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ORIGINAL ARTICLE

Episcissors-60™ and obstetrics anal sphincter injury: a systematic review and meta-analysis

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Abstract

Introduction and hypothesis The National Health Service (NHS) in England has chosen the Episcissors-60™ as one of the products included in the NHS Innovation Accelerator programme. However, the evidence for its effectiveness is scanty. We therefore set out to systematically review the literature to compare risk of obstetric anal sphincter injury (OASI) in women who had undergone episiotomy with Episcissors-60™ versus those who had an episiotomy with other scissors.

Methods Electronic search was performed on the Healthcare Databases Advanced Search (HDAS) platform using the MEDLINE, EMBASE and CINHAL search engines up to September 2018. The search words used were 'Episcissors-60' or 'episcissors 60.' Studies were included if patients who had episiotomies with Episcissors-60™ were compared with parallel or historic patients who had episiotomy with other scissors. The only restriction used was "human" studies.

Results Of the initial 21 citations, 4 studies had enough information to be included in the meta-analysis. The number of study participants ranged from 63 to 4314. When comparing 797 patients who had episiotomies with Episcissors-60™ to 1122 patients who had episiotomies with other scissors, there was a significant reduction in OASI: 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). This was not associated with an increase in episiotomy rate.

Conclusions We reported the first systematic review on the effect of Episcissors-60™ on OASI rate. Although the studies are few, and of small size and low quality, the results are promising in terms of possible reduction in OASI.

Keywords Episcissors-60 · Episiotomy · Obstetric anal sphincter injury

Introduction

Obstetric anal sphincter injury (OASI) is the main cause of anal incontinence in young women. Anal incontinence has a significant negative effect on women's quality of life [1]. It is associated with postpartum sexual dysfunction [2], ongoing perineal pain [3] and psychological distress [4]. It also carries a significant financial burden, most of which is hidden, such as the cost of sanitary products, but some of it is traceable, such as the cost of medical and nursing care especially for the patients who end up with surgical interventions such as caesarean section to prevent further trauma to the anal sphincter or sphincter repair and neuromodulation to treat fecal incontinence. The environmental impact of incontinence and the sanitary products used by its sufferers are also attracting significant attention [5]. The relationship between episiotomies and risk of OASI has been the subject of academic interest, but the worldwide variation in episiotomy rates throughout history (22.0% in the UK in 2017 [6] compared with 11.6% in the USA in 2012 [7], 17.0% in Canada in 2007 [7], 4.9% in Denmark in 2010 [7], 24.1% in Finland in 2010 [7] and 10.5% in France in 2013 [7]) and the wide variation of OASI rate (3.5% in the UK in 2017 [6] compared with 4.4% in the USA in 2010 [8] and 1.04% in Germany in 2012 [9]) has made it

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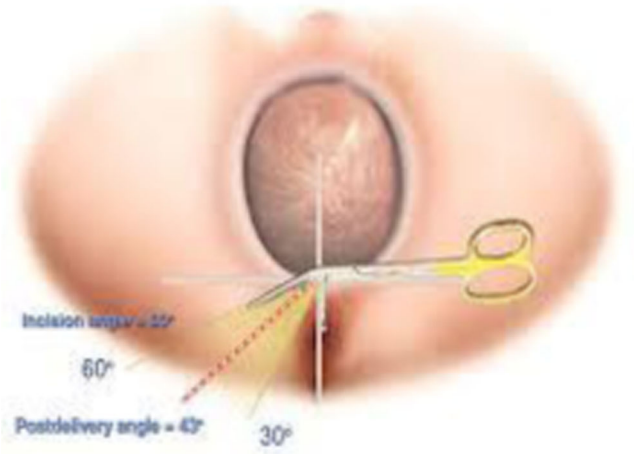
difficult to ascertain the exact nature of this relationship. Nonetheless, a systematic review in 2016 pooled data from seven studies and found a protective effect of mediolateral episiotomy (MLE) against OASI [10]. The Royal College of Obstetricians and Gynecologists in the UK has therefore reacted to the rise in OASI rate in England over the last 10 years by adopting measures based on a programme in Norway which led to 50% reduction in the OASI rate [11]. These measures include, but are not limited to, episiotomy at 60° from the midline when necessary. The current method used by most clinicians with regard to judging the episiotomy angle is "eyeballing" it. Many studies have demonstrated that the 60° angle is difficult to achieve even when practitioners were asked to draw it on a piece of paper in a simulation scenario. Post-delivery suture episiotomy angles < 30° or > 60° carry significantly higher risk of OASI [12]. To avoid human error in estimating the angle required for mediolateral episiotomies, the Episcissors-60™ (Picture 1) were developed (Medinvent Ltd., Romsey, UK): These are episiotomy scissors especially designed to attain a post-suturing angle between 40° and 60° and achieve a post-suture episiotomy 4.5 mm away from the midline [13].

