

The Effect of Mediolateral Episiotomy on Obstetric Anal Sphincter Injuries following Vaginal Delivery

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ABSTRACT

Mediolateral episiotomy (MLE) is one of the most performed procedures on women worldwide. However, the protective effect of MLE against Obstetric Anal Sphincter Injuries (OASIS) is conflicting. The aim of this study was to evaluate the relationship between MLE and OASIS in primiparous, using 2D transperineal ultrasound (TPUS) immediately after delivery to aid in the diagnosis of anal sphincter injuries. This randomized control trial was carried out in Ain Shams University Maternity Hospital labour ward, between October 2018 and October 2021, included 260 primiparous at 37 weeks of gestation or beyond, which were randomly assigned to either routine or no episiotomy groups and the types of perineal injuries were analysed following childbirth. The episiotomy rate was 100% in the routine group versus 6.9% in the no episiotomy group. The overall incidence of third-degree perineal tears in both groups was 3.46%, with no cases of fourth-degree tears in the studied population. Routine MLE was associated with higher frequency of third-degree perineal tears (3.8% versus 1.7%); statistically significant. To conclude, the routine use of MLE in primiparous was associated with higher incidence of third-degree perineal tears, and as anal sphincter injuries are known to have short- and long-term morbidities, therefore the restrictive use of MLE is advised. TPUS is a helpful tool in detection of OASIS immediately postpartum. A delivery practice change is required in our local setting, through enhancing awareness, increasing structured training of junior staff, adherence to updated delivery protocols, and increased surveillance, which can lead to lower episiotomy rates with better outcomes.



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1. INTRODUCTION

Mediolateral episiotomy (MLE) is a surgical incision of the perineum and the posterior vaginal wall, for enlargement of the posterior aspect of the pelvic outlet, performed during fetal head crowning and is considered as an 'iatrogenic' second degree perineal tear [1], [2]. It was first described in 1742 and became more popular by mid-19 century [3]. However, the evidence of protective effect of episiotomy against obstetric anal sphincter injuries (OASIS) is still debatable due to paucity of high-quality data [4]. OASIS

involve third- and fourth-degree perineal tears, which are the most common cause of anal incontinence in females [5], [6]. Primary diagnosis of OASIS is therefore important, as a missed anal sphincter injury increases short- and long-term complications, anal incontinence and fistula [7], [8]. Transperineal ultrasound (TPUS) is a valuable method to diagnose and properly manage OASIS immediately postpartum [9]. TPUS was found to be acceptable by patients as it is pain free and less invasive, in addition to its wide availability. It also allows for studying the anal sphincter complex anatomy in resting position without distortion in both sagittal and coronal planes, compared to Endoanal ultrasound [10]. Sonographic signs that indicate anal sphincter damage include discontinuity of the EAS and/or IAS, inability to measure the anal sphincter complex thickness and atypical rectal mucosal folds- ‘mucosal star sign’, considered abnormal if some deviation from the symmetrical star shape is observed. This simple and easily applicable scanning method seems to be of use whenever the anatomical integrity of the anal sphincter is questioned [10].

Table (1): Classification of perineal tears [6]

| | |
|------------------------|---|
| First-degree tear | Injury of perineal skin and/or vaginal mucosa. |
| Second-degree tear | Injury to perineum involving perineal muscles but not the anal sphincter. |
| Third-degree tear | Injury to perineum including the anal sphincter complex, subdivided into: |
| | Grade 3a tear: < 50% of external anal sphincter (EAS) thickness torn. |
| | Grade 3b tear: > 50% of EAS thickness torn. |
| | Grade 3c tear: Both EAS and internal anal sphincter (IAS) torn. |
| Fourth-degree tear | Injury to perineum involving the anal sphincter complex (EAS and IAS) and ano-rectal mucosa. |
| Rectal buttonhole tear | A tear that involves the rectal mucosa with an intact anal sphincter complex, it is by definition, not a fourth-degree tear and has to be documented as a rectal buttonhole tear, if not recognised and repaired, this type of tear may lead to a rectovaginal fistula. ^[11] |

It was found that OASIS can be prevented by 1. *Perineal massage* antenatally decreases perineal trauma incidence requiring suturing [12]. 2. *Warm compression* during the second stage of labour [13]. 3. *Manual perineal protection* at crowning [14]. 4. *Episiotomy*; data on its protective effect against OASIS is conflicting [4], however, only during instrumental deliveries, its evidence is well established [15]. However, if an episiotomy is indicated, the mediolateral technique is recommended, with an angle of 60 degrees from the midline [4].

