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A Randomised controlled trial for evaluation of Liberal v/s Optional use of episiotomy in primigravida: A Benchmark initiative!

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Abstract
Introduction: 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. So, this study aimed to compare the maternal morbidity during first vaginal birth in women with or without episiotomy.
Methodology: This was a hospital based randomized controlled trial conducted in the Department of Obstetrics and Gynaecology. Nulliparous women in active stage of labour attending labour unit with singleton pregnancy with cephalic presentation at term. Multiparous women, mal-presentations and mal-positions, multifetal pregnancy, pregnancy with medical disorder, instrumental deliveries, big baby (Clinically or USG weight > 4 kg), preterm and previous perineal surgery cases were excluded. The collected data were entered in Statistical Package for Social Science (SPSS) and analysis was using Chi-Square test. P value<0.05 was considered as significant.
Result: Among the 200 cases selected, 100 cases were in the Liberal (routine) episiotomy and 90 cases in Optional (restrictive) episiotomy group after randomization via computer generated table. 10% cases in the optional episiotomy group converted to episiotomy. In the current study comparison of the two groups in terms of vaginal and paraurethral tear showed that they are more common in the optional (restrictive) group. In the present study rate of episiotomy had reduced remarkably with 10% women delivering with an episiotomy in the restrictive group compared to routine episiotomy where 100% episiotomy rates were observed. On comparison of the requirement of analgesia in restrictive group, and in routine group statistically significant difference was found. There was no statistically significant difference in the neonatal outcome in the two groups in our study.
Conclusion: It is necessary to establish documented protocols to decide in which cases, when and how to perform episiotomy. Individualization of cases for approach of episiotomy is a need of the hour.

Keywords: Shoulder apophysis, painful shoulder, athlete, sports, cricket, acromion, Paediatric

Introduction

An **episiotomy** also known as perineotomy, is a surgically planned incision on the perineum and the posterior vaginal wall during second stage of labor when the perineum is stretched and distended just prior to the crowning. The purpose is to increase the diameter of soft tissue pelvic outlet thereby preventing lacerations and facilitating delivery & reducing the time for expulsion of fetus.

As per American College of Obstetricians and Gynecologists (ACOG) [1], "*based on the existent evidence, there are no specific situation in which episiotomy is essential, and the decision to perform an episiotomy should be based on clinical considerations*". The World Health Organization (WHO) [2] recommends an episiotomy rate of 10% as "*a good goal to pursue*". According to Cochrane systematic review indications for episiotomy includes premature delivery, breech presentation, fetal macrosomia, shoulder dystocia, instrumental delivery (forceps or vacuum extraction), non-reassuring fetal heart rate, and rigid perineum or imminent perineal tears. 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 hematoma), fewer cases of postpartum loss of perineal muscle strength and less risk of dyspareunia.

So, this study aimed to compare the maternal morbidity during first vaginal birth in women with or without episiotomy.

Methodology

This was a hospital based randomized controlled trial conducted in the Department of Obstetrics and Gynaecology at a tertiary care centre. Nulliparous women in active stage of labour attending labour unit with singleton pregnancy with cephalic presentation at term (Gestational age 37- 42 weeks) were included in the study. Multiparous women, mal-presentations and mal-positions, multifetal pregnancy, pregnancy with medical disorder, instrumental deliveries, big baby (Clinically or USG

weight > 4 kg), preterm and previous perineal surgery cases were excluded.

Primigravidae managed with Routine use of episiotomy formed group A and group B comprised of women subjected to Restrictive use of episiotomy. Progress of labor and delivery monitored. Both the cohorts were evaluated during labor, immediate postpartum period and first postnatal day. Under the policy of Routine or liberal use of episiotomy all primigravidae in group A were given an episiotomy. However, with the use of Restrictive episiotomy great restraint was observed in giving an episiotomy. Since the aim of the study was not to cause any harm to maternal and fetal health, episiotomy was given in group B in the following conditions- Unduly prolonged second stage of labour ≥2 hrs with an unyielding perineum, need of an episiotomy to prevent more serious perineal tears, maternal exhaustion/poor maternal bearing down effort and non-reassuring fetal heart rate patterns.

