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End colostomy - with or without mesh reinforcement

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HTA-centrum
Sahlgrenska Universitetssjukhuset

VÄSTRA GÖTALANDSREGIONEN
SAHLGRENSKA UNIVERSITETSSJUKHUSET

End colostomy - with or without mesh reinforcement [Terminal kolostomi - med eller utan nätförstärkning]

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HTA-centrum

Summary of the Health Technology Assessment

Method and patient group

The construction of a colostomy is a surgical procedure for deviation of the gastrointestinal tract when intestinal continuity cannot be restored. Rectal cancer is the most common indication for the procedure.
The conventional technique is marred with a high frequency of parastomal hernias that may require additional surgery. Use of a synthetic mesh as reinforcement of the abdominal wall has been suggested to prevent the development of parastomal hernias.

Question at issue, PICO

Is the construction of a colostomy with a mesh better than construction of a colostomy without a mesh, in terms of health related quality of life, stoma function, need for reoperation, frequency of parastomal hernias, or other complications?

PICO: (P= Patients, I= Intervention, C= Comparison, O=Outcome)

P = Adults who need an end colostomy.
I = Construction of an end colostomy with the use of a mesh.
C = Construction of an end colostomy without the use of a mesh.
O = Critical:
- Health related quality of life.
- Stoma function.
- Reoperation.
- Other complications.

Important:
- Parastomal hernia.

Results

Seven relevant articles were identified: one systematic review (SR) with a partly different PICO, three randomized controlled trials (RCTs, four articles) and two cohort studies. The SR was only commented upon, whereas the other six articles were critically reviewed. The quality of evidence according to GRADE was based on the three RCTs. Different surgical techniques were used in the RCTs. In two RCTs open surgery with mesh in a sublay position was used while laparoscopic surgery with intra-peritoneal mesh was used in the third RCT. Different diagnostic techniques for parastomal hernias were used: clinical in one, radiological (CT) in one, and clinical + radiological in one RCT. Because of the heterogeneity between studies, it was decided not to perform a meta-analysis.

Health related quality of life and Stoma function

The systematic literature search did not identify any study reporting on health related quality of life, or stoma function.

Reoperation

Three randomized controlled trials reported on reoperations due to parastomal hernia. Indications for reoperation were not well described. The reported frequency of reoperations in the RCTs did not differ significantly between the two groups (0-6% with, as compared to 0-19% without a prophylactic mesh). Very low quality of evidence (GRADE⊕◯◯◯).

Other Complications
There were no significant differences regarding complications between the treatment groups.

Parastomal Hernia
Three randomized controlled trials (four papers) showed a moderate to strong, significant reduction in the frequency of parastomal hernias with, as compared to without, the use of a prophylactic mesh (median 11%, range 4–50%, as compared to median 61%, range 41–94%). The cohort studies showed similar findings. Moderate quality of evidence (GRADE⊕⊕⊕◯).

Ethical aspects
The main conclusion of this report is that there is moderate quality evidence for prevention of parastomal hernia with a synthetic mesh. Many patients have small or no problems with a limited parastomal hernia. However, there are no health related quality of life or stoma function data reported. Several large RCTs are underway.

Economical aspects
With the present frequency of colostomy operations the expected cost increase will be approximately 600,000 SEK. Long-term cost effectiveness will be dependent on whether a reduced frequency of revisional surgery can be demonstrated.

Concluding remarks
Construction of an end colostomy is frequently necessary for rectal cancer treatment as well as for treatment of other conditions. Parastomal hernia is a common complication that sometimes requires surgical repair. It is uncertain whether construction of a colostomy with a mesh reinforcement, as compared to without, leads to a reduced frequency of reoperations (GRADE⊕◯◯◯). Consequences for health related quality of life, or stoma function with the use of a mesh are not studied. Construction of a colostomy with a mesh reinforcement, as compared to without, probably reduces the incidence of parastomal hernia (GRADE⊕⊕⊕◯). There are several ongoing large (200-300 patients) RCTs, expected to be completed within two years.

Which health technology or method will be assessed?

1a **The question was posed by**

Anders Hyltander, MD, Ass Professor, Department of Surgery, Sahlgrenska University Hospital/Östra, Göteborg, Sweden.
Haglind Eva, MD, Professor, Department of Surgery, Sahlgrenska University Hospital/Östra, Göteborg, Sweden.

1b **Participants, in the project**

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1c **Participants, from the HTA centre and external reviewers**

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External reviewers

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Christian Rylander, MD, PhD, Department of Anesthesia and Intensive Care, Sahlgrenska University Hospital, Göteborg, Sweden.

1d **Conflicts of interest for the proposer or any of the participants in the work group**

No conflicts of interest reported.

Disease/disorder of Interest and Present Treatment

2a Disease/disorder of interest and its degree of severity

- ☐ Risk of premature death.
- ☑ Risk of permanent illness or damage, or reduced quality of life.
- ☑ Risk of disability and health-related quality of life.

The construction of a colostomy is a surgical procedure for deviation of the large bowel (colon). The distal end of the healthy part of the large bowel is pulled through a hole in the abdominal wall and fixated. The distal portion of the bowel is either excised or closed, depending on the indication for surgery (see below for a more detailed description).

There are different reasons to construct a colostomy; malignant tumors of the colon, or more commonly, the rectum, fecal incontinence, or acute large bowel perforations (i.e. perforated diverticulitis).
Parastomal herniation is one of the most common complications of a colostomy. Risk factors associated with parastomal hernia include high age, high BMI, high ASA (the American Society of Anaesthesiologists) risk classification, previous abdominal surgery, raised intra-abdominal pressure, diabetes, corticosteroid use, malignancy and emergency surgery.
Although a parastomal hernia usually is asymptomatic, it sometimes requires surgical intervention due to pain, obstruction, leakage problems, or for cosmetic reasons.

2b Prevalence and incidence of the disease/disorder

Approximately 100 to 150 patients per year receives a colostomy in the Sahlgrenska University Hospital catchment area of about 700,000 inhabitants.

2c Present treatment of the disease/disorder in the outpatient setting/ in-patient setting

A colostomy can be permanent or temporary. The colostomy is most commonly placed in the upper part of the left lower abdominal quadrant. However, colostomy location should be as convenient as possible for the patient from a bandaging point of view.
An end colostomy is performed as follows:
a. A circular incision in the skin at the (preferably) preoperatively marked place is done.
b. Dissection through the subcutaneous tissue to the anterior (rectus) abdominal fascia, which is opened by an incision (cross, circle or longitudinal).
c. The muscular fibers are separated bluntly.
d. The dorsal fascia and the peritoneum is opened.
e. The distal end of the healthy part of the colon is pulled through the incision and fixed by sutures.

2d **Number of patients per year who undergo current treatment regimen**

In 2012, 186 patients received a colostomy at the Sahlgrenska University Hospital. (cf. 2b).

2e **The normal pathway of a patient through the health care system**

The patient is referred from a primary care physician, or from other hospital departments, or admitted as an emergency case. Surgery is planned in relation to the underlying disease. All patients who will receive a colostomy meet a stoma nurse (or sometimes in the acute setting, the operating surgeon) for preoperative marking of the stoma site. After surgery the patient will be trained in management of the stoma. At discharge from the hospital, there should be a plan for periodical checks at the stoma nurses office.

