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EVALUATION OF THE INCISION ANGLE OF MEDIOLATERAL EPISIOTOMY AT 60 DEGREES – A PILOT STUDY

<u>Hypothesis / aims of study.</u> Mediolateral episiotomy (MLE) is defined by the following: the location of the beginning, the incision angle, the length, and the exact timing of the procedure. No safe lower limit for the incision angle of MLE had been reported or quantified.

Aim of the study: To define a correct technique to perform MLE that reduces the risk of anal sphincter tear during delivery and assessing the effect of MLE on postpartum maternal health. The primary aims of this study were: to compare the 60° incision angle for MLE with the suture angle after its repair, to evaluate if the suture angle of MLE corresponds to the scar angle of MLE measured 6 months postpartum. The secondary aims were: to find out the incidence of obstetric anal sphincter injuries, the rate of perineal pain and anal incontinence 6 months postnatally, and to evaluate the applicability of the recently described scar evaluation scale [1] to this cohort.

Study design, materials and methods. Intervention study. Two obstetricians performed MLE in 75 (57%) of 131 consecutive primiparous women who delivered spontaneously.

The following set of measurements was chosen: the length of MLE, the angle of MLE after repair (suture angle) and 6 months postpartum (scar angle), tear in the continuation of the MLE, the shortest distance from the anal canal, maternal age, BMI, the duration of the second stage of labor, epidural, fetal distress, shoulder dystocia and birth weight. The exclusion criteria were multiparity, instrumental delivery, breech, twins, premature delivery.

Gentian-violet in 1% aqueous solution was used to mark the lines. The top point of the angles was defined by the fourchette and lines were drawn at 60° from the midline.

To improve the precision of the diagnostics of obstetric perineal trauma, the rectal examination was made (visual inspection combined with palpation) by performing a pillrolling motion between the index finger in the rectum and the thumb over the anal sphincter after every delivery.

The evaluation of perineal pain was performed using the Verbal Rating Score. The verbal rating score took a scale of 0 to 3 (where 0=no pain and 3=severe pain). It was used to record women's experience of pain in four domains: at rest, sitting, moving, and during coitus. The incidence and degree of anal incontinence was evaluated by the St. Mark's score. Women were asked to report any defecatory problems within the last month before completion of the questionnaire. The cosmetic effect of the healed episiotomy scar was evaluated by the novel scar evaluation scale [1]. Scars were assigned 0 or 1 point each for the presence or absence of the following: width greater than 2mm, elevation or depression, discoloration, suture marks, and overall negative appearance. A cosmetic score was calculated from 0 (worst) to 5 (best).

Follow-up was performed 6 months after the delivery. Women completed questionnaires, the scar angle of episiotomy was measured and a scar evaluation scale completed.

The local ethics committee approved the study and all participants signed a detailed informed consent form before they were included.

Basic statistical values (mean, median, standard deviation, variance, minimum, maximum, quantile, and frequency) were computed. The distribution of variables within groups was compared by non-parametric ANOVA (2-sample Wilcoxon test). The relations between variables were described using Spearman correlation coefficients, Pearson correlation coefficients and Linear Regression. Differences between dependent (paired) data were computed by the nonparametric paired test (Signed Rank Test).

To determine interobserver reliability in the measurement of angles of episiotomy, two blinded researchers measured the same suture angle of 12 women and the scar angle of 28 women. The interobserver results were analyzed using the paired Signed Rank Test and Spearmen's rank correlation. For the suture angle, the interobserver variability was 2.4% and for the scar angle 2.2%.

<u>Results.</u> 60 women signed a detailed informed consent and were included in this trial. In 4 (7%) women a continuing tear in the perineum has been diagnosed. No anal sphincter injury was detected in this cohort. Fetal distress was diagnosed in 12 (20%) women. Epidural was required and given to 2 (3%) women. No delivery was complicated by shoulder dystocia. The median suture angle of episiotomy originally incised at 60° was 45° (p <.0001).

6 months after the index delivery the women were asked to come for the follow-up. 2 could not be reached due to changes in contact details. From the remaining 58 women, 46 (79%) attended the follow-up and underwent a physical examination and completed questionnaires. Another 5 (8%) women answered the questionnaire by telephone. Altogether 51 (86%) women completed the questionnaires. Of all obstetric variables, no measured variable was found to be statistically significant in relation to suture or scar angles of episiotomy.

The median scar angle of episiotomy was 48°. There was a poor correlation between this angle and the suture angle of episiotomy.

At the time of follow-up two (4%) women registered symptoms of anal incontinence. Only one (2%) reported anal incontinence *de novo*. She registered one episode of flatal incontinence per month. The other reported mild impairment of her previous symptoms, two episodes of leakage of flatus a month and exceptional fecal urgency (once a month). The remaining 49 women who completed the questionnaire were asymptomatic.

Perineal pain related to episiotomy was reported by 7 (14%) women. None of them referred to pain at rest, sitting or while moving. 5 women scored their pain during coitus at 1 and two women scored 3. 49 (96%) women had regular coitus.

Using a novel scar evaluation scale, 37 (80%) women were scored 5 points and another 9 (20%) women were scored 4 points. No woman had a total score lower than 4 points.

<u>Interpretation of results.</u> This study shows that if the mediolateral episiotomy is cut at an angle of 60° at the time of crowning, the median angle between episiotomy and midline is 45° after the repair and 48° later after the delivery. For technical reasons, the suture or scar angle cannot become a part of the definition of mediolateral episiotomy. However the data presented by Eogan [2] is supported mathematically. A "safe" scar angle (38°) was measured and can serve as a reference [2]. In this study only 3 women had a suture angle more acute than 38°, and only 3 (7%) women had a scar angle of less than 38 degrees.

No anal sphincter tear was detected in this cohort. However there was one anal sphincter tear diagnosed among the remaining 15 women who were not included in this study. It was the case of a woman with fetal distress, persistent occipito-posterior presentation and a neonatal weight of more than 4000g.

The incidence of anal incontinence 5-9 months after the first vaginal delivery usually stands between 8-26%. In this study only one (2%) woman referred to minor symptoms of *de novo* flatal incontinence. One other (2%) also referred to flatal incontinence before the delivery, which is a reported predictive factor for the occurrence of symptoms after delivery [3].

Perineal pain 6 months after delivery was reported in 14% of the present cohort which is in accordance with other authors. Both women with a higher score of dyspareunia had a minor skin duplicature that caused narrowing of the introitus and was easy to repair. Another 5 women reported mild entrance pain which was felt only during the initial phase of coitus and then disappeared or which was due to the lack of lubrication.

The suggested angle of 60° is also suitable from a technical point of view. In daily routine practice it is difficult to make a fast incision at angle that is not easily estimated. As a rationale, the clinical selection should be made between 0° (median episiotomy), 30° , 45° , 60° and 90° . The angles of 0° , 30° and 45° are currently considered too acute.

<u>Concluding message</u>. This pilot study shows that the incision angle of episiotomy of 60° seems to be suitable for the implementation of a large randomized control trial and it seems that this could be proposed to define mediolateral episiotomy. It might be difficult to make the desired angle with absolute accuracy. On the basis of the latest results, the authors propose to define mediolateral episiotomy as "an incision of the perineum during the last part of the second stage of labor beginning in the perineal midline but directed laterally at an angle of at least 60° in the direction of ischial tuberosity." <u>References</u>

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What were the subjects in the study?	HUMAN
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Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes