NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA128 Stapled haemorrhoidopexy for the treatment of haemorrhoids

This guidance was issued in September 2007
The review date for this guidance is August 2010

Recommendation

- A review of the guidance should be deferred until completion of the eTHoS trial (anticipated end date March 2015). That we consult on the proposal.

Consideration of options for recommendation:

Options	Comment
A review of the guidance should be planned into the appraisal work programme.	Very little new evidence has been found that may change the recommendations made in TA128. However, one of the products included in TA128 appears to be discontinued while several new products have since come to market.
The decision to review the guidance should be deferred until completion of the eTHoS trial	**The eTHoS trial (scheduled to complete in March 2015) addresses the recommendations in TA128 for further research into the clinical and cost effectiveness of stapled haemorrhoidopexy in people with full circumferential second degree haemorrhoids.**
A review of the guidance should be combined with a review of a related technology and conducted at the scheduled time for the review of the related technology.	No related technologies exist at this time
A review of the guidance should be combined with a new appraisal that has recently been referred to the Institute.	No new appraisals were found
A review of the guidance should be incorporated into an on-going clinical guideline.	There are no applicable on-going clinical guidelines
A review of the guidance should be updated into an on-going clinical guideline.	There are no applicable on-going clinical guidelines
A review of the guidance should be	The eTHoS trial (scheduled to

transferred to the 'static guidance list'.	complete in March 2015) addresses the recommendations in TA128 for further research into the clinical and cost effectiveness of stapled haemorrhoidopexy in people with full circumferential second degree haemorrhoids.

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.

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.

Current Research Recommendation

6.1 The Appraisal Committee recommends further research to evaluate the clinical and cost effectiveness of stapled haemorrhoidopexy in people with full circumferential second degree haemorrhoids.

Relevant Institute work

Published

Circular stapled haemorrhoidectomy. Interventional Procedures Guidance IPG34. Issued Dec 2003

Haemorrhoidal artery ligation. Interventional Procedures Guidance IPG342. Issued May 2010

Stapled transanal rectal resection for obstructed defaecation syndrome. Interventional Procedures Guidance IPG351. Issued June 2010

In progress

None

Suspended/terminated

None

In topic selection

[redacted]

Safety information

FDA Medical Devices (Jun 2007). 'Class 2' recall: Proximate PPH, Procedure for Prolapse and Hemmorroids Set, REF PPH03

Details of changes to the indications of the technology

The EEA™ Hemorrhoid and Prolapse Stapler (Covidien) also has application in the distal alimentary tract for the creation of end-to-end and end-to-side anastomoses.

Details of new products

Drug (manufacturer)	Details
Hemorrhoidal circular stapler (Avental)	CE marked (CE0086)
Circular staplers for rectal prolapse and haemorrhoids (Medical Top Tree Ltd)	CE marked (CE0197)
Disposable Circular Stapler for Hemorrhoids(PPH) (Haiers Medical)	CE marked
EEA Hemorrhoid and prolapse stapler set (Covidien)	Launched 2010.
Chex CPH32 and CPH34 (Frankenman)	CE marked (CE0123)

On-going trials

Trial name and contact	Details
Prospective Randomized Trial Comparing THD Versus Stapler Operation for 3rd Degree	Phase III – currently recruiting. Study commenced Jan 2008 completion date was estimated as July 2009 but

Hemorrhoids (THD (Transanal Hemorrhoidal Dearterialization)/stapler) NCT00823784	the study is still actively recruiting participants according to clinical trials.gov.
eTHoS The eTHoS study will investigate stapled haemorrhoidopexy compared with 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 ISRCTN80061723	A pragmatic multicentre randomised controlled trial comparing stapled haemorrhoidopexy to traditional excisional surgery for haemorrhoidal disease (n= 800) Anticipated end date March 2015 Trial started May 2010

Proposal for updating the guidance
If the guidance is to be updated as an appraisal, it would be scheduled into the work programme accordingly.

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 June 2006 onwards were reviewed. The results of the literature search are discussed in the 'Appraisals comment' section below.

Implementation

No submission was received from Implementation.

Equality and diversity issues

No issues were raised in the original guidance

Appraisals comment:

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 and there are no plans to remove the CE mark.

The Autosuture stapler (Tyco Healthcare), which can be used in conjunction with the STRAM adaptor kit to perform haemorrhoidopexies, appears to be no longer available. This needs to be highlighted with a note on the webpage for TA128.

The following products 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);
- Avental Ltd, Medical Top Tree Ltd and Haiers Medical also manufacture haemorrhoidal circular staplers.

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 review at this stage.

Thirty three studies have been identified from the literature searches that were published since the publication of TA128. Twelve of these studies were randomised controlled trials, five were systematic reviews of randomised controlled trials, while the remaining articles identified were on non-randomised prospective studies. The majority of studies compared stapled haemorrhoidopexy to conventional haemorrhoidectomy; however, it is unclear which products have been used in each study.

The outcomes used in the newly identified studies are largely consistent with those considered in the previous guidance.

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. Furthermore, these new studies show that stapled haemorrhoidopexy is associated with reduced post-operative pain. These results are broadly consistent with the evidence used in TA128.

In addition to the completed studies, the eTHoS Study is an ongoing 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 is anticipated to address the recommendations made in TA128 for further research into the clinical and cost effectiveness of stapled haemorrhoidopexy in people with full circumferential second degree haemorrhoids. The anticipated end date for this trial is March 2015.

Key issues

A substantial amount of new evidence has become available since the publication of TA128, but this new evidence appears to support the findings that underpinned TA128, rather than indicating a need to change the recommendations. The new devices that have become available do not seem

to differ from the previously appraised devices. Because the recommendations are sufficently generic, there appears to be no need to review of the guidance at this stage. However, this situation should be reviewed when the eTHoS Study is reported because this study addresses a research recommendations related to full circumferential second degree haemorrhoids in TA128.
A note should be placed on the TA128 webpage to indicate that the Autosuture stapler (Tyco Healthcare) is no longer available.

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