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Review Article

PRACTICE OF EPISIOTOMY: NEED FOR A SERIOUS REVIEW

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ABSTRACT

The routine use of episiotomy was popularized in 1940s and 1950s; with the widely accepted justification for liberal use especially in nulliparous women being that it facilitates delivery, prevents perineal lacerations, spares the baby's head from trauma, and avoids undue stretching of pelvic floor, which could predispose to subsequent uterovaginal prolapse. The rates of episiotomy from eleven developing countries including India showed that episiotomy rates for nullipara were higher than 90% in all countries (mean 93%, range 91-100%). In India the overall episiotomy rate for women delivering in tertiary level public hospitals is about 70%. The present clinical randomized trial was performed to compare maternal and perinatal outcomes in women submitted to a restrictive episiotomy vs. liberal usage of episiotomy.

INTRODUCTION

Episiotomy is a surgically planned incision, made on the perineum and posterior vaginal wall, during the second stage of labour. It was first described by Sir Fielding Ould[1] in 1741, and introduced in the early 1920s to cut short second stage of labour and prevent pernieal tears.[2] The routine use of episiotomy was popularized in 1940s and 1950s; with the widely accepted justification for liberal use especially in nulliparous women being that it facilitates delivery, prevents perineal lacerations, spares the baby's head from trauma, and avoids undue stretching of pelvic floor, which could predispose to subsequent uterovaginal prolapse. However, over the last three decades, concern has been expressed that these claims lack a scientific basis and in addition the benefits of routine use of episiotomy were challenged due to the high level of pain and other problems faced by women after episiotomy.[3,4,5] Several randomized controlled trials in varied populations of women found that the routine use of episiotomy was associated with greater problems as compared to restrictive use [6,7,8,9,10] and was associated with higher risk of anal sphincter and rectal injuries. Systematic reviews of prospective RCTs comparing routine with restrictive episiotomy have also suggested that the immediate maternal outcomes from routine episiotomy are worse than those from restrictive use.[11,12] Despite no clear benefit of routine episiotomy, and reportedly increased frequency as well as severity of perineal damage shown in the published literature; a survey among eleven developing countries including India reported over 90% episiotomy rates for nulliparous women. [13] Another recent study involving 18 tertiary care hospitals in India reported episiotomy rate of about 85% among nullipara and 39% among multipara.[14] Since the institution was still following the liberal episiotomy policy, the present clinical randomized trial was performed to study maternal and perinatal outcomes in women submitted to restrictive episiotomy vs. liberal usage.

METHODOLOGY

It was a randomized study conducted in the Department of Obstetrics and Gynaecology at Safdarjung Hospital, New Delhi. Study design and protocol were approved by the ethics and research committee of the medical faculty before the experiment. All participants were aware of the study and gave their informed consent to participate. Women were eligible for entry to the study if they were nulliparous, 37-41 weeks of

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gestation with an uncomplicated pregnancy, with a live singleton fetus in vertex presentation in 2nd stage of labour. During the one year study period 200 women were allocated at random to one of the two management policies: (a) Restrictive (n=100) - Episiotomy was avoided unless if it was indicated for instrumental vaginal delivery, fetal distress or imminent severe perineal trauma; (b) Liberal (n=100) - Episiotomy was made routinely in all nulliparous women except when the perineum was so lax [on clinical assessment] that the baby could be delivered without perineal tear. The aim in the 'restrictive' group was to have an intact perineum in as many subjects as possible whereas in the 'liberal' episiotomy, it was to avoid any degree of spontaneous perineal tear. Randomization was carried out by the technique of allocation concealment, using sealed opaque envelopes, with the different policies enclosed for every particular participant, ensuring a 50% chance for every participant to be assigned to one of the two groups. None of the participants were aware of the group to which they had been assigned.

All deliveries were conducted by the same obstetrician to prevent inter-observer bias. Ironing of perineum was done in all the cases to relax the perineum. Perineal support was provided during the controlled delivery of head and shoulders. Episiotomies were given in both the groups, during second stage of labour at the time of crowning of head. Episiotomies were right mediolateral and were performed with episiotomy scissors. Careful examination was made for any perineal and/or vaginal tear, or any extension of the episiotomy. After delivery of placenta, the episiotomy was sutured with the same technique using similar suture material in both the groups. All the subjects were assessed on day 1, day 7 and 6 weeks after delivery. Outcome measures included incidence of episiotomy, the type (anterior, posterior, or both) and the degree of perineal trauma, duration and degree of pain measured by visual analogue scale, other complications such as swelling/ haematoma/ infection/ gaping of wound, along with the return of sexual activity and dyspareunia. Neonatal assessment was made with the APGAR scores, and nursery admissions. Discrete variables such as incidence of episiotomy/ perineal tear, infection, and haematoma were analyzed using chi-square test and fisher exact test, whereas sample student t-test and non-parametric Wilcoxon Mann Whitney test was used for continuous variables like pain.

