



## The role of mediolateral episiotomy during operative vaginal delivery

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### ABSTRACT

The role of episiotomy with regard to prevention of anal sphincter injuries (OASIS) is under discussion. The recently published guideline of the WHO “Intrapartum care for a positive childbirth experience” states that the role of episiotomy during operative vaginal deliveries remains to be established. This guideline is based on the evidence coming from randomised clinical trials. However, since the turn of the century large observational studies have pointed out that adequately performed mediolateral episiotomies may play an important role in the prevention of OASIS during operative vaginal deliveries. In this paper we present this evidence and plead for a broader vision on, and use of other evidence than randomised clinical trials solely, the preventive role of mediolateral episiotomy with regard to the occurrence of OASIS.

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### Introduction

Recently, the World Health Organization (WHO) published their guideline “Intrapartum care for a positive childbirth experience” [2]. This extensive paper contains evidence based recommendations for women and their newborns for all stages of childbirth. This guideline contains a detailed chapter on care of second stage of labour in which several intrapartum techniques, e.g. perineal massage and warm perineal compresses to reduce the risk of severe perineal trauma or obstetric anal sphincter injuries (OASIS) are recommended.

In the guideline, the routine use of episiotomy is not recommended, nonetheless, the guideline development group determined that due to the lack of evidence with regard to a protective effect of episiotomy in general, the selective use of episiotomy was not endorsed either. The guidance states that the role of episiotomy in obstetric emergencies such as fetal distress requiring operative vaginal deliveries remains to be established, whereas the role of episiotomy in other indications for operative vaginal delivery was not addressed at all.

In the guideline the mediolateral episiotomy technique is recommended over the midline episiotomy, but no specific advice is given with regard to the angle of the mediolateral incision to the midline.

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As with the vast majority of the evidence used for this guideline, the evidence used for the chapter on episiotomy comes almost solely from randomized clinical trials (RCTs). However, this may cause a skewed view on this subject. An RCT may be the best way to compare two treatments for a certain condition, but episiotomy is not a treatment for impending OASIS.

In fact, it should be seen as a risk-modifying factor for the occurrence of OASIS. Given the fact that there is significant evidence from large observational studies [3–7] to support the use of mediolateral and lateral episiotomy during operative vaginal delivery, this type of evidence should be taken into account. As an operative vaginal delivery in itself is a major risk factor for OASIS, it is important to take active measures to mitigate such high risk.

Our aim was to review the scientific literature on the role of episiotomy in operative vaginal deliveries. As there have been considerable changes in birth practices over the years, we present the evidence generated after the year 2000. In this review article, we report and review the evidence focusing on episiotomy technique, characteristics and study design.

*“The achievement of a vaginal delivery at the expense of a woman’s long-term fecal incontinence is not an obstetric success”- JE Dickinson [1]*

## Mediolateral episiotomy in operative vaginal deliveries

### Evidence from national registries

The first large cohort study on this subject from a national registry was published in 2008 [3]. This study described the results of 21 254 women delivered with vacuum extraction and 7478 women delivered with forceps, derived from the Dutch National Obstetric Database from the years 1994 to 1995 containing almost 285 000 vaginal deliveries. In this cohort, the rate of OASIS during vacuum extraction was 9.4% without episiotomy and 1.4% with episiotomy. In forceps delivery, these rates were 22.7% and 2.6%, respectively. In the multivariate analysis, the calculated odds ratios were 0.11 (95% CI 0.09–0.13) for mediolateral episiotomy in vacuum extraction and 0.08 (95% CI 0.07–0.11) in forceps delivery. However, in this study no distinction was made between nulliparous and multiparous women.

After the publication of the Dutch study, four other studies [4–7] using national registries addressing this subject in nulliparous women have been published (Table 1)

The study of Gurol-Urganci et al from 2013 including 1.2 million nulliparous women who underwent their first vaginal delivery showed a lower incidence of OASIS with the use of mediolateral episiotomy in nulliparous women during both vacuum extractions and forceps deliveries [4]. The OASIS incidence during vacuum

extraction was almost three times lower when a mediolateral episiotomy was performed (2.3% versus 6.4%). In forceps deliveries, this difference was even more pronounced (6.1% versus 22.7%). The Royal College of Obstetricians and Gynaecologists (RCOG) Green-Top Guideline calculated the risk of OASIS from this cohort [8]. In vacuum extractions the odds ratio for OASIS was 1.89 (95% CI 1.74–2.05) times greater without episiotomy. In forceps deliveries, the odds ratio for OASIS was 6.53 times greater without episiotomy (95% CI 5.57–7.64).

