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Review article

Obstetric anal sphincter injury events prior and after Episissors-60 implementation: A systematic review and meta-analysis

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ABSTRACT

Objective: To assess the effect of Episissors-60 upon obstetric anal sphincter injuries (OASIS) reduction in nulliparous women.

Study design: Independent literature search for relevant studies was performed up to 30th May 2021 on five databases: Embase (OVID), MEDLINE (R) (OVID), CAB Abstracts (OVID), ClinicalTrials.gov, and Google Scholar. The primary outcome was to assess OASIS events prior and after Epi-60 implementation in clinical practice in natural births (NB), whilst secondary outcomes included overall operative vaginal delivery (OVD) %/spontaneous vaginal deliveries (SVD) % deliveries, episiotomy rates and operator satisfaction. All included studies (retrospective, prospective and time-series) examined the effect of Episissors-60 implementation upon observed OASIS %.

Results: A total of 14,027 nulliparous females were included in the meta-analysis. Overall, study heterogeneity was high at I^2 : 79% with collectively fair quality of studies, as assessed by the Newcastle-Ottawa scale. Overall, this analysis highlights significant differences of OASIS events that might suggest their implementation as standard practice [RD -0.02 , 95% CI -0.03 to 0.00 ; $P = 0.03$].

Conclusion: The present analysis highlights significant differences of OASIS events pre- and post- Epi-60, that may suggest Episissors-60 implementation as standard practice. Nonetheless, to ensure data integrity, well reported observational studies and robust randomized controlled trials (RCTs) are required prior to introduction of Epi-60 as standard episiotomy technique in clinical practice.

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Introduction

Obstetric anal sphincter injuries (OASIS) present a significant complication that may occur during vaginal delivery [1]. OASIS may be interchangeably referred to as third- and fourth-degree perineal tears, which involve the anal sphincter, and in severe cases, may extend to the anal mucosa. OASIS represent a principal risk factor of bowel incontinence in parous women in the long term while contributing to short-term morbidity, due to wound breakdown, infection, and perineal pain [2,3]. Overall, OASIS risk may reach up to 6.3 %, of which a 5.7% reflects the risk of OASIS in prims. The risk for parous women with no previous OASIS falls at 1.5 % [4]. Consequently, OASIS incidence extends beyond the pathological spectrum, with detrimental effects upon women's quality of life [5]. Other risk factors include birthweight greater than 4 kg, shoulder dystocia, occipito-posterior position, prolonged second stage of labour and operative vaginal delivery (OVD) with forceps carrying a greater risk of OASIS than ventouse [6]. The OASI care bundle was designed in 2016 to address the alarming rates of OASIS by improving awareness regarding OASIS injuries. Among bundle suggestions was episiotomy completion, when required, at 60° mediolateral angle at crowning from the midline, supporting manually the perineum at the time of delivery and performing a systematic rectal examination to detect non-visible initially, perianal tears. This initiative was implemented in 16 maternity units across the UK from 2016 to 2018 [7] with promising results [0.3% decrease of OASIS post-bundle implementation, $p = 0.03$] [8].

Among the key factors in reducing OASIS is the angle of episiotomy [9]. The incidence of OASIS has been shown to reduce by 50% for every 6° of the episiotomy angulation away from the midline, whilst the safe zone of post-delivery sutured angle has been deemed at 40–60°. An incision angle of 60° is required to achieve a post-delivery sutured angle of 45° due to the increasing perineal distension at crowning [10].

Episcissors-60 were devised with a marker guide limb pointing towards the anus to ensure an angle of 60° between the scissor blades and the guide limb and avoid operator dependent decision making during the episiotomy [11]. Given the limited period of time that Episcissor-60 implementation has been available in clinical centres and consequently reflected in the literature body, here we present a contemporary meta-analysis of the effect of Episcissors-60 upon OASIS reduction in nulliparous women. The primary outcome was to assess OASIS events prior and after Epi-60 implementation in clinical practice in natural births (NB), whilst secondary outcomes included overall OVD%/spontaneous vaginal deliveries (SVD) % deliveries, episiotomy rates and operator satisfaction.

Materials and methods

Search strategy and selection criteria

A systematic literature review was conducted according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Fig. 1) [12].

