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Optimization of Safe Zone Suture Angle in Mediolateral Episiotomy Using Triangular Set Square

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Abstract

Objectives: Episiotomy is a surgical intervention to decrease the risk of obstetric anal sphincter injuries (OASIs) that adversely affect normal vaginal delivery (NVD). However, the intervention itself may lead to significant perineal laceration and postpartum anal incontinence. This research aimed to compare the suture angle and postpartum anal incontinence of mediolateral episiotomy aided with a 60-degree triangular set square (TRSS-60) with those of a routine mediolateral episiotomy.

Materials and Methods: This prospective study was performed on primiparous pregnant women with NVD requiring episiotomy in Yas hospital from April 2020 to November 2020. The subjects were assigned to control and intervention groups at a 1:1 ratio. Outcome measures included suture angle and Wexner fecal incontinence scores between the groups.

Results: Forty primiparous women have enrolled in the study. The average perineal body length was 3.64 ± 0.54 cm at the first stage of labor and 4.86 ± 0.71 cm during crowning. The mean suture angle varied significantly ($P < 0.001$) between the intervention and control groups (48.5 vs. 33.7). The suture angle of all participants in TRSS-60 was higher than 40°. Wexner score assessment revealed that the most frequent complaint was gas incontinence in postpartum women (four in the control group and one in the intervention group).

Conclusions: This study suggests that TRSS-60 could be used as an affordable, highly accessible, inexpensive, and effective approach to reach the safe zone angles during episiotomies, reduce OASIs, and supply an appropriate replacement for EPICSISSOR-60 in low-resource areas.

Keywords: Obstetric anal sphincter injury, Normal vaginal delivery, Suture angle, EPICSISSOR-60

Introduction

Obstetric anal sphincter injuries (OASIs) are recognized as adverse effects of normal vaginal delivery (NVD) that can cause short and long-time complications such as anal incontinence, continual perineal discomfort, dyspareunia, and a variety of psychological disorders. Although these undesired side effects remarkably decline the affected women's quality of life, they are mostly under-reported due to embarrassment (1-4).

The reported incidence of OASIs ranges from 0.6% to 16% according to the routine practice of different countries and hospitals, and its rate is increasing in recent years. For instance, in England, the OASI rate continuously increased from 1.8% to 5.9% from 2000 to 2011 (5,6).

Possible reasons behind the increased rate of OASIs include higher maternal age and weight at the first pregnancy, which results in higher birth weight and risk of perineal trauma. Some other causes include increasing the knowledge and awareness of doctors and midwives, better obstetric trauma case identification and collection, and alterations in controlling the second stage of labor (7).

The risk factors for OASIs include primiparity, instrumental delivery, birth weight of more than four kilograms, persistent occipital-posterior position, maternal age >25 years, Asian ethnicity, water immersion in labor, water birth, and shoulder dystocia as well as median episiotomy (7,8). Median episiotomy results in a greater chance of deep perineal tears compared to mediolateral episiotomy. Thus, the latter should be preferred when both are indicated. The cutting angle of mediolateral episiotomy is an important contributing factor in the prevention of anal sphincters trauma.

The Royal College of Obstetricians and Gynecologists (RCOG) has recommended medical specialists clarify the conflicting evidence regarding the protective effect of episiotomy on the patients. Furthermore, RCOG notes that mediolateral episiotomy should be performed at the posterior fourchette and guided at a 60-degree angle from the midline as the perineum distends (9).

The safe zone for suture angle ranges between 40 and 60°; suture angles less than 30 degrees and more than 60 degrees increase the chance of OASIs (10,11). However, previous evidence showed that both gynecologists and midwives fail to accurately estimate the episiotomy angle both on paper and on patients and may need instruments to efficiently and accurately estimate the angle of mediolateral episiotomy (5,12).

In an attempt to minimize the risk of perineal injuries,

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Key Messages

- Triangular Set Square could be used as an affordable, highly accessible, inexpensive, and effective approach to reach the safe zone angles during a mediolateral episiotomy.

the Urologynaecology Unit and the Directorate of Healthcare Science and Technology at Plymouth Hospitals NHS Trust initially designed a device; Episcissors-60. The participants of their initial study comprised 17 women with instrumental vaginal delivery in which the median suture angle was 43°, indicating that Episcissors-60 could be a proper alternative to eyeballing (13).

