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Review article

The use of Episissors-60 to reduce the rate of Obstetric Anal Sphincter Injuries: A systematic review

Jennifer Cole^{*}, Lauren Lacey, Supriya Bulchandani

University Hospital Coventry, Clifford Bridge Road, Coventry, UK

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ABSTRACT

Objectives: The aim of this systematic review is to evaluate the effect of Episissors-60, which were designed to improve the accuracy of episiotomies, on the rate of Obstetric Anal Sphincter Injuries.

Study design: This review is registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42018094935). A literature search of the PubMed, Embase and Cochrane databases was performed from inception to May 2018. All peer-reviewed studies evaluating the use of Episissors-60 in clinical practice and the resulting Obstetric Anal Sphincter Injury incidence were included. Data on study population demographics, incidence of Obstetric Anal Sphincter Injuries, rate of episiotomies and angle of episiotomy achieved while using the Episissors-60 were recorded.

Results: A total of seven studies were identified, five of which were included in the review. A total of 3509 women of whom 1050 had episiotomies performed. Included studies demonstrated that introduction of Episissors-60, when combined with other preventative measures including manual perineal support at delivery, can reduce Obstetric Anal Sphincter Injuries by up to 50%. In all studies, operators were able to consistently achieve post-suturing episiotomy angles of more than 40°. An increase in episiotomy rates, especially during spontaneous vaginal deliveries, was also reported.

Conclusion: The results of this systematic review support the use of Episissors-60, combined with other preventative measures, to reduce the incidence of Obstetric Anal Sphincter Injuries.

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^{*} Corresponding author.

E-mail address: jennifercole@doctors.org.uk (J. Cole).

Introduction

Obstetric Anal Sphincter Injuries (OASIS) are common and have been increasing over the last decade, from 1.8% in 2000 to 5.9% in 2012 [1,2]. These injuries are associated with significant morbidity, with 30–50% of women experiencing anal incontinence [2,3,4]. The OASIS care bundle has been designed to address this rising rate of OASIS and includes performing a mediolateral episiotomy, when indicated, at 45–60° from the midline [5]. It is the accuracy of the mediolateral angle that is crucial to its protective effect. The incidence of OASIS decreases by 50% for every 6° that the episiotomy is cut away from the midline, with a minimum incidence of 0.5% at a post-suturing angle of 43° [6–8]. The rate of OASIS then begins to rise, with episiotomy angles of greater than 60° leading to an increased risk of OASIS as it fails to adequately relieve the pressure on the perineum [6–8].

To ensure the desired post-suturing angle of 43° is achieved, the operator must take into account the curvature of the perineum as the episiotomy is performed while the perineum is distended by the fetal head. This results in a difference between the cutting and suturing angles, with an episiotomy performed at 45° achieving a post-suturing angle of 22–24° [6,7,9]. Therefore, to ensure a post-suturing angle of 43° the episiotomy must be performed at 60°. However, research has shown that only a minority of episiotomies are actually performed at the recommended angle, with fewer than 20% at an angle of 40–60° [6,7,9]. The Episcissors-60 have been designed to improve the accuracy of mediolateral episiotomies, with blades at a fixed angle to ensure a cutting angle of 60° when the guide arm is aligned with the anus, which should reduce the rate of OASIS. This systematic review aims to assess the effect of the use of Episcissors-60 on the rate of OASIS.

Methods

This study was designed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement and a prospective search and evaluation protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42018094935). A literature search of the PubMed, Embase and Cochrane databases was performed using the key terms episiotomy, Episcissors-60, episiotomy scissors and Obstetric Anal Sphincter Injuries (OASIS) from inception to May 2018. The reference lists of any identified studies were also reviewed for studies that potentially met the inclusion criteria. No language filters were applied to the search.

All peer-reviewed studies evaluating the use of Episcissors-60 in clinical practice and the resulting OASI incidence were eligible for inclusion. The primary outcome measure was the rate of OASIS. The secondary outcome measures were episiotomy angle achieved and episiotomy rates with the use of Episcissors-60.

