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REVIEW ARTICLE

Episcissors-60 for Mediolateral Episiotomy: Evaluation of Clinical and Economic Evidence to Inform NICE Medical Technologies Guidance

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Abstract

Obstetric anal sphincter injury (OASI) occurs in 2.9% of all vaginal births in the UK and can result in faecal incontinence. Where there is a clinical need for episiotomy, OASI can be minimised by accurate selection of the optimum angle of mediolateral episiotomy. Episcissors-60 are adapted surgical scissors incorporating a guide-limb to help achieve an accurate angle of mediolateral episiotomy. The ability of Episcissors-60 to reduce OASI by preventing inaccurate visual estimates of episiotomy angles was considered by the National Institute of Health and Care Excellence (NICE) as part of the Medical Technologies Evaluation Programme (MTEP). NICE concluded that Episcissors-60 shows promise for mediolateral episiotomy both in terms of clinical effectiveness and potential cost savings, but that there was not enough evidence to support routine adoption into the NHS at this time. NICE MTG47 recommends that key gaps in the evidence including patient-reported outcomes and the addition of Episcissors-60 to care bundles be addressed through research with specific focus on potential equality considerations.

Key Points for Decision Makers

National Institute of Health and Care Excellence (NICE) concluded that Episcissors-60 show promise for mediolateral episiotomy, but there is currently not enough evidence to support the case for routine adoption in the National Health Service (NHS). Research is recommended to address uncertainties about the efficacy and safety of using Episcissors-60.

Because not much good evidence is available, NICE recommends that new studies are done to determine with more certainty whether Episcissors-60 are better than standard scissors, when used with other best-practice care measures to prevent obstetric anal sphincter injury (OASI).

1 Introduction

The paper is part of a series that provides insight into the development of National Institute for Health and Care Excellence (NICE) Medical Technologies Guidance (MTG) [1]. NICE MTG makes recommendations on new or innovative

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medical devices or diagnostics. The aim of the guidance is to support adoption of clinically effective and cost saving technologies in the UK National Health Service (NHS).

This paper summarises Cedar's assessment report [2] and discusses how it was used to inform the recommendations of NICE MTG 47 on Episcissors-60 for mediolateral episiotomy [3]. Cedar is a healthcare technology research centre formed through collaboration between Cardiff and Vale University Health Board and Cardiff University.

1.1 Background to Technology and Application

Episiotomy is an incision made to the tissue around the vaginal opening to assist safe delivery of the baby, where there is difficulty delivering the baby's head through the vaginal opening, at the crowning stage. Episiotomy is intended to prevent serious perineal tears that can lead to obstetric anal sphincter injury (OASI) which occurs in 2.9% of all vaginal births in the UK and can result in faecal incontinence [4]. The NICE clinical guideline CG190 'Intrapartum care for healthy women and babies' recommends that an episiotomy should be performed where there is a clinical need, such as instrumental birth or suspected foetal compromise, and that episiotomy should not be performed routinely during spontaneous vaginal birth [5]. The guideline also recommends that an episiotomy should use a mediolateral technique encompassing an angle of between 45° and 60° from the vertical axis [5]. There is evidence that achievement of an optimal angle within this range reduces the incidence of OASI, and also that doctors and midwives fail to achieve the optimal angle of episiotomy by visualisation alone [6].

The 2019 National Maternity and Perinatal audit reported that out of 400,386 women in England who had a vaginal, cephalic delivery of a singleton baby at term, 21.6% had an episiotomy. Of 20,150 women in Wales, 21.1% had episiotomy [7]. A systematic review and meta-analysis of a large number of women undergoing vaginal birth, most of whom were nulliparous, concluded that mediolateral episiotomy has a beneficial effect in prevention of OASI [8]. In 150,068 nulliparous/multiparous births with episiotomy, the rate of OASI was 1.8%, and in nulliparous births with episiotomy the rate of OASI was 2.1% [8]. Therefore mediolateral episiotomy retains some risk of OASI.