In an early study, 17 women had an episiotomy during an instrumental delivery, the Episcissors-60™ delivered a post-delivery episiotomy angle between 30° and 60° consistently (median of 43°) [13]. Later, a before-after study assessed the effect of introducing Episcissors-60™ in two hospitals in the UK and showed that the majority of healthcare professionals achieved appropriate post-suturing episiotomy angles between 40° and 60° using Episcissors-60™ [14]. It also demonstrated a reduction in OASI in nulliparous women with spontaneous vaginal delivery, but this was associated with an increase in episiotomy rate [14]. Consequently, the National Health Service in England (NHS England) selected the Episcissors-60™ in its NHS Innovation Accelerator programme. NHS England's Innovation and Technology Tariff (ITT) was introduced to incentivize the adoption and spread of transformational innovation in the NHS. Obstetric units are allowed to claim a tariff from NHS England each time they cut an episiotomy with reusable Episcissors-60™ up to 20 times per pair of Episcissors-60™ they buy. This will enable them to them to recoup the cost of the Episcissors-60™ over time. Other examples of ITT themes include web-based applications for the self-management of chronic obstructive pulmonary disease and frozen fecal microbiota transplantation for recurrent *Clostridium difficile* infection (www.england.nhs.uk/ourwork/innovation/nia/). However, there still seems to be resistance to the universal adoption of the use of Episcissors-60™. Anecdotally, this has been blamed on the paucity of substantial evidence for its effectiveness. We therefore conducted a systematic review of studies reporting on the effect of Episcissors-60™ on the risk of OASI, episiotomy rate and achieving a post-delivery suture angle between 40° and 60°.



Picture 1 Episcissors-60™ (reproduced with permission from Medinvent Ltd.)

Materials and methods

This meta-analysis was performed in accordance with the PRISMA statement [15]. Ethical approval was not necessary.

Search strategy

The Healthcare Databases Advanced Search platform was used to conduct a comprehensive literature search of the MEDLINE, EMBASE and CINHAL databases up to September 2018. Our search strategy consisted of the words 'Episcissors-60' or 'episcissors 60'. The advanced search strategy was adapted to suit the databases being searched. The search was restricted to 'humans'. No language or age group restrictions were applied.

Study selection and data extraction procedures

The following process was used to identify eligible studies: the titles and abstracts of the citations identified by the electronic searches were screened and full text papers of potentially eligible abstracts were retrieved. Hand searching of reference lists of the articles was also performed to retrieve other articles that might have been missed by our search strategy. The manufacturing company of Episcissors-60™ (Medinvent

Table 1 Quality assessment of studies

Author, year, country	Study size ≥ 650 = 1 < 650 = 0	Generalizability of study sample Generalizable = 1 Not readily generalizable = 0	Comparator Contemporaneous = 1 Historic = 0	Total score
van Roon [14] 2015, UK	1	0 as reported on nulliparous women only	0	1
Sawant [16] 2015, India	0	0 as only one operator	1	1
Lou [17] 2016, UK	0	0 predominantly instrumental deliveries done by senior operators	0	0
Mohiudin [18] 2018, UK	1	0 data on primiparous patients	0	1

Ltd., Romsey, UK) was also asked to provide a list of any studies it was aware of, but had no further input into our study.

