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Selective episiotomy versus no episiotomy – A clinical study on primigravida

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ABSTRACT

Background: Episiotomy is the incision given over the pudendum, i.e. on the external genitalia organ during the vaginal delivery. Aims and Objective: In this study it has been tried to evaluate the benefits and the risks of selective episiotomy over spontaneous lacerations. Materials and Methods: This is an institution based interventional longitudinal study carried out in the Department of Obstetrics & Gynaecology of College Of Medicine & JNM Hospital, Kalyani over a period of 18 months in 218 patients (109 in each group) fulfilling the inclusion criteria. The recruitment and allocation in episiotomy and non-episiotomy groups were random after proper consent from the participants. Results: The frequency of postpartum perineal pain was around 47% in no episiotomy group and around 60% in selective episiotomy group. There were no cases of dehiscence, haematoma or wound infection in either of the groups. Around 96.22% of the women in the non-episiotomy group were satisfied or very satisfied compared to 89.52% in the selective episiotomy group. Conclusion: An episiotomy rate of less than 1% found in no episiotomy group as compared to around 18% episiotomy rate in selective episiotomy group. However, they have almost same feto-maternal outcome which successfully establish the effectiveness of no episiotomy practice over the selective one.

Key words: Episiotomy; Wound haematoma; Wound dehiscence

INTRODUCTION

A woman may have spontaneous laceration of the perineal area during her vaginal delivery. However, if it is a surgically planned incision over the perineum then it is called perineotomy. Episiotomy is the incision given over the pudendum, i.e., on the external genital organ during the vaginal delivery. Episiotomy was once the most frequently performed operation in obstetrics, during vaginal delivery.1 At that time, it was performed like routinely in each and every vaginal delivery. But since that time, the routine use of episiotomy and its beneficial effect has been increasingly questioned.

Aims and objective
In this study it has been tried to evaluate the benefits and the risks of selective episiotomy over spontaneous lacerations.

MATERIALS AND METHODS

The current study was an institution based interventional longitudinal study, with a sample size of 109 cases and 109 controls. This was conducted in the maternity ward of the hospital from November 2017 to February 2019.

Recruited participants during the study period were allocated at random to one of the two management policies. Random allocation to one of the groups was done using computer generated random numbers. It included participants who were aware of the study and were asked for their willingness to participate in the study, written and informed consent was taken. The study was pre-approved by the Institutional Ethical Committee.

Inclusion criteria
1. Uncomplicated pregnancy (Normal pregnancy).
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2. Singleton live gestation.
3. >37 weeks POG.
5. Patient in first stage of labour.

Flowchart for the participants included in the study

Exclusion criteria
1. Multiple pregnancy.
3. Mal position vertex.
5. Preterm deliveries.
6. Foetal macrosomia (>4,000gm.).
7. Associated systemic illness.
8. Bleeding disorder.

Tools
1. Episiotomy scissor.
2. Labour table.
3. Stand for lithotomy positioning.
4. Spotlight.
5. Local anaesthetic.

The mothers in the control group were delivered with the current practice of selective episiotomy. The mothers in non-episiotomy group i.e. study group were planned to deliver by the principle that episiotomy is unnecessary even in situation in which the literature suggests that it may confer some benefit.

In the selective episiotomy group, when episiotomy was performed using medio-lateral incision at the time of crowning. Both laceration and episiotomy were repaired by using chromic catgut suture material with continuous transcutaneous closure of skin. Amount of blood loss assessed during first hour of postpartum period by measuring blood collected in specially adapted plastic bag and also weighting sponges and gauzes soaked in blood deducting from their original dry weight (calculating as, 1.06 gm of blood = 1 cc of blood).

Laceration or extension of episiotomy, whenever present, laceration was classified. Only third and fourth degree tears were classified as severe perineal damage or severe perineal trauma.

The primary maternal outcomes were episiotomy rate, duration of second stage of labour; frequency of spontaneous lacerations and also the degree of lacerations, frequency of instrumental deliveries, postpartum loss of blood, frequency of perineal trauma (both by episiotomy or laceration), need of perineal suturing, number of required threads. The perinatal outcomes were 1st and 5th minute APGAR score and need for neonatal resuscitation.