In our institution, the stoma nurse usually sees the patients at least five times per year. If the patient does not have any stoma related complications or problems with bandaging after the first year, further stoma care will be carried out at a primary care setting.

Some elderly or disabled patients are not capable of managing their stomas and receive help from home care services.

If a patient needs additional assessment, because of stoma related complications, a surgeon is contacted.

2f **Actual wait time in days for medical assessment /treatment**

In case of a colorectal cancer (in the non-emergency setting) as the underlying condition, surgery is usually performed within four weeks. However, if neoadjuvant treatment (radio/chemotheraphy) is needed, surgery may be performed later.

In benign disease, the expected maximum waiting time for an elective colostomy is three months.

Present Health Technology

3a **Name/description of the health technology at issue**

End colostomy, with reinforcement using a mesh.
Access to the abdominal cavity is gained by a midline incision, or by laparoscopy. A circular incision is made at the preoperatively marked site, through all layers of the abdominal wall. As a reinforcement of the abdominal wall, a synthetic mesh is inserted around the bowel. The most commonly used placement for the mesh is 'sublay', i.e. below the rectus abdominis muscle, anterior to the posterior rectus sheath. The mesh is fixed with sutures or some other device. An alternative mesh placement is 'intra-peritoneal', i.e. directly on the peritoneal surface.
Different types of mesh, with varying proportions of polypropylene content and absorbable material, are used.

3b **The work group's understanding of the potential value of the health technology**

It is suggested that using mesh reinforcement at the construction of a colostomy may reduce the rate of parastomal hernia.
A prophylactic mesh at colostomy construction has been used in several hospitals in Sweden, and worldwide for years. Clinicians from other surgical departments in Sweden have reported (personal communication) a lower frequency of parastomal hernias without excess morbidity compared to the conventional technique.
The technique involves increased costs for the mesh and slightly longer operating time. However, if there is a reduction in the number of parastomal hernias, that require revisional surgery or other extended management, cost-effectiveness is plausible.

A mesh can be used in all patients who receive a colostomy, regardless of the underlying condition (rectal/colon cancer (C20), fecal incontinence (R15, 9)).
The use of a prophylactic mesh is increasing in Sweden. There is an ongoing development of the mesh technology, including non-synthetic/biological meshes.

Within our group, we have previously feared that the use of a mesh may result in more complications. Another reason for not using a prophylactic mesh is the low frequency of parastomal hernias requiring reoperation.
We have made efforts in improving/changing the surgical technique during the construction of the colostomy hoping to reduce the incidence of hernia without using prophylactic mesh.

3c **The central question for the current HTA project in one sentence**

Is the construction of a colostomy with a mesh better than construction of a colostomy without a mesh, in terms of health related quality of life, stoma function, need for reoperation, frequency of parastomal hernias, or other complications?

3d **PICO: (P= Patients, I= Intervention, C= Comparison, O=Outcome)**

P = Adults who need an end colostomy.

I = Construction of end colostomy with the use of a mesh.

C = Construction of end colostomy without the use of a mesh.

O = Critical:

Health related quality of life.
Stoma function.
Reoperation.
Other complications.

Important:

Parastomal hernia.

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Review of the Quality of Evidence

4 Search strategy, study selection and references – Appendix 3

During December 2012 two librarians (YH, ME) performed systematic searches in PubMed, Embase, the Cochrane Library, ProQuest Nursing & Allied Health Source and a number of HTA-databases. Reference lists of relevant articles were also scrutinized for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are accounted for in Appendix 3. The librarians conducted the literature searches, selected studies and independently assessed the obtained abstracts and a first selection of full-text articles for inclusion or exclusion. Any disagreements were resolved in consensus. The remaining articles were sent to the work group, who read the articles independently and then decided in a consensus meeting which articles that should be included.

The literature search identified a total of 300 articles (after removal of duplicates). The librarians then excluded 271 articles after reading their abstracts. Another 14 articles were excluded by the librarians after reading the articles in full text. The remaining 15 articles were sent to the work group. Seven of them were finally included in the report, including one systematic review only commented upon. The other six articles were controlled studies that have been critically appraised, using checklists from SBU (Swedish Council on Health Technology Assessment) for randomized controlled trials and cohort studies.

5a Describe briefly the present knowledge of the health technology

Seven articles were identified, one systematic review (SR) including the articles described below but with a partly different PICO, three randomized controlled trials (RCTs, four articles) with low to moderate risk of bias, and two cohort studies. The SR was only commented upon, whereas the other six articles were critically reviewed. The quality of evidence according to GRADE was based on the three RCTs.

The SR included also ileostomy construction (Wijeyekoon *et al*., 2010). The conclusions in the SR were similar to those of the present HTA.
In our present HTA, there were four RCTs (two articles reported one and five year follow-up, respectively, for the same group of patients). Of the articles published by Jänes *et al.*, the five year follow-up study (Jänes *et al*., 2009), was used for assessment of the quality of evidence (GRADE).

Parastomal hernia was diagnosed with different methods in the studies; clinical (Jänes *et al*., 2004, 2009), radiological by computed tomography (Lopez-Cano *et al*., 2012), and both clinical and radiological (Serra-Aracil *et al*., 2009).
In addition, different techniques were used for mesh placement. In two of the studies (Jänes *et al*., 2004, Serra-Aracil *et al*., 2009) the mesh was placed sub-muscularly and in the third (Lopez-Cano *et al*., 2012) intra-peritoneally.
Follow-up times and surgical techniques (open and laparoscopic surgery respectively) were different. Because of the clinical heterogeneity between studies, it was decided not to perform a meta-analysis.

Health related quality of life and stoma function were not studied in any of the articles.

Reoperation (Appendix 1:2)
Three RCTs reported on reoperations due to parastomal hernia. The surgeon deciding to reoperate a parastomal hernia was not blinded to the surgical technique used for the stoma construction, which introduced a significant risk of bias. The frequency of reoperation was not different in the three RCTs in the mesh (median 0, range 0–6%), versus the conventional (median 19, range 7–19%) groups, respectively.
Conclusion: It is uncertain whether the frequency of reoperations for parastomal hernia after end colostomy is lower after mesh versus conventional end colostomy construction. Low quality of evidence (GRADE⊕◯◯◯).

Complications (Appendix 1:3)
The frequency of complications was low and similar in the two groups in the RCTs where open surgery was used. In the laparoscopic study (Lopez-Cano *et al*., 2012) more general complications were reported in the mesh group: 11 general, and two stoma-related complications, among the mesh group (n=18), and three general and two stoma-related complications in the control group (n=18).

Parastomal hernia (Appendix 1:1)
The outcome was reported in three RCTs (four articles).
One RCT (Jänes *et al*., 2004) was stopped prematurely because of a large observed difference in the rate of parastomal hernia, which led the authors to consider it unethical to proceed with further inclusions. Forty-seven out of 54 patients had surgery due to malignant disease and 12 versus six patients, in the mesh and control groups respectively, died before five-year follow-up. Seven per cent had parastomal hernia in the mesh group compared to 74% among the controls ($p< 0.001$).
In the study by Serra-Aracil *et al*. (2009), parastomal hernia in the mesh group was diagnosed clinically in 15%, and radiologically in 22% of the patients. The corresponding figures for the control group were 41% and 44%, respectively (n.s. between groups).
Laparoscopic surgery with intra-peritoneal mesh was used in the Lopez-Cano *et al*. (2012) study. Diagnosis of parastomal hernia was radiological and the frequencies were 50% and 94%, respectively, in the mesh and control groups ($p= 0.008$).
Conclusion: The frequency of parastomal hernia is probably reduced by mesh versus conventional colostomy construction. Moderate quality of evidence (GRADE⊕⊕⊕◯).

5b **Outcome tables – Appendix 1:1-1:3**

5c **Excluded articles – Appendix 2**

5d **Ongoing research**
A search in Clinicaltrials.gov (2012-12-11) using the search terms (colostomy OR "end colostomy" OR stoma) AND mesh identified 12 trials. Eight were relevant for our question. Two of these are completed and included in this report (Serra-Aracil *et al*., 2009, Jänes *et al*., 2009). Five RCTs with parastomal hernia as the primary end point and an estimated inclusion of 790 patients are reported as ongoing. One of these (32 patients) investigates laparoscopic mesh placement, the remaining studies concerns open surgery. One additional study investigates the safety and efficacy of a collagen mesh.
Short description of the RCTs:

1. 60 patients with the need for a permanent colostomy are randomized to mesh/no mesh, and followed for 48 months after surgery (Oslo University hospital, Norway). Planned study completion in September 2015 (http://ClinicalTrials.gov/show/NCT00496418).

2. 198 patients with recto-sigmoidal cancer are randomized in a multicenter trial, to one of two techniques for mesh placements (not specified), or no mesh, and followed for 60 months (University Hospital, Gentofte, Copenhagen, Denmark). Planned completion in February 2015 (http://ClinicalTrials.gov/show/NCT00641342).

3. 300 patients are randomized to mesh/no mesh in a multicenter trial and followed for 36 months (Dept. of Surgery, Sunderby Hospital, Luleå, Sweden). Planned completion in December 2013 (http://ClinicalTrials.gov/show/NCT00917995).

4. 200 patients are randomized in a multicenter trial to mesh/no mesh and followed for 24 months (Centre Hospitalier Universitaire de Nīmes, France). Planned completion November 2015 (http://ClinicalTrials.gov/show/NCT01380860).

5. 32 patients with rectal cancer are randomized in a multicenter trial to laparoscopic intraperitoneal mesh placement, or no mesh, and followed for 12 months (Corporacion Sanitaria Universitaria Parc Tauli, Barcelona, Spain). Planned completion in June 2014 (http://ClinicalTrials.gov/show/NCT01722565).

6 Medical societies or health authorities that recommend the new health technology

No current recommendation.

- ☐ **The National Board of Health and Welfare**
- ☐ **Medical societies**
- ☐ **Other health authority**

Ethical aspects

7 Ethical consequences

The main conclusion of this report is that there is very low quality of evidence for a reduced reoperation rate with, as compared to without, mesh reinforcement and there are no health related quality of life or stoma function data reported. For prevention of parastomal hernia, there is moderate quality evidence for a beneficial effect of using a synthetic mesh. Many patients have few or no problems with a small parastomal hernia. Longer surgical time may reduce the operating room capacity for other patient groups.

Organisation

8a **When the new health technology can be put into practice**
Promptly. No major structural changes or large investments are needed.

8b **Usage of the technology in other hospitals in Region Västra Götaland**
To our knowledge, prophylactic mesh at colostomy construction is used more or less as a routine in the surgical departments in SÄS, NÄL and SKAS hospitals.
Prophylactic mesh is routine in the surgical clinic at the Sundsvall hospital.
Eight surgical clinics (Nyköping, Helsingborg, Huddinge, Solna, Mora, Sunderbyn, Umeå, Uppsala) are engaged in one of the studies referred to in 5d ’ongoing research’ (StomaMesh).

8c **Consequences of the new health technology for personnel, according to the work group**
Besides surgeon training in the surgical technique, no other consequences are expected.

8d **Consequences for other clinics or supporting functions at the hospital or in the Region Västra Götaland**
No.

Economy aspects

9a Present costs of currently used technologies

The basic cost for patients who receive a colostomy is about 5,329 SEK per day. Total cost varies depending on what care the patients have required during the hospitalization (intensive care, radiology, drugs etc). The average cost for operation of rectal cancer including construction of an end colostomy varies widely. The cost ranges between approx. 20,000 SEK and 100,000 SEK, depending on whether the operation solely concerns rectal cancer, or if additional organs need to be involved during the surgery.

The stoma nurse usually sees the patients at least five times per year and the cost for each visit is 616 SEK.

9b Expected costs of the new health technology

The cost for the mesh varies depending on size of the mesh. The most commonly used mesh, 10x10 cm, costs about 460 SEK per mesh. The estimated cost for surgery is 213 SEK per minute. Operation time varies widely for each type of surgery as well as for each patient depending on complexity of the case, surgeons experience etc. Placement of a prophylactic mesh is estimated to add fifteen to twenty minutes to the operation time, which gives a total extra cost of 3,188-4,250 SEK.

9c Total change of cost

The extra cost per patient receiving a prophylactic mesh will be 3,648–4,710 SEK. If a prophylactic mesh is used for 150 end colostomies per year, the increased cost will be around 600,000 SEK. If the use of a prophylactic mesh is cost effective or not will depend on results of future studies, mainly whether the frequency of reoperations is reduced and health related quality of life improves.

9d Possibility to adopt and use the new technology within the present budget (clinic budget/hospital budget)

No.

9e Available analyses of health economy cost advantages or disadvantages

No.

Unanswered Questions

10a **Important gaps in scientific knowledge**

There is currently insufficient evidence to determine whether the use of a prophylactic mesh during end colostomy construction reduces the need for revisional surgery, improves health related quality of life, stoma function, or is cost-effective.

10b **Interest in the own clinic/research group/organisation to start studies/trials within the research field at issue**

Yes. We are planning to start a randomized controlled multicenter trial this year (three-arms), in which we compare the standard incision in the external muscular fascia with another type of incision (round instead of cruciate) or a mesh. The primary end-point for this trial is parastomal hernia rate within one year. Furthermore we aim to answer questions regarding health related quality of life, reoperations, stoma function, and health economy.

Statement from HTA-centrum of Region Västra Götaland, Sweden

End colostomy – with or without mesh reinforcement

Question at issue, PICO

Is the construction of a colostomy with a mesh better than construction of a colostomy without a mesh, in terms of health related quality of life, stoma function, need for reoperation, frequency of parastomal hernias, or other complications?

PICO: (P= Patients, I= Intervention, C= Comparison, O=Outcome)

P = Adults who need an end colostomy.
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O = Critical:
- Health related quality of life.
- Stoma function.
- Reoperation.
- Other complications.

Important:
- Parastomal hernia.