Inclusion criteria: Studies that fulfilled the following criteria were included:
Population: Pregnant women who had undergone mediolateral or lateral episiotomy.
Intervention: Mediolateral or lateral episiotomy with Episcissors-60™.
Comparator: Women who had undergone mediolateral or lateral episiotomy with any scissors other than Episcissors-60™.
Outcome: The primary outcome was rate of obstetric anal sphincter injury (OASI). Other outcomes such as episiotomy rate and post-delivery suture angle were examined as secondary outcomes, but were not essential for inclusion.
Study designs: All studies which reported two measurements of OASI rate, whether these measurements were for contemporaneous parallel groups (comparative studies) or for cohorts at two different time points (before-after and time series studies), were included in our review.

Our exclusion criteria were: case reports; commentaries and general reviews; overlapping publications from the same center; studies on midline episiotomy and case series studies which reported data on episiotomy using Episcissors-60™ without comparison with episiotomies with other scissors. Historic comparison was accepted such as before-after studies and time series analyses. For overlapping publications and presentations, only the most updated and comprehensive publication was retained. Two reviewers (OD and AK) independently assessed the full text of papers to determine if they met the above criteria. Any disagreements surrounding the eligibility of a paper were solved through either consensus or involvement of the third reviewer (PB). Unpublished data from audits presented in scientific meetings were included in our systematic review only if they was verified by the authors. The following information was collated: study characteristics, mode of delivery, episiotomy rate, number of patients with OASIS in patients who had a vaginal delivery and in patients who had an episiotomy, and post-delivery suture angle. We contacted primary authors via email for any further information that was required. If no reply was received, co-authors were contacted via email. If still no reply was received, a decision to include the study in the systematic review or in the meta-analysis was based on the available information.

Methodological quality assessment and data synthesis

The quality of all the papers fulfilling the inclusion criteria was assessed using a quality assessment tool which we designed and tailored to suit the majority of our studies (Table 1). The tool was based on National Heart, Lung and Blood Institute's tool for assessing the quality of before-after studies (https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools), but modified to suit our study. The studies were scored as follows:

Size: Studies which included ≥ 630 subjects, around 315 in each arm at a 1:1 ratio, were awarded a score of 1; others were awarded a score of 0. This number was based on the ability of the study to detect a 50% reduction in OASI from 5% to 2.5% with 90% power.

Generalizability: Studies which were readily generalizable as they did not super-select their population were awarded a score of 1, whilst other studies which selected especially high risk group were awarded a score of 0.

Comparator: Studies with a contemporaneous comparator group were awarded a score of 1, whilst studies with a historic comparator group were awarded a score of 0.

A random effect model was used to allow for the effect of other potential factors—such as previous OASI—on the risk of OASI. Heterogeneity was evaluated statistically using the I^2 test [19]. An I^2 value of < 25% was considered indicative of low heterogeneity, 25–75% was considered indicative of moderate heterogeneity and > 75% was considered indicative of high heterogeneity. Statistical analysis was performed using Review Manager 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration 2011).