Independent literature search for relevant studies was performed up to 30th May 2021 on five databases: Embase (OVID), MEDLINE (R) (OVID), CAB Abstracts (OVID), ClinicalTrials.gov, and Google Scholar. Additional records were identified through other sources, including Research Square and MedRxiv. The MedRxiv

search was simplified according to database search functionality. The references of the included studies were scrutinized for additional relevant studies. Search limitations included human participants and English language articles. The following search term was used in OVID: (Episcissors-60 and episiotomy).mh,tw,ab,hw,kw. AND (OASIS OR Obstetric anal sphincter injury).mp. limit to (English language and humans). The same search strategy was adapted for the remaining databases.

Inclusion and exclusion criteria

All included studies (retrospective, prospective and time-series) examined the effect of Episcissors-60 implementation upon observed OASIS %. Restrictions included English language and human. No geographical, age or gender restrictions were applied. Full-text exclusion criteria were: No comparison but only reporting of OASIS upon Episcissors-60 implementation. Excluded studies and justifications are recorded in Table S1.

Data extraction

After removing duplicates, citations were screened by title and abstract, then full texts were appraised to determine their eligibility by three authors (GK, SK, OT) (Fig. 1). Two authors (GK, SK) independently conducted the abstract and full text screening. Disagreements were resolved by a consensus meeting. Peer-reviewed full-text papers that reported mortality outcome were selected.

Data from each article was extracted by two authors (SK, GK) and validated independently by a third researcher (OT): (1) Total number of participants, (2) Number of participants and % treated with episiotomy before (N^1) and after (N^2) implementation of Episcissors-60, (3) Total % [x/n] of OASIS injuries per group (N^1 , N^2), (4) Age, (5) BMI, (6) Gestational age, (7) Weight at birth.

Outcomes

The primary outcome of this study was to identify the benefit of implementation of Episcissors-60 in clinical practice in respect to OASIS events. Secondary outcomes included the identification of Episiotomy % and overall % OASIS injuries in the included studies.

Quality assessment

Quality of the included studies were assessed by three independent reviewers (GK, SK, OT) using the Newcastle-Ottawa Scale (NOS) for observational studies [13]. Bias analysis was conducted via the Cochrane recommended tool (RevMan V. 5.4). Studies were considered to be high quality if they had a NOS score ≥ 6 . Adequate follow-up was considered to be of low risk for all studies given the immediate nature of OASIS injuries.

Data analysis and meta-analysis

Clinical, study context and design were compared and in those where studies were considered suitably homogeneous for pooling [14]. The meta-analysis was conducted by computing the risk difference (RD), random effects (RE) from the original data using the Haensel-Mantel method with Review Manager (RevMan) v5.4 software using a random-effect model. Statistical heterogeneity was quantified using I^2 statistics and Cochrane Q tests. Asymmetry was assessed by funnel plot, and asymmetry was assessed formally