Summary of the health technology assessment

Method and patient category

The construction of a colostomy is a surgical procedure for deviation of the gastrointestinal tract when intestinal continuity cannot be restored. The most common indication for the procedure is rectal cancer. The conventional technique is marred with a high frequency of parastomal hernias. Use of a synthetic mesh as reinforcement of the abdominal wall has been suggested to prevent the development of parastomal hernias. Many parastomal hernias do not require surgical repair, however.

Scientific documentation

Seven relevant articles were identified: the latest published systematic review (SR), with a partly different PICO, three randomized controlled trials (RCTs, four articles) and two cohort studies. The SR was only commented upon, the other six articles were critically appraised. Assessment of the quality of evidence (GRADE) was based on the three RCTs. Different surgical techniques were used in the RCTs. Open surgery with mesh reinforcement in a sublay position was used in two RCTs, and laparoscopic surgery with intra-peritoneal mesh was used in one RCT. Different diagnostic techniques for parastomal hernias were used: clinical, radiological (CT), and combined. Because of the clinical heterogeneity, it was decided not to perform a meta-analysis.

Results

Health related quality of life and Stoma function

The systematic literature search did not identify any study reporting on these outcomes.

Reoperation

Three RCTs reported reoperations due to parastomal hernia, although indications were not well described. The frequency of reoperations in the RCTs did not differ significantly between the two groups (0 – 6% with, as compared to 0-19% without a prophylactic mesh). Conclusion: It is uncertain whether construction of a colostomy with, as compared to without, mesh reinforcement reduces the frequency of reoperations for parastomal hernias. Very low quality of evidence (GRADE⊕◯◯◯).

Other Complications

There were no significant differences regarding other reported complications between the two groups.

Parastomal Hernia
Three RCTs (four articles) showed a moderate to strong, significant reduction in the frequency of parastomal hernias with, as compared to without, the use of a mesh (median 11%, range 4–50%, as compared to median 61%, range 41–94%). The cohort studies showed similar findings. Conclusion: Construction of a colostomy with, as compared to without, mesh reinforcement probably reduces the incidence of parastomal hernia. Moderate quality of evidence (GRADE⊕⊕⊕◯).

Ethical aspects
The main conclusion of this report is that there is moderate quality evidence for prevention of parastomal hernia with a synthetic mesh. Many patients have few or no problems with a small parastomal hernia. However, there are no health related quality of life or stoma function data reported. Several large RCTs are underway.

Economical aspects
With the present frequency of colostomy operations the expected cost increase will be approximately 600,000 SEK per year. If this is long-term cost effective or not will depend on the results of future studies and mainly depend on whether a reduced frequency of revisional surgery and improved health related quality of life can be demonstrated.

Concluding remarks
Construction of an end colostomy is sometimes necessary for rectal cancer treatment as well as for treatment of other conditions. Parastomal hernia is a common complication that in many cases is not associated with symptoms but occasionally necessitates surgical repair. It is uncertain whether construction of a colostomy with, as compared to without, mesh reinforcement reduces the frequency of reoperations (GRADE⊕◯◯◯). Consequences for health related quality of life, or stoma function with the use of a mesh have not been studied. Construction of a colostomy with, as compared to without, mesh reinforcement probably reduces the incidence of parastomal hernia (GRADE⊕⊕⊕◯). There are several ongoing large (200-300 patients) RCTs, expected to be completed within two years. The results of future studies may elucidate whether the use of mesh reinforcement is cost effective.

The Regional Health Technology Assessment Centre (HTA-centrum) of Region Västra Götaland, Sweden (VGR) has the task to make statements on HTA reports carried out in VGR. The statement should summarise the question at issue, scientific documentation, efficacy, risks, and economical and ethical aspects of the particular health technology that has been assessed in the report.
HTA was accomplished during the period of 2012-12-05–2013-05-29. Last search updated in December 2012.

On behalf of the HTA quality assurance group, in Region Västra Götaland, Sweden
Göteborg, Sweden, 2013-05-29
Christina Bergh, Professor, MD, Head of HTA-centrum of Region Västra Götaland, Sweden

Utlåtande från HTA-centrum Västra Götalandsregionen

Terminal kolostomi – med eller utan förstärkning med nät

Fokuserad fråga, PICO

Är konstruktion av en terminal kolostomi med nätförstärkning bättre än terminal kolostomi utan nätförstärkning vad gäller hälsorelaterad livskvalitet, stomifunktion, reoperationsbehov, frekvensen av parastomalt bråck, eller andra komplikationer?

PICO: (P= Patients, I= Intervention, C= Comparison, O=Outcome)

P = Vuxna (> 18 år) som behöver terminal kolostomi.
I = Konstruktion av terminal kolostomi med nätförstärkning.
C = Konstruktion av terminal kolostomi utan nätförstärkning.
O = Kritiska:
- Hälsorelaterad livskvalitet.
- Stomifunktion.
- Reoperation.
- Övriga komplikationer.

Viktiga:
- Parastomalt bråck.

Sammanfattning

Metod och patientkategori

Terminal kolostomi är en kirurgisk åtgärd för att deviera magtarmkanalen när kontinuitet i tjocktarmen inte kan återställas. Den vanligaste indikationen är ändtarmscancer. Den konventionella tekniken för terminal kolostomi belastas av en relativt hög frekvens av parastomala bråck (utbuktning av bukinnehåll bredvid stomin), vilka ibland kräver kirurgisk åtgärd. Användning av ett syntetiskt nät för förstärkning av bukväggen har föreslagits som en metod för att förebygga uppkomsten av parastomala bråck.

Resultat

Sju relevanta artiklar identifierades: den senast publicerade systematiska översikten, med ett delvis annorlunda PICO, tre randomiserade kontrollerade studier (RCT, fyra artiklar) och två kohortstudier. Den systematiska översikten kommenterades endast medan de övriga sex artiklarna granskades. Bedömningen av evidenskvalitet (GRADE) baserades på de tre randomiserade studierna. Olika kirurgiska tekniker användes i dessa tre studier. I två av studierna användes öppen kirurgi med nätförstärkning intrafasciellt medan laparoskopisk kirurgi med intraperitonealt nät användes i den tredje studien. Olika diagnostiska metoder för diagnos av parastomalt bråck användes: enbart klinisk diagnos i en, radiologisk (datortomografi) i en och klinisk + radiologisk i den tredje studien. På grund av denna kliniska heterogenitet beslutades att en meta-analys ej var tillämplig.

Hälsorelaterad livskvalitet och stomifunktion

Inga studier som använt dessa utfall identifierades

Reoperation

Tre RCT rapporterade reoperation för parastomalt bråck men indikationerna för reoperation var dåligt beskrivna. Frekvensen reoperationer i de randomiserade studierna skiljde sig inte signifikant mellan de två grupperna med (0 – 6% med nät jämfört med 0 – 19% utan förstärkning med nät).
Slutsats: Det är osäkert huruvida konstruktion av en terminal kolostomi med, jämfört utan, nätförstärkning reducerar frekvensen reoperationer av parastomala bråck. Otillräckligt vetenskapligt underlag (GRADE⊕◯◯◯).

Andra komplikationer

Det förelåg inga signifikanta skillnader vad gäller andra komplikationer mellan konstruktion av en terminal kolostomi med, jämfört utan, nätförstärkning.

