NICE National Institute for Health and Care Excellence

NICE guidance

Episcissors-60 for mediolateral episiotomy

Medical technologies guidance
Published: 11 February 2020

www.nice.org.uk/guidance/mtg47

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB33.

1 Recommendations

1.1 Episcissors-60 show promise for mediolateral episiotomy. But there is currently not enough evidence to support the case for routine adoption in the NHS.

1.2 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 episiotomy-related obstetric anal sphincter injuries (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.

Why the committee made these recommendations

Episcissors-60 are adapted surgical scissors. They are used to guide and make a cut between the vagina and anus (episiotomy) at an optimal angle (45 to 60 degrees to the midline, according to NICE's guideline on intrapartum care) during delivery. This is called a guided mediolateral episiotomy.

Cutting at the optimal angle is important to reduce the chance of OASI, which can have severe long-term effects, such as faecal incontinence.

Because not much good evidence is available, it is recommended 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 OASI (such as the Royal College of Obstetricians and Gynaecologists OASI care bundle).

2 The technology

Technology

2.1 Episcissors-60 are adapted surgical scissors used to perform an incision for mediolateral episiotomies. The scissors have 5 cm long blades with a guide limb mounted at the blade pivot point and angled at 60 degrees from the blades. A cutting angle of 60 degrees is ensured by pointing the guide limb towards the anus in the vertical perineal midline.

2.2 Episcissors-60 are available in reusable and single-use disposable versions (available from June 2019).

Innovative aspects

2.3 Episcissors-60 are designed to achieve a mediolateral cut at 60 degrees to the perineal midline, so preventing inaccurate visual estimation of the cutting angle. The device aims to reduce the incidence of obstetric anal sphincter injuries (OASI). Episcissors-60 are an alternative to current standard episiotomy scissors when visual estimation of the cutting angle is required.

Intended use

2.4 Episcissors-60 are intended for use in women who have a clinical need for an episiotomy, such as for instrumental deliveries or in cases of suspected fetal compromise.

2.5 Episcissors-60 are intended to be used by obstetricians or midwives. The use of Episcissors-60 does not need any special training measures.

Costs

2.6 The cost of single-use disposable Episcissors-60 is £16 (excluding VAT). The reusable Episcissors-60 were priced at £320 (excluding VAT).

2.7 For more details, see the website for Episcissors-60.

3 Evidence

Clinical evidence

The evidence for Episcissors-60 is limited in quality and quantity and relates only to the reusable Episcissors-60

3.1 The clinical evidence for reusable Episcissors-60 comprises 8 published studies and 3 unpublished studies:

- 1 systematic review and meta-analysis (Divakova et al. 2019; included studies are van Roon et al. 2015, Sawant et al. 2015, Lou et al. 2016 and Mohiudin et al. 2018)
- 1 systematic review (Cole et al. 2019; included studies are Freeman et al. 2014, Patel et al. 2014, van Roon et al. 2015, Sawant et al. 2015 and Mohiudin et al. 2018)
- 1 proof of concept study (Freeman et al. 2014)
- 1 case series (Patel et al. 2014)
- 1 cohort study (Sawant et al. 2015)
- 3 before and after studies (van Roon et al. 2015, Mohiudin et al. 2018, Ayuk et al. 2019)
- 2 abstracts (Farnworth et al. 2019, Condell et al. 2017)
- 1 observational study (Lou et al. 2016).

The evidence includes patients who had a mediolateral episiotomy with reusable Episcissors-60 or standard episiotomy scissors. Two studies introduced reusable Episcissors-60 with other care measures (see sections 4.3 and 4.4), which makes it difficult to ascertain the impact of reusable Episcissors-60 alone on the rate of obstetric anal sphincter injuries (OASI). All of the studies used only the reusable version of Episcissors-60, so there is no

evidence evaluating the single-use disposable version of Episcissors-60. For full details of the clinical evidence, see section 3 of the external assessment centre's (EAC) assessment report in the supporting documents – committee papers.

The evidence base is limited to a small number of non-comparative studies and before and after studies with a high risk of bias

3.2 The EAC assessed the quality of the evidence base as very low. This is primarily because there are no randomised trials, only observational studies, 3 of which had no comparator group or information on the comparator. There is a high risk of bias because outcomes were measured differently across the studies, and most studies did not report the 'before' data for accurate comparison. In addition, not all studies reported who carried out the episiotomies and suturing after delivery.