The secondary maternal outcomes evaluated were frequency of severe perineal trauma; complications with perineal suturing (oedema, hematoma, dehiscence, perineal pain and infection) identified during postnatal consultation; intensity of postpartum perineal pain assessed according to a Visual Analogue Scale or visual pain scale, analgesic (NSAID) consumption, duration of hospital stay and all-over maternal satisfaction.

On the 3rd postpartum month follow up we enquired about the anorectal incontinence, any urinary incontinence, dyspareunia, measuring pelvic floor muscle strength by Oxford scoring system (women asked to contract levator ani muscle as forcefully as possible in lithotomy position), also monitor the anal sphincter tone (both resting score and squeeze score) by DRESS (digital rectal examination scoring system).

Anal sphincter tone (resting and squeeze pressure by DRESS): The assessment of outcome was compared between both groups.

Data collection
Data was assessed using questionnaire and followed up after 3 months for examination of necessary details mentioned earlier.

Data analysis
The two groups were compared at one time using percentages and chi square tests, probability values of less than 0.05 were considered as significant. Values are given as numbers (percentage), n (%), unless otherwise shown.
RESULTS

In this institution based interventional longitudinal study, out of 230 women approached for the study 218 women agreed to participate. They were randomly divided into two groups as selective episiotomy group and non-episiotomy group. Out of 109 patients in selective episiotomy group 4 women and non-episiotomy group 3 women were excluded from the study as they underwent caesarean section.

The baseline characteristics of the women in the two groups were similar with mean age around 23 years and BMI in and around 25. The percentage of primiparous women in the study was 64.2%, with no statistically significant difference between the groups. The majority of the participants had eight or more years of formal schooling (around 68.86% of those included in the non-episiotomy group and 71.4% of those in the selective episiotomy group). Median gestational age at delivery was around 39 weeks in both groups. The mean birthweight was similar in the two groups (2756g in the experimental group versus 2738 g in the control group).

No significant differences were found in relation to the primary maternal outcomes evaluated (Table 1). The frequency of episiotomy was much higher 18.09% in selective episiotomy group and 0.94% in the non-episiotomy group. The episiotomy performed in the non-episiotomy group was indicated because of a prolonged second stage (112 min) in association with a non-reassuring foetal heart rate, while in the selective episiotomy group 19 episiotomies were performed due to a prolonged second stage, clinical assessment and judgement. There was no significant difference between the experimental and control groups with respect to the duration of the second stage. The frequency of spontaneous lacerations was around 73% in no episiotomy a 78% in selective episiotomy groups. There was only one case of an instrumental delivery (forceps) in the non-episiotomy group. Severe perineal trauma like 3rd/4th degree perineal injury did not occur in any of the groups. Around 72.68% of the women in no episiotomy group and 78.09% in selective episiotomy group required suturing. There was difference in the number of suture threads required, with a median of around 1.43 and 1.87 respectively in two groups.

Analysis of the secondary maternal outcomes showed no significant difference between groups, excepting postpartum perineal pain and level of maternal satisfaction (Figure 1). The frequency of postpartum perineal pain was around 47% in no episiotomy group and around 60% in selective episiotomy group. There were no cases of dehiscence, hematoma or wound infection in either of the groups. Around 96.22% of the women in the non-episiotomy group were satisfied or very satisfied compared to 89.52% in the selective episiotomy group.

There were no significant differences between the groups with respect to the secondary perinatal outcomes.3 cases in no episiotomy group and 4 in selective group had an APGAR <7 in 1min and required neonatal resuscitation.