The preventive effect of mediolateral episiotomy during vacuum extraction was confirmed in the study of Jangö et al from Denmark [5] although the actual incidence of OASIS was much higher in this cohort compared with other studies (Table 1). A major difference between the two studies was the actual rate of mediolateral episiotomy during vacuum extractions. In the Danish cohort, a mediolateral episiotomy was cut in only 28.7% of vacuum extractions compared to a mediolateral episiotomy rate of more than 70% of vacuum extractions in the studies from the UK and the Netherlands [4–6]. The suggestion that the protective effect of mediolateral episiotomy in vacuum extraction is associated with the actual rate of mediolateral episiotomies is also demonstrated by the results of a Dutch cohort study in 2018 [6] describing the results of more than 130,000 vacuum extractions. In this study, the OASIS incidence during vacuum extraction was 14.0% among women without episiotomy, and 2.5% with episiotomy. The rate of mediolateral episiotomy in the Dutch study was 87.3%. (Table 1). The observed OASIS incidence in forceps deliveries was 26.7% without episiotomy versus 3.4% with episiotomy, and the episiotomy rate was 93.4%. Moreover, multiparous women with operative vaginal delivery with episiotomy had a lower incidence of OASIS compared with women without episiotomy, 2.1% and 7.5% in vacuum extractions and 2.6 and 14.2% in forceps deliveries.

In Finland, lateral episiotomy is used traditionally. A study by Räisänen et al. based on data from the Finnish Medical Birth Registry, assessed 16 802 women delivered by vacuum extraction [7]. Nulliparous women with lateral episiotomy had a significantly lower incidence of OASIS (3.2%) compared with women without episiotomy (4.3%),  $p = 0.01$ . Episiotomy rate for nulliparous women was 84.9%. In multiparous women, OASIS rates with and without episiotomy were 2.2% and 0.8%, respectively ( $p = 0.002$ ). In multiparous women, 47.9% had an episiotomy. (Table 1).

In contrast to the European situation, midline episiotomy has been the preferred type of episiotomy in the USA. In 2015, Friedman et al analysed 7.1 million births from the United States over a 10-year period [9]. Although the type of episiotomy was not described, it can be assumed that the midline episiotomy was most prevalent in this dataset. Unfortunately, the outcomes for nulliparous and parous women were analysed together. Nulliparous women are at higher risk of OASIS and thus episiotomy is

**Table 1**  
Observational studies based on national obstetric databases.

Source	Gurol-Urganci 2013 N = 1.035.253 births	Räisänen, 2012 N = 189.834 births	Van Bavel, 2017 N = 1.534.850 births	Jangö 2015 N = 214.256 births
Type of delivery (N)	OASIS (UK) % (N) aOR (95% CI) Mediolateral “intent”	OASIS (FL) aOR (95% CI) Lateral “intent”	OASIS (NL) % (N) aOR (95% CI) Mediolateral “intent”	OASIS (DK) % (N) aOR (95% CI) Mediolateral “intent”
Forceps with epi	6.1%	NA	3.4%	?
Forceps without epi	22.7%	NA	0.09 (0.07–0.11)	?
Vacuum with epi	2.3%	3.2	26.7%	10.6%
Vacuum without epi	6.4%	0.54 (0.42 – 0.70)	0.14 (0.13–0.15)	0.60 (0.56 - 0.65)
NVD with epi	2.2%	4.3	14.0%	14.9%
NVD without epi	0.57 (0.51–0.63)	NA	NA	?
	3.4%	NA	NA	0.95 (0.89 - 1.02)
				?

more frequently cut. The incidence of a third degree tear was 3.3% and 1.1% for fourth degree tears in the entire population. In forceps deliveries, the OASIS incidence was 18.3% with and 19.3% without episiotomy. In vacuum deliveries, the incidence was 18.6% and 10.4%, respectively. Thus, in this cohort, midline episiotomy had no effect in forceps deliveries and was associated with a higher prevalence of OASIS compared to vacuum deliveries. This result confirmed earlier studies from single USA institutes in which midline episiotomy during operative vaginal delivery was associated with a significantly higher OASIS rates. However, compared to studies from the European continent where mediolateral episiotomies are predominantly used, the OASIS incidence in forceps deliveries with midline episiotomy was four- to eight-fold higher. The OASIS incidence in vacuum extractions with midline episiotomy was 8-fold higher compared with studies from the UK and the Netherlands and almost double the OASIS incidence reported in the Danish cohort.

