NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Episcissors-60 for guided mediolateral episiotomy

1 Technology

1.1 Description of the technology

Episcissors-60 are adapted surgical scissors made from stainless steel used to perform an incision for mediolateral episiotomies. There are reusable and single use versions. The scissors have 5-centimetre 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 positioning the guide limb pointing towards the anus in the vertical perineal midline.

Evidence suggests that the cutting angle of a mediolateral episiotomy affects the incidence of OASIs (Stedenfeldt et al. 2012, Eogan et al. 2006). The aim of Episcissors-60 is to prevent inaccurate visual estimation of the cutting angle and so reduce the incidence of obstetric anal sphincter injuries (OASIs).

Two versions of Episcissors-60 are available based on operator preference: a straight version and an angled version. The straight version has blades in line with the handles, whereas the angled version has blades at 150 degrees to the handles. Both versions give an incision point 1 centimetre horizontally offset from the posterior vaginal fourchette.

The reusable version of Episcissors-60 can form part of a reusable equipment birthing pack following cleaning and sterilising between uses. They are intended for use in secondary care midwifery and obstetric units, primary care midwifery units and birth centres, and for home births. Episcissors-60 was included in the NHS Innovation and Technology Tariff (ITT) 2017/18.

1.2 Regulatory status

Episcissors-60 was CE-marked as a Class I medical device in March 2014. The single use version is planned to launch in the NHS in June 2019 after which the reusable version will be phased out. Episcissors-60 are currently made by 2 manufacturers under license from MEDINVENT LTD.

1.3 Claimed benefits

The benefits to patients claimed by the company through the use of Episcissors-60 for guided mediolateral episiotomy are:

- Cuts at a fixed 60 degree angle at crowning in line with the Royal College of Obstetricians and Gynaecologists' recommendation
- Prevention of OASIs
- Fewer complications such as wound breakdown, infections and anal incontinence

The benefits to the healthcare system claimed by the company are:

- Preferred by staff over normal scissors
- Cost-saving because of fewer OASIs
- Reduced costs associated with fewer complications
- Reduced length of stay

1.4 Relevant diseases and conditions

Episcissors-60 are intended for use in mediolateral episiotomy, which is recommended only when there is a clinical need, such as for instrumental deliveries or in cases of suspected fetal compromise. Routine episiotomy is not indicated during spontaneous vaginal birth or after third or fourth-degree tears from previous childbirth.

According to HES online, 15.2% of all births in England between 2011 to 2012 required an episiotomy. OASIs can be minimised by mediolateral episiotomies, but only if the correct cutting angle is achieved. OASIs occur in 2.9% of all vaginal births in the UK, 6.1% of first-time births and 1.7% of births in women who have given birth 2 or more times before (Thiagamoorthy et al.

2014). A meta-analysis found that 30% of women who had an OASI still had symptoms 1 year after childbirth (Oberwalder et al. 2003). Symptoms include faecal urgency, inability to control wind and uncontrolled bowel movements (Dudding et al. 2008).

Perineal trauma was the 4th highest reason for obstetric claims settlements. The compensation cost for perineal trauma across NHS organisations for the 10 years to March 2010 was £31.2 million according to the NHS Litigation Authority 2012. Perineal trauma was the 4th highest reason for obstetric claim settlements over this period of time.

1.5 Current management

Current clinical practice in the NHS for a woman requiring mediolateral episiotomy is described by several guidelines. NICE clinical guideline on intrapartum care for healthy women and babies recommends that an episiotomy should only be performed if there is a clinical need, such as an instrumental birth or suspected fetal compromise. An episiotomy should be mediolateral, originating at the vaginal fourchette and directed towards the right side. The angle of the cut to the vertical axis at the time of episiotomy is recommended to be 45 to 60 degrees. Tested effective analgesia should be provided before carrying out an episiotomy, except in emergency cases such as acute fetal compromise.