All studies identified were independently reviewed in full by two researchers in accordance with the PRISMA statement to confirm eligibility for inclusion, any disagreements were resolved through discussion and involvement of a third reviewer where necessary. Studies that only used Episcissors-60 in a birth simulation model were excluded, as the primary outcome of this review is to examine the rate of OASI. Two reviewers, using the Cochrane risk of bias tool, independently assessed the risk of bias in each study. The quality of the studies was assessed using the Newcastle-Ottawa Scale, expressed as Agency for Healthcare Research and Quality (AHRQ) standards, (for non-randomised studies) and Jadad Scale (for randomised studies). As OASI is an acute outcome that occurs during childbirth the Newcastle-Ottawa Scale categories for length of follow-up were not relevant to this review.

Data from included studies were extracted using a structured, pre-designed proforma. Information on the sample population included in the study, incidence of OASIS, rate of episiotomies and angle of episiotomy achieved while using the Episcissors-60 was recorded. For the purposes of this review, only OASI rates in women who had an episiotomy were analysed.

Results

Seven potentially relevant studies were identified and underwent detailed review (Fig. 1). Two studies were excluded as one involved the use of Episcissors-60 in a birth simulation model and another recommended the use of Episcissors-60 to prevent OASI, but had yet to implement this intervention. Therefore, 5 studies (1 cluster randomised trial and 4 non-randomised studies) were included in the review, comprising a total of 3509 women, of whom 1050 had episiotomies performed (Table 1) [10–14].

Characteristics and methodological quality for the included studies are presented in Table 1. The randomised trial was considered to be of average quality due to its cluster-randomised design. Other included non-randomised studies had mixed methodological qualities. Nevertheless, exposed cohorts were generally representative of the maternity population. All studies included were subject to bias as it is not possible to blind observers to the intervention (Table 1).

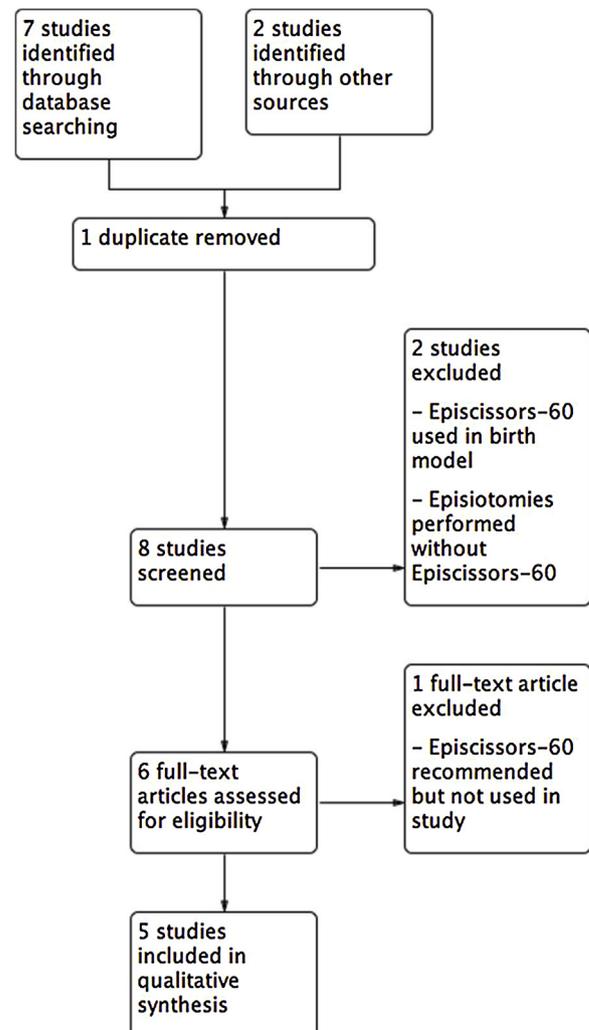


Fig. 1. Flow diagram of study selection.

Table 1
Summary of included studies.