RESULTS

The study population was considered to be representative of all the spontaneous vaginal deliveries in the hospital, and both the groups were identical (p>0.05) with regard to age, weight, period of gestation at delivery and the mean duration of second stage of labor (*Table 1*).

Table 1 Patient Characteristics

Parameters (Mean ± SD)	Restrictive Policy (n=100)	Liberal Policy (n=100)	p
Age (years)	23.10 ± 2.83	22.86 ± 2.47	> 0.05
Weight (Kg)	56.74 ± 3.37	57.64 ± 3.77	> 0.05
POG (weeks)	38.94 ± 1.09	38.93 ± 1.10	> 0.05
2nd stage Labor Duration (minutes)	36.55 16.54	37.17 16.0	> 0.05

The Episiotomy rate was 13% in the group allocated to the restrictive policy and 95% in the liberal policy group (*Table 2*).

Table 2 Perineal Trauma

	Restrictive Policy (n=100)	Liberal Policy (n=100)	p
Episiotomy	13	95	
Perineal Tears (Extent)	69	02	
1st degree	52	01	
2nd degree	17	01	
3rd /4th degree	00	00	<0.001
Total 2nd degree trauma (Episiotomy+2nd degree tear)	30	96	
Perineal Tears (Location)			
Anterior only	10	0	
Posterior only	40	1	
Both Anterior & Posterior	19	1	
Any Anterior trauma	29	01	<0.05
Any Posterior trauma	72	97	
Intact perineum	18	03	

Five women in the liberal policy group were not given episiotomy as their perineum was felt to be lax; whereas in the restrictive policy group episiotomy had to be given for an imminent risk of severe perineal trauma in 77% (10/13), big baby in 7.69% and fetal distress in 15.38%. Incidence of perineal tears was higher in the restrictive group, however, majority (75.36%) were first degree; only 24.64% were second degree (*Table 2*). So the overall second degree perineal trauma (combined episiotomy and 2nd degree tear) of 96% in liberal group was significantly higher as compared to 30% in the restrictive group (p value < 0.001). There were no third/fourth degree tears and no extension of episiotomy in any of the group. Location of tears was another significant feature. The 'restrictive' episiotomy group had a higher incidence of anterior vaginal trauma (10% isolated anterior wall tears and 19% involving posterior wall also), though it was of a minor nature involving only the vaginal mucosa, whereas the 'liberal' group had a higher (97%) incidence of posterior perineal trauma versus 72% in restrictive group (p value < 0.001). Even after considering minor vaginal and perineal tears, 18% in the restrictive group had intact perinea compared to only 3% in the liberal group.

Table 3 compares the mean perineal pain score between the two groups with different activities like sitting, walking and defecation. Women allocated to the restrictive group had significantly lower mean pain scores on day one, day 2-6 and day 7 as compared to the liberal group.

Pain was minimal at rest and increased during various activities, with maximum pain and discomfort during sitting in both the groups (Student t test, p<0.001, p value <0.05). Patients having intact perineum did not experience pain and discomfort. The mean duration of pain was 5.95 ± 4.03 days in the restrictive group vs. 8.87 ± 4.19 days in the liberal group (p value <0.005). The duration of pain lasting for more than two weeks was seen in only 4% (6/97) in restrictive group and 6% (4/82) in the liberal group. Majority of these were the patients who had infection, hematoma, or gaping of episiotomy wound. Complications related to perineal trauma like swelling, haematoma, gaping and infection were more in liberal group as compared to restrictive group (*Table 4)*. However, the difference was not statistically significant (p>0.05 for all the complications).