<table>
<thead>
<tr>
<th>Outcome variable</th>
<th>Non episiotomy n-106</th>
<th>Selective episiotomy n-105</th>
<th>Chi square value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of 2nd stage of labour Mean ± SD</td>
<td>27.42± 20.55</td>
<td>29.4± 21.87</td>
<td>0.49</td>
<td></td>
</tr>
<tr>
<td>&lt;1 hr</td>
<td>92 86.79</td>
<td>90 85.71</td>
<td>0.05 0.82</td>
<td></td>
</tr>
<tr>
<td>&gt;1hr</td>
<td>14 13.20</td>
<td>15 14.28</td>
<td>18.08 0.0002</td>
<td></td>
</tr>
<tr>
<td>Episiotomy yes</td>
<td>1 1.31</td>
<td>19 18.09</td>
<td>0.84 0.36</td>
<td></td>
</tr>
<tr>
<td>no</td>
<td>105 99.05</td>
<td>86 81.90</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Spontaneous laceration yes</td>
<td>77 72.64</td>
<td>82 78.09</td>
<td>0.99 0.32</td>
<td></td>
</tr>
<tr>
<td>no</td>
<td>29 27.35</td>
<td>23 21.90</td>
<td>0.30 0.56</td>
<td></td>
</tr>
<tr>
<td>Instrumental delivery yes</td>
<td>1 1.31</td>
<td>0 0</td>
<td>0.99 0.32</td>
<td></td>
</tr>
<tr>
<td>no</td>
<td>105 99.05</td>
<td>105 100</td>
<td>0.30 0.56</td>
<td></td>
</tr>
<tr>
<td>Severe perineal trauma yes</td>
<td>0 0</td>
<td>0 0</td>
<td>0.30 0.56</td>
<td></td>
</tr>
<tr>
<td>no</td>
<td>106 100</td>
<td>105 100</td>
<td>0.30 0.56</td>
<td></td>
</tr>
<tr>
<td>Post partum blood loss Mean ± SD</td>
<td>402.72±129.33</td>
<td>420.76±142.77</td>
<td>0.33</td>
<td></td>
</tr>
<tr>
<td>&lt;500ml</td>
<td>91 85.84</td>
<td>89 84.76</td>
<td>0.04 0.82</td>
<td></td>
</tr>
<tr>
<td>&gt;500ml</td>
<td>15 14.15</td>
<td>16 15.23</td>
<td>2.14 0.14</td>
<td></td>
</tr>
<tr>
<td>Number of suture threads Median</td>
<td>1 (1,2)</td>
<td>1 (1,2)</td>
<td>1(1,2)</td>
<td></td>
</tr>
<tr>
<td>≥2 threads</td>
<td>51 66.2</td>
<td>45 54.87</td>
<td>0.30 0.56</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Primary Maternal Outcome
At 5 minutes <7 APGAR reduced to 1 and 2 respectively. So, the neonatal resuscitation rate was 2.83% and 3.80% respectively.

About 4% of the new born infants in both groups required some form of oxygen therapy while the neonatal ICU admission rate was 3%. The duration of neonatal hospitalization was also similar in the two groups, with only 1.88% of those in the non-episiotomy group and 1.9% of those in the selective episiotomy group needing to stay in hospital for 48 h or more (Figure 2).

Comparing the secondary maternal outcome after 3 month of delivery during follow up, 2.83% in no episiotomy group and 14.28% in selective episiotomy group were complaining of dyspareunia. No cases were found complaining of anorectal incontinence (fecal/flatalt) in both groups. 2 and 1 cases respectively in no episiotomy and selective episiotomy group had some amount of urinary incontinence. Pelvic floor muscle strength assessed by Modified Oxford Grading System, having moderate to good amount of strength in all patients in both groups. Anal sphincter tone assessed by The Digital Rectal Exam Scoring System (DRESS) having normal tone for both resting tone score and squeeze tone score in all patients in both groups (Table 2).

