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Evaluation of Episiotomy Characteristics of EPISCISSORS–60 Scissors Compared with Mayo Scissors: A Single-Blind Randomized Clinical Trial

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Abstract

Background: It seems that angled scissors may be able to minimize the occurrence of obstetric anal sphincter injuries (OASIS) during vaginal delivery by correcting the angle of the episiotomy incision.
For this purpose, this study aimed to evaluate the episiotomy characteristics of EPISCISSORS–60 scissors compared with Mayo scissors.

Methods: In this single-blind clinical trial study, 64 pregnant women candidates for natural childbirth were included; 32 women underwent episiotomy with Mayo scissors and 32 underwent episiotomy with the EPISCISSORS–60 instrument. Then, post-suturing angle, incision length, episiotomy, postpartum pain, bleeding volume, and the incidence of OASIS and dyspareunia were assessed. The collected data were analyzed by independent sample t test, chi-square test, and the Fisher exact test.

Results: Episiotomy incision length in the EPISCISSORS–60 group with a mean of 4.75 ± 0.72 cm was significantly longer than the Mayo group with a mean of 3.91 ± 0.52cm ($P < 0.001$). In addition, the incidence of dyspareunia was not significantly different between the 2 groups (6.3% vs 15.6%; $P = 0.426$). Sphincter damage did not occur at all in the EPISCISSORS–60 group and only 2 cases of grade 3 sphincter rupture occurred in the Mayo group ($P = 0.238$). The mean of post suturing angle in the EPISCISSORS–60 group (59.09° ± 3.47°) was significantly higher than the Mayo group, with a mean of 31.06° ± 7.21° ($P < 0.001$).

Conclusion: According to the results of the present study, the use of EPISCISSORS–60 can be associated with a higher post-suture episiotomy angle compared with Mayo scissors. As a result, both the incidence of OASIS and its long-term side effects, like dyspareunia, were decreased. However, in our study, the incidence of these complications was very rare and not different between the 2 groups.

Keywords: Normal Delivery, Mayo Scissors, EPISCISSORS–60, Episiotomy, Obstetric anal Sphincter Injuries, Dysparonia

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Introduction

Episiotomy is one of the most common surgeries. This incision is made in the perineum during fetal head crowning to enlarge the vaginal opening, facilitate labor, and reduce fetal withdrawal time. Episiotomy is not usually recommended in standard delivery but is performed in fetal distress and instrumental vaginal delivery (1, 2).

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↑What is "already known" in this topic:
The type of episiotomy incision and its appropriate angle are among the factors affecting many delivery complications. Errors caused by the episiotomy incision angle can have a significant role in the occurrence of delivery complications such as obstetric anal sphincter injuries (OASIS). Now, according to the design and manufacturing of angled scissors, which play an effective role in the errors caused by the episiotomy incision angle, it seems that this common complication can be minimized.

→What this article adds:
The use of EPISCISSORS–60 with creating a 60° mediolateral episiotomy incision can play an important role in the larger post-suturing angle compared with Mayo scissors. Therefore, it can significantly reduce the rate of OASIS and postpartum pain.

In addition to these benefits, this incision may be associated with short- and long-term complications, such as increased patient's pain, increased bleeding, obstetric anal sphincter injuries (OASIS), and dyspareunia (3, 4). Various risk factors are influential, including Asian ethnicity, first delivery, birth weight of more than 4 kg, prolonged second stage of labor, shoulder dystocia, occiput posterior position, type of episiotomy, and angle of incision episiotomy in the incidence of complications, such as OASIS, perineal rupture, and heavy bleeding (5-7). Some of these factors can be changed, and complications can be prevented by modifying them. For example, an episiotomy is divided into 2 main types mediolateral and midline. True mediolateral episiotomies protect against OASIS but only a minority of episiotomies are cut at the recommended angle, thus depressing the true effect episiotomies could have on the incidence of OASIS. If the mediolateral episiotomy is performed at a suitable angle of about 45° to 60°, it can be effective in reducing pressure on the perineum, preventing perineal rupture, and OASIS (1, 8, 9). However, 12% to 22% of midwives are relatively incapable of estimating and cutting episiotomies at the desired angle (10, 11).

