

# A randomized control trial evaluating the prevalence of obstetrical anal sphincter injuries in primigravida in routine versus selective mediolateral episiotomy

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## ABSTRACT

**الأهداف:** دراسة انتشار اصابات الولادة والعضلات القاصر الشرجية والتي تشمل على الدرجة الثالثة والرابعة لتمزقات العجان في الحامل للمرة الأولى في بضع الفرج الجانبي الاختياري والروتيني. وتحديد دور بضع الفرج في مكان محلي.

**الطريقة:** أجريت دراسة حالة عشوائية في جناح التوليد، مستشفى جامعة كابنجانس الطبي، كوالالمبور، ماليزيا خلال فترة 6 أشهر من مايو حتى أكتوبر 2009م. اشتملت الدراسة على 171 حامل للمرة الأولى بعد 38 أسبوع من الحمل وصلت للولادة المهبلية قسموا بشكل عشوائي إلى مجموعة بضع الفرج الاختياري والروتيني. تم تقييم اصابات العجان بعد ولادة المولود في 171 امرأة.

**النتائج:** كان معدل بضع الفرج من كلا المجموعتين 76.6%. كما كان معدل الإصابة بتمزج العجان للدرجة الثالثة كان 3.7% في المجموعة الروتينية بالمقابل 1.1% في بضع الفرج الاختياري الجانبي. لم يظهر أي تمزق من الدرجة الرابعة في كلا المجموعتين. لكن كان هنالك ارتباط بين بضع الفرج الاختياري الجانبي وارتفاع الإصابة حول الإحليل وإصابات الشفوية بالمقارنة مع المجموعة الروتينية 4.5% مقابل 0%.

**خاتمة:** أن بضع الفرج الجانبي الروتيني متلازم مع ارتفاع اصابات الولادة والعضلات العاصرة الشرجية. وتسبب العضلات العاصرة الشرجية الوفاة، وبضع الفرج الجانبي في الحامل للمرة الأولى. لذا نقترح باستخدام طريقة للولادة جديدة لتقليل من معدل بضع الفرج.

**Objectives:** To evaluate the prevalence of obstetrical anal sphincter injuries (OASIS), which include third and fourth degree perineal tears in primigravida in routine versus selective mediolateral episiotomy. Secondly, to determine the rate of episiotomy in local settings.

**Methods:** This randomized control trial was carried out in the labor ward of a tertiary hospital of the Universiti Kebangsaan Malaysia Medical Center, Kuala Lumpur, Malaysia between May and October 2009. The trial included 171 primigravida beyond 38 weeks gestation who achieved vaginal delivery, and randomly assigned to selective and routine episiotomy groups. The type of perineal injuries following childbirth among 171 women were evaluated.

**Results:** The overall episiotomy rate from both groups was 76.6%. The prevalence of third degree perineal tears was 3.7% in the routine compared with selective mediolateral episiotomy at 1.1%. There was no occurrence of fourth degree tears in both groups. However, selective mediolateral episiotomy was associated with an increased risk of periurethral and labial injury compared with the routine group (4.5% versus 0%).

**Conclusion:** Routine mediolateral episiotomy in primigravida is associated with a higher prevalence of obstetrical anal sphincter injuries. As anal sphincter injuries are known to have morbidities, selective mediolateral episiotomy in primigravida is therefore recommended in the implementation of new delivery practice, and in an attempt to reduce our high episiotomy rate.

