Clinical Practice Guidelines

European Hernia Society Guidelines on Prevention and Treatment of Parastomal Hernias

APPENDIX I

Guidelines Development Protocol
Protocol
for the Development of Clinical Guidelines
on Parastomal Hernias

prepared by
Stavros A. Antoniou and Filip E. Muysoms

under the auspices of the
European Hernia Society

2016
Guidelines Development Group

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- from the Advisory board of Education
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- from the Advisory board of Congress
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- Editorial board of Hernia
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- EHS board
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- Consensus voting organization
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Cornelia Frei-Lanter (Switzerland)
Frederik Helgstrand (Denmark)
Alexander Hotouras (United Kingdom)
Arthur Jänes (Sweden)
Jan Lambrecht (Norway)
Léon Maggiori (France)
Michel Prudhomme (France)
Tero Rautio (Finland)
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Preface

Clinical practice guidelines (CPGs) are intended to help physicians and patients make informed healthcare decisions and to aid policymakers in making policy-related decisions (1). The Board of Governors of the European Hernia Society decided to embark on the development of CPGs on parastomal hernia prevention, diagnosis and treatment, due to the lack of relevant summarized evidence and recommendations.

There are several approaches used for the development of CPGs. The evidence-based medicine approach requires that the widest possible spectrum of published evidence is taken into account to form clinical recommendations. The EHS adopted this framework for the 2015 Guidelines on Closure of Abdominal Wall Incisions (2) and will use it also for the present guidelines. Similar to other institutions, we use a four-step approach (Fig. 1): formulating clinical questions, searching for relevant evidence, grading the evidence and making relevant statements or recommendations. This process puts maximum weight on pertinent clinical evidence and minimizes the influence of each group member’s perceptions and beliefs.

The purpose of the present manuscript is twofold. Drafting the protocol and publication on the EHS website intends to guarantee transparency of the methodology and each member’s involvement. Further it intends to guarantee adherence to the methodology, standardization of the process and subjectivity of the end result. Submission of the protocol for public comment aims at receiving feedback from the
surgical community, patients and policymakers regarding the clinical questions to be addressed. Depending on the timing, these will be considered either in the present CPGs or in a future update. Physicians, researchers, professional groups, individual patients, patient groups and policymakers may contact the coordinator or the supervisor of the project to provide their feedback.

Every effort has been made for this project to conform to the strategy proposed by the AGREE Collaboration (Appraisal of Guidelines, Research, and Evaluation), an international team of guideline developers and researchers. This strategy is reflected in the latest update of their statement, the AGREE II instrument (3). Nevertheless, due to time, budget and practical constraints, it was not possible to satisfy all proposed steps. The Steering Committee recognizes this fact and these issues will be highlighted in the Guidelines manuscript.
1. Composition of the members of the Guidelines Development Group

The Guidelines Development Group (GDG) comprises of the Steering Committee, which includes members of the EHS Advisory Board of Quality, the EHS Advisory Board of Science, the EHS Advisory Board of Education, the Advisory board of Congress and secretory support. External members were included upon invitation by the EHS Board of Governors represented by the supervisor of the project, Filip Muysoms (Belgium). Invitations aimed at including representatives from the widest possible spectrum of European countries, in view of the variability of surgical practices, health care systems and cultural backgrounds across Europe, which need to be reflected on the Guidelines development process and the produced recommendations. Priority was set to young and scientifically active participants, aiming at enhancing productivity and innovation throughout the Guidelines development process. Supervisor of the project will be Filip Muysoms (Belgium) and coordinator will be Stavros Antoniou (Greece/Germany), supported by the former.

The inclusion of policymakers was not feasible due to time constraints. Moreover, the input of patient/community representatives (for example through representatives of ostomy associations) and allied professionals (ostomy nurses) was not sought after for similar reasons. The Steering Committee recognizes the potential shortcomings of the final product introduced by the omission to include these groups and plans to include them in a future update of these Guidelines. An external review is planned to be sought after by the European Ostomy Association and the European Council of Enterostomal Therapist upon completion of the project.
2. Formulating clinical questions

Clinical questions were formulated by the Steering Committee and were sent to the external members via e-mail in December 2015 seeking for feedback. These were formulated in their final form at the end of the same month. The questions are divided into introductory questions (IQs), which provide an evidence-based approach to the subject, and key questions (KQs), which are the clinical questions needed to be answered through the evidence-based process.

