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Title Assessment of the endoscopic transluminal necrosectomy procedure in the treatment of acute necrotizing pancreatitis

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Aim

The objectives of this work were i) to assess the benefit/risk balance of this therapeutic procedure, compared with currently validated techniques, in order to determine the relevance of its potential coverage by the French National Health Insurance, ii) to define the specific conditions for carrying it out, and iii) to determine the organizational impact of its implementation and potential dissemination.

Results

A total of eight comparative studies, including 820 patients, were selected to evaluate the efficacy and safety of this medical procedure. Meta-analyses of the main criteria showed that endoscopic intervention (pancreatic necrosectomy alone or step-up approach including drainage ± necrosectomy), compared with surgery (laparotomy and/or laparoscopy), significantly reduces:

• The risk of death by around 62 % (RR = 0.38 [95 % CI: 0.26 - 0.55], with a moderate level of certainty.

• The risk of new or persistent organ failure by about 66 % (RR = 0.34 [95 % CI: 0.22 - 0.51], with a moderate level of certainty.

• The risk of major complications or death (composite criterion) by around 60 % (RR = 0.40 [95 % CI: 0.23 - 0.67]), with a low level of certainty.

• The risk of systemic inflammatory response syndrome or sepsis by around 81 % (OR = 0.19 [95% CI: 0.07 - 0.52]), with a low level of certainty.

Differences in absolute risk confirm these results: around 369 patients out of 1,000 treated by endoscopy instead of surgery (laparotomy and/or laparoscopy) would avoid a major complication or death.

Sensitivity analysis comparing “endoscopic necrosectomy alone” to “laparotomy alone” also showed a significant reduction in mortality (RR = 0.34 [95 % CI: 0.21 - 0.56]). However, there were insufficient data to compare “endoscopic necrosectomy alone” with “laparoscopy alone”.

Conclusions

In view of these results, the HAS considered that the benefit/risk balance was favorable to “endoscopic necrosectomy alone” compared with “laparotomy alone”, particularly in terms of a significant reduction in mortality. However, the available data were insufficient to determine the benefit/risk balance of “endoscopic necrosectomy alone” compared with “laparoscopy alone”. With regard to the endoscopic step-up approach (drainage ± necrosectomy), the HAS judged the benefit/risk balance of this combination to be favorable to its surgical comparators (laparotomy and/or laparoscopy).

It should be emphasized that these conclusions are mainly based on short and medium-term data, with moderate to low levels of certainty.

The specific conditions under which endoscopic transluminal necrosectomy is performed (multidisciplinary team, qualifications, authorizations, technical platform, guidance modalities, patient information, etc.) are described in detail in the report. They are derived from the available literature and have been supplemented or adapted to the French context upon consultation of medical experts and stakeholders.

Finally, potential coverage of this medical procedure by the French National Health Insurance should have no impact on the current organization of the practice, given that the target population has already been reached (around 1,000 procedures performed per year) and that its integration is already effective (centers are already equipped, with qualified personnel).

Methods

The standard HAS method for evaluating therapeutic procedures was followed to achieve the objectives of this work. This method involved: i) systematic literature search with critical analysis of selected literature and meta-analyses according to the GRADE methodology, ii) consultation with medical experts, and iii) collection of opinions from stakeholders.

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