Parastomalt bråck
Tre RCT (fyra artiklar) visade en avsevärd och signifikant minskning av frekvensen parastomalt bråck med, jämfört utan, nätförstärkning (median 11%, range 4–50% jämfört med median 61%, range 41-94%). Kohortstudierna visade liknande fynd.
Slutsats: Konstruktion av terminal kolostomi med, jämfört utan, nätförstärkning reducerar frekvensen parastomalt bråck. Måttligt starkt vetenskapligt underlag (GRADE⊕⊕⊕◯).

Etiska aspekter
Det finns ett otillräckligt vetenskapligt stöd för att nätförstärkning av en terminal kolostomi reducerar frekvensen av reoperationer och data om hälsorelaterad livskvalitet och stomifunktion saknas helt. Det föreligger ett måttligt starkt vetenskapligt underlag för att nätförstärkning av en terminal kolostomi förebygger parastomalt bråck, men många av patienterna har få eller inga besvär av ett litet parastomalt bråck. Flera stora RCT är pågående.

Ekonomiska aspekter
Med föreliggande antal terminal kolostomi operationer beräknas en kostnadsökning med 600 kkr årligen om terminal kolostomi med nätförstärkning införs som rutin. Huruvida detta är kostnadseffektivt kan inte bedömas.

Sammanfattande slutsats
Konstruktion av terminal kolostomi är ibland nödvändigt vid behandling av ändtarmscancer liksom vid behandling av vissa andra sjukdomar. Parastomalt bråck är en vanlig komplikation som i flertalet fall inte ger några symtom men som ibland gör att reoperation krävs. Nätförstärkning av en terminal kolostomi har införts som en metod att kunna reducera frekvensen parastomala bråck. Det är osäkert huruvida nätförstärkning reducerar behovet av reoperation (GRADE⊕◯◯◯). Konsekvenserna av nätförstärkning för hälsorelaterad livskvalitet och stomifunktion är okända. Konstruktion av en terminal kolostomi med, jämfört utan, nätförstärkning reducerar frekvensen av parastomala bråck (GRADE⊕⊕⊕◯). Det pågår flera stora (200-300 patienter) randomiserade studier avseende dessa patienter och dessa studier beräknas vara färdigställda inom två år. Dessa studier kan troligen belysa om nätförstärkning av en terminal kolostomi är kostnadseffektivt och förbättrar den hälsorelaterade livskvaliteten.

HTA-kvalitetssäkringsgruppen har ett uppdrag att yttra sig över genomförda HTA i Västra Götalandsregionen. Yttrandet skall innefatta sammanfattning av frågeställning, samlat kunskapsläge och evidensgradering för patientnytta och risker samt ekonomiska och etiska aspekter för den studerande teknologin.

Projektet har pågått under perioden 2012-12-05 – 2013-05-29
Sista uppdatering av artikelsökning december 2012

För HTA-kvalitetssäkringsgruppen 2013-05-29

Christina Bergh
Ordförande

HTA-kvalitetssäkringsgruppen:

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Professor, överläkare
Thomas Franzén
Bibliotekschef
Magnus Hakeberg
Professor, övertandläkare
Lennart Jivegård
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Peter Johansson
Med dr, överläkare

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Med dr, tandläkare
Henrik Sjövall
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Therese Svanberg
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Kjell-Arne Ung
Docent, överläkare
Margareta Warrén Stomberg
Docent, Universitetslektor

Project: End colostomy, with or without mesh reinforcement
Appendix 1:1
Outcome variable: Parastomal hernia (clinical and/or radiological assessment) after end-colostomy

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Mesh	Control Without Mesh				
Jänes, 2004	Sweden	RCT	n=54	6+1	1/27 (4%) p<0.001 (between groups)	13/27 (48%)	Mesh placed in sublay position Mesh: Vypro®. Inclusion was stopped prematurely because of an observed large difference in PH between the groups. 47/54 had surgery due to malignant disease. Clinical assessment of PH.	?	?	+
Jänes, 2009	Sweden	RCT	n=54	12+6	2/27 (7%) p<0.001 (between groups)	20/27 (74%)	Mesh placement and type of mesh, see above. 5-year follow up of Jänes, 2004. Many lost to follow up (mainly deaths). Clinical assessment of PH.	?	?	+
Lopez-Cano, 2012	Spain	RCT	n=36	1+1	9/18 (50%) p<0.008 (between groups)	15/16 (94%)	All included patients underwent laparoscopic surgery. Mesh placed preperitoneal. Mesh: Proceed™.Pre-peritoneal onlay mesh. Radiological assessment (CT: a loop of intestine or any abdominal organ, as well as preperitoneal fat, protruding through the defect alongside the ostomy was considered as parastomal hernia).	+	+	+

Project: End colostomy, with or without mesh reinforcement
Appendix 1:1
Outcome variable: Parastomal hernia (clinical and/or radiological assessment) after end-colostomy

* + No problem
? Some problems
- Major problems

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Mesh	Control Without Mesh				
Serra-Aracil, 2009	Spain	RCT	n=55	1+0	4/27 (15%) Clinical p=0.033 (between groups) 6/27 (22%) CT p=0.083 (between groups)	11/27 (41%) Clinical 12/27 (44%) CT	Mesh placed in the sub-lay position. Mesh: Ultrapro™. Pre-randomization selection unclear. Clinical and radiological assessment CT assessment classified as: 0=Peritoneum follows the wall of the bowel forming the stoma, with no formation of a sac Ia=Bowel forming the colostomy with a sac < 5 cm. Ib=Bowel forming the colostomy with a sac > 5 cm. II=Sac containing omentum. III=Intestinal loop other than the bowel forming the stoma.	-	-	?
Jänes, 2010	Sweden	Kohort	n=79	19	7/52 (13%)	7/8 (88%)	Mesh placement and type of mesh, see Jänes 2004. Patients selection to non-mesh group partially unclear. Clinical assessment of PH.	?/-	-	?
Ventham, 2012	UK	Kohort	n=41 (17+24)	0	6/17 (35%) type II, III (4/17 (2%) type Ia, Ib)	13/24 (54%) type II, III (1/24 (4%) type Ia, Ib)	Mesh placed in sublay position Mesh: Prolene™. Radiological assessment of PH. Unclear exclusions. Type 1a – III: See Serra-Aracil.	?/-	?	-

Project: End colostomy, with or without mesh reinforcement
Appendix 1:2
Outcome variable: Re-operation, after end-colostomy with or without mesh

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations*	Precision*
					Intervention Mesh	Control Without Mesh				
Jänes, 2004	Sweden	RCT	Total 54 27+27	6+1	0/27	0/27	Follow-up 12 months	?	?	-
Jänes, 2009	Sweden	RCT	Total 54 27+27	12+6	0/27 p=0.06* between groups (two-tailed test).	5/27 (19 %)	Follow-up (mean): 57-83 months. Point of time for re-operation not specified	?	?	-
Lopez-Cano, 2012	Spain	RCT	Total 36 (19+17)	1+1	1/18 (6 %) ns*	3/16 (19%)	All included patients underwent laparoscopic surgery. Clinical follow-up (median): 317 days. All patients had a CT 12 months post surgery. Point of time for re-operation not specified.	+	+	-
Serra-Aracil, 2009	Spain	RCT	55 (28+27)	3+4	0/27 ns*	2/27 (7 %)	Clinical follow-up (median): 29 months, range: 13-49. Point of time for re-operation not specified.	-	-	-
Ventham, 2012	UK	Cohort	68 initial 41 (17+24)	27/68	0/17	0/24	Follow-up (mean) 58 weeks	?/-	?	-