It was decided to include the following questions:

- **Introductory questions**
  - IQ 1: What is the incidence of parastomal hernias?
  - IQ 2: Is there a difference in the incidence of parastomal hernia for colostomy, ileostomy or ileal conduit?
  - IQ 3: Which classifications of parastomal hernias have been published and what is their use in the literature on parastomal hernias?

- **Key questions**
  - KQ 1: What is the diagnostic accuracy of the clinical diagnosis of parastomal hernias versus a diagnosis by CT scan?
  - KQ 2: Is there a place for watchful waiting in patients with parastomal hernia?
  - KQ 3: Are there techniques for stoma creation without prophylactic mesh augmentation, which result in less parastomal hernias?
  - KQ 4: Is prophylactic mesh augmentation beneficial during stoma creation?
  - KQ 5: Is a non-mesh repair for parastomal hernia repair an option?
  - KQ 6: Is laparoscopic parastomal hernia repair superior to open parastomal hernia repair?
  - KQ 7: Which open parastomal hernia repair is superior?
  - KQ 8: Which laparoscopic technique is superior?
  - KQ 9: Which meshes are the most effective?

Members of the GDG have been divided into subgroups, each subgroup being responsible for a subject chapter, containing one or two questions.
The chapter synthesis and the subgroups composition is as follows:

- **Incidence of parastomal hernias**
  
  **Cesare Stabilini, Neil Smart, Frederik Helgstrand, Maciej Smietanski, Diego Cuccurullo**
  
  *IQ 1: What is the incidence of parastomal hernias?*
  
  *IQ 2: Is there a difference in the incidence of parastomal hernia for colostomy, ileostomy or ileal conduit?*

- **Diagnosis of parastomal hernias.**
  
  **Tero Rautio, Joachim Conze, Jan Lambrecht, Marc Miserez**
  
  *KQ 1: What is the diagnostic accuracy of the clinical diagnosis of parastomal hernias versus a diagnosis by CT scan?*

- **Classification of parastomal hernias.**
  
  **Kamil Bury, Agneta Montgomery, Birgitta Hansson, Marek Szczepkowski**
  
  *IQ 3: Which classifications of parastomal hernias have been published and what is their use in the literature on parastomal hernias?*

- **Indications for parastomal hernia repair.**
  
  **Frederik Helgstrand, Neil Smart, Frederik Berrevoet, Rene Fortelny, Vincenzo Mandala**
  
  *KQ 2: Is there a place for watchful waiting in patients with parastomal hernia?*

- **Prevention of parastomal hernias.**
  
  **Alexander Hotouras, Michel Prudhomme, Ferdinando Agresta, Arthur Jänes**
  
  *KQ 3: Are there techniques for stoma creation without prophylactic mesh augmentation, which result in less parastomal hernias?*
  
  **Léon Maggiori, Manuel Lopez Cano, Salvador Morales Conde**
  
  *KQ 4: Is prophylactic mesh augmentation beneficial during stoma creation?*

- **Treatment of parastomal hernias.**
  
  **Stavros A. Antoniou, Filip Muysoms, Thijs Brandsma, Ulrich Dietz**
  
  *KQ 5: Is a non-mesh repair for parastomal hernia repair an option?*
  
  *KQ 6: Is laparoscopic parastomal hernia repair superior to open parastomal hernia repair?*
  
  **Cornelia Frei-Lanter, Jan Lambrecht, Alexander Hotouras, Dieter Berger, Rene Fortelny**
  
  *KQ 7: Which open parastomal hernia repair is superior?*
  
  *KQ 8: Which laparoscopic technique is superior?*
  
  *KQ 9: Which meshes are the most effective?*
3. Searching the evidence

The quality of a CPG is related to a systematic literature search. It is important to make recommendations based on the widest possible spectrum of published and unpublished information. The Cochrane collaboration suggests searching of at least one database in addition to MEDLINE (4). Experts in the field suggest the routine search of the grey literature, because unpublished material may account for a significant proportion of studies demonstrating non-significant comparative outcomes (5).

