จำนวน 88 คนจาก 112 คนได้รับการแบ่งกลุ่มแบบสุ่มเป็น 2 กลุ่ม กลุ่มละ 44 คน คือ กลุ่มที่ได้รับการตัดฝีเย็บแบบ MLE ด้วยการใช้ Episioguide และกลุ่มที่ไม่ได้ใช้เครื่องมือช่วย พบว่ากลุ่มที่ใช้ Episioguide วัดมุมหลังการเย็บฝีเย็บอยู่ในระยะปลอดภัยมากกว่า (relative risk (RR) 1.526, 95%confidence interval (CI) 1.023-2.277, p = 0.032) และมีค่าเฉลี่ยของมุมหลังการเย็บฝีเย็บที่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ (mean difference 7.022, 95%CI 3.057-10.988, p = 0.001).*

สรุป: *มารดาที่ได้รับการตัดฝีเย็บโดยใช้เครื่องมือ Episioguide มีมุมหลังการเย็บฝีเย็บอยู่ในช่วงปลอดภัยมากกว่ากลุ่มที่ไม่ได้ใช้เครื่องมือช่วยอย่างมีนัยสำคัญทางสถิติ*

คำสำคัญ: *การตัดฝีเย็บ, Episioguide, มุมของฝีเย็บ, การบาดเจ็บของหูรูดทวารหนัก*

Introduction

An episiotomy is the incision made along the perineum during the second stage of labor to enlarge the opening for the baby to pass through. There are two main types of episiotomy: midline and mediolateral episiotomy (MLE). A midline episiotomy begins at the posterior fourchette, makes a 2-3 cm incision along the midline of the perineum, ending well before the external anal sphincter, while the MLE also begins at the midline of the fourchette but extends down either to the right or left direction at a 60-degree angle to the midline[1]. The midline episiotomy has a higher tendency of leading to obstetrical anal sphincter injuries (OASIS)[2], which is a severe perineal laceration after vaginal delivery that extends into or through the anal sphincter complex[3]. An OASIS leads to higher risk of wound complications during the early postpartum period (i.e. one study reported 19.8% of wound infections and 24.6% of subsequent wound breakdowns during the first 6 weeks postpartum were related to the episiotomy), is a common cause of fecal incontinence and increased postpartum perineal pain[3-5]. Regarding\OASIS, the recent meta-analysis found no statistically significant between non-episiotomy and selective episiotomy[6]. However, the World Health Organization (WHO) has recommended the restrictive use of episiotomy. If an episiotomy is required to assist delivery, the mediolateral episiotomy is preferred[7].

There is limited evidence regarding clinical outcomes from different incision angles in MLE. Eogan et al reported that every 6° away from the perineal midline decreased the risk of third-degree tear by 50%[8]. Stedenfeldt et al found that scarred episiotomy angle ranging from 30°-60° was significantly associated with less risk of OASIS[9].

Interestingly, it has been reported that a 60° MLE incision angle resulted in suture angles of 32°-59° and a low incidence of anal sphincter tearing, anal incontinence and perineal pain[10]. However, currently even when physicians attempt to perform an MLE, only 15% of the incisions are made within the desired 58-62° range[11]. Given this low range of accurate performance of the MLE, a technique to accurately create a 60° incision angle 60° would be beneficial for clinical outcomes.

The Episcissors-60® (Medinvent, United Kingdom) is a tool for right-handed users, which was modified from surgical scissors to achieve a 60° incision angle in MLEs by adding a 60° angled guide limb to the blades[12]. A previous randomized trial found that post suture episiotomy angles when using the Episcissors-60® were much further than 60 degrees and had a lower risk of OASIS[13-16]. However, the cost of a reusable Episcissors-60® is 400 British Pounds, approximately 16,000 Thai Baht, which is too expensive for many hospitals in developing countries to add to their routine equipment.

Given these considerations, for the present study, we developed a device we call the Episioguide a cheaper Episcissors-alternative stainless-steel medical device to be used in MLEs to achieve a more precise 60° incision angle. This device can be placed on the perineum during fetal head crowning to guide an accurate 60° incision angle. To determine the accuracy of the Episioguide, we compared the post-suture episiotomy angle between groups on which the Episioguide was used and not used in the performance of MLE.