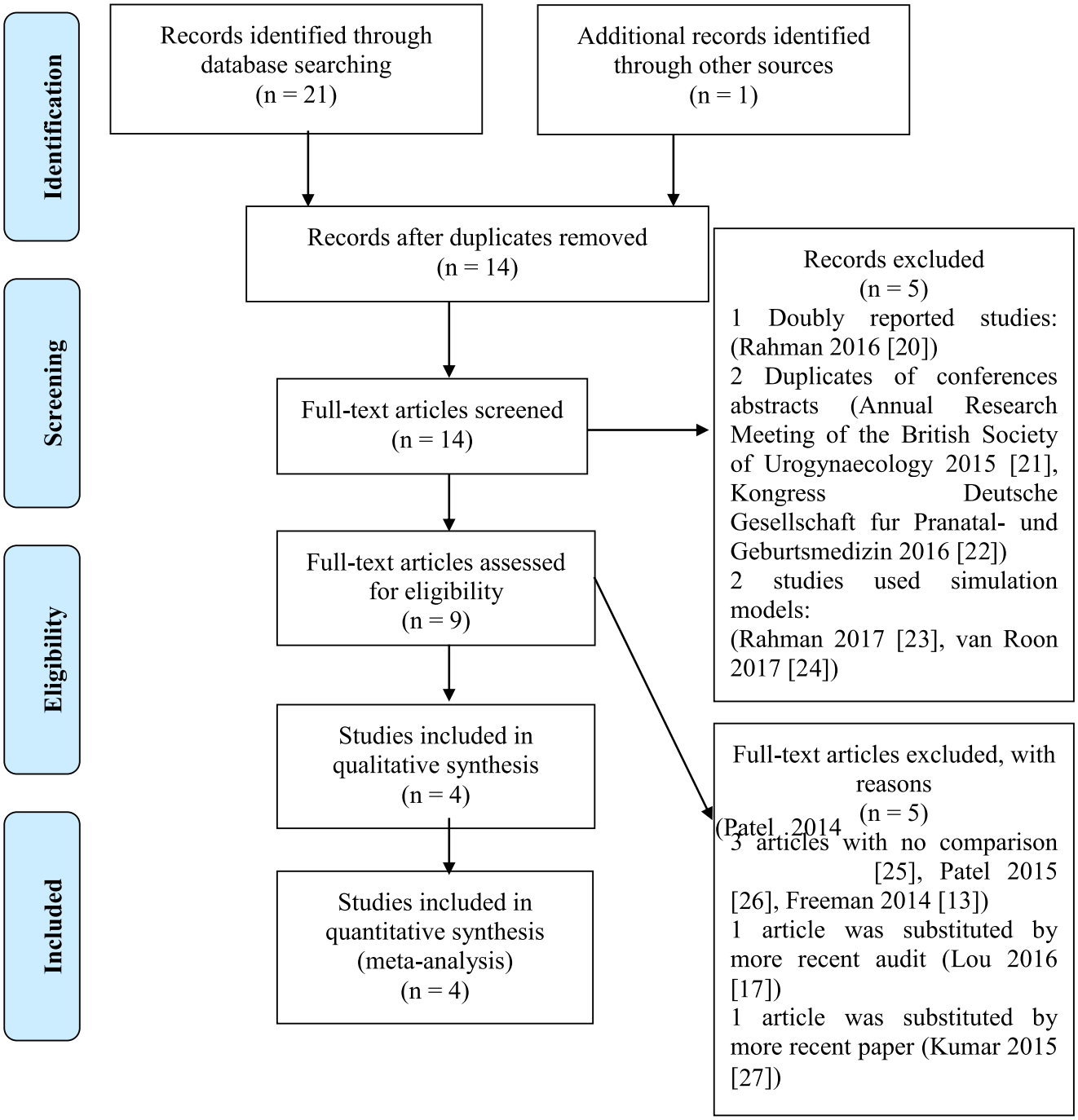


Fig. 1 PRISMA diagram

Table 2 Characteristics of studies included in the systematic review and meta-analysis

Author, year, country	Study design	Age	Sample size	Intervention	Control
van Roon [14] 2015, UK	Service evaluation programme	Not mentioned	4314	MLE	Episiotomy with normal scissors
Sawant [16] 2015, India	Randomized prospective study	Mean 24.8/ 25	63	MLE	Episiotomy with Braun-Stadler scissors
Lou [17] 2016, UK	Before-after study	Not mentioned	2509	MLE	Episiotomy with normal scissors
Mohiudin [18] 2018, UK	Time series analysis	Not mentioned	1630 (Barnet Hospital) 936 (RFL Hospital)	MLE	Episiotomy with normal scissors