*Saudi Med J 2013; Vol. 34 (8): 819-823*

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*Received 20th May 2013. Accepted 7th July 2013.*

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Perineal trauma is common following process of childbirth. The incidences of obstetrical anal sphincter injuries (OASIS) consisting of third and fourth degree tears is approximately 1%.<sup>1</sup> Perineal injuries as described earlier is classified as follows; first degree tears involve perineal and vaginal skin, second degree tears involve torn perineal, and vaginal muscles with an intact anal sphincter; third degree tears involve perineal skin, muscles, and anal sphincter torn partially and fourth degree tears involving complete tears of anal sphincter.<sup>1</sup> Anal sphincter injuries were associated with long term morbidities such as flatus and anal incontinence, rectovaginal fistulas, dyspareunias and psychosexual disturbance.<sup>2</sup> These injuries were previously thought by many obstetrician prevented by performing an episiotomy.<sup>3</sup> Episiotomy is a perineal incision used to create enlargement of vaginal introitus during delivery of fetus, thus equivalent to an 'iatrogenic' second degree tears.<sup>2</sup> At present, it is controversial whether episiotomies prevent anal sphincter injuries.<sup>4</sup> Carroli et al<sup>5</sup> suggested that mediolateral episiotomy is associated with higher risk of anal sphincter injuries. Some studies reported that mediolateral episiotomy was found to be protective of OASIS, and that there were significant associations between anal sphincter injuries and parity, birth weight, delivery method and shoulder dystocia.<sup>6</sup> Recommended episiotomy rate in primigravidae should be lower than 10%.<sup>5</sup> Despite recommendation for selective episiotomy, the rate of episiotomy remained high globally especially in developing countries. Graham et al<sup>7</sup> reported that episiotomies among primigravida were as low as 9-13% in developed countries such as Sweden, Denmark, England, New Zealand, and up to 60-100% in Taiwan, Nepal and South Africa. Our local episiotomy rate was high (69%) and was similar to previous literatures (Universiti Kebangsaan Malaysia Medical Center, labor room survey: 2007 to 2009; unpublished data). Carroli et al<sup>5</sup> reviewed a multi-centered trial approximately 5000 deliveries with the smallest sample of 188 deliveries and the largest sample of 2606 Argentinean deliveries and found that the prevalence of episiotomy rate fluctuated approximately 30% in the selective group (up to 80% in the routine episiotomy group). Selective episiotomy instead of its routine use is recommended based on a review of randomized control trials with a decreasing incidence

of posterior perineal trauma (RR: 0.67, 95% confidence interval [CI]: 0.49-0.91)<sup>5</sup> The shift of delivery practice from routine to selective episiotomy has taken place in most part of the world. Routine midline episiotomy has been shown to be associated with higher incidence of anal sphincter injuries.<sup>8</sup> Episiotomy performed routinely were also found to be associated with perineal pain, fecal or urinary incontinence, pelvic floor dysfunction, and poor sexual function among women.<sup>9</sup> Previous literatures have concentrated on midline episiotomies when used routinely or selectively. Randomized studies have shown that mediolateral episiotomy is less likely to extend into the anal sphincter than median episiotomy.<sup>2</sup> The rates of obstetrical anal sphincter injuries were higher in restricted use of lateral episiotomy as shown in a retrospective population-based register study.<sup>10</sup> Therefore, this study was designed primarily to address the prevalence of anal sphincter injuries when mediolateral episiotomy was used routinely or selectively among primigravidas. The secondary aim was to determine the rate of episiotomy in our setting as previous studies showed that it is still frequently done especially in developing countries such as Malaysia.

**Methods.** The MEDLINE and Cochrane databases were searched using keywords search 'routine', 'selective', 'mediolateral', 'episiotomy', 'perineal injuries', 'anal sphincter' and 'primigravida'. The search was limited to human and English language. This was a randomized controlled trial which was conducted in the labor ward of a tertiary center in Universiti Kebangsaan Malaysia Medical Center, Kuala Lumpur, Malaysia during the period of 6 months between May to October 2009. The study conformed to the principles of Helsinki Declaration and it was commenced following an ethical approval obtained from the local research and ethical board prior to study commencement (project code: FF-272-2008).