Materials and Methods

This prospective randomized controlled trial (RCT) was approved by the Strategic Wisdom and Research Institute of Srinakharinwirot University (certificate number: SWUEC/F-341/2561) and registered at the Thai Clinical Trials registry (TCTR identification number: TCTR20190924002). The participants were recruited at the labor room at HRH Princess Maha Chakri Sirindhorn Medical Center (MSMC), Faculty of Medicine, Srinakharinwirot University, Ongkharak, Nakhon Nayok, Thailand between March and September 2019. All singleton low risk term pregnant women who planned for vaginal delivery were considered to be eligible for this study and required to sign a written informed consent form. The exclusion criteria were (1) women in whom an episiotomy was not required, (2) women who delivered by operative vaginal delivery, (3)

women who had an emergency caesarean section, and (4) women who declined to participate.

If an episiotomy was required, the participant was randomized during the second stage of labor prior to making the incision into two groups using a block randomization list (block size 4) from www.sealedenvelope.com, the participants in the first group were assigned to receive a MLE using the Episioguide and all in the second group received a conventional MLE.

The MLEs were performed by 12 residents of Department of Obstetrics and Gynaecology, Faculty of Medicine, Srinakharinwirot University. They were trained to use the Episioguide with at least 50 paper models by placing the Episioguide at a picture of the perineum during fetal head crowning at the proper position before performing MLE prior to the beginning of the study.

The Episioguide is a stainless-steel medical device which is designed to guide an MLE to achieve a 60° incision angle. As shown in Fig. 1, the Episioguide consists of 3 main parts, a shank, guide-limb and clip. The shank is the core of the device. The guide-limb is designed to make an angle of 60° with the shank. The clip is located at the back of the device and used to make a tight connection between the device and the perineum. We designed the Episioguide to be suitable for both right and left MLEs. Its edge is blunt in order to prevent perineal trauma. Since it is reusable, sterilization is required prior to every use of the device.

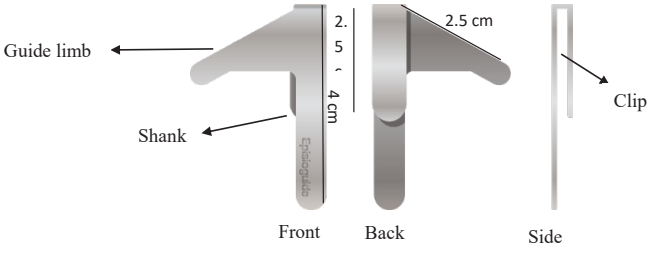

Fig. 1. A labeled schematic illustration of Episioguide.

Using the Episioguide at the time of fetal head crowning, place it at the perineum as shown in Fig. 2.

1. Align the position of the shank to be vertically in line with the perineal midline and pointed toward the anus
2. Tightly fasten the clip to the perineum
3. Use either Mayo or episiotomy scissors to perform either a left or right MLE next to the guide-limb at a 60° angle

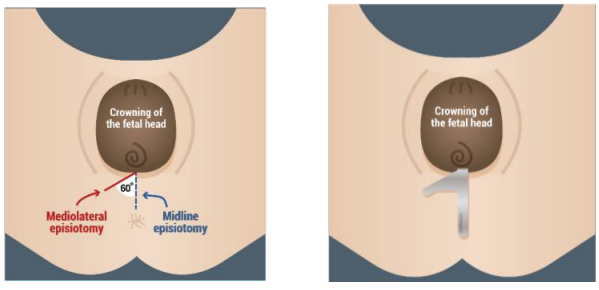

Fig. 2. Illustrative diagram of mediolateral episiotomy (MLE) and midline episiotomy (left) and the use of Episioguide in MLE (right).

The primary outcome of the study was post suture episiotomy angle in the safe zone of 30°-60°. The measurements were taken immediately after the perineorrhaphy with the patient in the lithotomy position with both legs flexed at the hip joints. The angle in relation to the midline was measured by drawing lines onto a translucent plastic sheet placed over the perineum, using a standard protractor. The measurements were done by another obstetric trainee (C.T.) who was blinded to all identifying participant details and group. Apart from the post suture episiotomy angle, the occurrence of third or fourth degree perineal tears was an additional parameter considered in this study.

The sample size required to compare two independent group proportions was calculated using the power of 80%. We expected that 80% and 50% of patients from the Episioguide and conventional groups, respectively, would receive the incision which would result in a post suture angle between 30° and 60° with 95% confidence intervals. From the calculation, 40 women were required in each trial group. Allowing for 10% missing data, we set an overall recruitment goal of 88 women.