In another study, Sawant and Kumar compared the episiotomy suture angles of Episcissors-60 with those of Braun Stadler (BS) scissors. Their study revealed that the episiotomy suture angles episcissors-60 were far from the midline in regards to angular and distance measures and the risk of OASIS in this method of performing episiotomy was significantly lower in comparison to BS scissors (14).

Accordingly, there is an urgent need for an instrument that can exactly show a 60-degree angle on the perineal body during an episiotomy. As the Episcissors-60 is not routinely available in all clinical settings, we designed a 60-degree set square guide that could assist physicians and midwives in areas with limited access to optimal delivery care (Figure 1). The guide can be incorporated into the vaginal delivery set to assist obstetricians and midwives in performing episiotomy at the time of crowning.

This research aimed to compare the suture angle of routine mediolateral episiotomy (performed by eyeballing) with the suture angle of mediolateral episiotomy performed with the aid of 60-degree triangular set square (TRSS-60) in primiparous women.

Materials and Methods

At first, for eliminating the experience effect and estimate sample size, a pilot study was done with limited participants by the junior (first-year) and senior (second-year) obstetrics and gynecology residents. Each resident group was divided into two groups: the control group (performing mediolateral episiotomy with eyeballing) and the intervention group (performing mediolateral episiotomy with TRSS-60).

Analysis of pilot study data demonstrated a significant ($P = 0.010$) difference between the two study groups (the control group vs. the intervention group) in terms of suturing angle. The episiotomy suture angles in residents who worked with TRSS-60 was in the safe zone (40-60 degree); though this significant difference could not be attributed to increased proficiency in performing episiotomies. Hence, the main study was continued with junior residents who delivered most cases of the pilot study through NVD.

Using the pilot study values, study power of 80%, the two-sided significance level of 5%, and the sample size formula for mean difference studies, the sample size was calculated 15 in each group. Considering 30% attrition risk the sample size increased to 20 in each group.

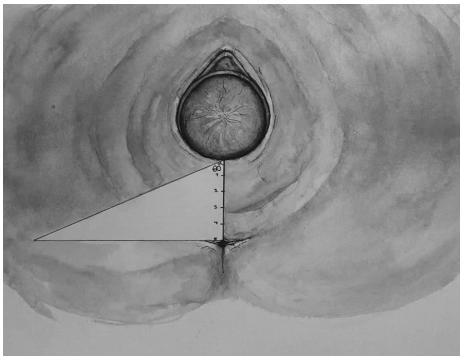

Figure 1. Schematic Drawing and Placement of TRSS-60 During the Crowning Phase of the Labor.

The participants in this study were screened from Gravida 1 women with a current term singleton pregnancy who were referred to the labor ward of Yas hospital affiliated with Tehran University of Medical Sciences from April 2020 to November 2020. The pregnant women were deemed eligible for inclusion and enrollment if the measured perineal body length at the first stage of labor (cervical dilatation: 3-4 cm) was greater than 3 cm. The exclusion criteria included multiparity, instrumental NVD, twin pregnancy, breech presentation, preterm delivery, and short first-stage perineal body length (<30 mm).

To reduce the risk of bias and limit the effect of training on investigators, using simple randomization, the participants were randomly assigned to the control group (1:1) first before the intervention group. In the control group, the angle of episiotomy was estimated by eyeballing, whereas for the intervention group, the angle was determined using TRSS-60. The sterile set squares were laid between the fourchette and anus to visualize a standardized incision angle of 60° to the midline on the perineal body during crowning. The episiotomy procedures of both groups were done by junior residents using Braun-Stadler episiotomy scissors. Local anesthesia was applied prior to incision. Left or right-sided episiotomy was performed based on the hand dominance and/or preference of the residents.