For this purpose, different types of scissors—such as straight, curved, and angled scissors—are used to cut the episiotomy and create a suitable angle. Curved or angled scissors are thought to make incisions away from the anal sphincter (12). The most commonly used scissors are Mayo scissors. Despite their ease of use, these scissors are usually unable to make an episiotomy incision at a suitable angle, and the angle must be estimated visually. In contrast, the EPISCISSORS–60 has recently been designed to achieve a correct incision angle of midline episiotomy at 60°. These scissors have 2 main differences from ordinary scissors. First, the scissors have a guide at a vertical angle that includes a stiff but movable spring with a blunt end to prevent damage. This part helps to cut the scissors at a constant angle of 60°. Second, the scissors begin cutting at a distance of 5 mm from the midline in the vertical plane (3). For this reason, many recent studies have found the use of these scissors to be effective in managing the correct cut and creating the proper incision angle so that it can reduce the risk of OASIS by 56% (13-16). In addition, Van Roon et al by comparing these scissors with Mayo scissors reported that although the ideal cut could not be achieved when using Mayo scissors due to the visual error in calculating the incision angle, EPISCISSORS–60 can help many physicians in creating an episiotomy incision angle of 60°, which can significantly reduce the rate of OASIS (3). However, since their study was performed in a simulated environment, they recommended that further studies compared with these scissors and other scissors are necessary. On the other hand, considering the incidence of complications in childbirth and their effects on quality of life and increasing medical costs, choosing suitable scissors to help the specialists during childbirth can play an essential role in reducing the incidence of these complications. Therefore, the present study aimed to investigate the incision and episiotomy angle created by EPISCISSORS–60 scissors compared with Mayo scissors.

Methods

The study population of this single-blind randomized clinical trial included all the women candidates for natural childbirth referred to Al-Zahra and Shahid Beheshti hospitals in Isfahan. The sample size from this population was calculated to be 68 women based on the 95% confidence level, 80% test power, and results of previous studies (16) based on the standard deviation of the post-suture angle in the 2 groups using standard procedure and EPISCISSORS-60 scissors equal to 9.45 and 9.27, and the difference of the mean incision angle equal to 9.5° (34 in each group).

Having a cephalic singleton during pregnancy, being a candidate for a natural or artificial delivery, and having a term baby were inclusion criteria. Patients with breech births, stillbirths, twin deliveries, preterm births, conventional deliveries following cesarean sections, and those without episiotomies were excluded from the study.

After obtaining the code of ethics from the ethics committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1399.796), the code of clinical trial (IRCT20160521027998N8), and written consent from eligible patients, the patient's demographic information, including maternal age, gestational age, body mass index (BMI), and gravidity were recorded. Then, the patients were divided into 2 groups using random allocation software and were entered into the labor process (Figure 1).

In both groups, the episiotomy angle was measured at 60° when the fetal head was crowning. A first-year obstetrics and gynecology resident performed an episiotomy with the aid of a pair of Mayo and EPISCISSORS-60 scissors, which was followed by labor. It should be noted that a gynecologist attended to the first-year resident during delivery. In addition, the resident placed 1 to 2 nondominant fingers between the fetal head and perineum while inserting the scissors blades.

The length of the episiotomy was then measured. The perineal rupture was also recorded, and the amount of bleeding was measured until repairing with blood gauze of 5 by 5 cm. After healing, the episiotomy angle was measured by a transparent protractor, and the patient was transferred to the postpartum section. The next day after delivery, patients' pain scores were recorded from 0 to 10 according to the visual analog scale.

Then, 3 months after delivery, they were visited for dyspareunia, and the results were recorded.

Also, to observe the conditions of blindness, the information was recorded by another gynecologist who did not know the type of scissors used in the 2 groups.