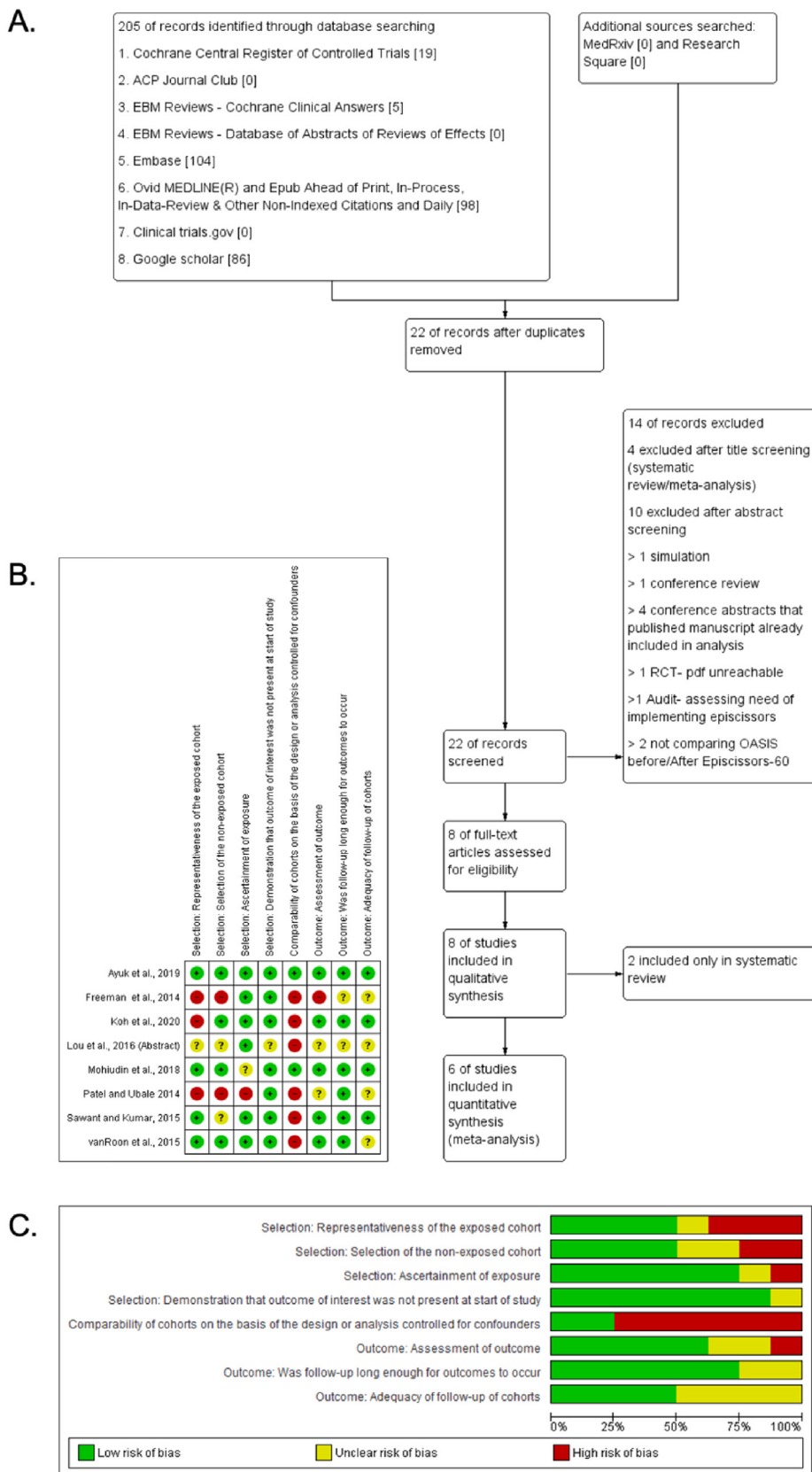


Fig. 1. PRISMA diagram and risk of bias assessment. (A) PRISMA Flow chart (B) Risk of Bias Summary (C) Risk of Bias Graph, per Newcastle-Ottawa Scale, summative percentages across all included studies.

by rank correlation test (Begg's test; RevMan V. 5.4) [15]. Sensitivity analyses were not feasible, given the underreporting of demographic parameters of patient populations in the included studies.

Results

Initial search retrieved 205 results. A total of 22 studies remained after removal of duplicates. We identified 8 studies eligible for full-text screening. A total of 7 studies and one conference abstract remained [11,16–22], all of which were included in the systematic review and six in the meta-analysis [16–21] (Fig. 1A; Table S1). Due to the lack of available RCTs, studies examining the effectiveness of Episissors-60 in the context of OASIS injuries, were assessed by the NOS tool for quality assessment. One study [21] was highlighted as high risk of bias given the incomplete data. One study was considered of good quality [20] whilst the remaining of fair. Given that demographic data of included patients were not reported, consequently assessment of confounders was not feasible (Fig. 1B, Fig. 1C).

Study characteristics

A total of 14,027 nulliparous women were included in the meta-analysis. Two studies were retrospective [19,20]; two prospective [16,17] and two were reported as time-series [18,21]. All included studies were conducted in a UK hospital setting, with the exception of two [17,22]. Nonetheless, the ethnicity of the participants was not reported in any of the studies. One study [22] reported that the use of Episissors-60 resulted in a postdelivery suture angle of 50°; a finding that was observed only across spontaneous delivery patients [N = 25] undergoing episiotomy. One study [6] reported a mean post-delivery angle of $42.4 \pm 7^\circ$ degrees in operative vaginal delivery patients requiring episiotomy. Furthermore, this study reported that 88% of clinicians agreed that the Episissors-60 were easy to use.