Data analysis was performed with IBM SPSS statistics version 22. All data were tested for normal distribution by the Shapiro-Wilk test. The demographic data were presented as mean and standard deviation, median and interquartile range or number and percentage. The proportions of women with a post suture episiotomy angle in the range of 30° to 60° between the two groups were compared with chi square test. The mean post suture episiotomy angle was compared with independent t test. The significance level was set at $p < 0.05$.

Results

During the study period, March-September 2019, one hundred and twelve eligible pregnant women were recruited, of whom twenty-four were excluded, leaving eighty-eight women to undergo randomization. Forty-four pregnant women were assigned to receive MLE using the Episioguide and the remaining 44 participants were assigned to receive conventional MLE as shown in Fig. 3.

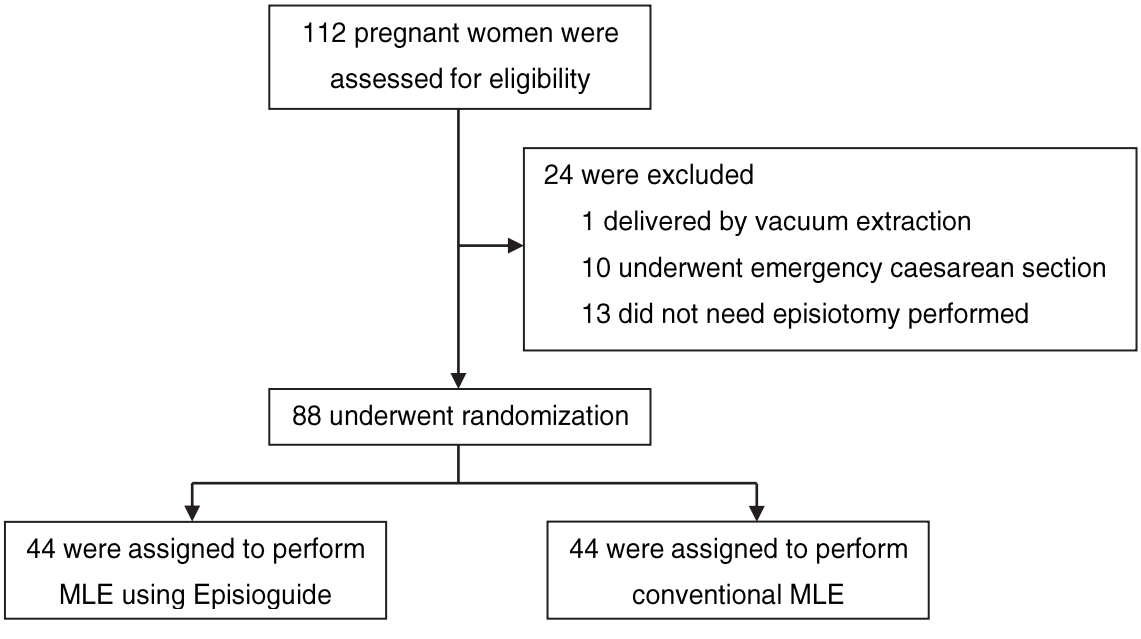

Fig. 3. The flow chart of clinical trial enrollment and randomization.

There were no statistically significant differences in baseline characteristics between the two groups (Table 1).

The study found a significant difference between the groups regarding the number of cases achieving a safe post suture episiotomy angle (30°-60°), in which 29 and 19 participants in the Episioguide and conventional groups, respectively (65.9% vs 43.2%, relative risk (RR) 1.526, 95% confidence interval (CI) 1.023-2.277, p = 0.032) (Table 2).

Table 1. Baseline characteristics of the participants.

	Episioguide (n = 44)	Conventional MLE (n = 44)	p value
Maternal characteristics			
Age [median (IQR)] years	23 (22-29)	26 (23.5-30.5)	0.066[2]
Parity			
0 [n (%)]	20 (46.5)	23 (53.5)	0.185[3]
1 [n (%)]	22 (57.9)	16 (42.1)	
2 [n (%)]	1 (16.7)	5 (83.3)	
3 [n (%)]	1 (100)	0 (0)	
GA [median (IQR)] weeks	39 (38-39)	39 (38-39)	0.791[2]
BMI [median (IQR)] kg/m^2	21.65 (19.9-24.2)	22.25 (20.1-23.95)	0.625[2]
Weight gain			
Poor weight gain [n (%)]	18 (62.1)	11 (37.9)	0.277[3]
Normal weight gain [n (%)]	15 (42.9)	20 (57.1)	
Excessive weight gain [n (%)]	11 (45.8)	13 (54.2)	
Fetal characteristics			
BBW (mean ± SD) g	3195 ± 381.43	3125 ± 362.16	0.380[1]
HC (mean ± SD) cm	33.44 ± 1.39	33.58 ± 1.40	0.647[1]
Sex			
Female [n (%)]	16 (45.7)	19 (54.3)	0.513[3]
Male [n (%)]	28 (52.8)	25 (47.2)	
Episiotomy characteristic			
Length [median (IQR)] mm	30 (25.5-33)	30 (25.5-32)	0.484[2]