2. Subjects and methods

2.1 Ethical considerations

Ethical approval was obtained from our local ethics committee prior to study commencement. All women included in the study provided an informed consent for study participation. All participants were aware that they can withdraw from the study at any point whenever they want.

2.2 Study setting

This study was performed in the labour ward of Ain Shams Maternity University Hospital in Cairo, Egypt from October 2018 to October 2021.

2.3 Study Population

Primiparous women with singleton pregnancies at ≥ 37 weeks of gestation who presented in labour at the Emergency room.

2.4 Study design and details

A randomized controlled trial to evaluate the relationship between MLE and incidence of OASIS in primiparous women delivering vaginally with the aid of ultrasound in delivery room prior to repair of obstetric trauma to improve detection rates of OASIS. Randomization was performed in advance by the random number generator in MS Excel (Microsoft, Seattle, WA, USA). Sealed opaque sequentially numbered envelopes that contain the assigned intervention were used. The envelopes were placed in a box from which only 1 envelope could be drawn at a time. The staff member responsible for the random generation and the allocation-concealment process were not involved in the recruitment phase of the trial. According to study design, women participating in the study and the investigator were not blinded.

2.5 Inclusion Criteria

Primiparous women with singleton viable pregnancy, vertex presentation, delivering vaginally, gestational age ≥ 37 weeks and estimated fetal weight 2.5-3.5 kg

2.6 Exclusion criteria

Patients with history of anal incontinence before pregnancy, previous anal sphincter pathology (e.g., injuries, previous anal surgery or neuropathies affecting pelvic innervation), persistent occipitoposterior position of fetal head and patients who required delivery via caesarean section or instrumental vaginal delivery.

2.7 Assignment for interventions

All women were clinically examined and had TPUS before and after delivery (before suturing of any tears or episiotomy), to compare the antepartum and the postpartum images. Women in both groups received perineal support during delivery of fetal head and the posterior shoulder. All women were examined and delivered by qualified specialist obstetricians. Women participating in the study were randomly allocated at time of delivery into 2 groups: Group 1: had routine MLE (the usual hospital protocol) at the delivery of the fetal head. (Control group) & Group 2: delivered with no episiotomy (except for end points, where unplanned episiotomy was required in cases of fetal and, or maternal distress). (Intervention group).

Clinical examination was done by inspection and palpation of the perineum and the anal sphincter complex with a “pill-rolling” motion to assess thickness. In the case of sphincter damage, the location of injury was recorded according to the clock (twelve o'clock being anterior and six o'clock posterior). The depth of the damage was classified according to Sultan's classification.

Maternal variables were recorded: Age, BMI, type of onset of labour, second stage of labour duration, estimation of the subpubic arch (narrow or wide by per vaginal examination where ≤ 2 fingers inserted in the vagina side by side just below the subpubic arch is considered narrow, 3 or more fingers is considered wide), intertuberos diameter (ITD) (using hand fist and applying it on a ruler, to the nearest 0.5cm), perineal body length (PBL) (using finger and applying it to a ruler, to the nearest 0.5cm), post-delivery angle of episiotomy measurement (using a transparent protractor and applying it near the perineum-disinfected between patients) all such measurements/estimations were performed antepartum, while patient lying in lithotomy position without any uterine contractions or Valsalva. Only post-delivery episiotomy angle was assessed postnatally. Neonatal variables were recorded as well: gestational age, estimated fetal weight by ultrasound, delivery position of neonatal head, neonatal weight, and neonatal head circumference (to the nearest 0.5cm).