Episcissors-60 are adapted surgical scissors, available as either a reusable or disposable, single use medical device, for performing episiotomy. The scissors have 5-cm-long blades and the key component is a guide-limb mounted at the blade pivot point and angled at 60° from the blades. During episiotomy the doctor or midwife aligns the guide limb in the vertical axis and this aims to ensure that the correct angle of episiotomy is achieved, preventing inaccurate visual estimation of the angle and reducing the incidence of OASI. Episcissors-60 are available with straight handles or angled handles for ergonomic handling, but in either case the guide limb is angled at 60° from the blades.

1.2 Decision Problem (Scope)

The scope of NICE MTG is defined by NICE in the form of a PICO table (population, intervention, comparator, outcomes; plus cost analysis and subgroups to be considered). In its evidence submission, the company must keep within the scope of the evaluation or provide a rationale for any variance.

1.3 Population

The population included women who have a clinical need for an episiotomy, including instrumental deliveries in cases of suspected foetal compromise.

1.4 Intervention

The intervention was defined as being reusable Episcissors-60.

1.5 Comparator

The comparator was standard reusable or standard disposable episiotomy scissors.

1.6 Outcomes

The outcomes defined in the scope included procedural outcomes such as device-related adverse events, incidence and severity of OASI, complication rates (wound breakdown, infections, faecal incontinence and postpartum haemorrhage), ease of use, operator learning curve, cost of complications, post-delivery suture angles, length of episiotomy and post-delivery distance from midline. Patient-specific outcomes included length of stay and quality of life.

1.7 Equality and Diversity

Women of Asian family origin may be more at risk of OASI due to a shorter perineal body length. The National Maternity and Perinatal Audit reports that 12.4% of births in England were to women of Asian ethnicity [9]. One retrospective cohort study in California ($n = 22,741$) reported an increased risk of OASI in Asian women compared with White women (adjusted odds ratio [aOR] 2.31; 95% confidence interval [CI] 1.99–2.69) [10]. A second cohort study ($n = 32,653$ births) in Australia reported an increased risk of OASI in South Asian (aOR 2.6; 95% CI 2.2–3.3) and South East/East Asian women (aOR 2.1; 95% CI 1.7–2.5) compared with White women [11]. The National Maternity

and Perinatal Audit did not report the incidence of OASI by ethnicity [9].

2 Cedar's Review of the Evidence

The company, Medinvent Ltd, provided an evidence submission to NICE presenting the available clinical and cost evidence, alongside a de novo cost model produced by the company. Cedar's assessment report aimed to provide the NICE Medical Technologies Advisory Committee (MTAC) with a balanced and independent appraisal of the evidence surrounding the use of Episcissors-60 for mediolateral episiotomy [2].

2.1 Review of Clinical Effectiveness Evidence

To ensure that all relevant literature had been identified and submitted by the company, Cedar undertook its own literature search across 10 databases, using a range of free-text terms and subject headings. Following study selection against the Scope document, Cedar considered that five published studies [12–16] and four unpublished studies [17–20] were relevant to the decision problem. Of the published studies, one was a cohort design [15], two were before and after studies [13, 16] and two were case series [12, 14]. The unpublished studies comprised of a before and after study [17] and a case series [20], however there were insufficient details for two studies [18, 19]. The unpublished before and after study conducted in the North East of England [17] has since been published in a peer review journal with no substantial changes [21]. Cedar assessed the quality of the evidence using GRADE software [22]. This showed that the quality of the published studies was low, with a high risk of bias; there was insufficient information to assess the unpublished studies. Seven studies were conducted in the UK [12, 13, 16–20] and two in India [14, 15]. In the published studies, patient numbers ranged from 17 [12] to 2566 [13].

The evidence considered by Cedar indicated that use of Episcissors-60 resulted in episiotomy post-suture angles within the safe range recommended by NICE guidance [5]. Individual study outcomes and results are presented in Table 1. In addition, the Cedar performed meta-analysis using Cochrane Rev Man software [23]. Pooled analysis conducted by the Cedar of five studies [13, 15–18] suggests no significant risk difference (RD) for OASI rate in women who had an episiotomy with Episcissors-60 compared with standard episiotomy scissors (RD − 0.02; 95% CI − 0.05 to 0.01; $p = 0.14$, Fig. 1). The Cedar's pooled analysis of two studies [13, 16] indicates that Episcissors-60 as part of a bundle of care may significantly reduce OASI rates in women who have an episiotomy (RD − 0.04; 95% CI − 0.08 to − 0.00; $p = 0.03$), though the heterogeneity between the studies remained high ($I^2 = 70\%$) (Fig. 2).