*Calculated based on published data

Project: End colostomy, with or without mesh reinforcement
Appendix 1:3
Outcome variable: Other complications

Author, year	Country	Study design	Number of patients n=	With drawals - dropouts	Result		Comments	Directness*	Study limitations *	Precision *
					Intervention Mesh	Control Without Mesh				
Jänes, 2004a	Sweden	RCT	54	6+1	0/27 (0%)	0/27 (0%)	No infection, fistula or pain was recorded during follow-up (mean) of 24 months , range (12-38).	?	?	+
Jänes, 2009	Sweden	RCT	54	12+6	0/27 (0%)	0/27 (0%)	No mesh infection, fistula or stenosis was recorded. Follow-up (mean) 65.2 months, range (57-83).	?	?	+
Lopez-Cano, 2012	Spain	RCT	36	1+1	General: 11/19(58%) p=0.013 Stoma related: 2/19 (11%) ns	General: 3/17 (18%) Stoma related: 2/17 (12%)	All included patients underwent laparoscopic surgery. Only perioperative (time-frame not defined) complications reported. Stoma related complications: cutaneous dehiscence and necrosis of stomal border. Other complications: pelvic abscess, perineal wound infection, trocar site evisceration, heart failure and lower respiratory tract infection.	+	+	+
Serra-Aracil, 2009	Spain	RCT	55	3+4	Wound infection: 3/27 (11%) ns Stoma related: 2/27 (7%) ns	Wound infection: 3/27 (11%) Stoma related: 2/27 (7%)	Only perioperative (time-frame not defined) complications reported. Stoma related compliastions: Peristomal infection and colostomy necrosis (one of each in both groups).	-	-	?
Jänes, 2010	Sweden	Cohort	79	19	Minor infection: 5/73 (7%) Major infection: 1/73 (1 %)	Minor infection: 3/15 (20%) Major infection: 1/15 (7%)	The study included 93 patients, of whom 14 were ileostomies. The frequency of complications for colostomies specifically is unclear. No infection related to mesh was recorded. No late (time-frame not defined) infectious complications were recorded.	?/-	-	?
Ventham, 2012	UK	Cohort	41	0	2/17 (12%)	2/24 (8%)	Three laparotomy wound infections and one stoma retraction (control group) was recorded.	?/-	?	-

Project: End colostomy, with or without mesh reinforcement
Appendix 2
Excluded articles

Study (author, publication year)	Reason for exclusion
Brandsma *et al*., 2012	Wrong design (report of an RCT protocol).
Hammond *et al*., 2008	Wrong patient population.
Helgstrand *et al*., 2008	Non systematic review.
Jänes *et al*., 2004b	Duplicate publication with Jänes *et al*., 2004a.
Sajid *et al.,*2012	Wrong patient population.
Shabbir *et al*., 2012	Wrong patient population.
Tam *et al*., 2010	Wrong patient population.
Wijeyekoon *et al*., 2010b	Wrong design (report of a systematic review protocol).

Appendix 3. Search strategy, study selection and references

Question(s) at issue:
Is the construction of a colostomy with a mesh better than construction of a colostomy without a mesh, in terms of health related quality of life, stoma function, need for reoperation, frequency of parastomal hernias or other complications?

PICO: (*P=Patient I=Intervention C=Comparison O=Outcome*)

P =	Adults who need an end colostomy
I =	Construction of an end colostomy with the use of a mesh
C=	Construction of an end colostomy without the use of a mesh
O=	Health related quality of life
	Stoma function
	Reoperation
	Parastomal hernia
	Other complications

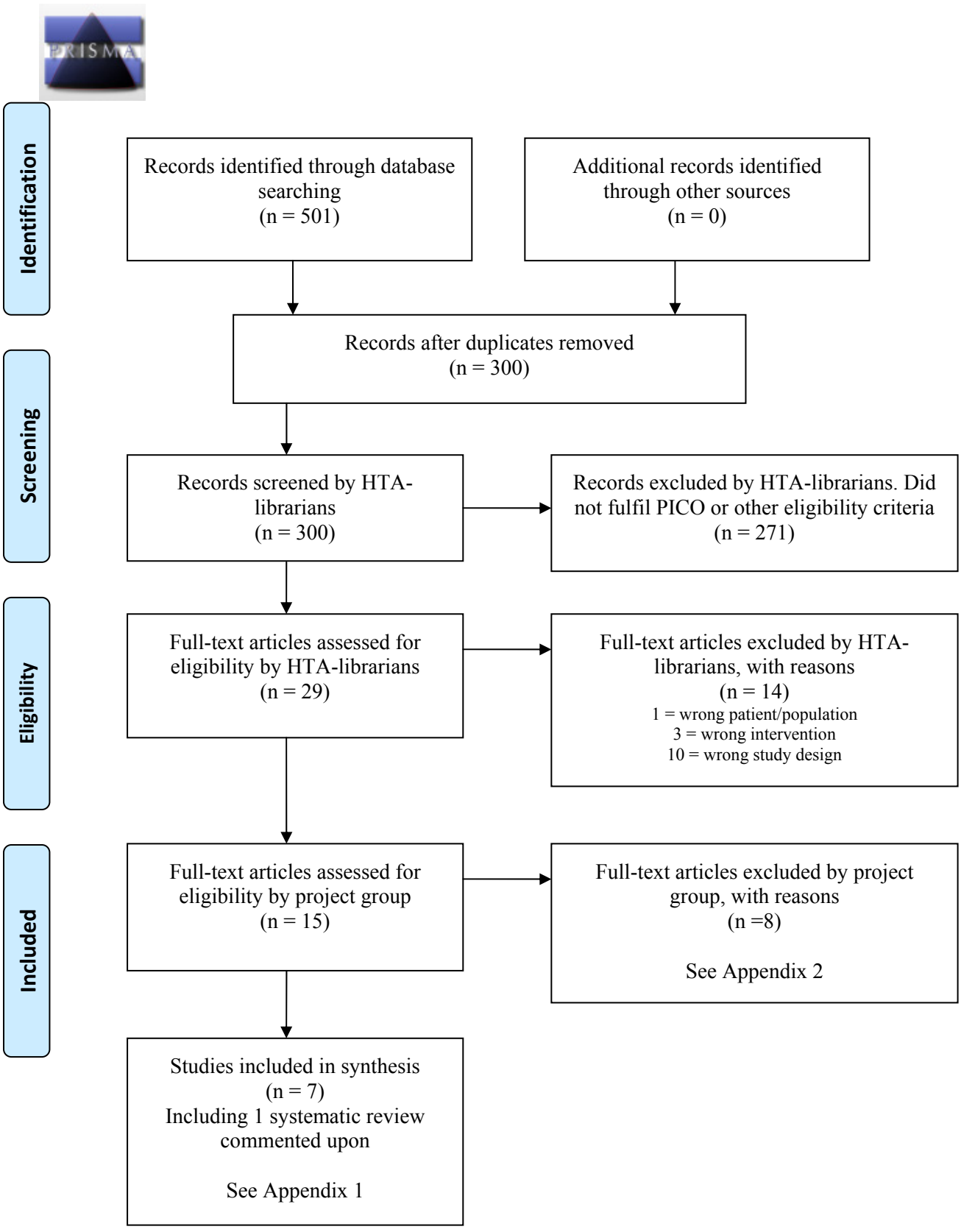
Eligibility criteria

Study design:
Controlled studies.
Case series etc. if ≥ 100 patients.
Systematic reviews or meta-analyses.
No case reports or non-systematic review articles.