The Royal College of Obstetricians and Gynaecologists' guidance on The Management of Third and Fourth Degree Tears recommends in a similar way that an episiotomy should be mediolateral and should only be performed if clinically indicated. The cutting angle is advised to be 60 degrees from the midline at the time of episiotomy. Should an OASI occur during vaginal delivery, it should usually be repaired in an operating theatre under general or regional anaesthesia. Broad-spectrum antibiotics should be given following repair of OASIs. Follow up should involve 6-12 week review. Women with ongoing OASI symptoms should be referred to a specialist gynaecologist or a colorectal surgeon.

The NICE clinical guideline on faecal incontinence in adults: management recommends that women with OASIs are identified as high risk for faecal incontinence. Women should be treated with condition-specific interventions as well as general measures for faecal incontinence. General measures include coping strategies, incontinence pads, anti-diarrhoeal medicines and pelvic floor muscle training.

2 Statement of the decision problem

	Scope issued by NICE
Population	Women who have a clinical need for an episiotomy, such as for instrumental deliveries or in cases of suspected fetal compromise.
Intervention	Episcissors-60
Comparator(s)	• Standard reusable episiotomy scissors • Standard disposable episiotomy scissors (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: Procedural outcomes: • Device-related adverse events • Incidence and severity of OASIs • Complication rates, e.g. wound breakdown, infections, anal incontinence and postpartum haemorrhage • Ease of use of instrument, including handedness • Operator learning curve • Costs of any complications (including OASI repair). Duration of follow up should be sufficient to capture all relevant complications. • Post-delivery suture angles • Length of episiotomy • Post-delivery distance from midline Patient outcomes: • Length of stay • Quality of life
Cost analysis	Comparator(s): • Standard reusable episiotomy scissors • Standard disposable episiotomy scissors Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	Ethnicity

Special considerations, including those related to equality	Episcissors-60 are intended for use in pregnant women during labour. Some women of Asian family origin may be more at risk of OASIs. People with severe faecal incontinence may meet the criteria for disability under the Equality Act 2010. Sex, pregnancy, race and disability are protected characteristics under the Equality Act 2010. Consideration will be given to whether Episcissors-60 can easily be used by lefthanded people.	
Special considerations, specifically related to equality issues	Episcissors-60 are intended for use in pregnant women during labour. Some women of Asian family origin may be more at risk of OASIs. Those with severe faecal incontinence may meet the criteria for disability under the Equality Act 2010. Sex, pregnancy, race and disability are protected characteristics under the Equality Act (2010).	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

3 Related NICE recommendations and NICE pathways

Published

NICE Clinical Guidelines

- Intrapartum care for healthy women and babies. NICE clinical guideline 190 (2014, updated 2017). Available from https://www.nice.org.uk/guidance/cg190
- Faecal incontinence in adults: management. NICE clinical guideline 49 (2007). Available from https://www.nice.org.uk/guidance/cg49

NICE Pathways

- Faecal incontinence. NICE pathway (2013, updated 2019). Available from https://pathways.nice.org.uk/pathways/faecal-incontinence

- Intrapartum care. NICE pathway (2011, updated 2019). Available from https://pathways.nice.org.uk/pathways/intrapartum-care
- Antenatal care for uncomplicated pregnancies. NICE pathway (2011, updated 2019). Available from https://pathways.nice.org.uk/pathways/antenatal-care-for-uncomplicated-pregnancies

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- Antenatal care for uncomplicated pregnancies update. NICE clinical guideline. Publication expected December 2020.

4 External organisations

4.1 Professional organisations

4.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Royal College of Midwives
- Royal College of Obstetricians and Gynaecologists
- British Society of Urogynaecology

4.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Royal College of Midwives
- Royal College of Obstetricians and Gynaecologists
- British Society of Urogynaecology
- British Society of Psychosomatic Obstetrics, Gynaecology and Andrology

4.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Baby Lifeline
- Birth Trauma Association (BTA)
- Disability, Pregnancy & Parenthood international (DPPi)
- Multiple Births Foundation
- PANDAS Foundation
- Tommy's – The Baby Charity
- Twins and Multiple Births Association (TAMBA)
- WellBeing of Women