Two studies reported that following introduction of Episcissors-60, the rate of episiotomy increased by 11% overall [16] and 15% overall [13], while one unpublished study [17] reported no change in the rate of episiotomies with the introduction of Episcissors-60. Two clinical experts, consulted as part of the NICE process, suggested that it is possible that the introduction of Episcissors-60 might result in a behaviour change with clinical staff; one clinical expert reported a small increase in episiotomies since the introduction of Episcissors-60 and two clinical experts indicated that the introduction of Episcissors-60 has increased awareness of the need for episiotomies and appropriate technique.

2.2 Safety Outcomes

Cedar did not identify any adverse events specifically related to the use of Episcissors-60. It was noted that all reusable scissors have the potential to become blunt over time and need regular resharpening. However re-usable Episcissors-60 are being phased out and disposable versions introduced, therefore the issue will not be relevant.

2.3 Review of Economic Evidence

One non-peer reviewed report [24] was identified, presenting a return on investment calculation. The company concluded that it did not contain sufficient information and that a de novo model was required. The Cedar agreed with their assessment.

2.3.1 Episcissors-60 Model Structure

The model structure is a simple decision tree with arms for Episcissors-60 and standard scissors (Fig. 3). Each arm has branches for OASI repair or no OASI repair. The time horizon is 1 year, so no discounting was applied and the perspective is NHS.

2.3.2 Key Assumptions

The key assumptions in the accepted base model are:

- The cohort in the model is 94,000 women having episiotomy.
- The cost per use of standard episiotomy scissors is based on the cost of standard reusable scissors from the NHS supply chain (data commercial in confidence).
- The cost per use of Episcissors-60 is £16 giving a cost per birth of £2.40 (Company submission).
- The cost of OASI repair based on NHS improvement costs is £1956 [25].

Table 1 Study outcomes and results

Study	Rate of OASI	Post-delivery suture angle	Length of episiotomy	Perineal body length (PBL)	Ease of use	Barriers to use
Freeman et al. [12] UK Case series (proof of concept study) $N = 17$ women giving birth	$N = 1$ patient sustained an OASI (grade 3a)	Mean post-delivery angle: 42.4 ± 7° Median post-delivery angle: 43° (95% CI 38.8–46)	Not reported	Not reported	Ease of use of the instrument as $N = 10$ 'strongly agree' $N = 5$ 'tend to agree' $N = 1$ 'neither agree nor disagree' $N = 1$ 'strongly disagree'	Not reported
Mohiudin et al. [13] UK Before-and-after study $N = 2566$ nulliparous women	Primiparous OVD Hospital 1: OASI decreased by 33% from 5.6 to 4.2% ($p = 0.4$) Hospital 2: 73% proportional decrease in OASI from 9.6 to 2% ($p = 0.001$) Primiparous SVD Hospital 1: OASI decreased by 51% from 5.5% to 2.3% ($p = 0.03$) Hospital 2: not reported	Not reported	Not reported	Not reported	Not reported	Not reported
Patel and Ubale [14]	$N = 0$	Median post-delivery angle: 50° (SD 3.5°)	Not reported	Not reported	Not reported	Not reported
Sawant and Kumar [15] India Cohort study $N = 63$ nulliparous women undergoing episiotomy for indications such as prolonged second stage of labour, instrumental delivery and foetal distress	Episcissors-60 = 0 Standard scissors = 1 (grade 3)	Mean post-delivery suture angle was significantly different between the groups ($p < 0.0001$) Episcissors-60: 40.6° (range 30–50; IQR 35–45; SD 5.7; 95% CI 38.6–42.6) Standard scissors: 28.3° (range 20–45; IQR 25–30; SD 5.6; 95% CI 26.3–30.3)	Episcissors-60: 47.2 mm (95% CI ± 3.5) Standard scissors: 40 mm (95% CI ± 1.9; $p < 0.001$)	Not reported	Not reported	Not reported