The studies suggest that using reusable Episcissors-60 results in reliable post-delivery suture angles

3.3 Four studies reported a median or mean post-delivery suture angle within a 40 to 60 degree range with reusable Episcissors-60. In one before and after study (van Roon et al. 2015) it was reported that 100% of midwives and 86% of doctors achieved a post-delivery suture angle between 40 and 60 degrees when using reusable Episcissors-60. However, this is based on only 76 episiotomies, limiting its reliability. Furthermore, no comparable data were reported for the 'before' period so no comment can be made on whether this outcome represented a significant change from previous practice with standard scissors.

Episcissors-60 as part of a care bundle may reduce OASI rates in women who have an episiotomy

3.4 Pooled analysis suggests no significant reduction in OASI rates in women who had an episiotomy with reusable Episcissors-60 compared with standard

episiotomy scissors. However, pooled results of 2 studies that included using reusable Episcissors-60 with a care bundle showed a significant reduction in OASI rates in women with an episiotomy.

Studies suggest that Episcissors-60 may result in more episiotomies

3.5 Pooled analysis suggests that rates of episiotomies could increase by between 1% and 4% (absolute increase) with using Episcissors-60. However the result was not statistically significant.

Episcissors-60 may result in a larger incision and increased blood loss in some patients

3.6 One study (Sawant et al. 2015) reported that the episiotomy incision was longer with reusable Episcissors-60 than with standard scissors. One study (Ayuk et al. 2019) reported an increase in the estimated mean delivery blood loss by approximately 50 ml after reusable Episcissors-60 were introduced. For full details of the adverse events, see section 3.7 of the EAC's assessment report in the supporting documents – committee papers.

The evidence for reusable Episcissors-60 is broadly generalisable to NHS practice

3.7 Most studies were done in the UK, providing directly applicable evidence for using reusable Episcissors-60 in the NHS. Two studies, a comparative cohort study and a non-comparative case series study, were in Indian hospitals. The EAC stated that women of Asian family origin may be at higher risk of OASI because of a shorter perineal body length, so those studies may also be applicable to the UK.

Cost evidence

The company's cost model shows that using Episcissors-60 is cost saving on a cost per birth basis in an all-births population

3.8 The company created a de novo cost analysis using a simple decision tree model. The model had a single decision node: using Episcissors-60 or standard scissors, leading to 2 outcomes: an OASI repair or no OASI repair. The time horizon was 1 year. The company's model showed that using Episcissors-60 saves £20.67 per birth based on all births. Costs were based on the cost of single-use disposable standard episiotomy scissors and a cost per use of reusable Episcissors-60. For full details of the cost evidence, see section 4 of the EAC's assessment report in the supporting documents – committee papers).

The EAC's revised model also shows Episcissors-60 as cost saving in an episiotomy-only population

3.9 The EAC agreed with the company's model structure, but did not agree with all the model inputs. The EAC suggested that the population should be confined to those having an episiotomy as opposed to all births, and the incidence of OASI should be for episiotomy births and not all births. The EAC's revised model shows that using Episcissors-60 saves £30.70 per patient.

Sensitivity analyses suggest that any cost savings with Episcissors-60 are driven by the baseline OASI rate

3.10 Assuming reduced OASI rates with Episcissors-60 compared with standard scissors, the EAC's sensitivity analysis showed that the cost analysis was most sensitive to the rate of OASI in the comparator (standard scissors) arm. The lower the baseline OASI rate, the less effect Episcissors-60 have on OASI rates and the lower the expected cost savings. The EAC base case comparator OASI rate was 5.1%. If the OASI rate in the comparator group is reduced in the model to 4%, then Episcissors-60 are cost incurring by £1.81 per patient per birth by episiotomy. If the OASI rate in the comparator group is increased in the model to 7%,

Episcissors-60 are cost saving by £63.21.

3.11 It was uncertain whether or not additional length of stay attributed to OASI should be included in the cost model. Additional analysis assessed the impact of including length of stay or not on the difference in total costs. Excluding the cost of an excess length of stay attributable to OASI from the cost model results in reduced cost savings associated with Episcissors-60.