Several measures have been undertaken to minimize the possibility of errors and to act as internal audit for the completeness of the search.

i. Conduction of the first level search by a single reviewer with experience in systematic reviews in a homogeneous manner, with regard to the included databases.

ii. Cross-checking of the study selection by the group members.

iii. Searching into multiple databases.

iv. Including the grey literature in the search.

v. Cross check of the search results with a pool of articles acknowledged by each member of the GDG to be relevant to an IQ or a KQ. If these articles are missed by the literature search, the search strategy has to be revised after consensus on the search process.

vi. Conforming to the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) guidelines (6).

First level search

The key words for each question will be defined by each subgroup in collaboration with the coordinator until January 15, 2016. The coordinator will develop the search strategy in collaboration with a clinical librarian at the University of Heraklion, Greece. The search will include the databases of MEDLINE, EMBASE (through OpenAthens), CENTRAL (through Wiley Online Library) and OpenGrey (through Exalead) with no date or language restrictions. Articles written in a language other than the native languages of the GDG members (irrespective of subgroup assignment) will be recorded and discarded from the further process, due to budget constraints for translation.
However, empirical evidence based on previous guidelines projects suggests that these articles account for less than 1% of the total number of recruited records.

The first level search will assess record titles and abstracts for relevance. A list of potentially relevant records will be provided to the members of each subgroup for further assessment until February 15, 2016. Between February 15 and February 29, 2016, one member of each subgroup will cross-check the first level search for potential omissions and all members will scrutinize the search results list to identify any articles missed in the search. The first level search strategy is summarized in Fig. 2.

**Second level search**

The second level search will be conducted by at least two members of each subgroup. Based on the full texts of articles retrieved from the first level search, relevance of the studies with regard to the key question will be assessed. Relevant articles will be included in the next step (quality assessment and grading of evidence). Reasons for rejection will
be recorded for the discarded articles. The final second level search will have the form outlined in Fig. 3.

![Second level full text screening diagram](image)

Figure 3. Second level search strategy

The complete search strategy is depicted in Fig. 4.

![Complete search strategy diagram](image)

Figure 4. Complete search strategy
4. Grading the evidence

The GDG will follow the GRADE approach (Grading of Recommendations Assessment, Development and Evaluation) for grading of the evidence of high and acceptable quality articles. The GRADE approach is currently recommended and used by many organisations: WHO, NICE, the Cochrane Collaboration, the Centers for Disease Control and Prevention (CDC), UpToDate, the British Medical Journal, the Scottish Intercollegiate Guidelines Network (SIGN) and NHS.

Relevant articles identified in the second level search will be uploaded by the subgroup members to a dedicated common account on Mendeley Reference Manager and PDF Organizer. These articles will enter a quality assessment procedure, according to the SIGN (Scottish Intercollegiate Guidelines Network) methodology using ad hoc checklists. At least two members of each subgroup will assess the quality of the articles, which are to be characterized as of high quality, acceptable or unacceptable quality. Unacceptable quality articles will be discarded and excluded from the further process.

Study data will be summarized in Summary of evidence tables (SoF). It is important to document the effect size expressed in odds ratio, risk ratio, risk difference or hazard ratio, with respective confidence intervals; p-values themselves do not express the effect size and do not reflect clinical significance. The reviewer is called to make a judgment regarding the clinical significance of the outcomes, which does not always equate to statistical significance (7). Furthermore, the lack of statistical significance does not confirm the null hypothesis, unless a plausible power size calculation has been undertaken (8). These issues must be highlighted by the reviewers under ‘General comments’ on the SoF tables. The quality of the evidence for each Key Question will be rated according to the GRADE approach, as shown in Table 1. The complete process is summarized in Fig. 5.

<table>
<thead>
<tr>
<th>Underlying methodology</th>
<th>Quality rating</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trials; or double-upgraded observational studies.</td>
<td>High</td>
<td>Further research is very unlikely to change our confidence in the estimate of effect</td>
</tr>
<tr>
<td>Downgraded randomized trials; or upgraded observational studies.</td>
<td>Moderate</td>
<td>Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate</td>
</tr>
</tbody>
</table>
Double-downgraded randomized trials; or observational studies.  
Low  
Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Triple-downgraded randomized trials; or downgraded observational studies; or case series/case reports.  
Very low  
Any estimate of effect is very uncertain.