Table 1 (continued)

Study	Rate of OASI	Post-delivery suture angle	Length of episiotomy	Perineal body length (PBL)	Ease of use	Barriers to use
Van Roon et al. [16] UK Before-and-after study $N = 838$ nulliparous women	14.2% reduction in OASI in nulliparous OVDs given episiotomies 12/223 (5.4%) compared with 2014 (37/583 [6.3%]) $p = 0.7$; relative risk 1.18 84% reduction in OASI in nulliparous SVDs (1/98 [1%]) compared with 2014 (13/208 [6.25%]) ($p = 0.04$) 18% reduction in OASI in nulliparous (SVD + OVD) vaginal deliveries (49/838 [5.8%]) overall compared with 2014 (159/2238 [7.1%]); $p = 0.22$	SVD: 53° (SD 6.5, 95% CI 50.7–55.8) OVD: 52° (SD 9.6, 95% CI 49–54) 100% of midwives and 86% of doctors achieved a post-suture angle between 40° and 60°	Not reported	Mean PBL SVD: 37 mm (SD 8.3, 95% CI 34–39) OVD: 38 mm (SD 8, 95% CI 35–40) PBL followed normal distribution and average length similar to other studies	84% of users rated Episcissors-60 as 'good' to 'very good' (55% rated it very good)	Not reported
Unpublished studies						
Ayuk et al. (2018) [17] UK Before-and-after study Nine maternity units	Standard scissors: 38/2115 OASI (1.8%) Episcissors-60: 30/1498 OASI (2%) No significant association between the introduction of Episcissors-60 and OASI in women who had an episiotomy	Not reported	Not reported	Not reported	Not reported	Not reported
Unpublished (abstracts only)						
Condell et al. [18] UK $N = 179$ instrumental deliveries	No fourth degree tears were sustained during the study period with Episcissors-60 One 3b tear was sustained using Episcissors-60 during a forceps delivery 2 women sustained OASI without episiotomy and 2 women sustained OASI using standard scissors	Not reported	Not reported	Not reported	Operators reported that Episcissors-60 helped to keep the angle of episiotomy fixed to a safe 40°–60°	Not reported

Table 1 (continued)

Study	Rate of OASI	Post-delivery suture angle	Length of episiotomy	Perineal body length (PBL)	Ease of use	Barriers to use
Farnworth et al. [19] UK 8 NHS trusts	Not reported	Not reported	Not reported	Not reported	Not reported	A number of bureaucratic, cultural and practical barriers to successful implementation and outcome evaluation were identified, including Fiscal assistance and support from clinical leaders Complex organisation procurement processes Storage/sterilisation issues Concerns about the strength of the evidence base
Lou et al. [20] UK Observational study *N* = 79 deliveries using Episcissors-60	*N* = 3 Reduction in OASI rate during the study period from 5.6 to 3.2% compared with the preceding 5 months	Mean post-delivery suture angle was 50.7 ± 3.4°			Operators rated ease of use of Episcissors-60, sharpness of the scissors, length of the blade and confidence about the episiotomy angle on a 5-point scale with a satisfaction rate of over 93% in each component 91% of operators preferred Episcissors-60	Not reported

IQR interquartile range, *OASI* obstetric anal sphincter injury, *OVD* operative vaginal delivery, *PBL* perineal body length, *SD* standard deviation, *SVD* spontaneous vaginal delivery