A structural questionnaire was used on all the participants, which were filled by the researcher. The collected data were entered in Statistical Package for Social Science (SPSS) and analysis was using Chi-Square test. P value<0.05 was considered as significant.

Outcome studied included

- Occurrence of vaginal/perineal,
- Tears/extension of episiotomies,
- Requirement of suturing a
- Analgesia,
- Wound complications,
- Neonatal outcome APGAR score at 1min and 5 min and
- NICU admission (if any)

Result

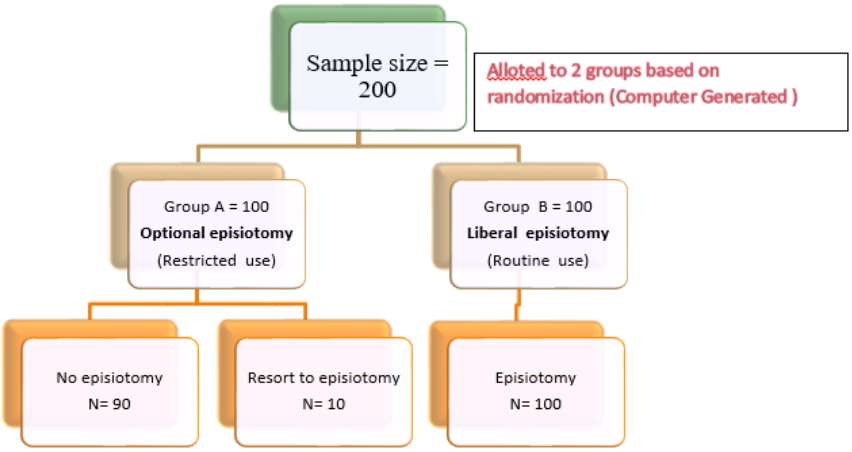

Fig 1

Consort diagram depicting randomisation of subjects into groups.

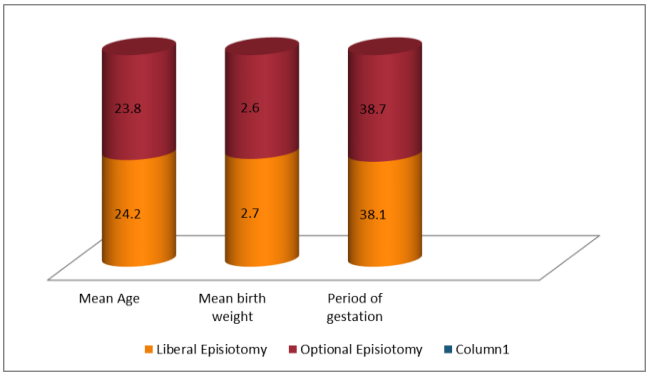

Fig 2: Comparison of maternal age, birth weight and gestational age

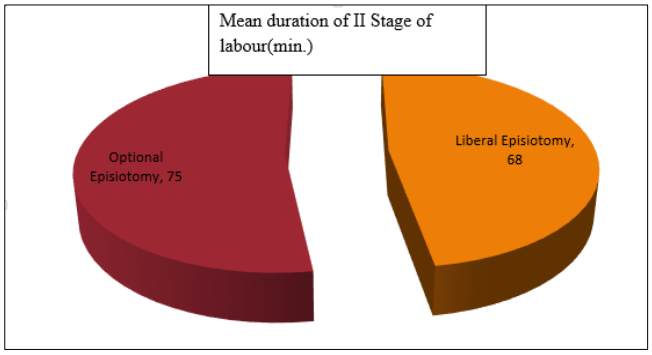

Fig 3: Mean perineal length (cm) comparison in both groups.

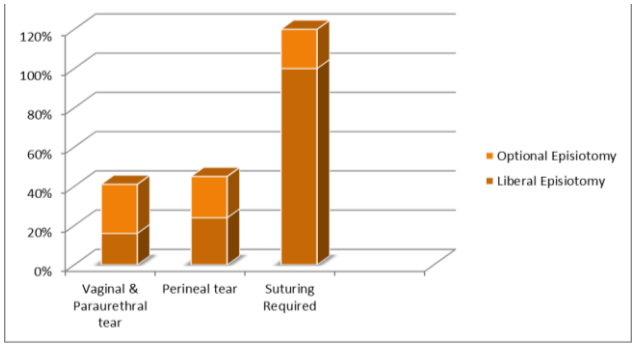

Fig 4: Mean duration of II Stage of labour (min.) in both groups.

