NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA128; Stapled haemorrhoidopexy for the treatment of haemorrhoids

This guidance was issued in July 2007.

In 2010, the decision was made to defer the review of TA128 until 2015.

1. Recommendation

TA128 guidance should be placed on the static list. That we consult on this proposal.

2. Original remit(s)

To appraise the clinical and cost effectiveness of stapled haemorrhoidectomy versus conventional haemorrhoidectomy in patients for whom surgery is considered, and to provide guidance to the NHS in England and Wales.

3. Current guidance

This technology appraisal examined the currently available devices for stapled haemorrhoidopexy. The evidence considered refers to the HCS33 circular stapler (models PPH01 and PPH03, Ethicon Endo-Surgery). At the time of the technology appraisal, there was no evidence to make recommendations for the Autosuture stapler with the STRAM kit adaptor

1.1. Stapled haemorrhoidopexy, using a circular stapler specifically developed for haemorrhoidopexy, is recommended as an option for people in whom surgical intervention is considered appropriate for the treatment of prolapsed internal haemorrhoids.

4. Rationale[1]

No new evidence has been identified that is likely to lead to a change in the recommendations. The only clinical study that addresses the research recommendation has been delayed and is now scheduled to report at the end of 2016. However, no issues with implementation of the existing guidance (i.e. uptake of the recommendations) have been reported, and therefore it is proposed to place this guidance on the static list.

5. Implications for other guidance producing programmes

[1] A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper

There is no proposed or ongoing guidance development that overlaps with this review proposal

6. New evidence

The search strategy from the original Assessment Report was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from July 2010 onwards were reviewed. Additional searches of clinical trials registries and other sources were also carried out. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

7. Summary of evidence and implications for review

Since the publication of the previous guidance there have been no changes to the EES haemorrhoidal circular stapler sets (models PPH01 and PPH03, Ethicon Endo-Surgery). These products are currently available.

The following products appear to have become available in the NHS since the publication of TA 128:

- EEA Haemorrhoid and Prolapse Stapler Set (Covidien - formerly Tyco Healthcare), launched in May 2010;
- Chex CPH32 and CPH34 circular staplers for rectal prolapse and haemorrhoids (Frankenman);
- Hemorrhoidal circular stapler (models 28QYZ-32 and 28QYZ-34 (Avental Ltd)
- Disposable Circular Stapler for Hemorrhoids (PPH) (Haiers Medical)
- Ultimate haemorrhoidal Circular Stapler (Purple Surgical)
- PPHplus for Single Use (Touchstone International Medical Science)
- Disposable PPH stapler AKYGC-32/33/34 (CAK Medical)

There appear to be only subtle differences between the available products. As the current guidance does not stipulate any specific product the emergence of the new products does not warrant a separate review at this stage.

Several studies were identified from the literature searches since the last review proposal paper was published in 2010. Sixteen of these studies were randomised controlled trials and 8 were meta-analyses. Of the newly identified randomised studies, most included a modest number of patients (n=37-207).

The majority of studies compared stapled haemorrhoidopexy to conventional haemorrhoidectomy; however, it is unclear which products have been used in some of the studies. Many of the studies identified since TA128 concluded that stapled haemorrhoidopexy is comparable in terms of efficacy and safety to conventional haemorrhoidectomy. Some studies found that stapled haemorrhoidopexy may carry a risk of higher incidence of recurrences and additional operations compared to conventional haemorrhoidectomy. The new studies show that stapled haemorrhoidopexy is associated with reduced post-operative pain. These results are broadly consistent with the evidence used in TA128.

TA128 recommended further research to evaluate the clinical and cost effectiveness of stapled haemorrhoidopexy in people with full circumferential second degree haemorrhoids. The eTHoS Study is a UK multicentre randomised controlled trial investigating whether stapled haemorrhoidopexy is more effective than traditional excisional haemorrhoidectomy in patients with grade II (having failed traditional therapy defined as two episodes of rubber band ligation), grade III or IV haemorrhoids. This could address the recommendations made in TA128. The anticipated end date for this trial was March 2015, but, we were notified that the completion of the eTHoS trial had been put back to September 2016. The primary objective in this trial is to compare patient reported overall health related quality of life (measured using the EQ-5D) over a period of 24 months. The recruitment target is 800 patients.

However, because the TA 128 recommendations themselves are broad, and informal feedback from the implementation team suggests that no issues related to implementation have been reported, a review of this guidance is not considered necessary and propose that the guidance be placed on the static list.

8. Implementation

No formal submission was received from Implementation.

9. Equality issues

No issues were raised in the original guidance

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Appendix 1 – explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	**Consequence**	**Selected – 'Yes/No'**
A review of the guidance should be planned into the appraisal work programme. The review will be conducted through the [specify STA or MTA] process.	A review of the appraisal will be planned into the NICE's work programme.	No
The decision to review the guidance should be deferred until the completion of the eTHoS trial in September 2016	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review. This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.	No

Options	Consequence	Selected – 'Yes/No'
The guidance should be updated in an on-going clinical guideline.	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).	No
The guidance should be transferred to the 'static guidance list'.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes

NICE would typically consider updating a technology appraisal in an ongoing guideline if the following criteria were met:

i. The technology falls within the scope of a clinical guideline (or public health guidance)

ii. There is no proposed change to an existing Patient Access Scheme or Flexible Pricing arrangement for the technology, or no new proposal(s) for such a scheme or arrangement

iii. There is no new evidence that is likely to lead to a significant change in the clinical and cost effectiveness of a treatment

iv. The treatment is well established and embedded in the NHS. Evidence that a treatment is not well established or embedded may include;

- Spending on a treatment for the indication which was the subject of the appraisal continues to rise
- There is evidence of unjustified variation across the country in access to a treatment
- There is plausible and verifiable information to suggest that the availability of the treatment is likely to suffer if the funding direction were removed

- The treatment is excluded from the Payment by Results tariff

v. Stakeholder opinion, expressed in response to review consultation, is broadly supportive of the proposal.

