AXA Health

Evidence review #2
February 2021

eXroid

Is there any new evidence to support the use of eXroid for the treatment of haemorrhoids?

Patient safety rating: red

Recommendation

The product remains a red treatment (AXA Health Red Patient Safety Rating). There is currently no evidence of safety or effectiveness and there is past evidence of product quality issues potentially affecting patient safety.

Background: NICE briefings and recommendations

Recommendations

In 2015 NICE made two recommendations in relation to Electrotherapy:

1.1 Current evidence on the efficacy and safety of electrotherapy for the treatment of grade I to III haemorrhoids is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 During the consent process patients should be informed, in particular, about other treatment options, including non-surgical treatments for lower grade haemorrhoids. They should be told that electrotherapy is not always successful and that repeat procedures may be necessary. They should also be told that the procedure can be painful, and general or regional anaesthesia may be needed to deliver electrotherapy at higher levels of current.

Briefing

In 2019 NICE published eXroid for internal haemorrhoids which reported the following summary:

- The technology described in this briefing is eXroid. It uses electrotherapy to shrink internal haemorrhoids.
- The innovative aspects are that the treatment does not need general, regional or local anaesthesia.
- The intended place in therapy would be instead of standard care treatments (such as rubber band ligation, injection sclerotherapy, bipolar diathermy, haemorrhoidectomy or stapled haemorrhoidectomy) in people with internal haemorrhoids.
- The main points from the evidence summarised in this briefing are from 2 non-comparative studies including 157 adults in hospital. They show that eXroid can treat internal haemorrhoids effectively without any complications.
- Key uncertainties around the evidence or technology are that there is very limited evidence comparing eXroid with any other treatments.
- The cost of eXroid is £745 per treatment. The company does not sell the device but negotiates treatment fees with clinicians and clinics. The resource impact would likely be similar or less than standard care, if surgery is avoided and the haemorrhoids are treated in 1 session. However, there is no evidence on the resource impact of the technology.

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Evidence: articles

Searching PubMed, Trip and Google Scholar for ("Hemorrhoids"[Majr] OR haemorrhoids[ti] OR hemorrhoids[ti]) AND (exroid OR electrotherapy OR electrocoagulation OR Ultroid) found no new published trials of the eXroid system. However, three articles were found that are relevant:

- Two trials for an alternative system, called the 'HET Bipolar System'. As the question relates to eXroid we have not examined it here. However, for interest, the papers are Haemorrhoid energy therapy versus rubber band ligation for the management of grade I and II haemorrhoids: a randomized trial and Prospective Case Series of a Novel Minimally Invasive Bipolar Coagulation System in the Treatment of Grade I and II Internal Hemorrhoids.
- A 2017 review Haemorrhoids: an update on management which reports:

  "Direct current therapy has gained recent favour in the form of Ultroid therapy, although the reasons for its popularity, other than aggressive marketing, are unclear. The procedure involves application of a probe onto the haemorrhoidal cushion and application of a low direct current for around 10 min per haemorrhoid. Results are at best equivalent to injection sclerotherapy18 and RBL, but with the procedure taking significantly longer."

Evidence: registries

Finally, the 2019 NICE guideline mentions a company-sponsored trial. We explored two trial registries:

- ClinicalTrials.gov
- International Clinical Trials Registry Platform

We're unable to locate it.

Further background

The Ultroid technology was removed from the market in September 2016. The Ultroid has four listings under the FDA class 2 device recalls:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=149384

- Z-0782-2017 - Ultroid Hemorrhoid Management Systems 110/220 VAC And Procedures Kit Including The Ultroid Disposable Sterile Probes
- Z-0785-2017 - Ultroid Sterile Disposable Probes Sold Individually
- Z-0784-2017 - Ultroid Procedure Pack Including The Ultroid Sterile Disposable Probes
- Z-0783-2017 - Ultroid Mobile Generator/Battery Operated Unit Including The Ultroid Sterile Disposable Probes

EXroid provided electrotherapy treatments in the UK from 2013 to 2016 using equipment from Ultroid Marketing Development Corporation.

In April 2015, the US FDA inspected Ultroid's offices and raised questions about their compliance with US regulations. The FDA sent a warning letter to Ultroid in 2015 (https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm463616.htm).