Statistical Analysis

Finally, the collected data were entered into SPSS software (Version 26. Data were shown as frequency (percentage) or mean ± standard deviation. According to the result of the Shapiro-Wilk test indicating the normal distribution of data, the independent t test was used to compare the mean of quantitative data between the 2 groups. The chi-square test and the Fisher exact test were used to compare qualitative data frequency distribution between the 2 groups. In all analyses, significance level was set at $P > 0.05$.

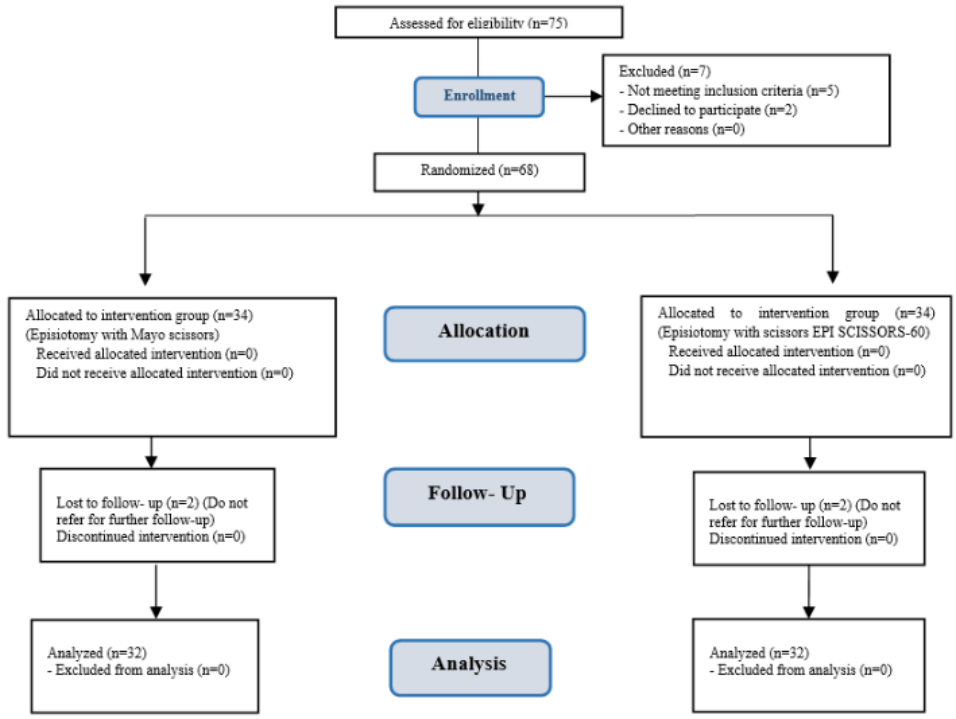

Figure 1. Consort flowchart of patients

Results

In the present study, the 2 groups of episiotomy with Mayo scissors and EPISCISSORS–60 were not significantly different in terms of maternal age, gestational age, and BMI (Table 1).

Episiotomy length in the Mayo group, with a mean of 3.91 ± 0.52 cm, was significantly shorter than the EPISCISSORS–60 group, with a mean of 4.75 ± 0.72 cm (P < 0.001). There was no significant difference in bleeding volume between the 2 groups (P = 0.722). Patients' pain score on the day after delivery in the EPISCISSORS–60 group, with a mean of 4.59 ± 0.66, was significantly lower than the Mayo group, with a mean of 6.38 ± 1.07 (P < 0.001). In addition, the incidence of dyspareunia in the EPISCISSORS–60 and Mayo groups was 6.3% and 15.6%, respectively, and there was no significant difference between the 2 groups (P = 0.426). Sphincter injury did not occur at all in the EPISCISSORS–60 group, and in the Mayo group there were only 2 cases (6.2%) of grade 3 sphincter rupture (P = 0.238) (Table 2).

Regarding the post-suture angle, the mean angle in the EPISCISSORS–60 group, with the mean of 59.09° ± 3.47°, was significantly higher than the Mayo group, with a mean of 31.06° ± 7.21° (P < 0.001) (Table 3).

