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James Madison University
Physician Assistant Clinical Medicine
PA 653

ROUTINE VERSUS SELECTIVE EPISIOTOMIES CAUSING SEVERE PERINEAL TEARS

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ABSTRACT

Objective: To determine if the use of routine episiotomies decreases the rate of severe perineal tears in comparison to selective episiotomies during vaginal delivery. **Methods:** PubMed and Google Scholar were used to generate a set of random control trials which all had the objective of comparing severe perineal tears in routine compared to selective episiotomies during vaginal delivery. Three trials were reviewed and included in this study. **Results:** The results of each trial were not all statistically significant in the rate of severe perineal tears when comparing the two interventions. However, a downward trend of third-degree perineal tears amongst the use of selective episiotomies was noted. **Conclusion:** Heterogeneity amongst each of the trials made it difficult to determine if the use of selective vs. routine episiotomies influenced the rate of severe perineal tears. While a decrease in severe perineal tears is found with selective episiotomies, more research is needed at this time.

INTRODUCTION

Women giving birth vaginally are often faced with unintended complications. One of the most common consequences is perineal tearing. Historically, in obstetrics, a common technique for preventing these tears includes the use of episiotomies. An episiotomy is an incision of the vaginal introitus to avoid natural tearing, and it is typically performed either posteriorly at midline or mediolaterally. Severe perineal tears, categorized as third- and fourth-degree tears, are an unfortunate possibility in vaginal deliveries. These tears extend into and through the anal sphincter, respectively, and repair often requires anesthesia in an operating room. This leads to more healthcare demand and spending. Additionally, healing from these severe perineal tears can take several weeks, and the trauma is accompanied by various complications such as fecal incontinence and painful intercourse.² With the intention of preventing these complications, extra cost, and increased maternal risk, episiotomies are used to assist in vaginal deliveries, both routinely and selectively. A policy of routine episiotomies is the preemptive and systematic application of perineal incisions during the second stage of labor. This is in contrast to the selective use of episiotomies which are only indicated in critical circumstances and are avoided in routine management. While a decreasing rate of episiotomies can be observed in the United States, there is still a relatively high prevalence for its use.

Current research on the two approaches of episiotomy heavily focuses on multiparous women with less attention on the nulliparous population. Multiparity refers to women who have had previous deliveries, in contrast to nulliparous who have never given birth. Studies show that the use of selective episiotomies is favored over routine episiotomies in multiparous women as

there is less perineal trauma.³ Considering the anatomical differences between nulliparous and multiparous women, an in-depth review of research regarding the appropriate type of episiotomy is needed for first time mothers. According to several large studies in Norway, Sweden, and Denmark, nulliparous women who sustain third- and fourth-degree perineal tears during birth have a fivefold increase in risk for a severe tear in subsequent pregnancies.^{4,5,6,7} Thus, it is imperative that further research of the use of selective vs. routine episiotomy be identified in this population.

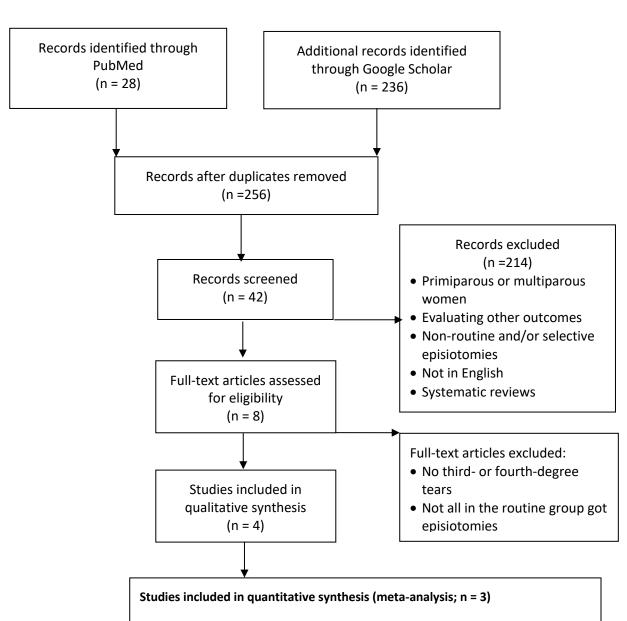


PRISMA 2009 Flow Diagram

Identification

Screening

Eligibility



Suliman 2013- A randomized controlled trial evaluating the prevalence of obstetrical anal sphincter injuries in primigravida in routine versus selective mediolateral episiotomy

http://applications.emro.who.int/imemrf/Saudi Med J/Saudi Med J 2013 34 8 819 823.pdf