Language:
English, German, Swedish, Norwegian, Danish.

Publication date: 1980-

Selection process – flow diagram



Search strategies

Database: PubMed
Date: 2012-12-11
No of results: 194
Search updated: 2012-12-12, 21 results

Search	Query	Items found
#11	**Search #6 AND #9 Filters: Publication date from 1980/01/01; English; Danish; Norwegian; Swedish**	**194**
#10	Search #6 AND #9	231
#9	Search #7 OR #8	21567
#8	Search mesh[tw]	21567
#7	Search "Surgical Mesh"[Mesh]	8773
#6	Search #1 OR #2 OR #3 OR #4 OR #5	12878
#5	Search stoma[tw] OR stomas[tw]	6513
#4	Search "surgical stomas"[MeSH Terms]	825
#3	Search end colostomy[tw]	224
#2	Search endcolostomy[tw]	3
#1	Search "Colostomy"[Mesh]	7488

*On 12th December 2012 an error was discovered in the search strategy and the following search term were added to the first search block: "Colostomy"[tw], "Colostomies"[tw], "Ostomy"[Mesh:NoExp], "ostomy"[tw], "ostomies"[tw], endcolostomies[tw], end colostomies[tw]. The end result did include 21 new hits.

Database: The Cochrane Library
Date: 2012-12-12
No of results: 12
Cochrane reviews 3
Other reviews 1
Technology assessments 0
Economic evaluations 0
Clinical trials 8

ID	Search	Hits
#1	MeSH descriptor: [Colostomy] this term only	132
#2	MeSH descriptor: [Surgical Stomas] explode all trees	34
#3	MeSH descriptor: [Ostomy] this term only	11
#4	endcolostomy or "end colostomy" or endcolostomies or colostomy or colostomies or stoma or stomas or ostomy or ostomies:ti,ab,kw (Word variations have been searched)	379
#5	#1 or #2 or #3 or #4	379
#6	MeSH descriptor: [Surgical Mesh] explode all trees	468
#7	mesh:ti,ab,kw (Word variations have been searched)	1102
#8	#6 or #7	1102
#9	**#5 and #8**	**12**

Database: EMBASE (OVID SP)
Date: 2012-12-12
No of results: 230

#	Searches	Results
1	exp colostomy/	10218
2	stoma/	4852
3	(endcolostomy or end colostomy or endcolostomies or colostomy or colostomies or stoma or stomas or ostomy or ostomies).ti,ab,kw.	15131
4	1 or 2 or 3	20870
5	exp surgical mesh/	114
6	mesh.ti,ab,kw.	23317
7	5 or 6	23345
8	4 and 7	261
9	**limit 8 to ((danish or english or norwegian or swedish) and yr="1980 -Current")**	**230**

Database: ProQuest Nursing & Allied Health Source
Date: 2012-12-12
No of results: 36

Set	Search	Result
S12	**S7 AND S10Limits applied Narrowed by: Entered date: 1980 - 2012**	**36***
S11	S7 AND S10	36*
S10	S8 OR S9	3726*
S9	ab(mesh) OR ti(mesh)	3599*
S8	MESH.EXACT.EXPLODE("Surgical Mesh")	544*
S7	S1 OR S2 OR S3 OR S4 OR S5 OR S6	2553*
S6	ab(endcolostomy OR colostomy OR "end colostomy" OR colostomies) OR ti(endcolostomy OR colostomy OR "end colostomy" OR colostomies)	565*
S5	MESH.EXACT.EXPLODE("Colostomy:E.04.579.338.225") OR MESH.EXACT.EXPLODE("Colostomy:E.04.210.338.225")	205*
S4	ab(stoma OR stomas OR ostomy OR ostomies) OR ti(stoma OR stomas OR ostomy OR ostomies)	1369*
S3	MESH.EXACT.EXPLODE("Surgical Stomas")	61*
S2	MESH.EXACT.EXPLODE("Ostomy")	34*
S1	SU.EXACT("Ostomy")	897*

Database: CRD
Date: 2012-12-12
No of results: 8
DARE 6
NHS EED 2
HTA 0

Line	Search	Hits
1	endcolostomy OR colostomy OR "end colostomy" OR endcolostomies OR colostomies	56
2	MeSH DESCRIPTOR Colostomy EXPLODE ALL TREES	24
3	stoma OR stomas OR ostomy OR ostomies	100
4	MeSH DESCRIPTOR Surgical Stomas EXPLODE ALL TREES	14
5	MeSH DESCRIPTOR Ostomy EXPLODE ALL TREES	168
6	#1 OR #2 OR #3 OR #4 OR #5	268
7	mesh	525
8	MeSH DESCRIPTOR Surgical Mesh EXPLODE ALL TREES	91
9	#7 OR #8	525
10	**#6 AND #9**	**8**

Reference lists
A comprehensive review of reference lists brought 0 new records

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The web-sites of **SBU, Kunnskapssenteret** and **Sundhedsstyrelsen** were visited 2012-12-11
Nothing relevant to the question at issue was found

Reference lists

Included studies:

Janes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh. Arch Surg. 2004a;139(12):1356-8.

Janes A, Cengiz Y, Israelsson LA. Preventing parastomal hernia with a prosthetic mesh: a 5-year follow-up of a randomized study. World J Surg. 2009;33(1):118-21; discussion 22-3.

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Ventham NT, Brady RR, Stewart RG, Ward BM, Graham C, Yalamarthi S, et al. Prophylactic mesh placement of permanent stomas at index operation for colorectal cancer. Ann R Coll Surg Engl. 2012;94(8):569-73.

Systematic reviews, no appraisal done, only commented on:

Wijeyekoon SP, Gurusamy K, El-Gendy K, Chan CL. Prevention of parastomal herniation with biologic/composite prosthetic mesh: a systematic review and meta-analysis of randomized controlled trials. J Am Coll Surg. 2010a;211(5):637-45.

Excluded studies:

Brandsma HT, Hansson BM, Haan HV, Aufenacker TJ, Rosman C, Bleichrodt RP. PREVENTion of a parastomal hernia with a prosthetic mesh in patients undergoing permanent end-colostomy; the PREVENT-trial: study protocol for a multicenter randomized controlled trial. Trials. 2012;13(1):226.

Hammond TM, Huang A, Prosser K, Frye JN, Williams NS. Parastomal hernia prevention using a novel collagen implant: a randomised controlled phase 1 study. Hernia. 2008;12(5):475-81.

