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Title Doppler-guided haemorrhoidal artery ligation - recto-anal repair

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Aim

The HAS performed this assessment at the request of the French national council (CNP) for hepato-gastroenterology professionals, which would like a new surgical method for the treatment of haemorrhoidal disease - DGHAL-RAR or Doppler Guided Haemorrhoidal Artery Ligation - Recto Anal Repair - to be funded by the French national health insurance system.
The objective of this study was to assess the efficacy and safety of DGHAL-RAR, to define the conditions for its performance and its role with respect to two other surgical methods (haemorrhoidectomy and stapled haemorrhoidopexy) in the surgical treatment of symptomatic grade 2, 3 or 4 internal haemorrhoidal disease (HD) following the failure of medical and instrumental treatment or as first-line treatment in the event of incapacitating and anatomically highly developed HD.

Conclusions and results

Eleven publications were analysed to assess the efficacy and safety of DGHAL-RAR compared to haemorrhoidectomy and stapled haemorrhoidopexy, including three meta-analyses, one randomised, controlled trial and one network meta-analysis, published between 2015 and 2018.
The analysis of the literature revealed that the available studies were of moderate to low quality, with a low risk of bias for a prospective follow-up ranging from 1.5 to 24 months. In addition, the study populations were heterogeneous and small and the management regimens could differ, with the multiplicity and lack of a homogeneous definition of assessment criteria making comparisons between the studies difficult.
Data concerning the recurrence and persistence of symptoms after one year (primary efficacy endpoint) appear to indicate that the rate of haemorrhoid recurrence is higher in the group of patients treated with DGHAL-RAR than in those treated with stapled haemorrhoidopexy for short-term follow-up (less than one year). Grade 4 haemorrhoids were a factor for a poor prognosis in terms of recurrence for DGHAL-RAR and stapled haemorrhoidopexy. In comparison with haemorrhoidectomy, the studies demonstrated that there was no significant difference for this recurrence rate endpoint between DGHAL-RAR and haemorrhoidectomy after 6 months. Assessment of the secondary efficacy endpoints appears to indicate that there is no significant difference between DGHAL-RAR and stapled haemorrhoidopexy. Furthermore, a more rapid resolution is observed for DGHAL-RAR compared to standard haemorrhoidectomy on the 15th day post-surgery; for longer follow-up periods, this difference was not significant.
The results for immediate complications after 3 months (primary safety endpoint), and for late complications - the most common being postoperative bleeding, postoperative pain, acute urinary retention and readmission or repeat surgery - do no enable any precise conclusions to be drawn. In fact, these data were reported in a descriptive manner, and were derived from studies with a low level of evidence, frequently including a limited number of patients (for rare expected events), often with a relatively short patient follow-up period. An underestimation of complication frequency cannot, therefore, be excluded.
Indirect comparison data appear to indicate that postoperative bleeding seems to be more common after DGHAL-RAR than with haemorrhoidectomy or stapled haemorrhoidopexy, which could explain why DGHAL-RAR is associated with fewer emergency repeat surgeries than the latter two methods. Moreover, the procedure time and postoperative pain are lower after DGHAL-RAR compared to the other two surgical methods, which may explain the shorter hospitalisation times and time until the first stool. Conversely, DGHAL is the procedure with the most frequent HD recurrence rate.
Considering the low level of evidence provided by the literature data analysed, it would appear that no precise conclusions concerning the superiority or non-inferiority of DGHAL-RAR compared to haemorrhoidectomy or stapled haemorrhoidopexy can be drawn. In addition, the quality of this data means that an additional risk of complications with DGHAL-RAR compared to the other two surgical methods can be neither confirmed nor excluded.
Professional organisations consider that DGHAL-RAR presents a positive benefit-risk balance compared to haemorrhoidectomy due to its lower morbidity, and has the same indications as stapled haemorrhoidopexy, i.e., grade 2 or 3 prolapse, following the failure of medical treatment and not having responded to instrumental treatment, or in which

the clinical presentation does not enable instrumental treatment to be proposed. They specify that DGHAL-RAR will very probably be favoured over stapled haemorrhoidopexy given the long-term adverse events recorded for the latter method. However, these data are not sufficient for DGHAL-RAR to replace stapled haemorrhoidopexy, since no long-term comparative data exist.

The optimal conditions for performing DGHAL-RAR have been partially defined in the literature and supplemented by professional organisations. Performance of the DGHAL-RAR method does not present any specific characteristics compared to the other two surgical methods; however, in particular, the surgeon must have been trained in an expert centre and be experienced in the field of proctological surgery. The general rules for performance on an outpatient basis are exactly the same in proctological surgery, irrespective of the method. The management of postoperative pain must be envisaged at an early stage, from the pre-/perioperative period and adopting a multi-method approach, irrespective of the type of anaesthesia used.

As regards patient expectations and preferences, the public consultation process revealed that method efficacy (few recurrences), a low number of complications and postoperative pain are the main criteria considered when choosing a surgical procedure. Patients have indicated that HD has a substantial impact on quality of life; consequently, they reiterated to practitioners the importance of better consideration of postoperative pain, and the provision of information concerning the real after-effects of the surgery, without minimising the convalescence time.

Recommendations

Given all these consistent data (literature analysis, position of professional organisations and patients' and users' opinions), it is concluded that DGHAL-RAR can be a surgical alternative to haemorrhoidectomy or stapled haemorrhoidopexy in patients with symptomatic, grade 2 or 3 internal HD.

The procedure must be performed by a surgeon well trained in an expert centre and with good knowledge of the equipment used, experienced in proctological surgery and, in particular the three surgical methods: haemorrhoidectomy, stapled haemorrhoidopexy and DGHAL-RAR. The optimal conditions to ensure quality of care and patient safety must be the same for DGHAL-RAR as for other types of proctological surgery.

The choice between the different surgical methods to treat HD is based on a medical decision, shared between healthcare professionals and patients. This decision must be based on clear and candid information of patients concerning the three techniques, taking into consideration the advantages and disadvantages of DGHAL-RAR, as well as any uncertainties with respect to its added value, particularly in the long term.

Finally, follow-up of DGHAL-RAR in real use conditions is recommended in order to identify, if applicable, any adverse events that may not yet been identified, given their frequency and the follow-up time required to observe them.

Methods

This work followed a standard assessment method based on:

- critical analysis of the literature identified after a systematic literature search and selected on the basis of explicit criteria;
- the point of view of patients and users collected via a questionnaire published for public consultation on the HAS website;
- the justified opinion of healthcare professionals involved in the surgical management of HD, collected via a questionnaire sent out to the French national councils for visceral and digestive surgery, hepato-gastroenterology and anaesthesia-intensive care professionals.

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