#### *Evidence from systematic reviews*

The Cochrane review assessing the effect of episiotomy on the risk of OASIS uses the results of randomised controlled trials (RCTs) solely. As stated in the most recent Cochrane review on this subject of 2017, there were no RCTs that compared the effect of episiotomy versus no episiotomy on the rate of OASIS in operative vaginal deliveries [10]. However, the review included one RCT that compared routine versus restrictive use of episiotomy, which is, in our opinion, a comparison based on subjective decision-making [11]. The authors from the review concluded that there was no difference with regard to OASIS between the two policies but acknowledged that the trial with 175 women was underpowered to assess OASIS. Furthermore, the authors of the review pleaded that future trials on use of episiotomy in operative vaginal deliveries need better and standardized outcome assessment methods.

The Swedish Agency for Health technology Assessment published a systematic review in 2016 on anal sphincter injuries ([www.sbu.se/249E](http://www.sbu.se/249E)) [12]. The review concluded that there is strong scientific evidence that an episiotomy prior to instrumental deliveries (particularly vacuum) will reduce the absolute risk of OASIS by 7%, resulting in an odds ratio of 0.16 (95%CI 0.14–0.19). However, it is unclear which studies were used for this review.

In a systematic review and meta-analysis of 15 studies comparing no episiotomy with mediolateral or lateral episiotomy among nulliparous women delivered by vacuum extraction episiotomy significantly reduced the risk of OASIS by 50% (OR 0.53, 95% CI 0.37–0.77) [13]. When the studies included in this review were sub-analysed by episiotomy rate, it appeared that the protective effect of episiotomy seemed most pronounced when performed in more than 75% of vacuum-assisted deliveries (OR 0.37, 95% CI 0.15– 0.92).

Other reviewers suggested [14] that the effect of mediolateral episiotomy in vacuum deliveries differed with parity where they reported that although lateral and mediolateral episiotomies reduced while midline episiotomies increased the risk OASIS in nulliparous women, mediolateral episiotomy was associated with an increased risk for OASIS in parous women. However, it is important to highlight that two of the, more recent, large cohort studies [6,7] mentioned earlier were not included in this review.

#### *Evidence from randomised trials*

As stated earlier, to date there are no RCTs of episiotomy versus no-episiotomy in operative vaginal deliveries. Murphy et al reported on a pilot randomised trial of routine v restrictive episiotomy during operative vaginal deliveries [11]. Of the 317

eligible women, 200 were randomised to a policy of routine (in all cases) versus restrictive (only if tearing appeared imminent) use of episiotomy at operative vaginal delivery. While the OASI rate was 35% higher in the restrictive group than the routine group (10.9% v 8.1%), this was not statistically significant. Interestingly, the sample size for this study was in part based on an earlier study from one of the participating centers [15]. This study showed a 7.5% OASIS incidence during operative vaginal delivery with episiotomy and 2.5% where episiotomy was avoided. The authors calculated that a RCT would need recruitment of 8000 eligible women with 1600 being randomized. Furthermore, the predetermined indications for performing ‘routine’ (100%) and ‘restrictive’ (when tearing became imminent) were not strictly followed such that in vacuum deliveries 87% and 17% while in forceps deliveries 95% and 64% had an episiotomy in the routine and restrictive groups respectively. The large difference between the incidence of episiotomies in the restrictive groups in both types of operative vaginal deliveries demonstrates the difficulty of addressing both types of operative vaginal deliveries in one RCT. Indeed, the authors acknowledged that participating obstetricians were concerned about the validity of a RCT evaluating a surgical approach that is not dichotomized into two types of practice (episiotomy versus no-episiotomy), but based on subjective clinical judgment of likelihood of perineal tearing. Another possible limitation of this trial was that other episiotomy characteristics, such as the actual angle and length were not recorded.

Macleod published the results of a follow-up study of this RCT with a focus on maternal morbidity associated with operative vaginal delivery [16]. This study reported significantly higher incidences of perineal pain, stress urinary incontinence and psychological morbidity in the ‘restrictive’ episiotomy group in the postpartum period.