Two hundred and nine women were recruited, but 38 dropped out as they ended up delivering via emergency cesarean section. The inclusion criteria include live singleton pregnancy with cephalic presentation, gestation beyond 37 weeks, primigravida, women with no history of severe perineal injuries, no life threatening medical or psychiatric conditions. Women with multiple pregnancy, fetal malpresentation, and delivery conducted by house officers and junior midwives were excluded. A written consent for study participation was obtained when women arrived in the labor ward. Randomization into selective and routine episiotomy group was performed by opening a sealed opaque envelope. During second stage of labor, women in both

**Disclosure.** Authors have no conflict of interests, and the work was not supported or funded by any drug company.

groups were assessed by experienced birth accouchers for determination of episiotomy requirement. These experienced birth accouchers consisted of midwives with experience of at least 5 years, third and final year postgraduate trainees in Masters of Obstetrics and Gynecology and qualified specialist obstetricians.

All women in the routine group were to undergo the usual hospital protocol. Women in the selective group were not to undergo episiotomy unless considered essential for various reasons such as fetal distress or imminent extended perineal injury. Maternal and fetal outcomes of the deliveries were recorded and analyzed.

The sample size for this study was calculated with 80% power, at a 5% level of statistical significance. Statistical analysis was performed using SPSS 19.0 and  $p < 0.05$  was taken as level of significance. The distribution of continuous variables were tested using the normality histogram and Kolmogorov-Smirnov test. Variables with normal distribution were summarized using the mean plus standard deviation. The student T test was used for comparing population characteristics for the normally distributed variables. The Chi square  $\chi^2$  test was used for comparing categorical variables.

**Results.** There were 209 patients randomly assigned to 2 groups, routine or selective mediolateral episiotomy. Thirty-eight patients were dropped out as these women proceeded to emergency cesarean sections. A total of 171 women were randomly assigned into selective (n=89) and routine (n=82) episiotomy group. The overall episiotomy rate from both groups was high at 76.6%. Only 40 women (23.4%) had no episiotomy and all were from the selective group. All women (100%) in the routine group were subjected to an episiotomy while about half (n=49.6%) in the selective group had episiotomy. In the selective group, 12 women (12%) had episiotomy due to fetal distress while the other 37 (76%) were performed due to imminent perineal tears. The general characteristics for delivery of women in both groups are as seen in Table 1.

The main outcome of this study was to evaluate the prevalence of OASIS in routine versus selective mediolateral episiotomy. The different types of

perineal injuries in both groups were observed and described in Table 2. Routine episiotomy shows higher incidence of third degree perineal tears compared with selective episiotomy (3.7% versus 1.1%). However, this did not reach the level of significance (RR=0.3, 95% CI: 0.03-2.89,  $p=0.3$ ). In addition, selective episiotomy was shown to have higher association with anterior lacerations inclusive of paraurethral, clitoral or labial tears (4.5% versus 0%). There were no significant findings between routine and selective episiotomy on outcomes of mean estimated blood loss, mean birth weight, and newborns with pH less than 7.2 and admission to the neonatal intensive care unit (Table 2).

**Discussion.** Episiotomy is the most common operation performed in obstetrics, with little evidence to demonstrate any benefits with its routine use. Major perineal injuries are third degree tears where perineal skin, muscles and anal sphincter are torn partially and fourth degree tears involving complete tears of anal sphincter.<sup>1</sup> Retrospectively, Revicky et al<sup>6</sup> demonstrated that mediolateral episiotomy was protective of OASIS but recommended a randomized trial. In this study, all women underwent mediolateral episiotomies, as this type of episiotomy has been our standard labor ward practice. They were randomly assigned to routine and selective group in order to compare the prevalence of OASIS between the groups.

The study was conducted in a maternity unit of approximately 6000 deliveries per annum. Randomization of the study population generated 2 groups of women with similar important aspects such

**Table 1 -** Demographics characteristics of women in selective and routine episiotomy groups.

Factors	Routine	Selective	F	Sig
Age (years)	26.2±4.12	26.±3.05	0.001	0.978
Wight (kg)	62.6±10.4	606±11.3	1.326	0.251
Height (m)	1.57±0.75	1.56±0.69	0.966	0.327