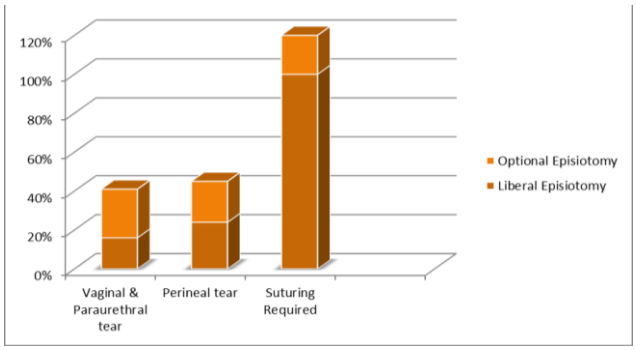

Fig 5: Intrapartum parameters comparison in both groups.

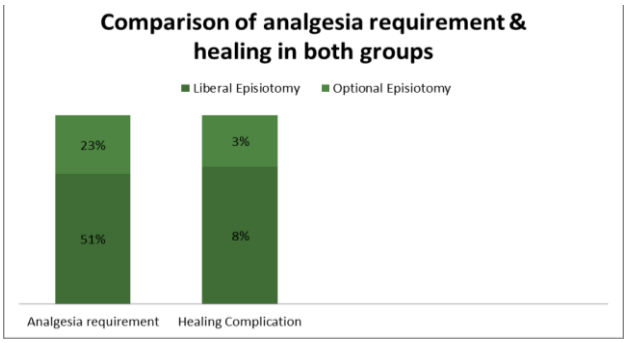

Fig 6: Comparison of analgesia requirement & healing complications in both groups.

P value<=0.05 when anaesthesia requirement is taken into consideration**.**

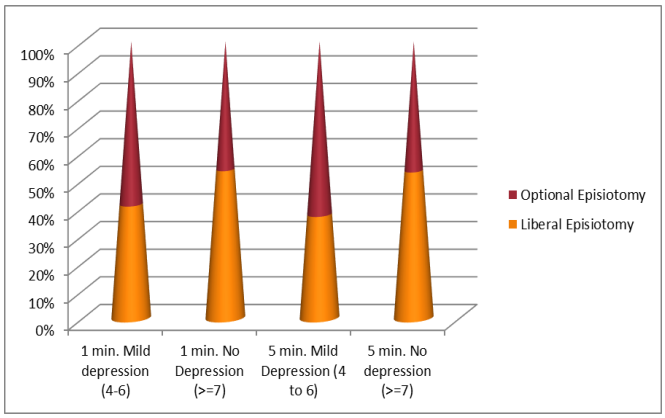

Fig 7: Comparison of APGAR Score in both groups.

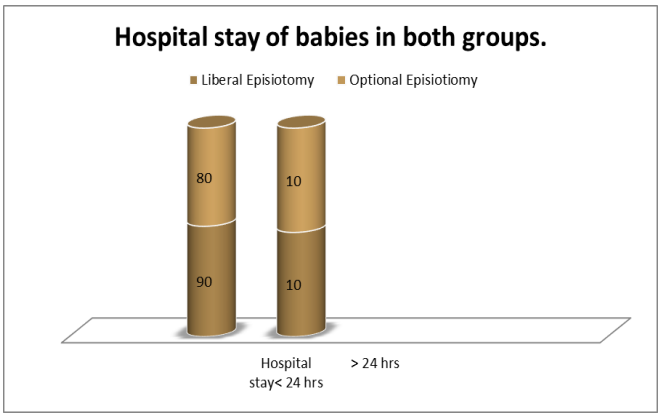

Fig 8: Comparison of Hospital stay of babies in both groups.

The association between the hospital stay and the 2 groups was assessed using corrected Chi-square test and it was found that there was no statistically significant difference between the hospital stay and the 2 methods of delivery.