TPUS was done with the patient in the lithotomy position, using a trans-vaginal probe (6-9MHz) connected to Mindray Digital Ultrasound Diagnostic Imaging system (model: DP-20). The probe was applied nearly 90 degrees to the posterior fourchette towards the anal sphincter, twisting the transvaginal probe at 90 degrees

to obtain both sagittal and transverse planes of the anal sphincter complex. All ultrasound examinations and analyses were performed by two well trained sonographers. Clinical and ultrasound examinations lasted < 10 min and were well tolerated by patients. Those diagnosed with OASIS were transferred to the operating theatre for further assessment by a senior obstetrician and repair the tear immediately.

3. RESULTS

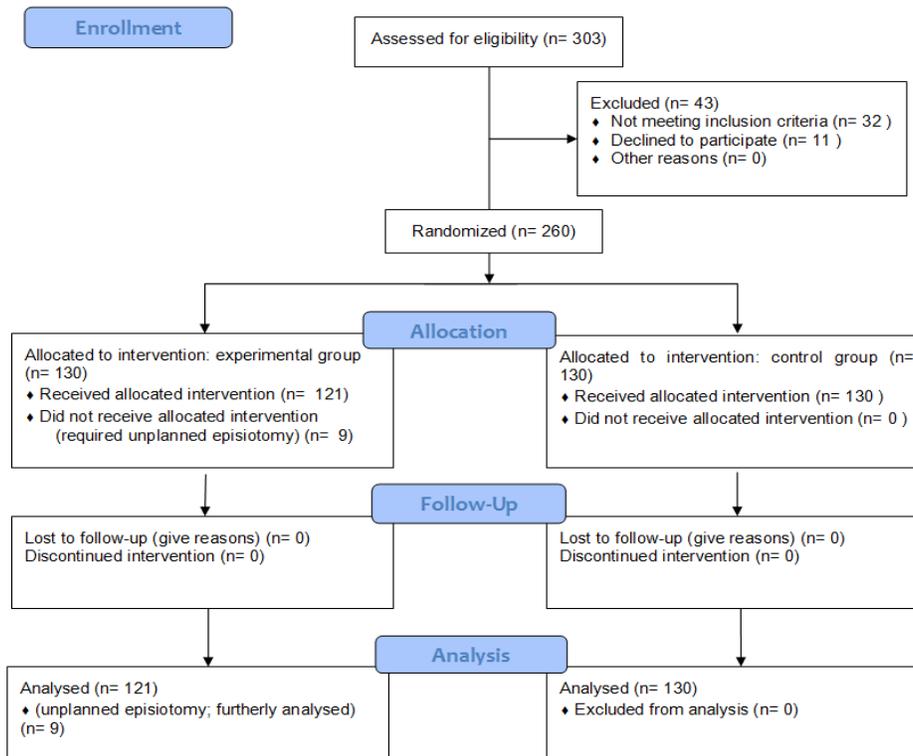


Figure (1): CONSORT 2010 Flow Diagram of the studied cases

Enrollment of 303 women, out of which 260 women were included and randomly allocated into either group, 43 dropped out, as 12 ended up delivering via instrumental vaginal delivery, 21 had emergency cesarean section and 11 refused to participate. Maternal, fetal and neonatal characteristics as well as labour circumstances showed no significant difference, with mean age around 23 years and BMI in and around 26, Median gestational age at delivery was around 39 weeks and mean birthweight around 3.1 kg. (Table 2)

Rate of episiotomy was 100% in routine episiotomy group versus 6.9% unplanned episiotomies in no episiotomy group. Those unplanned episiotomies (n=9) where end points met, in cases of fetal distress (n=4), maternal distress or prolonged second stage of labour > 60 minutes of pushing(n=5).