The OASI bundle was not co-assessed in any of the studies, either due to the included study preceding the implementation of the OASI bundle or due to hospital exclusion from the respective Episissor-60 reporting study [20]. All studies, with the exception of one [20], failed to report significant demographic variables affecting OASIS outcomes including patients' age and BMI, gestational age, birth weight, duration of labour. One further study reported the mean age of participants at 25 [17] (Table S2). A total of 66.43% (SD: 17.62) underwent spontaneous vaginal deliveries (SVD) pre-Episissors-60 implementation; while 70.62% (SD: 16.05) post-Episissors-60. A 24.13% (SD: 8.53) underwent operative vaginal deliveries (OVD) pre-Episissors-60 implementation and a 26.38% (SD: 10.48) (Fig. 2). Differences between the two groups, namely SVD % and OVD %, pre- and post- Episissors-60 introduction to clinical practice were not found to be significant (Fig. 2). The percentage of episiotomy in all natural births (SVD and OVD) that underwent episiotomy before and after the introduction of Episissors-60, did not significantly differ statistically, eliminating proxy effects upon final outcome (Fig. S2).

Meta-analysis

Collectively, studies favored the use of Epi-60 in view of less OASIS events (RD -0.02 , 95% CI -0.03 to 0.00 ; participants = 14027; studies = 6; $p = 0.03$). Overall, study heterogeneity was high at I^2 : 79% (Fig. 3, Subgroup 1.1.1; Fig. S3). Subgroup analysis, excluding high RoB studies [19,21] eliminated statistical significance ($p = 0.13$) of OASIS outcome (RD -0.02 , 95% CI 0 – 0.04 to 0.01 ; participants = 9137; studies = 4) (Fig. 3, Subgroup 1.1.2). Studies with weight < 8 were excluded in the consequent subgroup

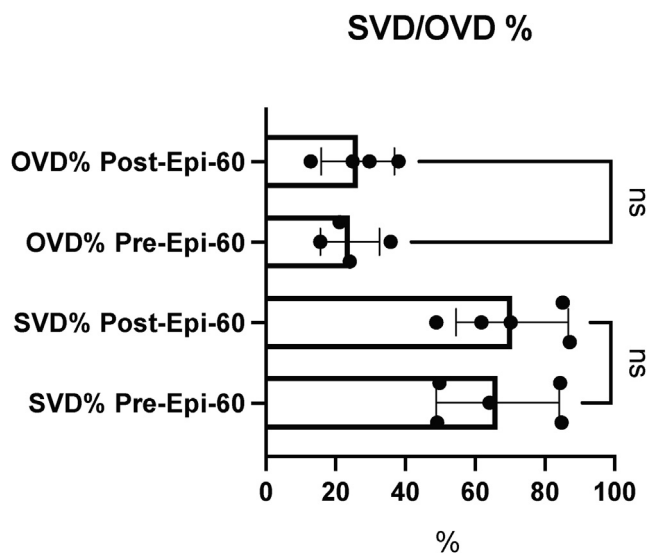


Fig. 2. Overall percentage of episiotomy in OVD and SVD before and after Episissors-60. Data were analyzed by ANOVA t -test. P values ≤ 0.05 were considered not significant.

analysis, aiming to identify sources of increased heterogeneity, a subgroup that favored the use of Epi-60 (RD -0.01 , 95% CI -0.02 to 0.00 ; participants = 13093; studies = 4, $p = 0.13$) (Fig. 3, Subgroup 1.1.3). Overall, this analysis does highlight significant differences of OASIS events that might suggest their implementation as standard practice, a finding that did not stand in terms of statistical significance in subgroup sensitivity analysis.