So, in the present study, some difference was found between the women randomized to the selective episiotomy group compared to those randomized to the non-episiotomy group, like in complaining of dyspareunia, level of maternal satisfaction, postpartum perineal pain and number of threads required for suturing. The rate of episiotomy was very low in no episiotomy group (around 1%), but in other group the rate was much higher (around 18%), not even close to the low rates already described by other authors.2,3

The episiotomy rate found in the present study in selective episiotomy group was well above the maximum of 10% recommended by the WHO 3 but lower than the overall episiotomy rate found in a Cochrane systematic review of around 28% in the group submitted to selective episiotomy.5

**DISCUSSION**

Episiotomy was introduced into obstetric practice without any scientific evidence corroborating any possible benefits. Its use became widespread in the twentieth century based on the recommendation of renowned obstetricians such as Gabbe and DeLee.5 The review published by Thacker and Banta in 1983 not only highlighted the lack of any scientific studies supporting the use of episiotomy, but also found the practice to be potentially associated with harmful consequences such as perineal pain, hematoma, infection, dyspareunia and healing complications.6

Keeping this in mind we conducted a study, 230 women in labour were considered for inclusion. Of these, 8 women were excluded and 4 women declined to participate. Therefore, 218 women were randomized, 109 to the non-episiotomy group and 109 to the selective episiotomy group. 7 women were excluded following randomization because non-reassuring fetal heart rate developed and a caesarean section was indicated, leaving 106 women in the non-episiotomy group and 105 in the selective episiotomy.
No significant differences were found except in relation to rate of episiotomy application in the groups, as evaluated in the primary maternal outcomes. The frequency of episiotomy was much higher in selective episiotomy group, 0.94% in the non-episiotomy group and 18.09% in the selective episiotomy group. The frequency of spontaneous lacerations was around 73% in no episiotomy and 78% in selective episiotomy groups. Severe perineal trauma i.e., 3rd/4th degree perineal injury didn’t occur in any group. There was also no difference in the mean postpartum blood loss between the no episiotomy and selective episiotomy groups (402 ml versus 420 ml, respectively). However studies in the University of Soroka Medical Centre, including 168,077 vaginal births in Israel, medio-lateral episiotomy was found to be an independent risk factor for third and fourth degree perineal lacerations, even in critical situations such as shoulder dystocia, instrumental deliveries, posterior presentations, fetal macrosomia and non-reassuring fetal heart rate. Then the episiotomy rates at that hospital fell from over 30% in the 1990s to less than 5% in 2010.7

Analysis of the secondary maternal outcomes showed no significant difference between groups. The frequency of postpartum perineal pain was around 47% in no episiotomy group and around 60% in selective episiotomy group. There were no cases of dehiscence, haematoma or wound infection in either of the groups. Around 96.22% of the women in the non-episiotomy group were satisfied or very satisfied compared to 89.52% in the selective episiotomy group.

There were no significant differences between the groups with respect to the secondary perinatal outcomes either, with around 4% of the new born infants in both groups requiring some form of oxygen therapy and around 3% requiring admission to the neonatal ICU. The duration of neonatal hospitalisation was also similar in the two groups, with only 1.88% of those in the no episiotomy group and 1.9% of those in the selective episiotomy group had to stay in hospital for 48 hours or more.

During follow up, 3 months after delivery, 2.83% in no episiotomy group and 14.28% in selective episiotomy group were complaining of dyspareunia, which was statistically significant. (P < 0.05) But no significant differences were found in urinary incontinence or anorectal incontinence in two groups.

So, in the present study, some difference was found in between the women randomized to the selective episiotomy group compared to those randomized to the non-episiotomy group, like in complaining of dyspareunia, level of maternal satisfaction, postpartum perineal pain and number of threads required for suturing.

Koskas M et al., conducted a retrospective monocentric study in France taking 5409 vaginal deliveries. They had analysed – episiotomy practice, maternal and neonatal consequences of a restrictive or selective episiotomy policy between 2004 and 2006. They found out that restrictive use of episiotomy is preferable than routine use similar to our present study.8

In 1984, the results of the first randomized clinical trial conducted in the United Kingdom, reported an episiotomy rate of 10% when the proposal was to perform the procedure selectively.9 Various other randomized clinical trials followed and are summarized in a Cochrane systematic review. The well-documented advantages of restricting the practice of episiotomy rather than encouraging its routine use include less risk of posterior perineal trauma and of severe perineal trauma. Other positive consequences are less blood loss, less need for sutures, a lower frequency of postpartum perineal pain, a lower risk of perineal suture complications (oedema, dehiscence, infection and haematoma), fewer cases of postpartum loss of perineal muscle strength and less risk of dyspareunia.10