Appendix 2 – supporting information

Relevant Institute work –

Published

Haemorrhoidal artery ligation (2010) NICE interventional procedures guidance 342

Circular stapled haemorrhoidectomy (2003) NICE interventional procedures guidance 34

Stapled transanal rectal resection for obstructed defaecation syndrome (2010) NICE interventional procedures guidance 351Details of changes to the indications of the technology

Indication and price considered in original appraisal	Proposed indication (for this appraisal) and current price
Indication: prolapsed internal haemorrhoids. The cost of the HCS33 PPH03 stapling device, the model currently in use, is £420 based on the submission from Ethicon Endo-Surgery. Costs may vary in different settings because of negotiated procurement discounts.	Indication is unchanged PPH01 Current price: £588.52 (£1,765.57 for a box of 3) Source: NHS Supply Chain PPH03 Current price: £566.88 (£1,700.65 for a box of 3) Source: NHS Supply Chain

Details of new products

Drug (company)	Details (phase of development, expected launch date)
Avental	Hemorrhoidal circular stapler (models 28QYZ-32 and 28QYZ-34)
Covidien	EEA haemorrhoid stapler

CAK Medical	Disposable PPH stapler AKYGC-32/33/34
Ethicon Endo-Surgery	HCS33 device (models PPH01 and PPH03)
Frankenman	Chex CPH32/CPH34 Circular Stapler for Rectal Prolapse and Hemorrhoids
Haiers Medical	Disposable Circular Stapler for Hemorrhoids (PPH)
Purple Surgical	Ultimate haemorrhoidal Circular Stapler
Touchstone International Medical Science	PPHplus for Single Use

Registered and unpublished trials

Trial name and registration number	**Details**
The eTHoS STUDY (haemorrhoids treatment): either Traditional Haemorrhoidectomy or Stapled Haemorrhoidopexy for haemorrhoidal disease ISRCTN80061723 eTHoS	Phase III Status: On-going Number of participants: 800 (400 to each of the two arms) Estimated study completion date: 30/09/2016
Comparing stapled hemorrhoidopexy vs. open and closed hemorrhoidectomy. ISRCTN12040297	Status: Completed Number of participants: 180 Study completion date: December 2014
Safety and Short Term Effectiveness of EEA Versus PPH Stapler for III Degree Hemorrhoids NCT01413867 EEA/PPH2011	Phase III Status: Completed Number of participants: 120 Study completion date: December 2013

Trial name and registration number	Details
Comparison Between Excisional Hemorrhoidectomy and Haemorrhoidal Dearterialisation With Anopexy NCT01263431 Emorroidi grado 3	Phase IV Status: Completed Number of participants: 50 Study completion date: April 2012
Randomized Controlled Trial Comparing Transanal Doppler-guided Arterial Ligation With Mucopexy and Stapled Haemorrhoidopexy NCT01240772 LIGALONGO	Phase III Status: Completed Number of participants: 407 Study completion date: February 2014
Transanal Haemorrhoidal Dearterialisation Versus Stapler Haemorrhoidopexy NCT01615575 URomLS1	Status: Completed Number of participants: 124 Study completion date: April 2012
Comparison Study of Surgical Staplers for the Treatment of Hemorrhoids NCT01306877	Status: Completed has results Number of participants: 149 Study completion date: January 2013
Suture hemorrhoidopexy Versus Milligan-Morgan hemorrhoidectomy for Grade 3 and 4 Symptomatic Haemorrhoidal Disease: A Prospective Randomized Controlled Study ChiCTR-TRC-13003686	Status: Recruiting Number of participants: 120 Study completion date: TBC
Hemorrhoidal Artery Ligation and Rectoanal Repair Versus Stapled Hemorrhoidopexy NCT01647763	Status: Recruiting Number of participants: 84 Estimated primary completion date: December 2015
Prospective Randomized Trial Comparing Tissue-Selecting Technique and Circular Stapled Haemorrhoidopexy for grade 3-4 hemorrhoids ChiCTR-TRC-11001506	Status: Ongoing Number of participants: 87 in each group Estimated primary completion date: TBC

Trial name and registration number	Details
PILE STOP Study (Prospective International triaL Evaluating Stapling Technique versus Open Procedure). A study comparing two surgical techniques for hemorrhoidal disease. NTR2981	Status: Recruiting Number of participants: 200 Estimated primary completion date: TBC

Relevant services covered by NHS England specialised commissioning NHS England (November 2013) N-SC016 Haemorrhoidectomy

Additional information

US Food and Drug Administration - FDA (October 2012) Ethicon Endo-Surgery Circular Stapler Sets: Class I Recall - User Difficulty With Firing Stapler Devices

References