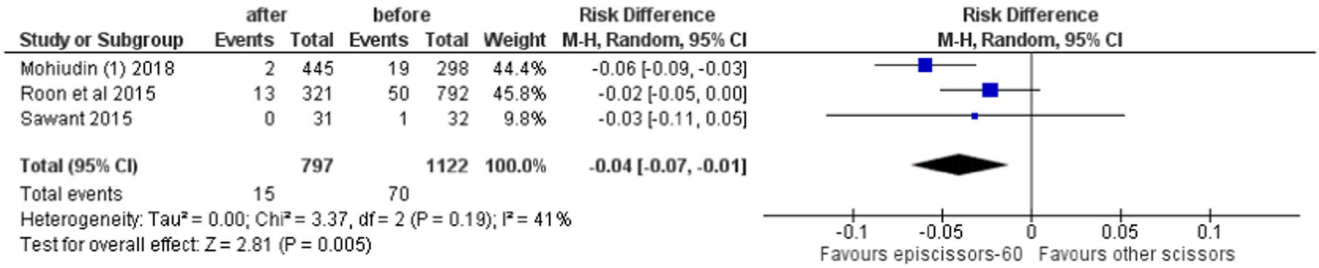


Fig. 2 The risk difference of obstetric anal sphincter injury in deliveries with episiotomy when episiotomy is done with Episcissors-60™ compared with other scissors

Results

Twenty-one studies were initially identified. After exclusion of duplicates and irrelevant studies, four citations were included in our systematic review and had enough information to be included in our meta-analysis. The PRISMA diagram in Fig. 1 summarizes the identification of citations through to inclusion in the review. Three studies were reported on in fully published articles and could be described as time series analyses, before-after studies of obstetric units and a randomized trial [14, 16, 18]. One study was published as an abstract only and was a before-after study [17]. Further information was obtained from one of the senior co-authors of this abstract.

Table 2 summarizes the characteristics of the studies included in this review. Only one study compared post-delivery suture angle before and after the introduction of Episcissors-60™, while others just measured the angle after using Episcissors-60™. Studies by Van Roon et al. [14], Sawant and Kumar [16] and Lou et al. [17] did not comment on study funding, while the study by Mohiudin et al. [18] declared no funding for their study.

For the outcome of OASIs in deliveries with episiotomies, when three studies were pooled together [14, 16, 18], there was a significant reduction in risk of OASIs when Episcissors-60™ were used (15/797 = 1.88%) compared with when other scissors were used (70/1122 = 6.23%). Figure 2 demonstrates the risk difference (RD) in favour of Episcissors-60™ (RD = −0.04; 95% CI = −0.07 to −0.01; $p = 0.005$, $I^2 = 41\%$). This gives a number needed to treat of 25 (95% CI = 14–100).

For the outcome of OASIs in the total number of vaginal deliveries, when three studies were pooled together [14, 17, 18], there was a significant reduction in risk of OASIs in units where Episcissors-60™ were used (125/3483 = 3.58%) compared with units where other scissors were used (295/4668 = 6.31%). Figure 3 demonstrates the risk difference in favour of Episcissors-60™ (RD -0.02; 95% CI = −0.04 to −0.01; $p = 0.002$, $I^2 = 59\%$). Figure 4 describes a 12° difference in the episiotomy angles between the two groups based on one study.

For the outcome of episiotomy rate, when three studies were pooled together [14, 17, 18], there was no significant difference between units which used Episcissors-60™ (829/3171 = 26.14%) and units which used other scissors (1160/4044 = 28.68%). Figure 5 demonstrates the pooled data (RD = 0.03; 95% CI = −0.04–0.10; $p = 0.44$, $I^2 = 92\%$). None of the studies scored 3 out of 3 on our quality score; therefore, no subgroup meta-analysis was undertaken. When the analysis was re-done calculating the risk ratio (RR) instead of risk difference (RD), the effect of Episcissors-60™ on OASI in deliveries with episiotomies lost its statistical significance (RR = 0.26; CI = 0.05–1.45; $p = 0.12$; $I^2 = 75\%$), but the protective effect was retained in the total number of vaginal deliveries (RR = 0.58; CI = 0.38–0.87; $p = 0.01$; $I^2 = 71\%$).