Author	Freeman	Patel	Sawant	Van Roon	Mohiudin
Year	2014	2014	2015	2015	2018
Study design	Observational study	Observational study	Cluster randomised study	Observational study	Observational study
Sample size (n)	17	25	63 EP-60 n = 31 Control group n=32	838	2566
Study population	Single unit in UK	Single unit in India	Single unit in India	Two units in UK: Hinchingsbrooke and Poole	Two units in UK: Barnet and Royal Free London (RFL)
Inclusion criteria	Operative vaginal delivery (OVD)	Spontaneous vaginal delivery (SVD) Clinical indication for episiotomy	Nulliparous women Clinical indication for episiotomy	Nulliparous women Clinical indication for episiotomy	Nulliparous women Clinical indication for episiotomy
Exclusion criteria	None documented	None documented	None documented	None documented	None documented
Control/ comparator group	–	–	Episiotomy with Braun- Stadler scissors	Nulliparous vaginal births before introduction of EP- 60	Vaginal births before introduction of EP-60
Risk of bias	Moderate	Low	Low	Moderate	Moderate
Quality assessment NRS (AHRQ)	Poor	Poor	–	Good	Fair
Quality assessment RCTs (Jadad Scale)	–	–	2	–	–
Rate of OASIS [*]	n = 1 (5.8%)	n = 0	EP-60: n = 0 Braun-Stadler: n = 1 (3.1%)	Without EP-60: Total: n = 50 (6.3%) OVD: n = 37 (6.3%) SVD: n = 13 (6.25%) With EP-60: Total: n = 13 (4%) OVD: n = 12 (5.4%) SVD: n = 1 (1%)	Without EP-60: Total: OVD Barnet: n = 14 (6.3%) OVD RFL: - ⁺ SVD Barnet: n = 5 (6.6%) SVD RFL: - ⁺ With EP-60: Total: OVD Barnet: n = 2 (0.63%) OVD RFL: n = 3 (2.6%) SVD Barnet: n = 0 SVD RFL: n = 0 Note measured
Post delivery suturing angle	Mean: 42.7° SD = 7, 95% CI 28.8 – 46 Median 43°	Median: 50° SD = 3.5, IQR 48 – 45	EP-60: mean 40.6° SD = 5.7, 95% CI 38.6–42.6 Braun-Stadler: mean 28.3° SD = 5.6, 95% CI 26.3–30.3	Mean in SVD: 53° SD = 6.5, 95% CI 49–54 Mean in OVD: 52° SD = 9.6, 95% CI 49–54	
Episiotomy rate	–	–	–	Without EP-60: OVD: 583 (87.4) SVD: 208 (13.2%) With EP-60: OVD: 223 (89.5%) SVD: 98 (16.6%)	Without EP-60: OVD Barnet: n = 223 (85.6%) OVD RFL: - ⁺ SVD Barnet: n = 75 (16.2%) SVD RFL: - ⁺ With EP-60: OVD Barnet: n = 315 (91.3%) OVD RFL: n = 113 (87%) SVD Barnet: n = 130 (23.2%) SVD RFL: n = 97 (47.8%)

^{*} Rate of OASIS in women with an episiotomy.

⁺ Data not available.

Rate of OASIS with Episissors-60

Three of the included studies compared the incidence of OASIS between women who had an episiotomy performed using Episissors-60 with a control group. Two studies compared rates of OASIS in nulliparous women during both operative and spontaneous deliveries following the introduction of Episissors-60 along with other measures including antenatal perineal massage and perineal support at delivery as part of the SUPPORT training programme across four UK hospitals (Table 1) [10,11]. Mohiudin et al demonstrated a 73% overall decrease in OASIS in the larger of the maternity units studied following the introduction of the SUPPORT training programme and Episissors-60, resulting in a 2% OASI incidence rate ($p=0.001$) [11]. However, these figures include OASIS in women who delivered without an episiotomy. A comparison of OASI rate in women who delivered with an episiotomy before and after introduction of Episissors-60 provides a more accurate reflection of the impact of this intervention. Among women who had an operative vaginal delivery with an episiotomy, Mohiudin et al reported a 33% and

83% reduction in OASIS in the two maternity units studies ($p=0.4$ and $p=0.01$), which resulted in an OASI rate of 2.6% and 0.6% respectively [11]. The number of OASIS sustained during spontaneous vaginal deliveries with an episiotomy halved across both units studied ($p=0.03$ and $p=0.24$) [11]. As the authors studied the effect of both the introduction of the SUPPORT programme and Episissors-60 on OASI rates, it is not possible to determine how much of the reduction in OASIS can be attributed to Episissors-60.