The following information was collected for both groups: age, body mass index (BMI), the second-stage labor duration, the first-stage labor and crowning phase perineal body length, birth weight, and the suture angle of mediolateral episiotomy. The suture angle was considered as the angle formatted by the midline and epidermal suturing line. This angle was measured via a protractor when the participant was in the lithotomy position and her legs flexed at the hip joints at a 90–120° angle in the labor ward. All data were collected under the supervision of the investigators. The rectal assessment

was done before suturing for each participant to identify OASIs. Anal and urine incontinence were evaluated with Wexner fecal incontinence scoring system questionnaires (Supplementary file 1) that were filled through phone interviews within the two-month postpartum period.

Statistical Analysis

SPSS version 24.0 (IBM, New York, USA) was applied for data analysis. A p-value lower than 0.05 in tests was considered statistically significant. Independent *t* test and non-parametric Mann–Whitney U test were utilized to recognize the variations in outcome measures. Spearman correlation test was utilized to evaluate the correlation between baseline measurements including maternal age, BMI, and perineal length as well as neonatal birth weight. To assess the proportion of episiotomy suture angles in the safe zone, the data was split into three groups based on designated safe zone range and lower-limit cut-off of previous studies: below 30 degrees, between 30 to 40 degrees, and greater than 40-degrees suture. The results were analyzed for significance with Pearson chi-square test for categorical variables.

Results

The main prospective study was performed on 40 primiparous women (20 in the control group and 20 in the intervention group) with spontaneous vaginal delivery that required episiotomy. Statistical analysis for baseline characteristics did not specify any considerable differences in the collected data between each group (Table 1).

The average perineal body length at the first stage of labor and during crowning was 3.64 ± 0.54 cm and 4.86 ± 0.71 cm, respectively, indicating a 1.25 ± 0.62 cm increase in perineal length throughout the labor. The increase in the average perineal body length was not significantly (*P* value = 0.056) different between the two groups.

The mean suture angle was 41.13 ± 12.27° in all participants and was significantly widened in the intervention group (mean 48.5, range 40-60, median 47.5) in comparison to the control group (mean 33.7, range 10-60, median 32.5) ($P < 0.001$). In contrast to the control group, no subject in the intervention group had a suture angle of less than 40° (Figure 2).

Third-degree perineal tears in which more than 50 percent of the external anal sphincter was damaged (3B category) were reported in three women in control groups; whereas no cases of OASIs were detected in the intervention group. Correlation assessment revealed no significant association (Spearman coefficient <0.3, $P > 0.05$) between baseline variables including maternal age, BMI, and perineal length as well as the neonatal birth weight with episiotomy suture angle in participants (Table 2).

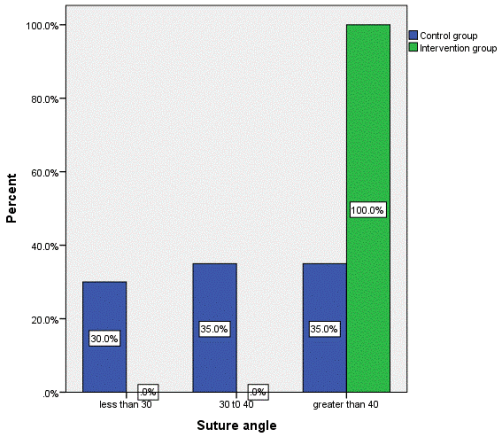

Figure 2. The Suture Angle Categories According the Study Groups.

Out of 29 (18 in the control group and 11 in the intervention group) postpartum women who responded to the follow-up phone interviews, five patients had Wexner score above zero. The most frequent complaint was gas incontinence in the subjects (four reports in the control group and one in the intervention group). The average Wexner score did not vary significantly ($P = 0.451$) between the two study groups.