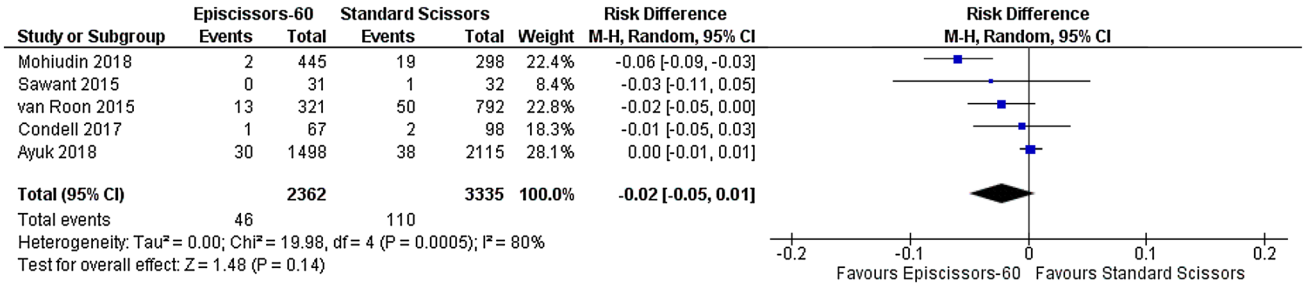

Fig. 1 Obstetric anal sphincter injuries in deliveries with episiotomy performed with Episcissors-60 versus standard scissors including all studies with reportable data

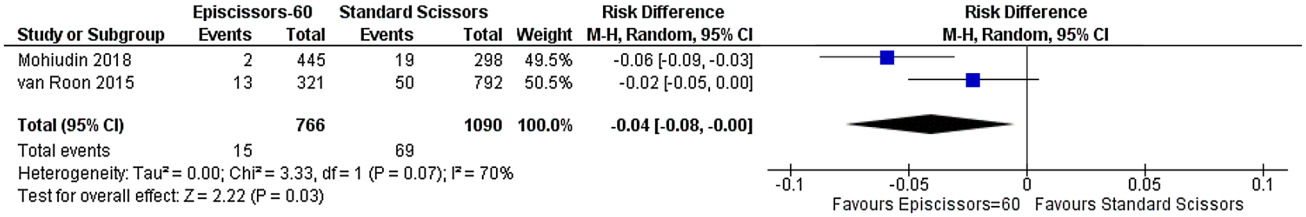

Fig. 2 Obstetric anal sphincter injuries (OASI) in deliveries with episiotomy performed with Episcissors-60 versus standard scissors including only studies which included other interventions to reduce OASI

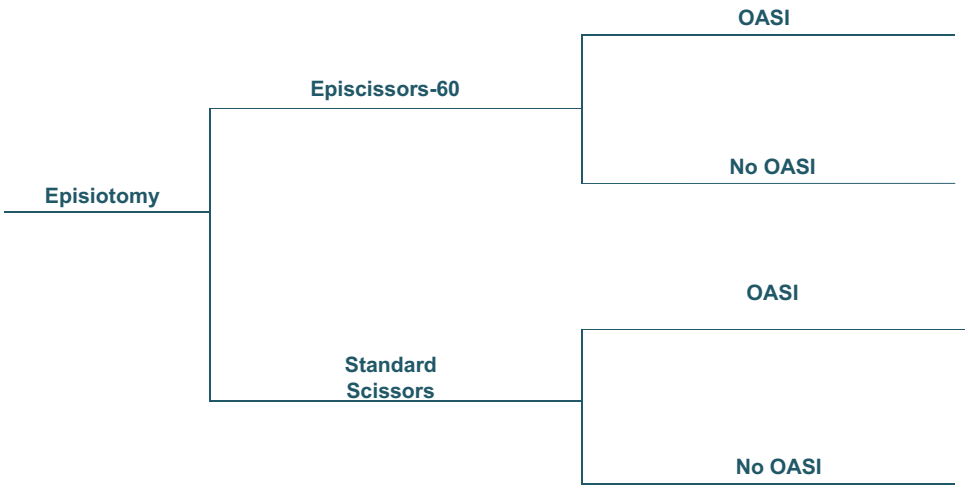

Fig. 3 Episcissors-60 decision tree

- The cost of an excess bed day based on NHS improvement costs is £366 [25].
- The incidence of OASI using standard scissors is 5.1% of all births based on Royal College of Obstetricians and Gynaecologists guidance [26].
- The reduction in OASI using Episcissors-60 is 39% based on Cedar's meta-analysis of five studies [13, 15–18].

2.3.3 Data Sources for Outcomes and Resources

Resource use is based on use of Office of Population, Censuses and Surveys' Classification of Surgical Operations and Procedures (OPCS) codes to identify codes for repair of third and fourth degree lacerations. The corresponding Healthcare Resource Group (HRG) code was used to identify the cost of an OASI repair using the 2019/20 National Non-Mandatory Tariff without the market forces factor (MFF). Rates of OASI are taken from published literature [4, 13].