The study by Van Roon et al also assessed the impact of the introduction of the SUPPORT programme and use of Episissors-60 on the incidence of OASIS [10]. The authors reported an 18% overall reduction among all nulliparous vaginal deliveries, with the incidence rate falling from 7.1% to 5.8% ($p=0.22$) [10]. Among women who had an operative vaginal delivery with an episiotomy, the authors report a 14% reduction in OASIS ($p=0.7$) following the introduction of Episissors-60 [10]. A statistically significant 84% reduction in OASIS was demonstrated in women who delivered by spontaneous vaginal delivery with an episiotomy ($p=0.04$) [10]. The study has similar limitations to that by Mohiudin et al, due to

the simultaneous introduction of other measure to reduce the incidence of OASIS along with Episissors-60.

A smaller study by Sawant et al cluster randomised nulliparous women into two groups; with one group using the Episissors-60 and another using standard episiotomy scissors to allow comparison of OASI rates [14]. Again, low rates of OASIS were reported with only 1 OASI in the control group ($n=1/32$) and none in the Episissors-60 group [14]. However, this study was not sufficiently powered to detect significant differences in OASI rates.

The two other studies included in this review reported the rate of OASI in a cohort of women who had episiotomies performed using Episissors-60 without a control group for comparison. Patel et al had no OASIS during the study period ($n=0/25$), while Freeman et al reported one OASI ($n=1/17$) [12,13].

Episiotomy angle achieved with Episissors-60

The post-suturing episiotomy angles achieved with Episissors-60 were measured in four of the included studies (Table 1). In all of these studies the authors reported an average post-suturing episiotomy angles of over 40° [10,12–14]. The use of Episissors-60 also resulted in 100% of midwives and 86% of doctors studied achieving the desired post-suturing episiotomy angle of 40 – 60° [10]. Sawant et al performed a comparison of episiotomy angles achieved using Episissors-60 with standard episiotomy scissors. In this study the mean post-suturing angle using standard episiotomy scissors was 28.3°, with the most acute episiotomy angle measured at 20° (range 20–45) [14]. Therefore, the use of Episissors-60 resulted in a statistically significant improvement in an operator's ability to perform an episiotomy at the desired angle to minimise the risk of OASI ($p = <0.0001$) [14].

Episiotomy rates

Two of the included studies analysed episiotomy rates before and after the introduction of Episissors-60 [10,11]. Both studies reported an increase in episiotomy rates following the introduction of Episissors-60, most notably during spontaneous vaginal deliveries. Mohiudin et al reported a significant increase of 43% in the number of episiotomies performed at spontaneous vaginal deliveries in nulliparous women ($p=0.005$) [11]. This finding is remarkably similar to that of van Roon et al, who demonstrated 47% increase in episiotomies in the same cohort in their hospital trust ($p=0.007$) [11]. More modest increases in episiotomy rates were seen in operative vaginal deliveries in both studies.

User satisfaction

Operator satisfaction with Episissors-60 was assessed using a 5-point Likert scale in two studies. Overall, feedback was very positive, with 84% rating the Episissors-60 as 'good' or 'very good.' [10] Furthermore, 88% 'agreed' or 'strongly agreed' that the scissors are easy to use [13].

Discussion

This systematic review summarises current evidence regarding the impact of the use of Episissors-60 on the incidence of OASIS. Results from four non-randomised studies and one cluster randomised study are presented; a total of 3509 women of whom 1050 had episiotomies performed. Included studies demonstrated that introduction of Episissors-60, when combined with other preventative measures including manual perineal support at delivery, can reduce OASIS by up to 50% [10,11,14]. In all studies, operators were able to consistently achieve post-suturing episiotomy angles of more than 40° [10,12–14]. An increase in episiotomy

rates, especially during spontaneous vaginal deliveries, was also reported [10,11].