Rodriguez 2008- Selective vs routine midline episiotomy for the prevention of third- or fourth-degree lacerations in nulliparous women https://www.sciencedirect.com/science/article/pii/S000293780702114X

Argentine 1993 – Routine vs selective episiotomy: a randomized controlled trial https://www.sciencedirect.com/science/article/pii/S0140673605800856

Clinical Scenario

A first-time mother is anxious about the possibility of having a severe vaginal tear during delivery of her child. She wants to know if using a routine episiotomy would lower her chances of a severe perineal tear in comparison to a selective episiotomy.

Clinical Question

Does the use of routine episiotomies reduce the chances of third- and fourth-degree perineal tears when compared to selective episiotomies in nulliparous women?

PICO

Population - Nulliparous/primigravida women
Intervention - Routine episiotomy
Control - Selective episiotomy
Outcome - third- and fourth-degree severe perineal tears

METHODS

In September of 2019, Google Scholar and the PubMed databases were used to search a variety of terms including: episiotomy, selective episiotomy, routine episiotomy, nulliparous, perineal tears, third-degree tears, fourth-degree tears, mediolateral episiotomy, and midline episiotomy. The search of these terms produced 28 articles from PubMed and 236 articles from Google Scholar. Duplicates of articles were excluded from the search which further narrowed down the results to 256 articles. Studies rejected included those that were meta-analyses, prospective cohort studies, retrospective cohort studies, and those not in English. Further screening of the remaining 42 articles excluded outcomes that did not compare perineal tears and those that did not have clear conclusions. The remaining 8 articles were fully reviewed, and 3 were chosen based on the quality of the study and those that included severe perineal tears as the measurable outcome. Those of which met all criteria included: "A randomized controlled trial evaluating the prevalence of obstetrical anal sphincter injuries in primigravida in routine versus selective mediolateral episiotomy" by Sulaiman and associates, "Selective vs. routine midline episiotomy for the prevention of third- or fourth-degree lacerations in nulliparous women" by Rodriguez and associates, and "Routine vs selective episiotomy: a randomized controlled trial" by Belazin and associates. Calculations used to compare the use of selective and routine episiotomies included p values and number needed to treat (NNT).

RESULTS:

Study 1

Selective vs routine midline episiotomy for the prevention of third- or fourth-degree lacerations in nulliparous women. Rodriguez A, Arenas E, Osorio A, Mendez O, and Zuleta J.⁸

Study Objective

To determine whether selective midline episiotomy prevents third- or fourth-degree perineal lacerations

Study Design

In this controlled clinical study, 446 nulliparous women with vaginal deliveries after 28 weeks of pregnancy were selected upon admission during the second stage of labor. They were randomly assigned to undergo either routine episiotomy or selective episiotomy. Episiotomies were performed under local anesthesia with lidocaine and involved an approximately 4 cm incision through the perineum at midline, from the vaginal introitus to the rectum. The incision included skin, subcutaneous tissue, superficial fascia, and perineal muscle as well as a 4-6 cm incision of the vaginal mucosa. Episiotomies in the selective episiotomy group were only performed in cases of shoulder dystocia, fetal distress, forceps delivery, or when a severe tear seemed imminent to the treating physician. The routine group underwent an episiotomy when the fetal head distended the vaginal introitus. Episiotomies were performed by the treating physician. After delivery, the perineum was observed for tears, and they were each classified according to the first- through fourth-degree scale. The study was performed at Vicente de Paul teaching hospital in Medellín-Antioquia and Hospital del Sur in Itagui-Antioquia between the years of 2002 and 2004.

