

HTA-Report | Summary

Health Technology Assessment of laparoscopic compared to conventional surgery with and without mesh for incisional hernia repair regarding safety, efficacy and cost-effectiveness

Friedrich M, Müller-Riemenschneider F, Roll S, Kulp W, Vauth C, Greiner W, Willich SN, Graf von der Schulenburg JM

Health policy background

Health policy aims to secure and restore people's health. To maintain the health care system at high standards as it has been is a current challenge as well as a future concern. In this context cost aspects have become increasingly important. Therefore the laparoscopic and conventional method to repair incisional hernias is investigated not only considering clinical aspects but economic aspects as well. To evaluate the status quo on this technology, a systematic research overview was conducted. Studies are evaluated with regard to clinical and economic evidence applying the latest tools for both, medical and economic dimensions. 200000 hernias were diagnosed in Germany in 2003. Amongst those, ventral hernias are the second most common diagnosed hernias following inguinal hernias. Due to that vast number the political and economic relevance is apparent. The economic implications play an important role for the unit cost and society as a whole.

Scientific background

Incisional hernias are a common complication following abdominal surgery and they represent about 80 % of all ventral hernia. In uncomplicated post-operative follow-up they can develop in about eleven percent of cases and up to 23 % of cases with wound infections or other forms of wound complications. Localisation and size of the incisional hernia can vary according to the causal abdominal scar. Conservative treatment (e. g. weight reduction) is only available to relieve symptoms while operative treatments are the only therapeutic treatment option for incisional hernia. Traditionally, open suture repair was used for incisional hernia repair but was associated with recurrence rates as high as 46 %. To strengthen the abdominal wall and prevent the development of recurrences the additional implantation of an alloplastic mesh is nowadays commonly used. Conventional hernia surgery as well as minimally-invasive surgery, introduced in the early 90s, make use of this mesh-technique and thereby showed marked reductions in recurrence rates. However, there are side effects associated with mesh-implantation. Therefore recommendations remain uncertain on which technique to apply for incisional hernia repair and which technique might, under specific circumstances, be associated with advantages over others.

DAHTA@DIMDI
Waisenhausgasse 36-38a
D-50676 Köln

Tel.: +49 221 4724-525
Fax: +49 221 4724-444
dahta@dimdi.de
www.dimdi.de

All HTA reports are available for free of charge as full texts in the DAHTA database (only in German) and at German Medical Science (gms).

Within the scope of the



Bundesministerium
für Gesundheit

Objectives

Medical questions

The goal of this report is to compare laparoscopic and conventional surgery with and without mesh for incisional hernia repair, regarding efficacy and medical safety. In order to do so, the following questions will be addressed from a medical standpoint:

- What are the medical efficacy and safety of laparoscopic compared to conventional surgery without mesh-implantation?
- What are the medical efficacy and safety of laparoscopic compared to conventional surgery with mesh-implantation?
- Which techniques of mesh-implantation and -fixation (e. g. Onlay, Inlay, Sublay, IPOM, suture, and metal clips) are associated with advantages over other techniques?
- Which factors (e. g. sex, age, recurrent hernia, hernia size, adiposity) are identifiable where certain techniques have advantages over other techniques?

Economic questions

The goal of this report is to compare laparoscopic and conventional surgery with and without mesh for incisional hernia repair, regarding cost effectiveness. In order to do so, the following questions will be addressed from an economic standpoint:

- How to judge the cost effectiveness of the respective methods?
- How to judge the transparency and the quality of the health economic studies?
- How can policy decisions be derived from the gained research results?
- What direct and indirect costs are reported in the literature?
- Is further research activity required?

Methodology

Relevant publications were identified by means of a structured search of databases accessed through the German Institute of Medical Documentation and Information (DIMDI) as well as by a manual search. The former included the following electronic resources:

SOMED (SM78), Cochrane Library – Central (CCTR93), MEDLINE Alert (ME0A), MEDLINE (ME95), CATFILEplus (CATLINE) (CA66), ETHMED (ED93), GeroLit (GE79), HECLINET (HN69), AMED (CB85), CAB Abstracts (CV72), GLOBAL Health (AZ72), IPA (IA70), Elsevier BIOBASE (EB94), BIOSIS Previews (BA93), EMBASE (EM95), EMBASE Alert (EA08), SciSearch (IS90), Cochrane Library – CDSR (CDSR93), NHS-CRD-DARE (CDAR94), NHS-CRD-HTA (INAHTA) as well as NHS-EED (NHSEED).