Discussion

Postpartum anal incontinence was reported as the most common long-term restricting complication of OASIs. Although a number of supportive measures including episiotomy with an incision angle of 60 degrees, gradually controlled labor of the head, and digital perineal protection have been suggested to reduce the chance of OASIs (15), adequate pressure relief in the central part of the perineum is highly reliant on the expertise of the healthcare provider. Therefore, due to the considerable adverse effects on anorectal function, quality of life, and subsequent deliveries, preventive strategies are needed to reduce unsafe episiotomies outside the described safe

Table 1. Basic Characteristics, Measurements During the Labor, and Birth Weight of the Neonate for the Participants of the Study

Procedure-Independent Characteristics	Control Group (n=20)	Interventional Group (n=20)	*P* Value
Maternal age (y)	24.88 ± 4.37	25.80 ± 4.03	0.511
Body mass index (prior to pregnancy)	23.98 ± 3.88	25.07 ± 9.26	0.840
Body mass index (at delivery time)	29.38 ± 3.16	30.72 ± 13.34	0.525
Perineal body length (cm)	3.47 ± 0.48	3.80 ± 0.57	0.120
Perineal body length in crowning(cm)	4.86 ± 0.67	4.87 ± 0.77	0.960
Birth weight (g)	3102.73 ± 348.37	2577.06 ± 1282.2	0.578

Table 2. Association of Baseline Study Variables and Birthweight With Suture Angle

Variables	Spearman Coefficient (*P* Value)
	Suture Angle of Episiotomy
Maternal age	0.231 (0.168)
Body mass index	-0.049 (0.769)
Perineal length (cm)	0.286 (0.077)
Birth weight (g)	-0.010 (0.960)

Spearman correlation test did not demonstrate any considerable correlation between the outcome and the variables.

zone and their ensuing OASIs (16).

To the best of our knowledge, this study was the first interventional study aiming to compare the suture angle of routine mediolateral episiotomy (perform with eyeballing) with that cut by the aid of a TRSS-60. Our results demonstrated that all episiotomy suture angles in the intervention group were in the safe zone and more than 40 degrees with a median of 47.5, which were greater than angles in Sawant and Kumar's study (14). This could be postulated because of the earlier timing of episiotomies in their study center.

Previous studies reported that a suture angle less than 30 degrees is a major contributing risk factor for OASI occurrence (17-19). In this study, episiotomy suture angles in 30% of the participants in the control group were lower than 30 degrees, 35% ranging between 30 and 40 degrees. These results were higher than those obtained by BS scissors in Sawant and Kumar's study, yet there was a noticeable risk for OASIs in these women.

In a recent study, a significant reduction in the risk of OASIs was reported (29% from 2014 to 2016–2017) after utilization of Episcissors-60 (20). In this study, we have also shown that using TRSS-60 is comparably efficient in achieving a safe suture angle.

In the existing literature, the average perineal body length was stated to be approximately 39 mm (37–41 mm) by the end of the pregnancy period or the first stage of delivery. In most women, this length will widen up to 60 mm (50-60%) in the crowning phase (21). While the perineal body length of the participants of this study at the first stage of delivery fell within this range, the level of change was noticeably lower (36%), strongly emphasizing the importance of a safe episiotomy angle.

Limitations of the Study

Although the findings of this study compared the effectiveness and safety of a novel method in reducing OASIs in mediolateral episiotomy, the study was limited by several factors. The lack of sustained access to endoanal ultrasound screening in the study center did not allow for an accurate evaluation of perineal tears in the participants. Furthermore, the ongoing COVID-19 pandemic resulted in low participation rates and follow up availability, evidenced by the small sample size and limited follow-up commitment in this study.

Conclusions

This study suggests that TRSS-60 could be used as an affordable, highly accessible, inexpensive, and effective approach to reach the safe zone angles during episiotomies, reduce OASIs, and supply an appropriate replacement for EPICSISSOR-60 in low-resource areas.

Authors' Contribution

NSH was responsible for conceptualization and project administration. ESH and ME collected the data. NSH and EF took part in the investigation and formal analysis of the results. NS and EF contributed to the validation and analyses of the obtained results of the study. All authors contributed to writing—Original Draft Preparation and Review and Editing; all authors approved the final manuscript and take responsibility for the integrity of the data.

Conflict of Interests

Authors declare that they have no conflict of interests.

Ethical Issues

This research was done in compliance with the Helsinki Declaration and approved by Tehran University of Medical Sciences ethics committee (IR.TUMS.MEDICINE.REC.1399.029). The nature of the study and the procedures involved were explained to the participants prior to obtaining written informed consent form.

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Supplementary files

Supplementary file 1. The study and Wexner fecal incontinence scoring system questionnaire.

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