Perineal tears of various degrees other than episiotomy occurred in both groups but were significantly more frequent in no episiotomy group (78.5% (n=95)) versus (12.3% (n=16)) in the routine episiotomy group, p-value<0.001, RR 6.38, (CI 3.99-10.19)). Linear association test was used to analyse the degrees of perineal tear among cases who had perineal tears in both groups and found that no episiotomy group had significantly lower values, p-value 0.016 (figure 2)

Diagnosis of OASIS clinically and sonographically (TPUS) had the same findings, where OASIS occurred

in 1.7% versus 3.8% no episiotomy versus routine episiotomy group respectively. P-value 0.026, RR 0.43, 95 % CI (0.08-2.17) (figure 3)

Statistically, OASIS occurred most frequent in cases with unplanned episiotomy, followed by planned episiotomy and least in no episiotomy. No fourth-degree perineal tears occurred in any of the studied groups. (Unplanned episiotomy ((n=2) 66.7%), routine episiotomy group ((n=5) 31.3%) versus no episiotomy ((n=2) 2.1%), p-value 0.006)

Mean Post-delivery angle of episiotomy was around 43°, no statistical significant difference between the routine and unplanned episiotomy groups regarding episiotomy angle. P-value 0.765

Multi-regression analysis of variables in women who sustained OASIS revealed the following factors to be significant BMI, subpubic arch and int. (Table 3)

Calculated Relative risk ratio of 3rd degree perineal tear was 7.66 times higher in episiotomy versus no episiotomy group. (95% CI 2.49-45.79) (Figure 4)

Table (2): Maternal, fetal and neonatal characteristics among the studied groups

| Variables | | No episiotomy (N=121) | Routine Episiotomy (N=130) | p-value |
|------------------------------------|-------------|-----------------------|----------------------------|---------|
| Age (years) | Mean±SD | 23.1±3.7 | 23.1±3.8 | ^0.982 |
| | Range | 18.0–33.0 | 18.0–36.0 | |
| BMI (kg/m ²) | Mean±SD | 25.5±3.1 | 26.2±3.5 | ^0.096 |
| | Range | 19.4–35.0 | 20.0–34.0 | |
| Subpubic angle, (n, %) | Wide | 108 (89.3%) | 110 (84.6%) | #0.227 |
| | Narrow | 13 (10.7%) | 20 (15.4%) | |
| Inter tuberous dimeter (cm) | Mean±SD | 12.1±0.8 | 12.0±0.8 | ^0.261 |
| | Range | 10.0–13.5 | 10.0–14.0 | |
| Perineal body length (cm) | Mean±SD | 3.9±0.5 | 3.9±0.5 | ^0.351 |
| | Range | 3.0–5.0 | 3.0–5.5 | |
| Onset of labour (n, %) | Induced | 24 (19.8%) | 27(20.8%) | #0.854 |
| | Spontaneous | 97 (80.2%) | 103 (79.2%) | |
| Duration of second stage (minutes) | Mean±SD | 64.3±31.8 | 61.2±33.0 | ^0.461 |
| | Range | 10.0-145.0 | 10.0-150.0 | |
| Gestational age (weeks) | Mean±SD | 38.9±1.2 | 38.9±1.3 | ^0.949 |
| | Range | 37.0–42.0 | 37.0–42.0 | |
| | Median | 39.0 | 39.0 | |
| EFW (kg) | Mean±SD | 3.1±0.2 | 3.1±0.2 | ^0.995 |
| | Range | 2.5–3.7 | 2.5–3.5 | |
| Neonatal weight (kg) | Mean±SD | 3.1±0.3 | 3.2±0.3 | ^0.241 |
| | Range | 2.5–3.7 | 2.4–3.9 | |
| Neonatal HC (cm) | Mean±SD | 32.0±1.2 | 31.9±1.2 | ^0.536 |
| | Range | 29.5–34.5 | 29.0–34.5 | |

BMI: Body mass index, EFW: Estimated Fetal weight by US, HC: Head circumference. ^Independent t-test. #Chi square test