Discussion

The results of the present study showed that using EPISCISSORS–60 is associated with longer episiotomy incisions and less postpartum pain than Mayo scissors. However, the volume of bleeding was not significantly different between the 2 groups as well as the incidence of dyspareunia and anal sphincter injury. The outcomes of childbirth were minimal and there were only 2 cases of OASIS in the Mayo group and no cases were reported in the EPISCISSORS–60 group.

In this regard, some studies have stated that perineal pain, sexual dysfunction, and other post-partum emotional-psychological consequences and OASIS are the most important complications of childbirth that have been less common with the use of EPISCISSORS–60 scissors (6, 5, 15). In addition, regarding the structure of EPISCISSORS–60, the length of episiotomy incision will be equal to 5 cm at maximum. Although the incision might be shorter with regular scissors, there is a greater chance that it will rupture during delivery (16). In one case in our study, the initial

Table 1. Demographic Information of Patients in the 2 Groups

Characteristics	Mayo Scissors(n=32)	EPISCISSORS–60 (n=32)	*P* Value
Maternal age, year	25.72±4.74	25.37±4.40	0.765*
Gestational age, week	38.66±1.23	38.94±1.81	0.470*
BMI, kg/m^2	23.91±2.02	23.94±1.60	0.946*
Gravidity			
Primigravida	32(100%)	32(100%)	-
Multigravida	0(0%)	0(0%)	

*Significance level of the independent t-test to compare the variable mean between the two groups

Table 2. Frequency Distribution of Complications in the 2 Groups

Complication	Mayo Scissors(n=32)	EPISCISSORS–60 (n=32)	*P* Value
Episiotomy incision length, cm	3.91±0.52	4.75±0.72	<0.001*
Bleeding volume, blood gauze	4.75±1.24	4.87±1.54	0.722*
Pain score	6.38±1.07	4.59±0.66	<0.001*
Sphincter injury	2(6.2%)	0(0%)	0.238**
Dyspareunia	5(15.6%)	2(6.3%)	0.426**

* Significance level of the independent t-test to compare the variable mean between the two groups
** Significance level of the Chi-Square test to compare the variable frequency percentage between the two groups

Table 3. Evaluation of Post-suture Angle in the 2 Groups

Complication	Mayo Scissors(n=32)	EPISCISSORS–60 (n=32)	*P* Value
Post-suturing angle, degree	31.06±7.21	59.09±3.47	<0.001*
20°-29°	17(53.1%)	0(0%)	<0.001**
30°-39°	10(31.3%)	0(0%)	
40°-49°	4(12.5%)	0(0%)	
50°-59°	1(3.1%)	12(37.5%)	
60°-70°	0(0%)	20(62.5%)	

*Significance level of the independent t-test to compare the variable mean between the two groups
**Significance level of the Chi-Square test to compare the variable frequency percentage between the two groups

incision of episiotomy with Mayo scissors was 3 cm, but during delivery, an 8-cm rupture occurred and eventually led to third-degree OASIS. Therefore, the appropriate incision size can be of particular importance in the occurrence of OASIS. For example, Freeman et al reported longer vaginal and skin incisions in women with OASIS than the women without OASIS (17). In addition, Koh et al evaluated the use of EPISCISSORS–60 for 2 years in the United Kingdom and reported a reduction of more than 50% in the incidence of OASIS (18). HA et al have also considered the use of angled scissors to be less effective in the incidence of OASIS (1). Kalis et al showed in their study that to have a post-suture angle away from the anal sphincter and to prevent injury, it should be performed a mediolateral episiotomy at an angle of 60° (19).

In addition, the results of the first recent meta-analysis study regarding the systematic review of the effect of EPISCISSORS–60 on the OASI rate also indicated that although the studies were of small size and low quality, the evidence indicated a possible reduction of OASI with the use of EPISCISSORS–60 (20).