Discussion

The protective effect of Episcissors-60™ against the risk of OASI was evident in our meta-analysis in the total number of deliveries as well as in the number of deliveries with

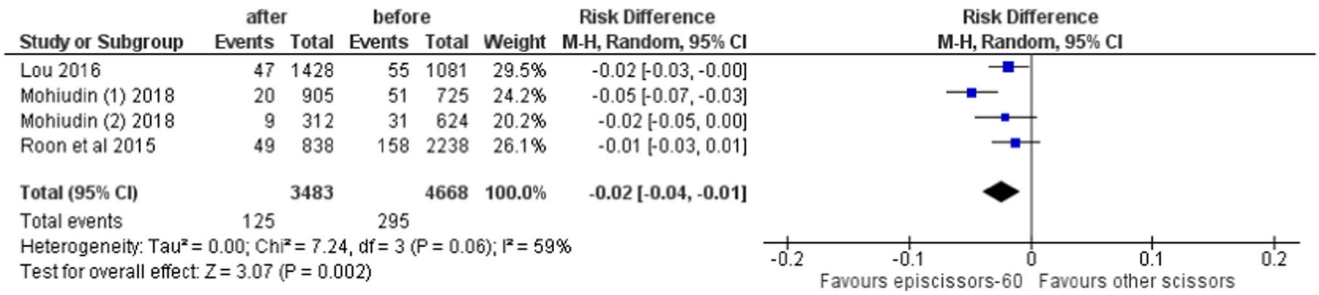


Fig. 3 The risk difference of obstetric anal sphincter injury in vaginal deliveries in units when Episcissors-60™ are used compared with when other scissors are used

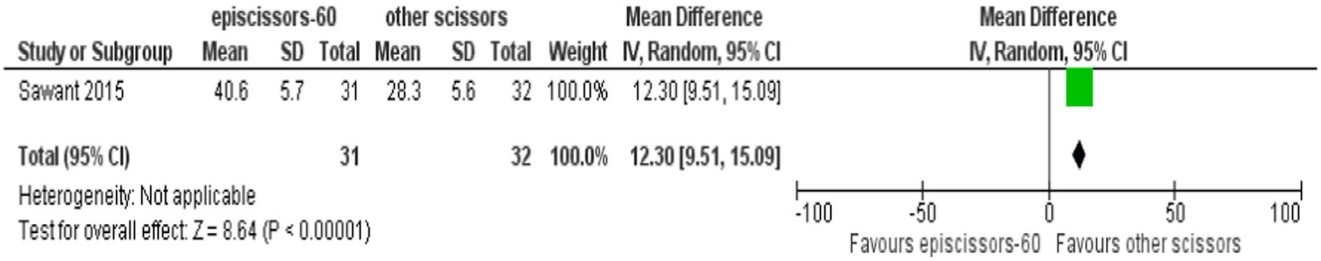


Fig. 4 Difference in post-suture episiotomy angle between episiotomies done with Episcissors-60™ compared with other scissors

episiotomies. This was achieved without a rise in episiotomy rate, which suggests that this protective effect is a genuine rather than proxy effect. We conducted an extensive search strategy without language restrictions. We also contacted the manufacturing company; therefore, we do not think we have missed any publications. We followed an a priori protocol and used valid data synthesis methods. We used the random effects model to compensate for the different biases introduced by the non-randomized studies included and to reduce the risk of over-exaggeration of the effect size of intervention [28]. Authors of studies were contacted if necessary and data were checked before inclusion. Most studies did not provide details on the post-delivery suture angle before the introduction of Episcissors-60™ to the obstetric units; therefore, only one study was included in our post-delivery suture angle meta-analysis.