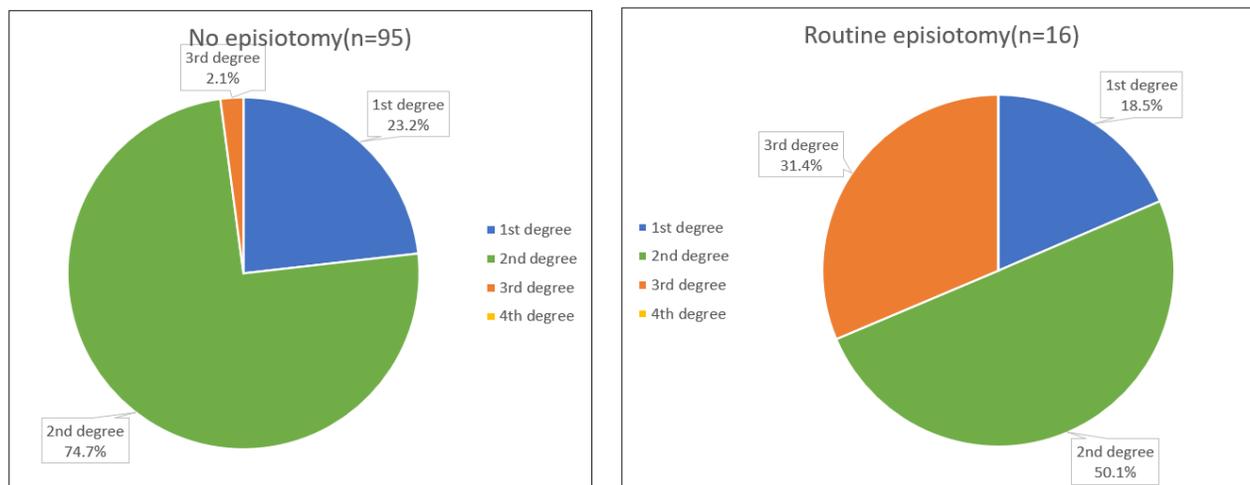


Figure (2): Perineal tear degree in cases who had perineal tear among the studied groups

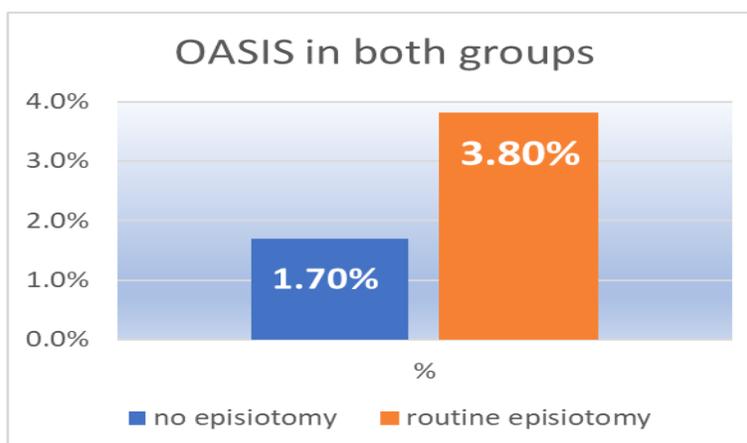


Figure (3): Percentage of obstetric anal sphincter injuries in both groups excluding unplanned episiotomy

Table (3): Multi-Regression analysis of the Dependent Variable in women who sustained an OASIS

| Model 1 | | | | | | | |
|---------------------------------|------------|--------|-------|------|---------|-------|------|
| Item | Reg. Coef. | t | p | Sig. | F-Ratio | p | Sig. |
| (Constant) | 0.648 | 1.185 | 0.237 | NS | | | |
| Age | 0.003 | 0.982 | 0.327 | NS | | | |
| BMI | 0.008 | 2.141 | 0.033 | S | | | |
| ITD | 0.04 | 2.104 | 0.036 | S | | | |
| PBL | -0.013 | -0.574 | 0.567 | NS | | | |
| GA | -0.001 | -0.15 | 0.881 | NS | | | |
| Estimated fetal weight | 0.004 | 0.078 | 0.938 | NS | | | |
| Neonatal Weight | -0.03 | -0.675 | 0.5 | NS | | | |
| Neonatal Head circumference | 0.001 | 0.134 | 0.893 | NS | | | |
| 2 nd stage of labour | 5.998E-09 | 0 | 1 | NS | | | |
| Subpubic arch | -0.125 | -2.892 | 0.004 | HS | | | |
| Induction of labour | 0.01 | 0.326 | 0.745 | NS | | | |
| | | | | | 1.236 | 0.259 | NS |

| Model 2 | | | | | | | |
|---------|------------|---|---|------|---------|---|------|
| Item | Reg. Coef. | t | p | Sig. | F-Ratio | p | Sig. |
| | | | | | | | |

| | | | | | | | |
|---------------|--------|--------|-------|----|-------|-------|----|
| (Constant) | 0.555 | 2.64 | 0.009 | HS | | | |
| BMI | 0.008 | 2.53 | 0.012 | S | | | |
| ITD | 0.04 | 2.146 | 0.033 | S | | | |
| Subpubic arch | -0.119 | -2.839 | 0.005 | HS | | | |
| | | | | | 4.346 | 0.005 | HS |

