

TitleA Systematic Review of Natural Orifice Translumenal Endoscopic
Surgery (NOTES)™ for Intra-Abdominal SurgeryAgencyASERNIP-S, Australian Safety and Efficacy Register of New Interventional Procedures
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Aim

To assess the safety and efficacy of various intraabdominal, Natural Orifice Translumenal* Endoscopic SurgeryTM (NOTESTM) procedures that do not cut the dermis, compared to traditional intra-abdominal surgery which cuts the dermis.

Conclusions and results

The evidence base for this review was limited since there were no comparative studies, and all 22 included studies were conducted in animals to test the feasibility of NOTES. Presently, NOTES does not appear to be as safe or effective as current intra-abdominal surgical techniques, and requires further development before it can be considered in a clinical setting. Although intraabdominal access via oral, anal, or urethral orifices could be achieved reliably in all cases, the evidence does not indicate the optimal access route and method. Viscerotomy closure could not be achieved reliably in all cases, and risk of peritoneal infection has not been adequately minimized.

Several technical problems with NOTES must be resolved. Many abstracts relating to NOTES suggest that this area of surgery is developing rapidly. The review indicates that NOTES is feasible for some intraabdominal surgical procedures, but it is too early to tell if these will be comparable to current procedures and if the advantages of NOTES outweigh the disadvantages.

Recommendations

Evidence rating: The available evidence was assessed as being poor.

Safety: Currently, NOTES for intra-abdominal surgery is less safe than laparoscopic and laparotomic alternatives. *Efficacy:* NOTES for intra-abdominal surgery is currently less efficacious than laparoscopic and laparotomic alternatives.

Methods

Search strategy: MEDLINE, EMBASE, CINAHL, Current Contents, the Cochrane Library, and Entrez-PubMed were searched for studies published from 2000 to March 2007. The clinical trials database (US), NHS CRD databases, and the National Research Register (UK) were searched in March 2007, and the SAGES 2006 and 2007 annual meeting abstracts were sourced for information.

Study selection: The review included live-human or animal studies involving surgery in the intra-abdominal region using natural orifice access (cadaver studies were excluded). Studies where the new intervention involved an incision to the dermis were excluded as were studies reporting established endoscopic procedures that are not transluminal, eg, abscess or cyst drainage or debridement.

Data collection and analysis: Data were extracted by one researcher using standard data extraction tables developed *a priori* and checked by a second researcher.

Further research/reviews required

NOTES is in the early stages of development, and more robust technologies are needed to achieve reliable closure and overcome technical challenges. Well-managed human studies are needed to determine the safety and efficacy of NOTES in a clinical setting. This may be approached by performing hybrid NOTES/laparoscopic procedures that may help evaluate safety in a human model before moving to larger trials. NOTES procedures and studies should adhere to strict guidelines, eg, the membership criteria developed by NOSCAR.

^{*} *Translumenal* is used in the trademarked name 'Natural Orifice *Translumenal* Endoscopic Surgery', however *transluminal* is accepted Australian version of the word.