4 Committee discussion

Clinical-effectiveness overview

Evidence for the clinical effectiveness of reusable Episcissors-60 is uncertain

4.1 The committee noted that the evidence for clinical benefit with reusable Episcissors-60 is uncertain. Published evidence and the opinions of experts indicate that they are easy to use. But their impact on the incidence of obstetric anal sphincter injuries (OASI) after episiotomy is uncertain. The clinical experts explained that several factors make an injury more likely. The committee noted that some of the studies introduced reusable Episcissors-60 at the same time as a care bundle of other measures of optimal care to reduce the risk of OASI. The evidence shows that when these studies are excluded from a pooled analysis, there was no difference in the incidence of OASI between women who had episiotomies using reusable Episcissors-60 and standard scissors. Given this, as well as the low quality and heterogenous nature of the studies available, the committee concluded that the impact of reusable Episcissors-60 alone on OASI rates could not be determined with certainty on the basis of the current evidence, and further research is needed.

Evidence on using the single-use disposable version of Episcissors-60 is needed

4.2 The committee noted that all of the published studies used the reusable Episcissors-60. The company stated that the differences between the 2 versions are that reusable Episcissors-60 have gold handles and tungsten carbide blades. These components are not in the single-use disposable version. The committee considered that the evidence cannot be extrapolated to the single-use disposable version. The committee concluded, therefore, that further evidence assessing the relative merits of the single-use disposable Episcissors-60 compared with standard scissors is also needed.

More evidence is needed to assess the impact of Episcissors-60 over and above standard bundles of care

4.3 The clinical experts explained that the Royal College of Midwives and the Royal College of Obstetricians and Gynaecologists (RCOG) published a list of evidence-based measures in 2017 to reduce the risk of OASI (the OASI care bundle). These have been incorporated since then across the NHS as part of routine care. These measures are instituted before, during and after birth and include:

- providing antenatal information to women
- performing a mediolateral episiotomy when indicated at 60 degrees at crowning
- using manual perineal protection during all vaginal births
- doing a perineal examination (including a per rectum examination) after childbirth.

4.4 The RCOG's Third- and fourth-degree perineal tears, management (green-top guideline no. 29) provides different evidence-based guidance to aid good clinical practice in the diagnosis, management and treatment of OASI, including:

- providing information to women that the evidence for the protective effect of episiotomy is conflicting
- considering the use of mediolateral episiotomy in instrumental deliveries
- performing mediolateral episiotomies at 60 degrees away from the midline when the perineum is distended.

  The guidance also states that perineal protection at crowning can be protective and warm compression during the second stage of labour reduces the risk of OASI.

4.5 The experts explained that, if implemented, Episcissors-60 would be used for the episiotomy as part of the standard RCOG OASI care bundle to reduce the incidence of OASI. The committee proposed that further evidence exploring the possible benefits of using Episcissors-60 compared with standard episiotomy scissors, in addition to the standard bundle of care, is needed to identify any

additional incremental clinical benefits.

Side effects and adverse events

Episcissors-60 may result in a longer episiotomy cut

4.6 The external assessment centre (EAC) considered that the evidence reporting a longer episiotomy cut with reusable Episcissors-60 than with standard scissors is limited and of poor quality. The company stated that reusable and single-use disposable Episcissors-60 have a blade length of 5 cm, and this is the same as for standard scissors. The clinical experts noted that the length of cut using standard scissors may be reduced by using less of the blade, allowing clinicians to make as small a cut as is needed. The experts were unsure if this would also be possible in a reliable way using Episcissors-60, and stated that the ability to alter the length of the cut may depend on clinical experience. The committee concluded that the length of the episiotomy incision should be addressed in future studies.

Episcissors-60 may result in increased blood loss

4.7 One study reported an increase in estimated delivery blood loss of approximately 50 ml per use after reusable Episcissors-60 were introduced. One clinical expert, who was involved in the trial, explained that this outcome was added to the study after anecdotal reports from clinicians that using reusable Episcissors-60 appeared to be associated with an increase in blood loss and a need for earlier suturing in some cases to seal bleeding points. The clinical expert was unsure about the clinical significance of this level of increased blood loss. The clinical expert also explained that estimating blood loss under these clinical circumstances is difficult and that the different centres involved in the study measured it differently. The EAC noted that this was not a predetermined outcome in the study in question and that blood loss is not reported as an outcome in any of the other studies. The committee concluded therefore that this finding should be interpreted with caution but is something that could be explored further in future studies.