In an RCT from Israel a policy of standard care was compared with a policy of “no episiotomy” [17]. After one year enrolment, an interim analysis was performed and published. 120 women in the standard care group and 119 women in the “no episiotomy” group who delivered vaginally were analysed. There were no differences in OASIS rates between the groups when analysed by intention-to-treat. However, anterior vaginal tears were observed in 31% of women who had vacuum assisted deliveries without episiotomy compared to no such injuries among women with episiotomy. A crucial issue with this study though was the fact that there was no significant difference in episiotomy rates between the groups (episiotomy rates of 21.4% and 26.5% in the “no episiotomy” and the standard care groups respectively ( $p = 0.35$ )). The lack of difference between the groups could not be explained because of a lower than anticipated rate of episiotomies in the standard care group. Apparently, in daily practice participating physicians and midwives had difficulty to adhere to the protocol of no episiotomy despite extensive briefing prior to the trial. The authors state that this shows the difficulty of conducting trials designed to examine deviation from common practice. A phenomenon previously recognized in another RCT [18].

#### *Evidence from care bundles*

This type of evidence describes the effect of intervention programs that usually consist of more than one intervention to change standard care programs. Hirsch et al [AJOG 2008] described the results of an intervention program that consisted of lectures, distribution of articles and manuals, training of physicians, and prominent display of an instructional poster [19]. The program aimed to change, among other parameters, the preference of instrument for operative vaginal delivery from forceps to vacuum and the use of mediolateral episiotomy instead of midline

episiotomy. In the time periods studied, nine months before and nine months after the intervention program, the rate of “high-order lacerations” in operative vaginal delivery declined from 41% to 26% ( $p=0.02$ ). During this period the rate of use of vacuum delivery increased from 16% to 29% of operative vaginal deliveries ( $p=0.02$ ). The OASIS rate concurrent with episiotomy declined from 63% to 22% ( $p=0.003$ ) although there was a non-significant increase in medio-lateral episiotomy rate from 14% to 30% of all episiotomies.

In 2008, Laine et al introduced a care bundle for perineal protection in Norway to reduce incidence of OASIS [20]. This program consisted of four components during the last part of second stage of delivery when the baby’s head is crowning, namely, slowing the delivery of the baby’s head with one hand, supporting the perineum with the other hand and squeezing from the lateral parts of the perineum towards the middle with the index finger and thumb to lower the tension on the posterior fourchette and asking the woman not to push. While, the fourth part of the intervention was training in performing a technically correct episiotomy aiming to avoid midline cuts.

The incidence of OASIS during the period 2003–2005 was compared with the period 2008–2010. In nulliparous women with operative vaginal delivery, i.e. mainly vacuum delivery, the OASIS incidence was reduced from 11.1% to 3.8% ( $p<0.001$ ). Following the implementation of the intervention the episiotomy rate increased from 60.8 to 85.1% between the first and second triennial ( $p<0.001$ ). The incidence of OASIS in women without episiotomies during operative vaginal delivery remained fairly similar at 12 and 10.9% ( $p=0.64$ ). This suggests that an increase in the number of episiotomies or eventually an improvement in the technique of cutting an episiotomy was contributory to the reduction in OASIS.

#### *Angle of the episiotomy*

In Europe, the most common type of episiotomy performed is a mediolateral or lateral episiotomy. The former is angled away from the midline and aims to start at the 6 o’ clock position on the posterior fourchette, although this is difficult to accurately estimate at the time of crowning when an episiotomy is typically performed. A lateral episiotomy is still mediolateral in angulation, but aims to start off-center at the 7–8 o’clock or 4–5 o’clock position.

Kalis et al. first published data on the difference between the angle of the episiotomy when cut during crowning of the fetal head and the suture angle of the episiotomy immediately after delivery [21,22]. A 40° angle pre-marked episiotomy resulted in a suture angle of 22°, while a 60° pre-marked episiotomy resulted in a suture angle of 45°. This suggests a significant degree of perineal deformation during birth. Similar degrees of perineal distension were also observed in the opposite side of the episiotomy (intact side of the perineum), ruling out an effect of the episiotomy itself.

In an Irish study of mediolateral episiotomies, the absolute risk of OASIs was 10% with a suture angle of 25°, while this risk reduced by 50% for every 6° the episiotomy was angled away from the midline, and ultimately reduced to 0.5% with a 45° suture angle [23]. Nevertheless, a Norwegian study on this phenomenon showed that if the episiotomy angle becomes nearly horizontal (90°), the pressure on the perineum was not sufficiently relieved and OASIS incidence increased by 9-fold [24].