Discussion

A total of 8 studies were included in the systematic review. A total of 14,027 nulliparous females (SVD and OVD), from 6 studies, were included in the meta-analysis. Overall study RoB was deemed fair with only two studies of good quality [18,20] heterogeneity was deemed high (I^2 66%). Studies seemed to favor the use of Epi-60 in view of less OASIS events (RD -0.02 , 95% CI -0.03 to 0.00) in a total of 14,027 patients, a finding which was found to be statistically significant ($p = 0.03$), in line with previous, smaller sample meta-analysis [23] and systematic review [24]. A finding that did not hold statistical significance in subgroup sensitivity analysis including only low RoB studies, or significant weight studies (weight > 8).

The majority of studies failed to report patient and birth variables that may significantly alter rates of OASIS, such as patient ethnicity, age and BMI, gestational age and birth weight, duration of labor [1]. None of the studies included centers where the OASI bundle was concurrently implemented, consequently the analysis for positive synergistic effects between simultaneous OASI bundle and Epi-60 based episiotomy implementation, was not possible. Furthermore, whilst one study [11] reported operator satisfaction at 88%, an outcome which was not explored in other studies, it has to be mentioned the inherent bias of this study, given that the authors were also the creators of Epi-60. On the other hand, none of the studies included patient-reported experience, an outcome which would be of great significance in view of Epi-60 inclusion in standard practice. Another variable of interest, that has not been reported consistently across studies, would be the level of experience of the operator. We may consider that in complex patient demographics, Epi-60 may be of benefit especially in the hands of colleagues in the early stages of their training.