The episiotomy angle alone is not a good surrogate marker for the likely risk or outcome of an OASI

4.8 The clinical experts explained that angle of incision to the midline at the time of delivery does not always correlate closely with the post-delivery suture angle because of the anatomical distension that results from the passage of the baby at the time of the episiotomy. Furthermore, they explained that in addition to the episiotomy angle, there are a number of other important factors which influence the rate of OASI. These include the timing and speed of delivery, the perineal body length, and whether the mother has given birth before. The committee concluded therefore that the post-delivery suture angle alone cannot be regarded as a reliable surrogate for either the risk or outcome of an OASI.

Diagnosing an OASI can be difficult and may be subjective

4.9 The clinical experts explained that, although there is a clear written definition of different levels of OASI, in practice it is subjective and often difficult to determine. The clinical experts highlighted that it is particularly difficult to differentiate between a 3b and 3c degree tear. This may be one compounding factor that influences the heterogenous rates of OASI in different populations and studies.

Other patient benefits or issues

The risk of OASI is determined by a number of factors that raise important equalities considerations

4.10 A number of equalities considerations are relevant to the risk of OASI. Older women, women with a short perineal body length (such as those of Asian family origin), and women who have undergone female genital mutilation may be at increased risk of OASI (although the last is uncertain from the evidence available). The clinical experts explained that women at higher risk of OASI may need an earlier episiotomy. Age, sex, pregnancy, race and disability are protected characteristics under the Equality Act 2010. The committee concluded that research is needed in those at greatest risk to address potential equality

considerations.

There are no data on patient-reported outcome measures

4.11 There is currently no evidence reporting the experiences of women who have had an episiotomy using Episcissors-60, even though OASI repair may impact sexual function and quality of life. The committee concluded that patient-reported outcome measures, including patient-reported experience measures to assess the impact of the process of care on the patient's experience, should be included in future research to assess the impact of Episcissors-60.

NHS considerations overview

Using single-use disposable Episcissors-60 may have an environmental impact

4.12 The company stated that disposable Episcissors-60 are discarded after a single use and cannot be recycled. Because of this the committee and experts raised concern about the sustainability of the technology and a possible negative environmental impact.

4.13 The clinical experts said there may be wastage when Episcissors-60 are opened in preparation for an episiotomy but not then used. Experts estimated that wastage of Episcissors-60 is most likely with midwife-supervised spontaneous vaginal deliveries. Experts thought that if Episcissors-60 were opened for all spontaneous births in preparation for a possible episiotomy, but the women delivered spontaneously, then wastage would result. On the other hand, the need for an episiotomy is more predictable when an obstetrician performs an operative vaginal delivery, meaning that wastage may be less likely. The EAC stated that the problem of wastage is more relevant with single-use disposable Episcissors-60 (which would need to be thrown away once opened) rather than reusable Episcissors-60 (which could then be resterilised).

Training

Using Episcissors-60 alongside a training package has increased midwives' confidence in doing episiotomies

4.14 In one clinical expert's hospital, a training package was delivered at the same time as introducing Episcissors-60, which included doing episiotomies on a dummy. Experts stated that this training increased midwives' confidence in doing episiotomies. The experts emphasised, however, the importance of focusing training on optimal episiotomy practice in the context of a wider bundle of measures to minimise the risk of OASIs.

Ease of use of Episcissors-60 is uncertain

4.15 Two studies report favourable data on how easy it is to use reusable Episcissors-60, but they are poor quality. The clinical experts were divided on their experiences and those of their colleagues about how easy it is to use Episcissors-60. Midwives were identified by some as the most supportive professional group of Episcissors-60 but opinion among obstetricians is mixed.

Service implications

Episcissors-60 may increase the rate of episiotomy

4.16 There is some evidence to suggest that introducing Episcissors-60 may increase the rate of episiotomy, but the quality of this evidence is poor. The clinical experts explained that, if episiotomy rates are increased, this may be because of increased staff confidence in doing episiotomies, and because of introducing the OASI care bundle. The clinical experts acknowledged that there is no consensus on what best-practice episiotomy rates should be either in spontaneous or operative vaginal delivery.