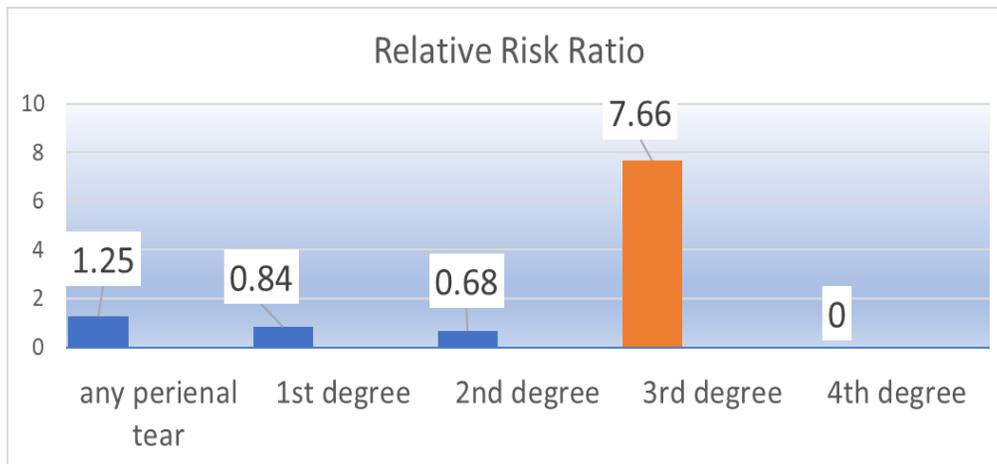


Figure (4): Calculated Relative Risk Ratio (RRR): (routine episiotomy versus no episiotomy)

3.1 Statistical methods

The collected data were coded, tabulated, and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software (V. 26.0, IBM Corp., USA, 2019).

4. DISCUSSION

Episiotomy is the most commonly performed operation in a woman's life and in obstetrics, with paucity of data to recommend its routine use. Although a retrospective cross-sectional study demonstrated a protective effect of mediolateral episiotomy on OASIS, but however recommended a randomized controlled trial [16]. However, a systematic review of literature concluded that episiotomy did not reduce incidence of urinary incontinence, pain, or sexual dysfunction, but rather increased the rates of perineal laceration, perineal repair, wound complications, and conferred no neonatal benefits [17].

In our study, all women were randomly assigned to either routine or no episiotomy group to compare the incidence of OASIS between both groups and the effect of mediolateral episiotomy. The study was conducted in a maternity unit of approximately 10,000 deliveries per annum. Randomization of the study population generated 2 groups of women with similar important aspects such as age and BMI (Table 2).

The total rate of third-degree perineal tears in this studied sample was 3.46%, with no cases of fourth degree tears. It was found in a per protocol analysis, that the incidence of third-degree perineal tears was 1.7% in the no episiotomy group versus 3.8% in the routine episiotomy group, statistically significant (RR 0.43, 95% CI 0.08-2.17, p-value 0.026), this was also supported by previous studies which showed a lower incidence of severe perineal tears in the selective episiotomy group [1], [18].

However, when unplanned episiotomies were added to the no episiotomy group in an intention to treat analysis, there was no significant difference (3.8% vs 3.7%, routine MLE vs no episiotomy, respectively, RR 1.25, 95% CI 0.331-4.802), but the RR of third degree perineal tear was 7.66 in the routine versus no episiotomy groups, which means that even though the incidence of third-degree tear appears to be the same

in an intention to treat analysis, the chances of any perineal tear being a third degree tear is seven times higher within the routine mediolateral episiotomy group.