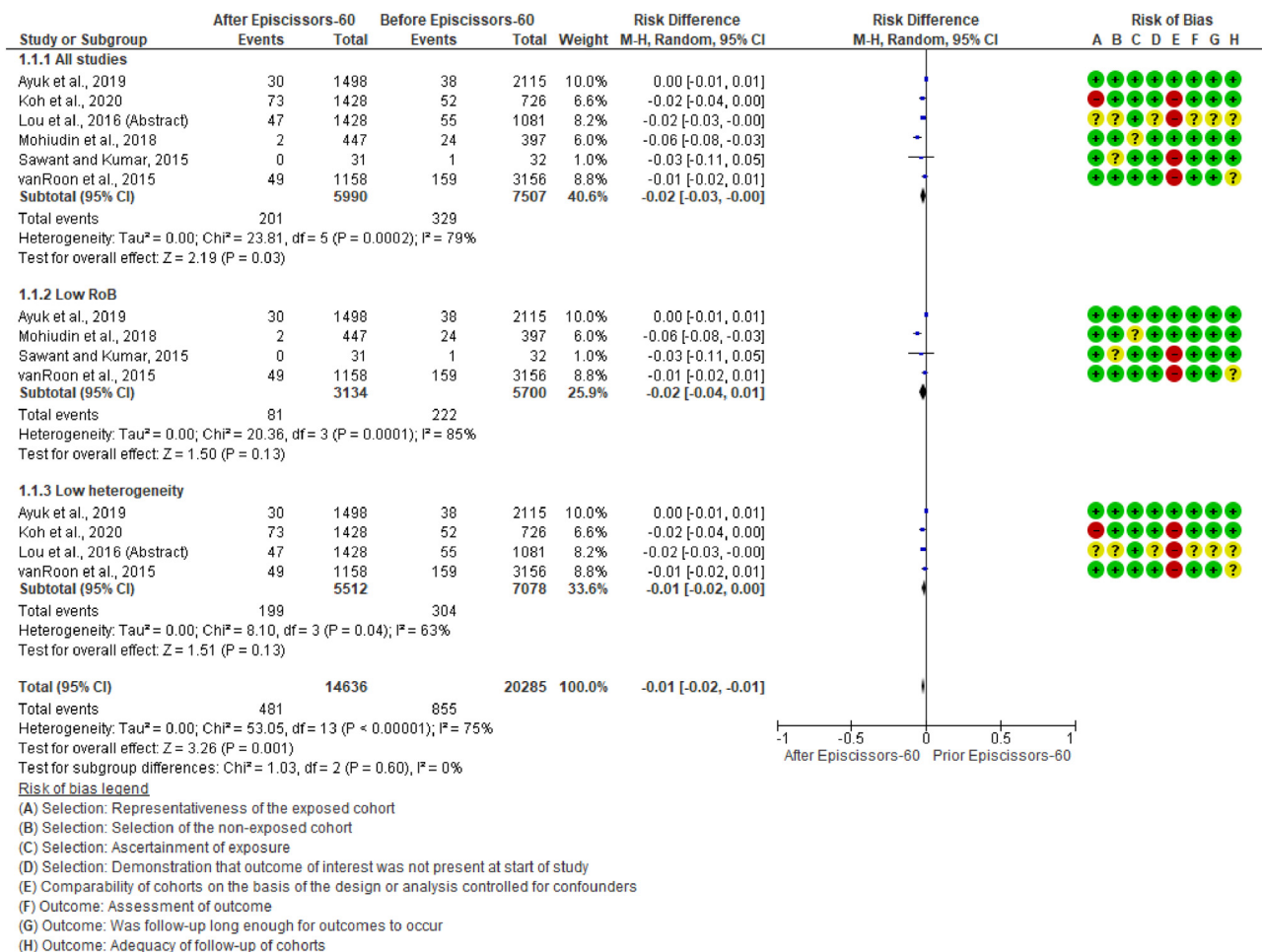


Fig. 3. Forest plot of comparison: Episissors-60 vs. other approaches and OASIS events. Forest plot 1.1.1 included all studies, 1.1.2 the studies that scored as low RoB, 1.1.3 included studies with low heterogeneity.

Strengths

Our study benefits from a contemporary, robust systematic search with published and unpublished data sought to minimise publication bias. Thorough search across five databases was performed to identify suitable papers alongside the formulation of inclusion and exclusion criteria. In comparison to a previous meta-analysis on this topic [23], where search was conducted in September 2018, this study offers a contemporary search (30th May 2021) along with an extended database inclusion. Three authors critically appraised the manuscripts according to the Newcastle-Ottawa standardised scale, to strive for consistency.

Limitations and implications for future research

In light of the recent integration of Epi-60 in an increasing number of UK hospitals, robust RCTs are necessary to offer further insight in a standardised setting, of the Epi-60 benefits in relation to patient outcomes. Importantly, patient demographics, labour variables and patient reported outcomes are fundamental in conducting robust sensitivity analyses to delineate Epi-60 protective effect against OASIS events. Additionally, whilst clinically important, the putative synergistic effects of OASI bundle and Epi-60 cannot be assessed given the current body of literature. Consequently, due to the overall poor quality of some of the included studies, results should be interpreted with caution.

Conclusion

The present analysis highlights significant differences of OASIS events pre- and post- Epi-60, that may suggest Episissors-60 implementation as standard practice. Nonetheless, to ensure data integrity, well reported observational studies and robust RCTs are required prior to introduction of Epi-60 as standard episiotomy technique. As per NICE guidelines [25], while Episissors-60 show promise for safe mediolateral episiotomy completion, up-to-date evidence support statistically significant benefit in the context of OASIS events.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejogrb.2021.08.030>.

References

[1] Keriakos R, Gopinath D. Obstetric anal sphincter injuries. *J Acute Dis* 2015;4 (4):259–65.