The impact on length of hospital stay with Episcissors-60 is

uncertain

4.17 The clinical experts said it was difficult to be certain about how an OASI affects length of hospital stay. They explained that there are several factors that affect length of stay after delivery, including the method of delivery and severity of OASI, as well as those relating to establishing feeding and wellbeing for the newborn baby and mother. Experts explained that women with fourth-degree tears stay in hospital longer than those with third-degree tears. One expert stated that women who have a spontaneous vaginal delivery and an OASI stay overnight, whereas women with uncomplicated spontaneous vaginal deliveries are normally discharged the same day. Women who have had an operative vaginal delivery normally stay in hospital overnight even in the absence of an OASI, so an increase in length of stay may not be a consequence of the OASI itself in these women.

Cost modelling overview

The EAC's updated model is acceptable but uncertainties remain

4.18 The committee considered that, because of the uncertainties about the possible clinical benefit of Episcissors-60, it was difficult to draw firm conclusions about any cost benefits. The committee concluded that further evidence is needed to show if reusable and single-use disposable Episcissors-60 lead to cost savings when compared with using standard scissors.

Main cost drivers

The OASI rate is a key driver in the model

4.19 The committee considered the factors that are likely to be important in determining the cost impact of Episcissors-60. The EAC identified the key driver in the cost model to be the OASI rate in the comparator, standard scissors arm. The lower the rate of baseline OASI, the less of an impact introducing

Episcissors-60 can have on the rates of OASI, and the potential for cost savings. The clinical experts discussed how the rate of OASI varies depending on the population studied and its different demographics. The committee concluded that more robust evidence is needed that includes these important considerations to better understand the cost impact of using single-use disposable Episcissors-60 in the NHS.

Cost savings

Cost modelling for Episcissors-60 has limitations but cost savings are likely if Episcissors-60 reduce the OASI rate

4.20 The EAC's revised cost model showed that over 1 year, compared with standard episiotomy scissors (based on a cost per use of reusable episiotomy scissors), Episcissors-60 are associated with a cost saving of around £30.70 per patient. In an EAC scenario analysis, the cost of standard scissors was increased to reflect a possible higher cost of single-use disposable standard scissors. This increased the incremental cost saving to £34.44 per patient. The cost of standard scissors cannot be reported because this cost is considered confidential by NHS Supply Chain. Further detail can be obtained by contacting NHS Supply Chain.

4.21 The clinical experts said that uncertainties in the evidence and the higher cost of reusable Episcissors-60 compared with standard scissors have affected the adoption of the device. The committee considered that the EAC may have underestimated the cost of an OASI repair in their model. The EAC confirmed that NHS reference costs for perineal trauma were used, but long-term costs associated with OASI, including managing faecal incontinence, are not accounted for in the EAC's model. The EAC and experts agree that there may be additional long-term costs to the NHS of managing patients with OASI including the need for additional therapies and social care. The committee suggested that the time horizon for future studies and cost estimates should be sufficiently long to capture these important aspects of holistic care. One clinical expert thought that the cost of a caesarean section should also be included because some women may elect to have this as an alternative to accepting the possible consequences of an OASI complication of a vaginal delivery.

Further research

Further research is needed to address the uncertainty in the safety and efficacy of Episcissors-60

4.22 The committee concluded that further research is needed to address uncertainties about the safety and efficacy of Episcissors-60. This research should be sufficiently robust in design and implementation to determine if Episcissors-60, in addition to an OASI care bundle, adds clinical value compared with using standard episiotomy scissors and visual assessment of the cutting angle in addition to an OASI care bundle. It was the opinion of the experts that a randomised controlled trial would be ethical and feasible to do. Trials would need to ensure that optimal bundles of clinical care to reduce OASI risk were defined and applied equally to both intervention and comparator arms and that OASI rates, length of hospital stay, incision length and blood loss, patient-reported outcome measures, and cost analysis were included. Studies should include women who have not given birth before, women having an operative vaginal delivery, and women of Asian family origin to ensure that equalities considerations are addressed. The research should provide data to inform cost modelling and should be designed within a timeframe to provide useful information before this guidance is reviewed.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more technical analysts (who act as technical leads for the topic), a technical adviser and a project manager.

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ISBN: 978-1-4731-3665-6