Therefore, considering that the incision angle plays an important role in the occurrence of these complications, it can be said that the ability to create an episiotomy incision with a suitable degree of 60° is the most important factor of EPISCISSORS–60 strength. This angle decreases to 45° to 50° after suturing. However, with Mayo scissors, physicians usually cut an angle of <50° (about 30°-50°), which decreases to <35° after suturing, and this post-suturing reduction of angle can significantly increase the risk of anal sphincter injury. In the evaluation of post-suturing angles in the present study, it was found that the mean post-suturing angle in the EPISCISSORS–60 group was significantly higher than the Mayo group. In fact, with Mayo scissors, the post-suturing angle was <30° in 53.1%, between 30° to 39° in 31.3%, and >40° in 15.6% of participants; however, with the EPISCISSORS-60, all the post- suturing angles were >50° and there was no less. This can significantly reduce the chances of sphincter injury.

Consistent with the present study, Thanapongpibul et al have also shown that post-suture episiotomy angles were in the range of 30° and 60°. Thus, in using EPISCISSORS–60, the mean of 34.636° ± 9.445° was significantly more than the conventional method of mediolateral episiotomy incision with the mean of 27.614° ± 9.267° (16).

Kalis et al also found that an angle of <45° in an episiotomy increased the risk of OASIS (19), and according to Stedenfeldt et al, an angle >60° could not reduce perineal injury and increased the risk of OASIS (13). Eogan et al also stated that the incidence of OASIS is 10% with a post-suturing angle of 25° and reduces by 50% for every 6° of mediolateral episiotomy angle, and a minimum incidence of 0.5% can be reached at post-suturing angel of 43° (21).

Therefore, it is necessary to pay attention to the difference between the incision angle of episiotomy during childbirth and the post-suturing episiotomy angle. The episiotomy incision is made on a spherical body when the fetal head is crowning, and there will be a difference between the incision and suture angles when the perineum returns to the plate position and sinks.

When an episiotomy incision is made at 40°, the resulting suture angle will be 22°. To achieve a post-suturing angel of 45°, an episiotomy incision should be made at 60° when the fetal head is crowing (22).

In our study, all the angles of episiotomy incision during childbirth were considered at 60° and our main goal was to measure the post-suturing angle. It is worth mentioning that although we tried to do episiotomy incisions at the angle of 60° with Mayo scissors, considering the post-suturing angles, we probably made a mistake in estimating some of them during labor with this visual method and there was not enough time to use the measuring tool to get the exact angle. However, the first-year gynecology resident with the least experience was able to perform episiotomies well in this study, which could also be related to the easier and perfect use of these scissors compared with conventional scissors.

Although many recent investigations have been conducted as simulated or open-label models, the strength of the present study was that it was a clinical trial and had only one blinding. Also, the supervision of a specialist, as a guide, along with the first-year resident of obstetrics and

gynecology, would be associated with lower visual error as much as possible. Although performing all episiotomy incisions by a person in both groups can control the skill and accuracy as confounding factors, the small sample size can be one of the weaknesses of the present study. Also, it appears that using regular, angled scissors may affect how quickly episiotomy wounds heal, as in our study, postpartum discomfort was markedly less common in the EPISCISSORS–60 group. Hence, we advise that future research take into account not only the angles of the episiotomy incision during labor and after suturing, but also the process of episiotomy improvement and the level of patient satisfaction.

Conclusion

According to the results of the present study, the use of EPISCISSORS–60 in creating a 60° mediolateral episiotomy incision can play an important role in the larger post-suturing angle compared with Mayo scissors. This resulted in no OASIS in the use of EPISCISSORS–60 in this study, although its incidence was very low in the use of Mayo scissors.

Authors Contribution

F.S.: conceptualization, data collection, investigation, writing the original draft, and reviewing and editing. M.H.: conceptualization, methodology, project administration, supervision, writing the original draft, and reviewing and editing. M.M.: conceptualization, methodology, writing, reviewing, and editing.

Ethical Approval

Ethical issues—including plagiarism, data fabrication, and double publication—have been completely observed by the authors. This research has the approval code of IR.MUI.MED.REC.1399.796 at the ethics committee of Isfahan University of Medical Sciences, Isfahan, Iran.

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Conflict of Interests

The authors declare that they have no competing interests.

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