This is the first systematic review on the role of Episissors-60 in preventing OASI. The strength of this review is consequent to a rigorous study selection, appraisal and data extraction methodology. All types of studies were eligible for inclusion, resulting in a larger, more varied sample, therefore strengthening the validity of this review.

The main limitation of this review is the lack of randomised controlled trials comparing Episissors-60 to standard episiotomy scissors available for inclusion. It is also important to note that two of the included studies did not include a control group for comparison. Therefore, despite both studies reporting a low incidence of OASI with Episissors-60, they failed to demonstrate whether this reflected a reduction in the OASI rate. Furthermore, another two studies implemented the SUPPORT training programme, which includes other preventative measures at the same time as the Episissors-60. This makes it difficult to determine what proportion of the effect on OASI rates is due to the Episissors-60 alone. Another limitation is the high level of heterogeneity between the included studies, which prevents the pooling of data to perform a meta-analysis. Finally, despite all types of study being eligible for inclusion the overall body of evidence for Episissors-60 remains limited.

The increasing rate of OASI has generated renewed interest in preventative measures. The effect of episiotomies on OASI rates has been controversial, however, recent evidence has demonstrated that restrictive use of mediolateral episiotomies has a protective effect. A recent meta-analysis suggested that a mediolateral episiotomy can reduce the risk of OASI by two-thirds (RR 0.67, 95% CI 0.49 – 0.92) [15]. The authors also found that an episiotomy can also have a protective effect on quality of life and pelvic floor symptoms at 12 months post-natal [15]. Other studies have demonstrated similar effects, with women delivering without an episiotomy 1.4 times more likely to have an OASI (95% CI 1.02–1.98) [16]. Furthermore, these findings are supported by national data, which found women who delivered with an episiotomy had the lowest risk of OASI [2].

However, it is the accuracy of the episiotomy angle that is crucial to its protective effect. The incidence of OASIS decreases by 50% for every 6° the episiotomy is cut away from the midline, with a minimum incidence of 0.5% at a post-suturing angle of 43° [6–8]. Therefore, the episiotomy should be performed to ensure a post-suturing angle of 45 – 60° [2,5,17]. Despite this, studies have shown that, using standard episiotomy scissors, less than 20% of obstetricians and midwives are able to perform an episiotomy to achieve the desired post-suturing angle [6,7,9]. This review has demonstrated that with the use of Episissors-60, 100% of midwives and 86% of obstetricians are able to achieve a post-suturing angle of 40 – 60° [18]. This finding explains the reduction in OASIS in studies following the introduction of Episissors-60.

The increased rates of episiotomies following the introduction of Episissors-60 noted in two of the included studies may also have contributed to the reduction in OASIS. Studies have demonstrated a significant correlation between increasing episiotomy rates and reduction in OASIS.¹⁵ The large increase in episiotomy rates in spontaneous vaginal deliveries may have significantly contributed to the reduction in OASIS demonstrated in this review, as OASI is 60% more common in nulliparous women who deliver vaginally without an episiotomy [1].

Conclusion

OASIS are relatively common, associated with significant morbidity and have been increasing over the last decade. It is therefore crucial to implement measures to reduce the incidence of

OASIS. This review has demonstrated that Episissors-60 are simple to use and significantly improve the accuracy of episiotomies, ensuring a post-suturing angle of 40 – 60°. The introduction of Episissors-60, when combined with manual perineal support, has been shown to significantly reduce the incidence of OASIS by up to 50%. Further research, in the form of an adequately powered randomised controlled trial is required to accurately assess the impact of Episissor-60 on OASI rates. However, the results of this systematic review would support the use of Episissors-60, as part of other preventative measures included in the OASI bundle, to reduce the incidence of OASIS.

Contribution of authorship

Study conception: SB; protocol design and data search, study selection and data extraction: JC, LL and SB. Production of final manuscript: JC, LL and SB.

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Disclosure of interests

None declared.

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