This led to the recall of Ultroid equipment and treatment kits (including those being used by eXroid) in September 2016.

Further background (continued)

On October 19, 2016 Ultroid sent a recall letter to cease further distribution of this product. The manufacturer's reason for the recall was that the products were not designed, qualified, manufactured, and/or managed under a state of control per internal quality system procedures and external laws, regulations, directives, standards, and/or guidance (such as 21 CFR 820 Quality System Regulation).

The company was renamed eXroid Technology Ltd and now designs and manufactures equipment in the UK in compliance with European regulations and standards.

The eXroid is a CE marked class IIa medical device previously known as Ultroid.

Medical devices in class IIa include surgical gloves, hearing aids, diagnostic ultrasound machines, etc. They are usually low to medium risk. Manufacturers of class IIa medical devices have to back up their declaration of compliance with a Notified Body assessment. These device approvals do not require clinical trial evidence for CE approval and can rely on equivalence to existing technologies.

The manufacturers claim that eXroid is a CQC registered service provider with over 3,500 treatments that have been conducted in the UK.

In April 2019 the NHS implemented the outcomes of a consultation it conducted in 2018.

> See Evidence-Based Interventions: Consultation Document Published by NHS England, NHS Clinical Commissioners, the Academy of Medical Royal Colleges, NHS Improvement and the National Institute for Health and Care Excellence
> https://www.engage.england.nhs.uk/consultation/evidence-based-interventions/user_uploads/evidence-based-interventions-consultation-document-1.pdf

This consultation set out:

"Numerous interventions exist for the management of haemorrhoids (piles). The evidence recommends that surgical treatment should only be considered for haemorrhoids that keep coming back after treatment or for haemorrhoids that are significantly affecting daily life. We would like to seek views on the proposed criteria included at Appendix 2 as part of this consultation.15 Changes to the diet like eating more fibre and drinking more water can often help with haemorrhoids. Treatments that can be done in-clinic like rubber band ligation, may be effective especially for less severe haemorrhoids.

"Often haemorrhoids (especially early-stage haemorrhoids) can be treated by simple measures such as eating more fibre or drinking more water. If these treatments are unsuccessful many patients will respond to outpatient treatment in the form of banding or perhaps injection. Surgical treatment should only be considered for those that do not respond to these non-operative measures or if the haemorrhoids are more severe, specifically: Recurrent grade 3 or grade 4 combined internal/external haemorrhoids with persistent pain or bleeding; or Irreducible and large external haemorrhoids

"Surgery should be performed, according to patient choice and only in cases of persistent grade 1 or 2 haemorrhoids that have not improved with dietary changes, OFFICIAL 51 banding or injection, and recurrent and symptomatic grade 3 and 4 haemorrhoids and those with a symptomatic external component. Haemorrhoid surgery can lead to complications. Pain and bleeding are common but usually resolve spontaneously. Urinary retention can occasionally occur and may require catheter insertion. Infection, iatrogenic fissuring (tear or cut in the anus), stenosis and incontinence (lack of control over bowel motions) occur more infrequently."

References

1. Watson AJM, Bruhn H, MacLeod K, et al. A pragmatic, multicentre, randomised controlled trial comparing stapled haemorrhoidopexy to traditional excisional surgery for haemorrhoidal disease (eTHoS): study protocol for a randomised controlled trial. Trials. 2014;15:439. doi:10.1186/1745-6215-15-439.
2. Watson AJM, Hudson J, Wood J, et al. Comparison of stapled haemorrhoidopexy with traditional excisional surgery for haemorrhoidal disease (eTHoS): a pragmatic, multicentre, randomised controlled trial. Lancet (London, England). 2016;388(10058):2375-2385. doi:10.1016/S0140-6736(16)31803-7.
3. Brown SR. Haemorrhoids: an update on management. Therapeutic Advances in Chronic Disease. 2017;8(10):141-147. doi:10.1177/2040622317713957.
4. https://www.nhs.uk/conditions/piles-haemorrhoids/
5. https://www.rcseng.ac.uk/-/media/files/rcs/standards-andresearch/commissioning/rcsacpgbirectalble eding2017documentfinal_jan18.pdf
A company-sponsored trial is underway but there is no evidence of this taking place, it is not currently registered or ethically approved. A further request for use of this technology should require the details of ongoing trials and the clinical data used for CE approval.