It is important to recognize that a meta-analysis can only be as good as the studies it includes. The studies in our meta-analysis varied between low to moderate quality. There were no high-quality randomized controlled trials and some of the sample sizes were very small. The reason for this is that the Episcissors-60™ device is a relatively new one and was only introduced into practice in 2014 [13]. Therefore, the possibility of bias related to the observational nature of the studies included is a valid criticism. The main source of potential bias in studies of interventions is the Hawthorne effect. The mere introduction of a measure with the aim to reduce OASI could make operators feel they are being monitored and hence make them more alert and result in a reduction of OASIs [29]. Usually this effect is temporary and after a while the incidence of OASI would go back to baseline. None of the studies included in our review provided a multi-point longitudinal time series analysis. Long-term studies on the other hand risk the introduction of other variables. Therefore, the best way to overcome this effect and other confounders is a randomized controlled trial (RCT), but as blinding is impossible in this situation, even this design may not be bias free; operators who learn to use the Episcissors-60™ are likely to learn to cut episiotomies at 60° even when not using the Episcissors-60™, thus reducing the ability to detect a difference between the two scissors. One way to overcome this is to do a cluster RCT in which obstetric units are randomized into immediate or delayed adoption of Episcissors-60™. This will minimize the effect of most confounding variables. Another valid criticism of our results is the moderate heterogeneity of the results as measured by the I^2 test. We still believe that pooling the data was appropriate as the populations studied were similar. The protective effect of the Episcissors-60™ in all vaginal deliveries retained its significance when risk ratios were calculated instead of risk differences; this was not the case for vaginal deliveries with episiotomies only. This points to a possible bias similar to what is discussed above..

Although the number of episiotomies which needed to be done with Episcissors-60™ to avoid one OASI was 25 (95% CI = 14–100) according to our review, the health economic argument is still justifiable. Reduction in OASI has multiple health benefits. In addition to improvement in quality of life and the financial savings which would result from avoiding expensive life-long treatment such as neuromodulation, it has the potential to result in future reduction in the elective caesarean section rate. This not only strengthens the cost-effectiveness case for adopting the use of Episcissors-60™, but also brings with it all the obstetric benefits associated with a reduced caesarean section rate [30].

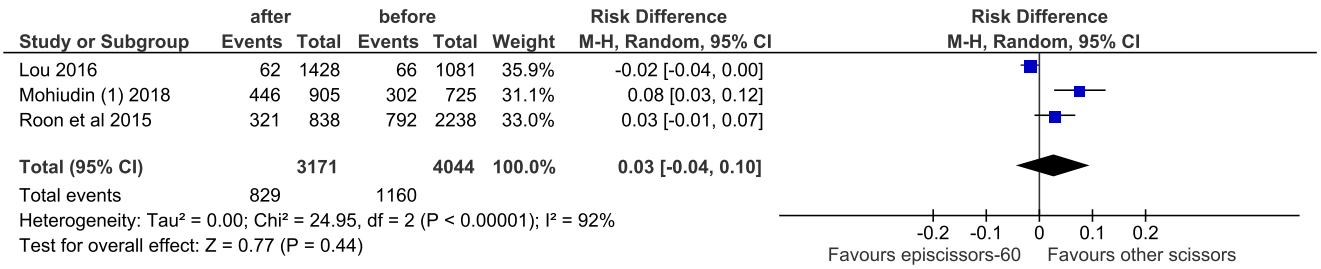


Fig. 5 Episiotomy rate before and after introduction of Episcissors-60™ in obstetric units

Conclusion

We reported the first systematic review on the effect of Episcissors-60™ on the OASI rate. Although the studies are of small size and low quality, the results are promising in terms of a possible reduction in OASI. We believe consideration should be given to the design of future studies to generate stronger evidence.

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Compliance with ethical standards

Conflicts of interest Olga Divakova: None.
Aethele Khunda: Educational travel grant from Medronic plc.
Paul Ballard: None.

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