Table 1. Inclusion and Exclusion Criteria for Study Participation.

Inclusion Criteria	Exclusion Criteria
 Nulliparous women Delivery after 28 weeks Vaginal birth 	 Women with multiple pregnancies Patients with breech presentations Those who did not sign the informed consent Patients who refused to participate

Results

In the routine group, all 223 patients underwent midline episiotomy. Within the selective group, 54 of the 223 patients underwent episiotomy. There were no statistically significant differences in the patient characteristics between the routine and the selective episiotomy groups. There were 22 women (9.9%) who developed third-degree lacerations in the routine group compared to only 10 (4.5%) patients in the selective episiotomy group (RR, 2.19; 95% CI, 1.06-4.52). As for fourth-degree lacerations, there was no significant difference in frequency between the routine group (4.5%) and the selective group (2.3%). In the selective episiotomy group, the third- and fourth-degree tears occurred 86.6% of the time. Only 2 women out of the 168 who did not undergo an episiotomy in the selective group had a third- or fourth-degree tear. Periurethral, superficial vaginal, and labia minora tears were all significantly increased in the selective group compared to the routine episiotomy group.

Number Needed to Treat (NNT)

The number of participants with third- or fourth-degree tears in both the routine and selective groups were used to calculate the NNT. The NNT indicated that 19 patients needed to have a routine episiotomy in order to prevent 1 woman from having a severe perineal tear.

Critique

Some strengths of this study include that it was a randomized controlled trial (RCT), and there was a relatively equal number of participants divided between the two groups. These aspects aided in minimizing bias. One weakness of the study was that it included the use of a midline episiotomy. The technique of midline episiotomy is less favored in the medical community as it is associated with an increased likelihood of iatrogenic anal sphincter laceration when compared to the mediolateral approach. Finally, statistical significance was not found for fourth-degree tears which could be attributed to the relatively small size of the study. Since fourth-degree tears are less common than third-degree tears, a larger study may have been able to more effectively identify the risk for complication of fourth-degree tears.

Study 2

A randomized controlled trial evaluating the prevalence of obstetrical anal sphincter injuries in primigravida in routine versus selective mediolateral episiotomy. Sulaiman A, Ahmad S, Ismail N, Rahman R, Jamil M, Dali A.¹⁰

Study Objective

To determine the prevalence of third- and fourth-degree perineal tears, referred to as obstetrical anal sphincter injuries, in primigravida in routine versus selective mediolateral episiotomy.

Study Design

For this randomized controlled trial, 171 primigravida women beyond 38 weeks gestation who had vaginal deliveries were randomly assigned to either the selective or routine mediolateral episiotomy groups. Of the 209 women originally recruited and randomized, 38 dropped out due to C-section delivery. Randomization between the two groups was carried out by opening a sealed opaque envelope. Episiotomies in the selective group only underwent episiotomy when considered essential in situations of fetal distress or imminent extensive perineal injury. The episiotomies were performed by midwives with experience of at least 5 years. With a 5% statistical significance, the sample size was calculated with 80% power. The study was carried out at the tertiary care of the University Kebangsaan Malaysia Medical Center, Kuala Lumpur, Malaysia during the time period of May through October of 2009.

Table 2. Inclusion and Exclusion Criteria for Study Participation.

Inclusion Criteria	Exclusion Criteria	
 Live singleton pregnancy Cephalic presentation Pregnancy gestation beyond 37 weeks Primigravida women 	 History of perineal injury Life threatening medical conditions History of psychiatric conditions A multiple pregnancy Fetal malpresentation Delivery conducted by house officers and junior midwives 	

Results

Mediolateral episiotomies were performed in each woman within the routine group (82 women). In the selective group of 89 women, only 49 women had an episiotomy. Within the

routine group, there was a higher incidence of third-degree perineal tears compared to the selective group (3.7% versus 1.1%); however, this was not significant (RR=0.3, 95% CI: 0.03-2.89, p=0.3). There were no significant differences between participants in the selective versus routine groups in maternal and fetal outcomes involving blood loss, birth weight, neonatal pH level, and NICU admission.