**Table 2 -** Outcomes (maternal and fetal) of routine versus selective mediolateral episiotomy.

Variables	Routine n=82	Selective n=89	P-value
Intact perineum	0	4 (4.5)	n/a
Anterior perineal (paraurethral/labial tears)	0	4 (4.5)	n/a
1st degree	0	14 (15.7)	n/a
2nd degree (inclusive of episiotomy)	79 (96.3)	66 (74.0)	
3rd degree	3 (3.7)	1 (1.1)	0.3
4th degree	0	0	n/a
Mean estimated blood loss (ml)	283.3±56.7	275±39	0.27
Cord pH <7.2	17 (20.7)	15 (16.9)	0.49
Neonatal ICU admission	5 (6.1)	1 (1.1)	0.07

ICU - intensive care unit

as age, height, and weight distribution (Table 1). The practice of performing an episiotomy in nulliparous women is still commonly seen in our hospital, with an overall high frequency of 76%. The episiotomy rate was 100% in the routine group and 55% in the selective group. This study has shown a higher episiotomy rate than was found in the United States;<sup>11,12</sup> however, it is still lower when compared with other developing countries with an average of 90%.<sup>13</sup>

The incidence of third degree perineal tears in our studied population was 4 (2.3%), with no reported cases of fourth degree tears. We found that routine mediolateral episiotomy was associated with higher frequency of third degree perineal tears (3.7% versus 1.1%); however, this did not achieved statistical significance. This finding was also supported by previous studies which showed a lower incidence of severe perineal tears in the selective group.<sup>5,8,12</sup> Clemons et al<sup>12</sup> recommended selective use as there was association with decrease in anal sphincter laceration rate by 44%. Our findings was similar to previous reviews comparing selective versus routine episiotomy use involving 6 studies recommending episiotomy used only for selective indications was better than routine episiotomy, with a decreasing incidence of posterior perineal trauma (RR: 0.67, 95% CI: 0.49-0.91).<sup>5</sup> In this study, women in the selective episiotomy group had a higher incidence of anterior lacerations inclusive of periurethral and labial tears (4.5%) compared with the routine group (0%) and this finding is similar to the previous study which looked into median episiotomy.<sup>8</sup> Anterior perineal trauma was more common with selective episiotomy use (RR: 1.84, 95% CI: 1.61-2.10).<sup>5</sup> In clinical practice, anterior lacerations may be considered as a minor problem in comparison to anal sphincter injuries and its associated morbidities.

The present study assumed much importance with it being a randomized controlled trial and it assessed a mediolateral episiotomy as many studies previously were based on median episiotomy.<sup>8</sup> Suitable women were randomized into either selective or routine mediolateral episiotomy group. Potential bias were minimized based on several factors such as a blinded study, randomization process only occurred in the labor ward when women were already in active phase of labor, and delivery accouchers who conducted the delivery and assessed the classification of perineal injuries were independent from the researchers. Furthermore, the decision to perform episiotomy was carried out at second stage of labor and were performed by experienced accouchers. This may be the attributing factor for low incidence of major obstetrical anal sphincter injuries in our study.

The limitation of the study was the study power was reduces as the sample size was low due to time constraint. A strict criteria were to be performed by experienced accouchers only may not be an ideal daily labor room situation where primigravidae who deemed as low risk deliveries could be performed by any staff. Another possibility of 'authority fear' may explain our high rate of episiotomy in both groups, when birth accouchers takes precaution by performing an episiotomy to avoid occurrence of anal sphincter injuries which requires formal incident reporting. This might explain such a high rate of 55% episiotomy performed among women in the selective group, supported by the large proportion of them being carried out based on imminent severe tears (76%). Ho et al,<sup>14</sup> described that episiotomy rate following intervention in the form of health personnel education provision fell significantly in most centres in 4 ASEAN countries. The rate of third and fourth degree perineal trauma also declined in nulliparous women whom did not receive episiotomy.<sup>14</sup>

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, selective episiotomy use is therefore recommended. We found that selective use is favorable despite using mediolateral episiotomy which thought to be protective when compared with median type.<sup>6,8,10</sup> Future delivery practice especially in our local setting needs change although its implementation may be challenging. Enhancing awareness, increasing staff training and adherence to delivery protocol leading to an increase in performing mediolateral episiotomy selectively could result in lower episiotomy rates and lower incidence of anal sphincter injuries in the future.