Table 3 Mean Perineal pain score during 1st week and onwards postpartum at different activities (using VAS scale)

Pain Score	Restrictive Policy (n=100) Mean ± S.D.				Liberal Policy (n=100) Mean ± S.D.			
	Day 1	Day 2-6	Day 7	Day 8 Onwards	Day 1	Day 2-6	Day 7	Day 8 Onwards
At Rest	4.13±2.58	2.42±1.61	1.08±1.50	1.06±0.24	6.25±1.74	3.82±1.61	1.60±1.40	1.2±0.41
Sitting	4.77±2.78	3.07±1.91	1.32±1.77	1.31±0.46	6.96±1.63	4.53±1.89	2.12±1.71	1.8±0.56
Walking	4.28±2.63	2.61±1.72	1.15±1.56	1.51±0.59	6.67±1.73	4.28±1.85	1.92±1.61	1.86±0.74
Defecation	4.01±2.46	2.45±1.60	1.03±1.44	1.60±0.77	6.41±1.75	4.15±1.79	1.77±1.52	1.6±0.51

Table 4 Complications related to Perineal trauma

Complications	Restrictive Policy(n=100)	Liberal Policy (n=100)	p
Swelling	04	07	> 0.05
Hematoma	01	03	> 0.05
Wound gaping	02	05	> 0.05
Infection	02	05	> 0.05
Resumption of sexual activity	30	22	> 0.05
Dyspareunia	6	11	< 0.05

All complications related to perineal healing were present in the patients either with episiotomy or second degree perineal tear. 30% subjects in the restrictive episiotomy group resumed sexual activity 6 weeks after delivery compared to 22% in the liberal group, the difference being not significant (p >0.05), the number being low in both the groups because of cultural reasons. Amongst those resuming sexual activity, dyspareunia at insertion was recorded in 20% (6/30) in the restrictive episiotomy group compared to 50% (11/22) in the liberal group (p<0.05).

Table 5 Neonatal outcome

Neonatal outcome	Restrictive Policy (n=100)	Liberal Policy (n=100)	p
Weight (gm.) - Mean	2746	2797	> 0.05
Caput succedaneum	07	08	> 0.05
1-minute Apgar score <7	05	04	> 0.05
Transfer to nursery	07	04	> 0.05

There was no significant difference in the neonatal outcome *(Table 5)*. 5% neonates in the restrictive group needed active resuscitation and 7% were transferred to nursery vs. 4% receiving active resuscitation and 4% requiring nursery care in the liberal group. All the neonates were discharged from the hospital in a healthy condition except one who expired having TOF.

DISCUSSION

Episiotomy is one of the most commonly employed procedures for vaginal deliveries with questionable benefits of 'routine/liberal' episiotomy and several studies demonstrating the benefits of 'restrictive' approach over the last 3 decades, yet the controversy remains and still the restrictive approach is not accepted by many, as shown by an episiotomy rate of about 85% among nullipara and 39% among multipara in a recent survey involving 18 tertiary care hospitals in India. [14] We studied the maternal and neonatal outcomes following the two policies at a tertiary care center in a prospective randomized trial. There was no difference in the duration of 2nd stage of labor among the two approaches, as was also noted by Harrison *et al* [7] .The restrictive approach group showed a significant reduction in the incidence of episiotomy to 13% compared to 95% in liberal group.

In the largest trial conducted till date, Argentine Episiotomy Trial Group, the incidence was 30.1% in the selective group and 82.6% in the routine group, when all the nulliparous as well as primiparous patients were included in the study, and 90.7% in routine group if only primipara were considered. The authors concluded that routine episiotomy should be abandoned and episiotomy rates above 30% cannot be justified. [9] Dannecker *et al*. reported episiotomy rates of 41% for women in the restrictive policy group where episiotomy was performed only for fetal indications and 77% if in addition a tear was presumed to be imminent (p<0.001). [10] Going further than the restricted/selective approach, some researchers have suggested a 'non-episiotomy' approach, with an episiotomy rate of less than 2%. [15] Recent Cochrane review noted episiotomy rates in different trials varying between 8-59% (median 32%) in the restrictive group and 47-100% (median 83%) in the liberal policy [16]. The variations in rates could be attributed to different definitions used for liberal and restrictive group and different inclusion/exclusion criteria. Based on this Cochrane review, World Health Organization report which had earlier recommended an episiotomy rate of 10% as "a good goal to pursue" [15]; now states that an "acceptable" rate of episiotomy is difficult to determine, and it is important to emphasize that routine/liberal use of episiotomy is "not recommended", rather than recommending the selective/restrictive use of episiotomy. [17] The American College of Obstetricians and Gynecologists also finds insufficient objective evidence-based criteria to recommend routine use of episiotomy, and recognizes that restrictive use of episiotomy remains the best practice with decision regarding episiotomy to be need based. [18]

The restrictive episiotomy group had a higher incidence (69%) of perineal tears, however, some of them were only anteriorly located, and three-quarters of them were only first degree causing much less discomfort to the patient. So the overall second degree perineal trauma (combined episiotomy and 2nd degree tear) of 30% in the restrictive group was significantly lower as compared to 96% in liberal group (p < 0.001). Amorim reported that 83% of the women had spontaneous lacerations in both non-episiotomy and selective episiotomy groups, 77% of which required suturing; therefore, a hospital policy of selective episiotomy might result in an increase in perineal tear but an overall reduction in rate of perineal suturing and suggested that the protective role of perineal protection strategies need to be evaluated further.[15] The American College of Obstetricians and Gynecologists (ACOG) practice bulletin also indicates a reduced likelihood of laceration at delivery with perineal massage and warm compresses on the perineum during the second stage of labor [18].