NNT

The number of participants with third-degree tears in both the routine and selective groups were used to calculate the NNT. The NNT indicates that 40 patients must have a routine episiotomy in order to prevent 1 woman from having a severe perineal tear.

Critique

A strength of this study included that it was a blinded RCT. There were also several weaknesses of the study. The episiotomy rate within the selective group was higher than the rate within the United States at 55%. Another weakness of the study was the complete lack of fourth-degree tears, and the delivery accouchers who performed the episiotomy also graded the tear, if present. Finally, the study power was low due to the small sample size.

Study 3

Routine vs selective episiotomy: a randomized controlled trial. Belazin J, Campodonico L, Carroli G, and Gonzalez L.¹¹

Study objective

The objective of this study was to determine if the routine use of episiotomies were advantageous over selective use of episiotomies in reducing the rates of severe perineal trauma during vaginal delivery.

Study Design

The study was a non-blinded randomized controlled trial that was completed throughout the country of Argentina at 8 different maternity hospitals between the years of 1990 and 1992. These maternity hospitals were all well known for their use of routine mediolateral episiotomies in the management of labor and delivery for their patients prior to the induction of this study. The

of episiotomy in the routine vs. selective setting. These women were fully educated about the possible use of episiotomies during their labor, and, thus, gave full consent to participate. The study further divided these women into 1555 nulliparous and 1051 primiparous groups. Nulliparous women were defined as those who had never given birth, and the primiparous women had given birth once before the trial. Of the nulliparous women, 778 of the participants obtained selective episiotomies, and the other 777 participants received routine episiotomies. The primiparous group was divided similarly with 520 participants receiving selective episiotomies, and 531 obtaining routine episiotomies. When the women were moved into the delivery room, they were given an envelope which contained the type of management that would be utilized during their labor. Thus, the women were either assigned to having a selective episiotomy or a routine episiotomy randomly. The hospitals that participated in this non-blinded RCT used the medical staff that routinely practiced regardless of this study. The episiotomies were applied using scissors, making a maximum 4cm length mediolateral cut in the perineum. The women assigned to the routine use of episiotomies were given the incision prior to delivery, whereas, the women of the selective group were only given episiotomies when there was thought to be fetal distress or when severe perineal tears were thought to be imminent. After delivery, the attending physician was to assess and determine the trauma that was sustained to the perineum.

study recruited a total of 2606 pregnant women to participate in this ongoing study of the effects

Table 3. Inclusion and Exclusion Criteria for Study Participation.

Inclusion Criteria	Exclusion Criteria
Uncomplicated labor at 37 to 42 weeks Nulliparous or primiparous	History of caesarean delivery History of severe perineal tears
Single fetus Cephalic position	

Results

Amongst the 1,308 women assigned to the selective episiotomy group, only 30.1% of the participants underwent the incision. This is in comparison to the routine episiotomy group of 1,298 participants where the use of these incisions was 82.6%. These outcomes were further broken down into nulliparous women where 39.5% in the selective group received an episiotomy, and 90.7% in the routine group received an episiotomy. Similarly, amongst the primiparous women, 16.3% in the selective group received an episiotomy, and 70.5% in the routine group received an episiotomy. The outcome of the trial showed that there was no statistically significant decrease in severe perineal tearing when comparing selective vs. routine

episiotomies. While not significant with a p value of .69, a .4% reduction in severe tears with a 95% confidence interval of .36% - 1.72% was noted favoring the use of selective episiotomies vs routine. Though women of the selective episiotomy group sustained less severe posterior perineal tears, they sustained more anterior tears.

NNT

261 nulliparous women would have to be treated with a routine episiotomy in order to prevent 1 woman from having a severe perineal tear.