The relevant OPCS codes were R322 (repair of obstetric laceration of perineum and sphincter of anus) and R325 (repair of laceration of perineum and sphincter and mucosa of anus), which correspond with HRG NZ27Z (post-natal therapeutic procedures).

2.3.4 Changes by Cedar

Cedar made a number of changes to the company economic submission, including:

- The use of NHS reference costs to identify cost of OASI repair.
- The use of NHS Supply Chain costs for comparator scissors.
- Population included in the model was the women having an episiotomy in line with scope.
- Changes to the rates of OASI before introduction of Episcissors-60.
- Changes to the percentage rate reduction in OASI through use of Episcissors-60.

2.3.5 Results from the Model

The model submitted by the company found reusable Episcissors-60 to be cost saving at £20.57 per patient compared with standard disposable scissors (Table 2).

Following changes made by the Cedar, the results of the model found Episcissors-60 to save £30.70 per patient with sensitivity analysis (across multiple variables simultaneously), indicating a highest cost saving estimate of £70.17 and a lowest estimate of − £38.96 (cost incurring) per patient.

2.3.6 One-Way Sensitivity Analysis, Scenarios and Key Drivers

The company submission included one-way sensitivity analysis, which explored the impact of changing input parameters in the intervention arm only. The Cedar noted that there were no low or high values included in the model for any parameters other than OASI rates.

Cedar conducted one-way sensitivity analysis to explore the impact of changing inputs in both the intervention and comparator arms. The key driver in the model is the OASI rate in the comparator (standard scissors) arm. The lower the rate of OASI in the baseline, the less impact the introduction of Episcissors-60 can have on rates of OASI; therefore, the potential for cost savings is reduced and there is a possibility that Episcissors-60 could be cost incurring. When varying the cost of Episcissor-60, cost of standard scissors and the cost of OASI repair and excess length of stay, sensitivity analysis of single variables shows the model remains cost saving.

2.3.7 Scenario Analysis

Cedar included two additional scenario analyses to assess the impact of possible clinical scenarios, including

- a re-usable Episcissors-60 may be used up to 50 times before it is disposed of. The impact of this would be to reduce the per-use cost of Episcissors-60;
- cost of standard disposable scissors is increased to reflect that, due to manufacturing processes, the cost of one pair of single-use disposable scissors may be higher than the cost per use of a pair of reusable scissors.

NHS reference cost NZ27Z includes some costs related to length of stay. There was some uncertainty as to whether additional length of stay attributed to OASI should be included in the cost model. Further exploratory analysis in which this additional length of stay was excluded from the model resulted in reduced cost savings associated with Episcissors-60 from £30.70 to £23.38.

3 NICE Guidance

3.1 Development of Guidance

The NICE Medical Technologies Advisory Committee (MTAC) met in September 2019 and considered the evidence from a range of sources, including the company's submission, Cedar's assessment report and advice from clinical

Table 2 Results of scenario analysis compared with base-case results

	Reusable Episcissors-60	Standard disposable scissors	Cost saving per patient
Company base case	£32.80	£53.36	£20.57
Cedar base case	£87.98	£118.68	£30.70
Scenario 1: Episcissors-60 used 50 times	£78.38	£118.68	£40.30
Scenario 2: cost of disposable scissors is greater than cost of reusable scissors	£87.98	£122.42	£34.44

experts and patient organisations. The committee made provisional guidance recommendations that were published for public consultation on the NICE website.

3.2 Consultation

During the consultation process, NICE received a total of 40 consultation comments from eight consultees including NHS professionals and company representatives. Comments covered issues including additional evidence, draft recommendations and wording changes. The comments were discussed at a second MTAC in November 2019. As part of the Innovation and Technology Payment Programme (ITP), NHS England have included Episcissors-60 in the technologies eligible for an innovative technology tariff. Information based on hospital episode statistics data from some trusts that used the technology was presented to the committee. The company clarified in the consultation that both the reusable and single-use versions of the technology will be available to the NHS. Following the committee discussion, minor amendments were made to the recommendations and additional information was added to the guidance to clearly distinguish the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines on the management of third and fourth degree perineal tears [26] and the OASI care bundle supported by RCOG and the Royal College of Midwives [27] and to highlight the potential issue of waste that may be associated with Episcissors-60.