The present report includes German and English literature published until 31.08.2005. The search parameters can be found in the appendix. No limits were placed on the target population. The methodological quality of identified studies was assessed, using the criteria recommended by the Scottish Intercollegiate Guidelines Network Grading Review Group and by the German Scientific Working Group technology Assessment for Health Care.

Results

Medical results

The literature search identified 693 medical publications of which 152 could be identified as relevant to the research question. Ten further publications have been identified through manual search, leaving a total of 162 medical studies. Of the 17 studies assessed to be relevant to our particular topic, including two systematic reviews, one HTA, one randomised controlled trial (RCT), and 13 cohort studies. Only one cohort study compared laparoscopic and conventional surgery with and without mesh-implantation for incisional hernia repair, while the remaining 16 studies compared laparoscopic and conventional surgery with mesh-implantation. The only study comparing laparoscopic and conventional surgery without mesh found substantial differences in terms of baseline characteristics between treatment groups. The outcome parameters showed decreased recurrence rates for the laparoscopic repair and similar safety of the procedures. Studies comparing laparoscopic and conventional surgery with mesh found similar outcome in terms of medical efficacy and safety with a trend towards lower recurrence rates, length of hospital stay and postoperative pain as well as decreased complication rates for laparoscopic repair in the majority of studies. The impact of the technique of mesh-implantation and mesh-fixation as well as the impact of certain patient related factors on the choice of technique has not been systematically investigated in any of the studies.

Economic results

Based on a systematic literature review 97 economic studies were identified. After studying the abstracts, 36 research papers were considered relevant and ordered to pore over. One more study was identified manually. Overall 37 entire economic research papers were considered. None of the economic studies matched the inclusion criteria. Therefore, the criteria economic evidence was loosened. Following that, five economic studies were identified and included.

Basically, there is no full economic evaluation focussing the relevant alternatives. Cost comparisons were available, even though only briefly attached to clinical research results. None of the studies primarily aimed to investigate costs or even effectiveness.

Discussion

In general, three operative techniques are available for incisional hernia repair: the conventional technique without mesh-implantation, the conventional technique with mesh-implantation and the laparoscopic technique. All identified studies suffer from significant methodological weaknesses, such as differences between treatment groups, mainly due to the non-randomised study design, small treatment groups causing low case numbers and lack of statistical power as well as the neglect of important risk factors or adjustment for those. Therefore, no conclusive differences could be identified concerning compared operative techniques, mesh-implantation and mesh-fixation techniques or certain risk factors. Only the comparison of laparoscopic and conventional technique with mesh provides some evidence for a trend towards similar or slightly improved outcome in terms of medical efficacy and safety for the laparoscopic technique. However, there is still a great need for further research to investigate these questions.

Basically, there is no full economic evaluation focussing on the relevant alternatives. Cost comparisons were available, even though only briefly attached to clinical research results. None of the studies primarily aimed to investigate costs or even cost-effectiveness.

Ethical, social and legal considerations

No ethical, social and legal aspects were identified in the literature.

Conclusion

When deciding on the choice of operative technique for incisional hernia repair, surgeons take various considerations into account, including patient characteristics, hernia characteristics and their own experience. The studies included in this HTA did not provide conclusive evidence to answer the research questions. Nonetheless, laparoscopic surgery demonstrated a trend towards similar or slightly improved outcome following incisional hernia repair. However, for more conclusive recommendations on the choice of operative technique, high quality trials are required

From the economic perspective, alternative methods are not yet assessed. Only five of the studies involve a cost analysis, though in an insufficient manner. None of the studies identified were laid out as a health economic evaluation. Hence, further research is strongly recommended.