**Acknowledgment.** *The researchers would like to thank the Universiti Kebangsaan Malaysia Medical Centre for the approval of the study and most importantly to all patients and health personnels involved during the study.*

## References

1. Royal College of Obstetricians and Gynaecologists. The management of third and fourth degree perineal tears. RCOG guideline no 29. London (UK): RCOG Press; 2007. p. 1-11
2. Fernando R. Risk factors and management of obstetric perineal injury. *Obstetrics, Gynaecology and Reproductive Medicine* 2007; 17: 238-243.
3. Aytan H, Tapisiz OL, Tuncay G, Avsar FA. Severe perineal lacerations in nulliparous women and episiotomy type. *Eur J Obstet Gynecol Reprod Biol* 2005; 121: 46-50.

4. de Vogel J, van der Leeuw-van Beek A, Gietelink D, Vujkovic M, de Leeuw JW, van Bavel J, et al. The effect of a mediolateral episiotomy during operative vaginal delivery on the risk of developing obstetrical anal sphincter injuries. *Am J Obstet Gynecol* 2012; 206: 404: e1-e5.
5. Carroli G, Mignini L. Episiotomy for vaginal birth. *Cochrane Database Syst Rev* 2009; CD000081.
6. Revicky V, Nirmal D, Mukhopadhyay S, Morris EP, Nieto JJ. Could a mediolateral episiotomy prevent obstetric anal sphincter injury? *Eur J Obstet Gynecol Reprod Biol* 2010; 150: 142-146.
7. Graham ID, Carroli G, Davies C, Medves JM. Episiotomy rates around the world: an update. *Birth* 2005; 32: 219-223.
8. Rodriguez A, Arenas EA, Osorio AL, Mendez O, Zuleta JJ. Selective vs routine midline episiotomy for the prevention of third- or fourth-degree lacerations in nulliparous women. *Am J Obstet Gynecol* 2008; 198: 285: e1-e4.
9. Hartmann K, Viswanathan M, Palmieri R, Gartlehner G, Thorp J Jr, Lohr KN. Outcomes of routine episiotomy: a systematic review. *JAMA* 2005; 293: 2141-2148.
10. Räisänen S, Vehviläinen-Julkunen K, Gissler M, Heinonen S. Hospital-based lateral episiotomy and obstetric anal sphincter injury rates: a retrospective population-based register study. *Am J Obstet Gynecol* 2012; 206: 347: e1-e6.
11. Scott JR. Episiotomy and vaginal trauma. *Obstet Gynecol Clin North Am* 2005; 32: 307-321.
12. Clemons JL, Towers GD, McClure GB, O'Boyle AL. Decreased anal sphincter lacerations associated with restrictive episiotomy use. *Am J Obstet Gynecol* 2005; 192: 1620-1625.
13. Kropp N, Hartwell T, Althabe F. Episiotomy rates from eleven developing countries. *Int J Gynaecol Obstet* 2005; 91: 157-159.
14. Ho JJ, Pattanittum P, Japaraj RP, Turner T, Swadpanich U, Crowther CA. Influence of training in the use and generation of evidence on episiotomy practice and perineal trauma. *Int J Gynaecol Obstet* 2010; 111: 13-18.

#### Related Articles

Frass KA, Al-Harazi AH. Episiotomy is still performed routinely in Yemeni women. *Saudi Med J* 2010; 31: 764-767.

Mesleh RA, Al-Sawadi HM, Kurdi AM. Comparison of maternal and infant outcomes between vacuum extraction and forceps deliveries. *Saudi Med J* 2002; 23: 811-813.

Shihadeh AS, Nawafleh AN. Third degree tears and episiotomy. *Saudi Med J* 2001; 22: 272-275.