[1] independent t test, [2] Mann-Whitney U test, [3] chi square test

IQR: interquartile range, GA: gestation age, BMI: body mass index, BBW: birth bodyweight, HC: head circumference, SD: standard deviation

Table 2. Difference between groups regarding number of cases achieving safe post-suture episiotomy angle (30-60°).

	Not safe	Safe	RR	95% CI	p value
Episioguide [n (%)]	15 (34.1)	29 (65.9)	1.526	1.023 - 2.277	0.032
Conventional MLE [n (%)]	25 (56.8)	19 (43.2)			

*Analysis using chi square test. RR: relative risk, CI: confidence interval

There was also a statistically significant difference between the two groups in terms of mean post suture episiotomy angle (34.6° ± 9.4° vs 27.6° ± 9.3°, respectively, mean difference 7.0, 95%

CI 3.1-10.9, p = 0.001) (Table 3).

Most post suture angles in the used group were 30°-39° while in the conventional group were 20°- 29°. The length of the episiotomy was not significantly different between two groups (18-52 mm vs 20-39 mm, respectively, p = 0.484). There were no cases of third- or fourth-degree perineal tears in either group.

Table 3. Difference between groups regarding mean post-suture episiotomy angle.

	Episioguide (mean ± SD)	Conventional MLE (mean ± SD)	Mean difference	95% CI	p value
Angle (degree)	34.6 ± 9.4	27.6 ± 9.3	7.0	3.1-10.9	0.001

* Analysis using independent t test. CI: confidence interval, SD: standard deviation

Discussion

We designed and developed the Episioguide to be a simple, convenient, and inexpensive device to guide an accurate 60° incision in MLE. The following research was a first RCT aimed to compare post suture episiotomy angle between Episioguide-guided MLEs and conventional MLEs. We found that the Episioguide-guided group had a 1.5 times higher proportion of episiotomies that successfully achieved post suture angles of 30° - 60° when compared to the conventional group. In addition, the use of the Episioguide resulted in a significantly smaller mean range of post suture episiotomy angle when compared with the conventional MLE group.

The mean post suture angle in the Episioguide-MLE group was 34.636°, within the safe zone similar to previous studies which marked the 60° line with gentian-violet[10] and using the Episcissors-60®[12], which achieved post suture angles of 44.43° and 40.6°, respectively.

The previous studies had shown that the post suture episiotomy angle differs from the incision angle[10,17]. The reasons for the difference might relate to the difference between elasticity and collagen content of connective tissue of individuals.

According to the low incidence of OASIS, our sample size was too small to demonstrate the incidences of third- and fourth-degree perineal tears. We suggest that further multicenter RCT studies of the Episioguide with a larger sample size would be useful to study the effects of using the Episioguide on OASIS and other postpartum outcomes including postpartum perineal pain, urinary and fecal incontinence and sexual intercourse related problems.

Our study found that the use of the Episioguide could be helpful to accurately achieve post suture episiotomy angles in the range of 30° - 60° from the midline. This device is easy to use and is inexpensive and thus easily accessible for any hospital. The cost of a reusable Episioguide is only 400 Thai Baht while the cost of the commercially available device such as Episcissors-60® is 400 British Pounds, approximately 16,000 Thai Baht. Physicians or even medical students can use it to perform MLEs together with episiotomy scissors. The Episioguide is designed to be used for either left- or right-side MLEs. Therefore, we suggest the usage of the Episioguide in every case in which it is decided to perform an MLE especially in medical and midwifery training schools. For further study, using the Episioguide to practice achieving a 60° MLE in medical students and their satisfaction with device usage should be evaluated.

Conclusion

In this prospective RCT study, we conclude that using the Episioguide to perform MLEs can achieve a significantly higher rate of 30° - 60° post suture episiotomy angle than the conventional MLE. In addition, the use of the Episioguide resulted in a significantly lower mean range of post suture

episiotomy angle.

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Potential conflicts of interest

The authors declare no conflicts of interest.

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