OASIS occurred most frequently in cases with unplanned episiotomy, followed by planned episiotomy and least in never episiotomy. This might be explained by the small number of women who required unplanned episiotomy (n=9) versus the routine (n=130) and no episiotomy groups (n=121).

The findings of this study were similar to previous systematic reviews (8 studies) which compared restrictive with routine episiotomy, and advised to use restrictive episiotomy only when indicated, with better outcomes when compared to routine episiotomy, their results showed significant decrease of posterior perineal injuries (RR: 0.67, 95% CI: 0.49-0.91) [1].

In their study, proved that the accuracy of TPUS in assessing anal sphincter measurements were comparable with EAUS and MRI data [19]. In this study TPUS has helped in detection & confirmation of OASIS whenever diagnosis was questionable as clinical and sonographic (TPUS) findings were the same in both groups, 1.7% versus 3.8% no episiotomy versus routine episiotomy group respectively. P-value 0.026, RR 0.43, 95 % CI (0.08-2.17), this was supported an observational study of eighteen patients by who were able to reliably identify OASIS with perineal tears of grades 3b and 3c but could not adequately identify the clinically less significant grade; 3a tear [9].

Described that episiotomy rate following training of health personnel in the form of education provision fell significantly in most centres. The rate of third- and fourth-degree perineal trauma also declined in primigravid women who delivered without an episiotomy [20].

The mean Post-delivery angle of episiotomy was around 43°, no statistical significant difference between the routine and unplanned episiotomy groups, this supports the fact that emergency or unplanned episiotomy will have no impact on the angle of episiotomy, which is known to be an important risk of developing OASIS [21].

Multi-regression analysis of variables in women who sustained OASIS (Table 3) revealed the following factors to be significant; BMI, ITD and subpubic arch (regression coefficient of 0.008, 0.04, -0.119, respectively) with a value <0.05 is considered significant and negative sign indicates inverse impact, in other words; the increase in BMI and ITD increases the chances of OASIS, whereas the subpubic arch is inversely related to OASIS- the narrower the high risk of OASIS. This finding can be explained by the possibility of pelvic deformities (e.g., rachitic pelvis) that can lead to occurrence of narrower subpubic arch along with wider ITD in overweight/obese patients, different pelvic and perineal muscles in patients with wider ITD, plus the relatively small number of affected patients analyzed, which is an area for future studies analyzing the demographics and pelvic outlet dimensions of patients sustaining OASIS.

Relative risk ratio (figure 4) of 3rd degree perineal tear was around 10 folds higher in episiotomy versus no episiotomy group, this means that although incidence of OASIS was nearly the same in an intention to treat analysis of both groups, but once a perineal tear/extension happens in routine episiotomy, the risk is around 7 times more to be complicated by OASIS.

4.1 Strengths and limitations

The strengths of our study included the relatively large number of deliveries analyzed and the randomized controlled study design, which ruled out selection bias that would have occurred in an observational study.

The use of transperineal ultrasound as a confirmatory tool that helped in diagnosis of OASIS in an acute setting. A possible limitation of our study is that the percentage of women who were aware of the antenatal preventive measures is not documented. To what extent this has influenced the outcomes is unknown. Another limitation is paucity of national data on incidence of OASIS in primigravida to compare against our results.

5. CONCLUSIONS

In conclusion, routine mediolateral episiotomy is associated with a higher incidence of third-degree perineal tears. As anal sphincter injuries are known to have morbidities and was found to be associated with routine use of episiotomy, restrictive episiotomy use is therefore advised. If indicated, a mediolateral episiotomy is preferred [4].

Although its future implementation might be challenging, a delivery practice change is required our local setting, through enhancing awareness, increasing structured training of junior staff and adherence to updated delivery protocols, preventive measures application, increased surveillance, and auditing, which can lead lower episiotomy rates as well as lower anal sphincter injuries in the future.

6. RECOMMENDATIONS

- Training the health care providers is mandatory to improve the recognition and management of OASIS, by raising the awareness of the magnitude of the problem and its consequences
- Case-control studies with larger numbers of OASIS to further evaluate the significance of the risk factors mentioned in our study.
- Multicentre randomised controlled trials are required to agree upon the optimal mode of delivery following OASIS, as evidence is lacking in this area.

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