The RCOG has taken into account the significant perineal distension of 15–30° at crowning and recently updated its guideline. The recommendation is to cut the mediolateral episiotomy at 60° to the midline at the time of crowning to achieve a post-delivery angle of between 40–60°, as this angle has been found to be associated with the lowest incidence of third-fourth degree lacerations.

The Society of Obstetricians and Gynecologists of Canada has also recommended an ideal cutting angle of 60° in its guideline of 2015, and the American College of Obstetricians and Gynecologists guideline also alludes to this [25,26].

Van Roon observed that when using the EPISCISSORS-60™ (Gosport, United Kingdom), a fixed angle scissors enabling a cut at 60° to the anal midline, the OASIS incidence was significantly lower among nulliparous women with operative vaginal deliveries at two English Hospitals [27]. The OASIS incidence in operative vaginal deliveries was 14% lower after introduction of the epi-scissors (6.5% versus 5.6%) A non-significant increase in the absolute episiotomy rate from 87.4% to 89.5% was observed.

Similar OASI reductions have been described with an assured 60° episiotomy angle at two British Hospitals [28].

Divakova et al performed a systematic review and meta-analysis regarding the risk of OASIS when using Episcissors-60 [29]. When 797 patients who had episiotomies with Episcissors-60™ were compared to 1122 patients who had episiotomies with standard scissors, a significant reduction in OASIS was demonstrated: risk difference = -0.04 (95% CI = -0.07 to -0.01;  $p=0.005$ ,  $I^2=41%$ ). The number needed to treat was 25 (95% CI = 14–100) without an increase in episiotomy rate.

#### **Conclusions**

The evidence based on the corresponding results of large observational studies presented earlier warrants the liberal use of an adequate mediolateral or lateral episiotomy during operative vaginal delivery to reduce the risk for delivering women to sustain OASIS.

We concur that a randomized trial is the best type of study to evaluate the effectiveness of a treatment intervention in certain conditions. However, episiotomy in this context is not a treatment for OASIS but instead it is a risk modifying factor. We believe that this type of relationship is best addressed in well-designed observational studies similar to those currently relied upon to evaluate the impact of certain environmental, nutritional or social factors on population risk for developing cancer or heart disease. Moreover, conducting an episiotomy-related RCT without objectively ensuring that an appropriate episiotomy angle is cut, can introduce significant bias and hence adding to this ethical dilemma [30–32]. Lastly, as stated earlier, recruiting women having an operative vaginal delivery to an RCT evaluating the effect of episiotomy on OASIs risk where the intervention is dichotomized to being routine (100%) versus no episiotomy (0%) appears to be challenging.

We are aware that episiotomy in itself is a trauma to the perineum that needs surgical repair with possible long-term consequences. But the long-term consequences of OASIS, such as anal incontinence, are much more serious and very difficult to manage. Clearly, adequate training in the recognition of the degree of perineal trauma and to achieve the best possible surgical repair of any type of perineal trauma is mandatory. Previous studies conclude that women with OASIS experience more pain than women with episiotomy only [33,34]. Furthermore, as stated earlier Macleod reported higher perineal pain scores in women in the restrictive episiotomy group compared to the routine episiotomy group in OVD and Fodstad et al found that OASIS were a significant factor in delayed resumption of intercourse and dyspareunia at one year postpartum while there was no significant association with episiotomy [33]. Additionally, no episiotomy does not equate to no perineal trauma or no need for perineal suturing. Indeed, in the British cohort study of 1.2 million births, reduction of episiotomy rates from 19% to 15% resulted in an increase of second degree tears by 23% [4].

Therefore, the evidence coming from the presented observational studies provides in our opinion enough basis to recommend the liberal use of a mediolateral or lateral episiotomy cut at 60° to the midline when operative vaginal delivery is needed.

*“The protection of the perineum by episiotomy at delivery seems at first glance a paradox. How is it possible by incising the perineum to protect it from injury? . . . . .an incision to spare the tissue of the vaginal outlet must now be planned to protect them all, if not all, then the most important tissue (sphincter ani) . . . .this is accomplished only by the mediolateral incision”- Dale Martin, 1921 [35]*

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