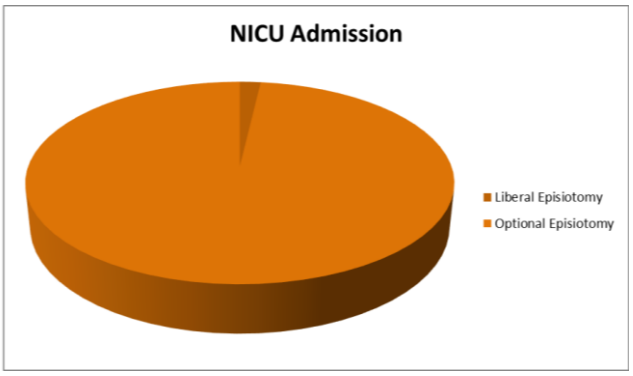

Fig 8: Comparison of NICU Admission in both groups.

Discussion

Among the 200 cases selected , 100 cases were in the Liberal (routine) episiotomy and 90 cases in Optional (restrictive) episiotomy group after randomization via computer generated table. 10% cases in the optional episiotomy group converted to episiotomy due to non-reassuring fetal heart pattern and prolonged second stage of labour. This finding emphasises that the rate of conversion to episiotomy in the restrictive group was minimal.

The results of this study indicated primigavida patients to have increased chance of retaining an intact perineum if episiotomy is carried out only when considered to be inescapable. It is supported by Shahraki *et al* [4]. There was no statistically significant difference between the duration of second stage of labour in two groups which is supported by Clemons *et al* [6]. In the current study comparison of the two groups in terms of vaginal and paraurethral tear showed that they are more common in the optional (restrictive) group. Eltorkey *et al* [7] concluded in their analysis that anterior lacerations, including anterior labial lacerations, were more common in the restrictive use group. Anterior lacerations did not contribute to overall higher use of suturing, suggesting that these tears were less severe than posterior tears. Venus *et al*. [10] also supported same finding. Saxena *et al*. [5] showed statistically significant reduction in the number of perineal lacerations in primipara and multipara with the practice of restrictive episiotomy. Carolli *et al*. [3] also concluded that optional (restrictive) use of episiotomy played a protective role on perineal tears.

In the present study rate of episiotomy had reduced remarkably with 10% women delivering with an episiotomy in the restrictive group compared to routine episiotomy where 100% episiotomy rates were observed. In a study carried out by Carroli *et al*. [3] in the routine episiotomy group, 75.15% of women had episiotomies, while the rate in the restrictive episiotomy group was 28.40%. According to Saxena et[5] al the policy of restricted use of episiotomy led to 64% women delivering with intact perineum, that is, without perineal trauma due to episiotomy or tear. Restricted use of episiotomy led to significant reduction in the incidence of perineal lacerations.

In our study there was no statistically difference in 2 groups when anterior vaginal, paraurethral tear & suturing was taken into account supported by Carolli *et al* [3]. On comparison of the requirement of analgesia in restrictive group, and in routine group statistically significant difference was found. In the liberal episiotomy group, pain relief in the form of oral and per rectal analgesics due to repair of tears and extension of episiotomy wounds in the immediate postpartum period. This is supported by Saxena *et al* [5], Carolli *et al* [3]. No statistically significant association between healing complication and type of delivery was found in our study which is also supported by Argentine trial [8].

There was no statistically significant difference in the neonatal outcome in the two groups in our study supported by Saxena *et al* [5], Venus *et al*. [10] and Murphy *et al* [9].

Episiotomy is one of the commonest obstetric interventions during child birth. Various studies demonstrate that the routine use of episiotomy should be abandoned and optional (restrictive) use of episiotomy should be adapted.

Conclusion

Despite decades of research, which many interpret as definitive evidence against routine use of episiotomy, little professional consensus has developed about the appropriateness of routine use. Lack of consensus in illustrated by variation in use. The time has come to take on the professional responsibility of setting and achieving goals for reducing episiotomy use. Therefore, obstetricians should develop guideline for performing episiotomies. The goals for quality of care must remain focused on both optimizing safety for the infant and minimizing harm to the mother.

Optional use of episiotomy is a goal that should be pursued within a humanized childbirth care model.

Key Message

It is necessary to establish documented protocols to decide in which cases, when and how to perform episiotomy. Individualization of cases for approach of episiotomy is a need of the hour.

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