- [2] Kumar R, Ooi C, Nicoll A. Anal incontinence and quality of life following obstetric anal sphincter injury. *Arch Gynecol Obstet* 2012;285(3):591–7.
- [3] Marsh F, Lynne R, Christine L, Alison W. Obstetric anal sphincter injury in the UK and its effect on bowel, bladder and sexual function. *Eur J Obstet Gynecol Reprod Biol* 2011;154(2):223–7.
- [4] Jha S, Parker V. Risk factors for recurrent obstetric anal sphincter injury (rOASI): a systematic review and meta-analysis. *Int Urogynecol J* 2016;27(6):849–57.
- [5] Meyer I, Richter HE. Impact of fecal incontinence and its treatment on quality of life in women. *Womens Health (Lond)* 2015;11(2):225–38.
- [6] RCOG Greentop guideline 29: The Management of Third and Fourth-Degree Perineal Tears. 2015. Available from: <https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-29.pdf> [accessed May 28 2021].
- [7] Bidwell P, Thakar R, Sevdalis N, Silverton L, Novis V, Hellyer A, et al. A multi-centre quality improvement project to reduce the incidence of obstetric anal sphincter injury (OASI): study protocol. *BMC Pregnancy Childbirth* 2018;18(1):1–11.
- [8] Gurol-Urganci I, Bidwell P, Sevdalis N, Silverton L, Novis V, Freeman R, et al. Impact of a quality improvement project to reduce the rate of obstetric anal sphincter injury: a multicentre study with a stepped-wedge design. *BJOG* 2021;128(3):584–92.
- [9] Eogan M, Daly L, O'Connell PR, O'Herlihy C. Does the angle of episiotomy affect the incidence of anal sphincter injury? *BJOG* 2006;113(2):190–4.
- [10] Kalis V, Landsmanova J, Bednarova B, Karbanova J, Laine K, Rokyta Z. Evaluation of the incision angle of mediolateral episiotomy at 60 degrees. *Int J Gynaecol Obstet* 2011;112(3):220–4.
- [11] Freeman RM, Hollands HJ, Barron LF, Kapoor DS. Cutting a mediolateral episiotomy at the correct angle: evaluation of a new device, the Episissors-60. *Med Devices (Auckl)* 2014;7:23–8.
- [12] Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Syst Rev* 2015;4(1):1–9.
- [13] Peterson J, Welch V, Losos M, Tugwell PJ. The Newcastle-Ottawa scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. Ottawa: Ottawa Hospital Research Institute; 2011.
- [14] Chapter 24: including non-randomized studies on intervention effects. Training. [cochrane.org; 2021 Available from: https://training.cochrane.org/handbook/current/chapter-24](https://training.cochrane.org/handbook/current/chapter-24) [accessed May 28 2021].
- [15] Begg CB, Mazumdar M. Operating characteristics of a rank correlation test for publication bias. *Biometrics* 1994;50(4):1088–101.
- [16] van Roon Y, Kirwin C, Rahman N, et al. Comparison of obstetric anal sphincter injuries in nulliparous women before and after introduction of the EPISCISSORS-60™ at two hospitals in the United Kingdom. *Int J Women's Health* 2015;7:949–55.
- [17] Sawant G, Kumar D. Randomized trial comparing episiotomies with Braun-Stadler episiotomy scissors and Episissors-60™. *Med Devices (Auckl)* 2015;8:251–4.
- [18] Mohiudin H, Ali S, Pisal PN, Villar R. Implementation of the RCOG guidelines for prevention of obstetric anal sphincter injuries (OASIS) at two London hospitals: a time series analysis. *Eur J Obstet Gynecol Reprod Biol* 2018;224:89–92.
- [19] Koh LM, van Roon Y, Pradhan A, Pathak S. Impact of the EPISCISSORS-60 mediolateral episiotomy scissors on obstetric anal sphincter injuries: a 2-year data review in the United Kingdom. *Int Urogynecol J* 2020;31(9):1729–34.
- [20] Ayuk P, Farnworth A, Rees J, Khunda A, Edmundson D, Raheja V, et al. Obstetric anal sphincter injuries before and after the introduction of the Episissors-60: a multi-centre time series analysis. *Eur J Obstet Gynecol Reprod Biol* 2019;241:94–8.
- [21] Lou YY, Thakar R, Sultan AH, Ajay B. Does Episissors-60™ reduce the incidence of obstetric anal sphincter injuries (OASIS)? *BJOG* 2016;123:51.
- [22] Patel RP, Ubale SM. Evaluation of the angled Episissors-60® episiotomy scissors in spontaneous vaginal deliveries. *Med Devices (Auckl)* 2014;7:253–6.
- [23] Divakova O, Khunda A, Ballard PA. Episissors-60™ and obstetrics anal sphincter injury: a systematic review and meta-analysis. *Int Urogynecol J* 2020;31(3):605–12.
- [24] Cole J, Lacey L, Bulchandani S. The use of episissors-60 to reduce the rate of obstetric anal sphincter injuries: a systematic review. *Eur J Obstet Gynecol Reprod Biol* 2019;237:23–7.
- [25] Episissors-60 for mediolateral episiotomy. NICE. 2021. Available from: <https://www.nice.org.uk/about/what-we-do/research-and-development/research-recommendations/mtg47/1> [accessed 29 May 2021].