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Title Endoscopic submucosal dissection as treatment for potentially cancerous superficial rectal lesions

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Aim

The aim of this report was to assess the efficacy and safety of the endoscopic submucosal dissection (ESD) technique for the treatment of potentially cancerous superficial rectal lesions presenting a low risk of node involvement, by comparison to mucosectomy or to surgery, in order to conclude on the appropriateness of its public funding.

Results

The analysis of the literature showed that the available studies, along with those included in the meta-analysis, were retrospective, with high risk of bias and having included heterogeneous populations.
Concerning efficacy, no prospective data comparing ESD to mucosectomy or to local surgical resection techniques have been identified in the literature. Furthermore, no comparative data on the rate of curative resection and overall survival have been identified. In terms of technical advantages, ESD is superior to mucosectomy and comparable to local surgical resection techniques.
Concerning safety, twenty-one clinical trials reporting data specifically relevant to rectal ESD were selected and analysed. The rate of serious complications related to ESD reported in the trials is low. The rate of perforations fluctuates between 0% and 3.3% among experienced endoscopists. Perforations are usually treated endoscopically by ESD qualified practitioners, and the need for surgical revision is rare.
The benefit/risk ratio of ESD is acceptable according to the experts from the working group, for carcinoid tumours measuring less than 16 mm and for flat, potentially cancerous lesions according to set criteria:

- non-macronodular, homogeneous granular LST lesion of size greater than 30 mm or;
- granular LST lesion with macronodule (larger than 10 mm) of size greater than 20 mm or;
- Sano IIIa type lesion of size greater than 15 mm or;
- modified Kudo type Vi lesion of size greater than 15 mm.

The professional bodies contacted confirmed the applicability in France of the ESGE's recommendations, defining training and procedural methods for ESD.

Conclusions

Considering all of these elements, HAS considers that ESD may represent a treatment alternative for potentially cancerous superficial rectal lesions (see above), subject to the procedure being supervised, as defined in article L.1151-1 of the public health code, with the following recommendations:

- structure: reference centre or expert centre; centre with a digestive surgery team;
- technical platforms: level 3 endoscopy centre;
- operator qualification: initial and advanced training required (hepato-gastroenterologist or visceral surgeon, qualified for interventional digestive endoscopy), along with ESD-specific training;
- team members: a qualified operator, along with a team of anaesthetists and nurse(s) with interventional endoscopy training;
- implementation of a common procedure between the structure and the centre conducting the anatomopathological examination, to ensure that the resected tissue is immediately conditioned and transported under the requisite conditions to ensure high-quality analysis of the resected tissue;
- maintenance of a prospective and centralised register for the exhaustive collection of data on the long-term safety and efficacy of rectal ESD.

Methods

The assessment method used in this report is based on the critical analysis of the data identified in the scientific literature, the position of a working group of experts, and the recording of the justified opinion of healthcare professionals, as well as that of patients' associations, in their capacity as stakeholders. A bibliographic search was performed between January 2007 and August 2019, followed by monitoring up to June 2020. The working group met in March 2020. The stakeholders were consulted in July 2020.

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