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Sajid MS, Kalra L, Hutson K, Sains P. Parastomal hernia as a consequence of colorectal cancer resections can prophylactically be controlled by mesh insertion at the time of primary surgery: a literature based systematic review of published trials. Minerva Chir. 2012;67(4):289-96.

Shabbir J, Chaudhary BN, Dawson R. A systematic review on the use of prophylactic mesh during primary stoma formation to prevent parastomal hernia formation. Colorectal Dis. 2012;14(8):931-6.

Tam KW, Wei PL, Kuo LJ, Wu CH. Systematic review of the use of a mesh to prevent parastomal hernia. World J Surg. 2010;34(11):2723-9.

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Other references:

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[Checklists from SBU regarding randomized controlled trials. [Internet]. [cited 2012 Mar 8]
Available from:
http://www.sahlgrenska.se/upload/SU/HTA-centrum/Hj%c3%a4lpmedel%20under%20projektet/B02_Granskningsmall%20f%c3%b6r%20randomiserad%20kontrollerad%20pr%c3%b6vning.doc

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Project: End colostomy, with or without mesh reinforcement

Appendix 4

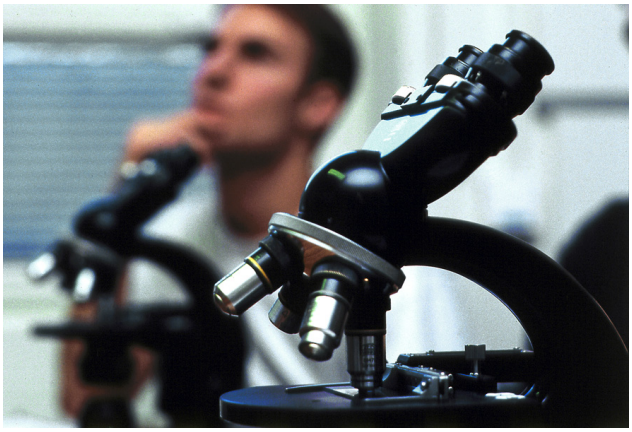
Summary of Findings

Outcome variable Number of studies	Design	Study limitations	Consistency	Directness	Precision	Publication bias	Magnitude of effect	Relative effect (95%CI)	Absolute effect Range (all RCT)	Quality of evidence GRADE
Parastomal hernia 3	RCT	Some limitations (?)	No serious inconsistency	Serious indirectness (-1)	No imprecision	Unlikely	Not relevant	-	22-63%	⊕⊕⊕◯ Moderate
Re-operation 3	RCT	Serious limitations (-1)	No serious inconsistency	Serious indirectness (-1)	Serious imprecision (-1)	Unlikely	Not relevant	-	0-19%	⊕◯◯◯ Very low

Only RCTs were used in the GRADE process.

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA



HTA

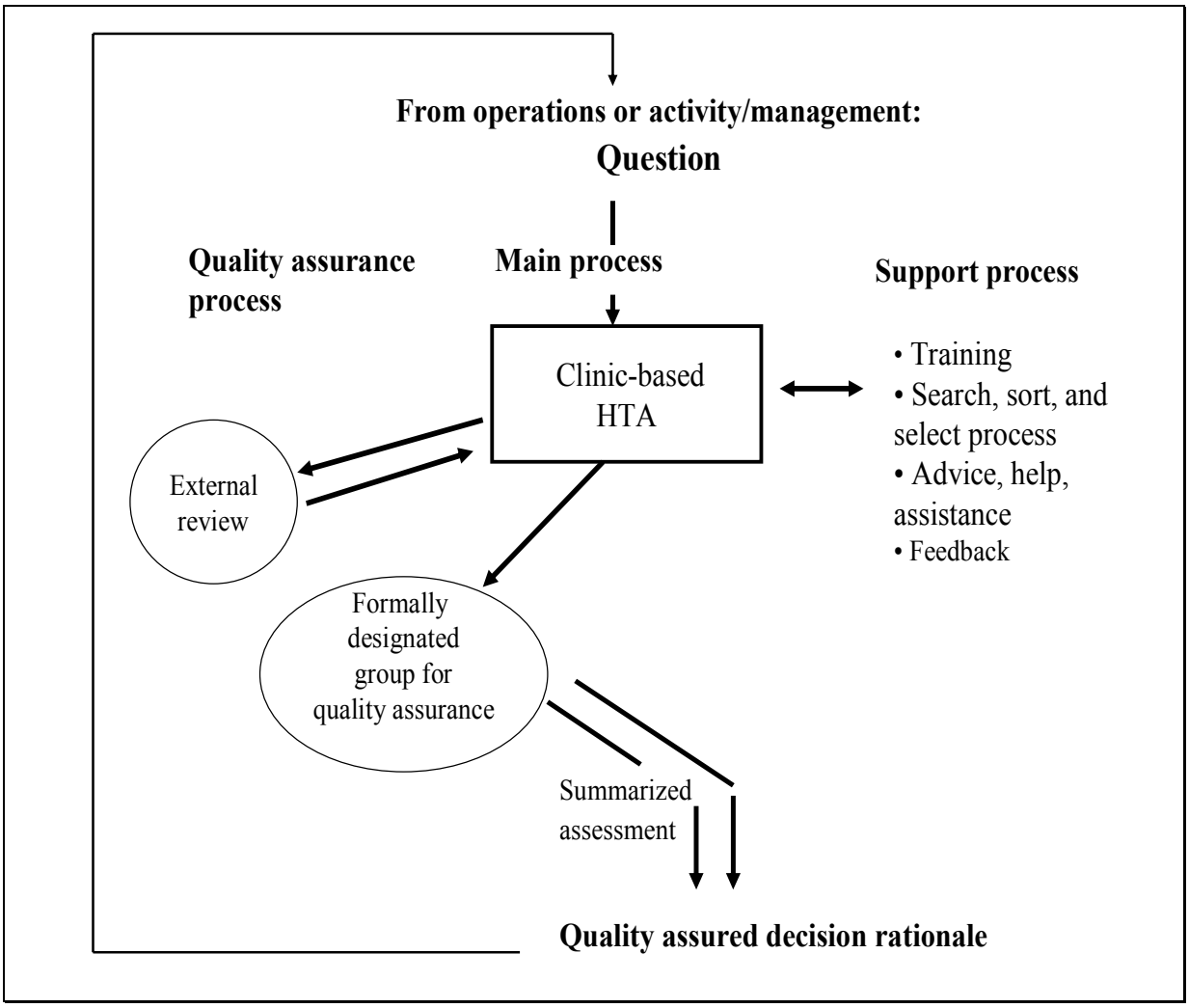
Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the quality of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High quality of evidence	= (GRADE⊕⊕⊕⊕)
Moderate quality of evidence	= (GRADE ⊕⊕⊕O)
Low quality of evidence	= (GRADE ⊕⊕OO)
Very low quality of evidence	= (GRADE ⊕OOO)

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh, Professor, MD.
Head of HTA-centrum


From operations or activity/management:
Question
Quality assurance process
Main process
Support process
Clinic-based HTA
• Training
• Search, sort, and select process
• Advice, help, assistance
• Feedback
External review
Formally designated group for quality assurance
Summarized assessment
Quality assured decision rationale

VÄSTRA GÖTALANDSREGIONEN
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