Critique

The study had strengths and weaknesses both of which influenced the statistical results of the final cumulative data. A key strength of this study was that it was done via RCT. The use of a RCT to investigate an intervention allows for strict inclusion and exclusion criteria of its participants which limits variables that could ultimately skew the data. The study was also strong in that did not have any dropouts of its participants which allowed for the data not to be influenced by failure of follow-up. A weakness of this study was that the treatment group did not all receive a routine episiotomy. If the group receiving the intervention had a 100% utilization rate of episiotomies, this could have possibly changed the outcome of the study and influenced the statistical significance. The study also implemented selective episiotomies based on the level of fetal distress and the likelihood of impending tear. Both of these measurements are subjective in nature and were made by several different medical providers throughout this study. This variability in the judgment of the providers was unable to be controlled, and, thus, is a downfall of this study. The RCT, ultimately, did not have enough power to show statistical significance of its data.

DISCUSSION

This review focused on the use of selective versus routine episiotomies within the nulliparous and primiparous populations and its effect on severe perineal tears. There was varying statistical significance on the outcomes of routine versus selective episiotomies; however, there was an overarching trend. The results of the systematically reviewed studies are summarized in table 4.

Table 4. Review of Studies

	Study #1 Rodriguez	Study #2 Sulaiman	Study #3 Belazin
Objective	To determine whether selective midline episiotomy prevents third-or fourth-degree perineal lacerations	To determine the prevalence of third- and fourth-degree perineal tears, referred to as obstetrical anal sphincter injuries, in primigravida in routine versus selective mediolateral episiotomy.	To determine if the routine use of episiotomies were advantageous over selective use of episiotomies in reducing the rates of severe perineal trauma during vaginal delivery.
Study Type	RCT	RCT	RCT
Sample Size	446	171	2606
Type of Episiotomy	Midline	Mediolateral	Mediolateral
Standard Treatment	Routine episiotomy	Routine episiotomy	Routine episiotomy
Conclusion	Selective midline episiotomy in nulliparous patients resulted in a significant reduction in the risk of third-degree perineal lacerations.	No statistical significance was found. Routine mediolateral episiotomy was associated with a higher prevalence of thirdand fourth-degree perineal tearing.	No statistically significant results in the rate of third- or fourth-degree perineal tearing.
NNH	19 (95% CI)	40 (95% CI)	315 (95% CI)

The three studies reviewed had a few notable differences. One of the largest includes the use of midline episiotomy in the Rodriguez study while the other two studies involve mediolateral episiotomies. These two types of episiotomy are commonly used, but the variation in incision location poses a potential difficulty in comparing severe perineal tear rates. A minute variation between the studies is in regards to the population. Rodriquez and Belazin studies both involved the nulliparous population while the Sulaiman study categorized the population of the study as primigravida. While both populations included women who presented for their first birth, the primigravida population is defined as also having a first pregnancy while the nulliparous population doesn't specify whether this is the first pregnancy. One additional difference between the studies is the procedure design of the Belazin study. The routine group

in this research did not all undergo episiotomy. The reason for this discrepancy was not specifically addressed beyond stating that it was based on the usual hospital policy which was not explicitly stated. Another large difference between the three studies included the provider which performed the episiotomies. Rodriquez and Belazin studies used physicians to conduct the procedure while Sulaiman study used birth accouchers, consisting of midwives with 5 years of experience. The training of these midwives was not identified. Ultimately, there was a notable amount of heterogeneity between the three studies.

Though the studies done by Rodriguez, Sulaiman, and Belazin were slightly heterogeneous, they had many similarities amongst them. An example of homogeneity of these studies is that they were all conducted via randomized controlled trials. Furthermore, all of the RCTs were conducted in the location of hospitals. The overarching objective of each trial focused on the rate of severe perineal tears in the presence of selective vs. routine episiotomies. Women of each of these RCTs all gave informed consent before participating and were educated about each type of intervention to be used. Other similarities between the studies can be seen in the inclusion and exclusion criteria which minimized confounding variables. The studies included fetuses with cephalic presentation during delivery. Furthermore, the use of selective episiotomy was done in the event of fetal distress and severe imminent perineal tears in each study. Per the results, the use of selective episiotomies had a higher incidence of anterior tearing than compared to routine episiotomies in all studies. While statistical significance was not uniform between studies, it was observed that the rate of third-degree perineal tears was lower with the use of selective episiotomy. Belazin showed a 0.4% reduction in severe tears, Sulaiman a 2.6 % reduction, and Rodriguez with a 5.4% reduction.