A question that has been raised is whether there is indeed any indication for performing episiotomy and whether the procedure, even when practiced selectively, confers any benefit at all, either immediately or later.
Indications such as a prolonged second stage, macrosomia, non-reassuring fetal heart rate, instrumental delivery, occiput posterior position and shoulder dystocia have been questioned. A systematic review of the effectiveness of episiotomy for prevention and management of shoulder dystocia found no evidence supporting the use of episiotomy.

The American College of Obstetricians and Gynaecologists recognises that there is an insufficient objective evidence-based criterion to define the indications for episiotomy and that restrictive use of episiotomy remains the best practice.

Recently, a retrospective study conducted in Tokyo, Japan, including 1,1521 women with spontaneous births without interventions (epidural, episiotomy, instrumental delivery) reported intact perineum rates of 49.5% in nulliparous and 69.9% in multiparous women, with only 0.1% of third-degree laceration (one case).

In this study we address the question if it is possible to never perform episiotomies for vaginal deliveries, the results and safety of definitively abolishing this procedure of the modern obstetric practice. The advantages of the study include its design, in which the women were randomly allocated to one of two groups, and the sample size, which was sufficient to show any possible benefits or harmful effects in either of the two groups. The analysis was performed on an intention-to-treat basis, which explains the one case of episiotomy in the group of women randomized to the non-episiotomy group. Since the indications recorded for these episiotomies were a “prolonged second stage” associated with non-reassuring fetal heart rate, the procedure may have been avoidable. But in the selective episiotomy group, the nineteen episiotomies were performed because of a clinical assessment and judgement with “prolonged second stage” may have been unnecessary. The considered limits for the duration of the second stage are currently more flexible. If mother and baby are well, patience to wait without intervening could have avoided some of the procedures performed.

Since this study was conducted at one single centre, further study needs to be carried out, in institutes where selective episiotomy rates are also higher, in order to verify whether there really are any relevant differences when the procedure is performed, even with restricted indications, versus when there is no intention to ever perform the procedure.

Despite the consistent evidence against its indiscriminate practice, in some places episiotomy is still performed routinely and indeed a recent study published in India showed a rate of 63.4% in this country. This rate is more than six times the maximum rate recommended by the World Health Organization. This may imply additional costs for the healthcare system.

As a study done in Brazil, just in suture threads, savings between $6.50 and $12.50 could be made with each vaginal delivery which could represent a current annual saving of US$ 15 to 30 million for Brazil.

Ideally, a future systematic review could include randomized clinical trials conducted for this purpose to enable solid recommendations to be proposed for routine obstetric practice. Until the results of such studies are available, it appears reasonable to propose that the World Health Organisation redefine its cut-off point for the “ideal” episiotomy rate and, also an effort to reduce rates of episiotomy, that nurses, midwives and doctors be trained not to perform the procedure indiscriminately. This effort may also be economically beneficial for economically burdened countries.

CONCLUSION

An episiotomy rate of less than 1% in no episiotomy group compared to 18% episiotomy rate in selective episiotomy group, with almost same feto-maternal outcome question the effectiveness of selective episiotomy over no episiotomy. Better immediate maternal satisfaction and reduced long term complications were observed in the study group. Large fraction of women delivered with intact perineum when episiotomy was withheld in the study group. The secondary perinatal outcome was also comparable in the two groups. Last but not the least, all women have the right to a positive childbirth experience with minimum intervention in a healthy surrounding.

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REFERENCES


Authors Contribution:
JN - Prepared first draft of manuscript and data collection; RC- Statistically analysed and interpreted the results and reviewed the literature; SN - Statistically analysed and interpreted the results; RR - Interpreted the results; reviewed the literature and manuscript preparation; MP - Concept and design of the study.

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