3.3 Recommendations

The final recommendations in NICE MTG 47 [3], published in February 2020, are that (1) Episcissors-60 show promise for mediolateral episiotomy, but there is currently not enough evidence to support the case for routine adoption in the NHS; and (2) research is recommended to address uncertainties about the efficacy and safety of using Episcissors-60. This research should

- determine if using Episcissors-60 in addition to other care bundle measures is more effective in achieving an optimal episiotomy angle and in preventing OASI than standard episiotomy scissors;
- include patient-reported outcome measures;
- address potential equality considerations by ensuring patients at greatest risk of OASI are recruited;
- determine the relative cost of using Episcissors-60 compared with standard episiotomy scissors.

4 Key Challenges and Learning Points

Cedar noted that the evidence relating to Episcissors-60 is taken from a small number of low quality, non-randomised studies. In some studies, Episcissors-60 was not the only intervention to have been introduced, which makes it difficult to accurately estimate the effectiveness of Episcissor-60 in isolation. The OASI bundle recommends, beside correct episiotomy angle, providing information on OASI to women, providing manual perineal support, and examining, grading and documenting any perineal tears [27].

The rates of OASI are variable across the published literature and, as noted previously, the extent to which Episcissors-60 will be clinically effective or cost saving will depend on the existing rates of OASI in the hospitals or maternity units where it is introduced. A statistically significant difference may not represent a clinically important difference and it is likely that achieving a 'zero' rate of OASI with Episcissors-60 is not clinically possible for all hospitals and trusts given the number of other factors at play. Clinicians should therefore consider their own clinical experience when determining what reductions in OASI might be achievable and the degree to which Episcissors-60 might contribute to a reduction.

There are some clear equality concerns, with women of Asian family origin at increased risk of OASI due to a shorter perineal body length. It is therefore imperative that any research includes a representative population of women to ensure that the impact of Episcissors-60 can be accurately assessed for all important subgroups.

None of the studies included any patient-reported outcomes exploring the experiences of women who have had an episiotomy using Episcissors-60. OASI repair can impact sexual function and quality of life and it is important that patient-reported outcomes, including patient-reported experience measures are included in future studies to assess the impact of the process of care on the women undergoing episiotomies with Episcissors-60.

5 Conclusions

The introduction of Episcissors-60 has the potential to be both clinically effective and cost saving by making episiotomies safer for women by reducing the need for inaccurate visual estimations of cutting angles. If the use of Episcissors-60 reduces OASI compared with standard scissors there will be cost savings to the NHS; however, the extent of the cost savings will depend on both the baseline rate of OASI before introduction of Episcissors-60 and the impact of Episcissors-60 on the baseline rate.

Cedar noted that some of the clinical evidence is drawn from studies that introduced additional interventions at the same time as Episcissors-60 as part of the development of bundles of care. It is therefore possible that any improvements in the rate of OASI may be the result of the combined effect of interventions in the bundles of care.

Declarations

Author contributions SO, MD, HM, AC, RM, BD and GC-R contributed to the preparation of this manuscript. GC-R reviewed the full assessment report as well as this article. RM reviewed the article and can act as a guarantor for the overall content.

Compliance with ethical standards Susan O'Connell, Megan Dale, Andrew Cleves and Rhys Morris and are employees of the NHS and Grace Carolan-Rees was an employee of the NHS until September 2020, which has a financial interest in the guidance on which this project is based. Helen Morgan is a Cardiff University employee and has no conflicts of interest to declare. Bernice Dillon is a NICE employee and had no role in the production of the assessment report but contributed to the preparation of this manuscript. This summary of the Medical Technology Guidance was produced following the publication of the final guidance report. The article has not been externally peer reviewed by Applied Health Economics and Health Policy, but has been reviewed externally by NICE. Cedar was funded by the NICE Medical Technologies Evaluation Programme for its work.

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