The present study did not report any 3rd or 4th degree tear in either of the groups, and the Argentine Episiotomy Trial Group also found no significant difference (1.2% in restrictive group vs. 1.5% in the routine group) in terms of severe perineal trauma[9]; Sleep *et al*. found a higher incidence in the restrictive group, although insignificant [6], Zafran *et al*. found the incidence of Obstetric Anal Sphincter Trauma to be significantly higher with restricted episiotomy (1%) compared to liberal (0.2 %), (p = 0.009; adjusted OR 4.15; 95 % CI, 1.42–12.10), among primipara [19] and Singh *et al*. also in the multicenter survey observed significantly higher (P<0.001) rate of combined 3rd and 4th degree perineal among nullipara who delivered without episiotomy (0.62%) compared to those who received episiotomy (0.13%) [14]. However, Cochrane systematic review of eleven RCTs from ten different countries comparing selective vs. routine use of episiotomy for women where an unassisted vaginal birth was anticipated, concluded that a policy of selective episiotomy may result in 30% fewer women experiencing severe perineal/vaginal trauma (RR 0.70, 95% CI 0.52 to 0.94; 5375 women) [16].

Regarding the complications related to healing of perineum following episiotomy or tears, like hematoma, swelling, gaping etc., the present study found them to be insignificantly higher in the liberal episiotomy group as compared to the restrictive episiotomy group, whereas the Argentine Episiotomy Trial Collaborative Group found the difference to be significant; "Dehiscence" and "healing complications" were detected in 9.4% and 29.8% respectively in the patients allocated to liberal use of episiotomy, compared to 4.5% and 20.5% in the restrictive use group [9] and Cochrane review reported little or no difference in perineal infection (RR 0.90, 95% CI 0.45 to 1.82, three trials, 1467 participants) [16].

A comparison of pain and other symptoms showed that there was a highly significant difference between the two groups with regard to the degree of perineal pain at rest and during activities like sitting, walking, defecation and also the duration of pain; being much more in the liberal group, making the women quite unhappy. Comparison of degree of pain was not possible with earlier RCTs due to the inconsistencies in the method and time of assessment of pain between various studies; however, our findings are consistent with those of Dannecker *et al*. regarding the methodology of assessment and the results. [10] Cochrane review could not comment if selective episiotomy compared with routine results in fewer women with moderate or severe perineal pain (measured on a visual analogue scale) at three days postpartum (RR 0.71, 95% CI 0.48 to 1.05, one trial, 165 participants, very low-certainty evidence). Our study found that the subjects in the restrictive group fared better than the liberal group with respect to resumption of sexual activity due to lower incidence of dyspareunia (p=0.047). These findings were consistent with previously reported trials. [9,10]. Other RCTs did not comment on dyspareunia. The Cochrane review concluded that there is probably little or no difference (RR1.14, 95% CI 0.84 to 1.53, three trials, 1107 participants, moderate-certainty evidence) regarding the perineal trauma associated dyspareunia six months or more after delivery [16].

There was no adverse neonatal outcome, nor an increase in the newborn nursery transfers with the restrictive episiotomy approach in our study as well as others who reported on the neonatal outcome including the Cochrane review [9,10,12,15,16] The major limitation of our study was collection of only hospital level data and conduct of all deliveries by one obstetrician only. Main strength of this study was 100% follow up till 6 weeks after delivery with assessment of the trauma suffered by the woman in terms of perineal pain and dyspareunia.

CONCLUSION

This study produced no evidence of prolongation of the second stage of labor, greater damage to the pelvic floor, trauma to the baby's head, or adverse neonatal outcome when routine episiotomy was not performed in nulliparous women. In fact there was a reasonable chance of avoiding second degree perineal trauma (70%) and retaining an intact perineum (18%). The subjects with restrictive policy experienced much less perineal pain and discomfort, and fared better in sexual outcome. Thus we conclude that restrictive episiotomy protocol appears to be safe for mother and the child, and the practice of routine/liberal episiotomy should be discontinued.

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