Variation in statistical significance and rates of severe perineal tears can potentially be attributed to the difference in sample size in each of these trials. In the Belazin study, conducted between the years of 1990 and 1992, a total of 2606 Argentinian women participated. This gave the study a statistical power of 80%. The Sulaiman study was conducted in the time span of 5 months with a total of 171 Malaysian women. Statistical power of 80% was also in the Sulaiman study when determining sample size. In the RCT by Rodriguez, a total of 446 Colombian women participated, and data was collected between the years of 2002 and 2004 with an unknown statistical power. If all studies had similar population sizes then data would be more consistent, and a greater trend could have been observed.

While the studies implemented criteria in order to limit confounding variables, there were still certain aspects of each study that skewed the data and potentially the reliability. In all three

studies, the use of selective episiotomy was implemented based on the clinical judgment of the providers. This subjective decision was not uniform due to the utilization of various medical staff involved. Providers may have deemed certain situations more severe than others and performed more selective episiotomies compared to their counterparts. An example that supports this comes from the RCT of Sulaiman in which they believed the rate of selective episiotomies may have been higher due to the hospital policies. It was noted that the accouchers were more likely to perform episiotomies on women because incident reports were written when a severe tear occurred. Thus, they may have done more episiotomies than necessary only in fear of authority. Another possible bias amongst these studies included that the medical staff was not blinded which could have further skewed the outcomes. Providers may have felt biased towards one intervention, and, thus, unconsciously approached care differently influencing the outcomes. While these characteristics of the studies could have potentially skewed the data, there were characteristics that made them dependable as well.

For instance, each of the individual studies received permission from their individual board of ethics before commencing studies. This helps support that these studies were done within humane parameters and reviewed by an outside party to make sure it was legitimate. Another aspect that made these studies reliable and consistent was the randomization of the women amongst the control and treatment groups. In the RCTs of both Rodriguez and Belazin, computer software generated a randomized sequence of who would belong to each group. Similarly, in Sulaiman, envelopes were randomly given to the participants with their assigned groups. The studies were also transparent in that they recorded those who were excluded from their studies and provided the reasoning for this. In the Rodriguez RCT, one participant was excluded from the selective group because she did not meet the inclusion criteria of being 28 weeks pregnant at the time of delivery. In Sulaiman, they excluded a total of 38 of its participants due to emergency cesarean sections. The RCT of Belazin stated that no women were excluded after the beginning of the study. Further reliability can be seen specifically in the studies of Rodriguez and Sulaiman. Rodriguez RCT had the degree of tear measured by both the attending performing the incision and a resident to control for skewed measurements. The accouchers in the Sulaiman study had no connection to the study, and, thus, possibly controlled for any bias when measuring the degree of tears. Unfortunately, this was not accounted for in the Belazin RCT.

Transparency is also seen in each of the studies by acknowledging potential support, conflict of interest, and funding. Sulaiman stated clearly that there was no affiliation or support from any outside groups. Belazin had a lengthy list of support from groups which included the

International Development Research Centre, Ottawa, Canada and the Special Programme of Research Training in Human Reproduction, WHO, Geneva, Switzerland, and the National Perinatal Epidemiology unit from Oxford. Rodriguez does not specifically state that they received support, however, they did acknowledge the hospital San Vincente de Paul of Medllin.

CONCLUSION

This systematic review does not allow for a final decision on whether selective vs. routine episiotomies are better in the setting of vaginal delivery. This is due to the variation in statistical significance seen throughout the studies. While there was heterogeneity in the population used, population size, and duration, there were similar trends observed. There appeared to be an increase in severe perineal tears in the presence of routine episiotomies vs. selective episiotomies. Having standardized variables throughout the studies could help differentiate the need for utilization of these interventions during vaginal delivery. These variables include similar sample size, one standard episiotomy technique, and stricter blinding of the providers performing the procedure. In conclusion, it is necessary for more research to occur in order to make a distinction between the risks and benefits of selective vs. routine episiotomies in the setting of nulliparous vaginal delivery.

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