Criteria for assigning grade of evidence

<table>
<thead>
<tr>
<th>Type of evidence</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trial</td>
<td>High</td>
</tr>
<tr>
<td>Observational study</td>
<td>Low</td>
</tr>
<tr>
<td>Any other evidence</td>
<td>Very low</td>
</tr>
</tbody>
</table>

- Serious or very serious limitation to study quality
- Important inconsistency
- Some or major uncertainty about directness
- Imprecise or sparse data
- High probability of reporting bias

Decrease* grade if

- Strong evidence of association—significant relative risk of > 2 ( < 0.5) based on consistent evidence from two or more observational studies, with no plausible confounders (+1)

Increase grade if

- Very strong evidence of association—significant relative risk of > 5 ( < 0.2) based on direct evidence with no major threats to validity (+2)
- Evidence of a dose response gradient (+1)
- All plausible confounders would have reduced the effect (+1)

* Each quality criterion can reduce the quality by one or, if very serious, by two levels.

Table 1. Levels of quality of the evidence and criteria for assigning grade of evidence

![Diagram](image-url)  
Figure 5. Process of quality assessment and evidence grading
5. Making recommendations

Based on the evidence summarized in the SoF tables for each Key Question and of the Level of Quality provided by the subgroups, the guidelines development group will formulate the recommendations for each Key Question. Applying the concepts of GRADE, two levels of recommendation will be used (strong/weak). If no evidence will be found on a specific Key Question, no recommendation will be proposed (Table 2).

<table>
<thead>
<tr>
<th>Strong recommendation</th>
<th>Based on the available evidence, if clinicians are very certain that benefits do, or do not, outweigh risks and burdens they will make a strong recommendation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weak recommendation</td>
<td>Based on the available evidence, if clinicians believe that benefits and risks and burdens are finely balanced, or appreciable uncertainty exists about the magnitude of benefits and risks, they must offer a weak recommendation.</td>
</tr>
<tr>
<td>No recommendation</td>
<td>If based on the literature research no evidence could be found, no recommendation can be made.</td>
</tr>
</tbody>
</table>

Table 2. Levels of recommendation

The recommendations will be formulated during the Guidelines Development Meeting on April 29-30, 2016 in Brussels. In order for the GDG to assess the available evidence on each topic, the evidence tables and a proposal for recommendations will be sent to the coordinator up to April 10, 2016 and he will distribute them to the GDG through e-mail on April 15, 2016.

The recommendations will be presented by a member of each subgroup, who will need to be in a position to support their judgment on the basis of the provided evidence. The GDG will validate their decision, amend the phrasing of the recommendations or modify the strength of recommendation on the basis of a consensus decision. The recommendations will be refined linguistically by a native English-speaking member of the GDG.
6. Presentation of the Guidelines

The Guidelines will be presented in a session of the EHS Congress on June 8, 2016 in Rotterdam. Priority will be given to younger members of the GDG.

The preliminary program is as follows:

**Panelists**

<table>
<thead>
<tr>
<th>Name</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stavros A. Antoniou</td>
<td>Greece</td>
</tr>
<tr>
<td>Diego Cuccurullo</td>
<td>Italy</td>
</tr>
<tr>
<td>Ulrich Dietz</td>
<td>Germany</td>
</tr>
<tr>
<td>Birgitta Hansson</td>
<td>The Netherlands</td>
</tr>
<tr>
<td>Manuel Lopez Cano</td>
<td>Spain</td>
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<tr>
<td>Agneta Montgomery</td>
<td>Sweden</td>
</tr>
<tr>
<td>Filip Muysoms</td>
<td>Belgium</td>
</tr>
<tr>
<td>Maciej Smietanski</td>
<td>Poland</td>
</tr>
</tbody>
</table>

**Presenters**

<table>
<thead>
<tr>
<th>Title</th>
<th>Presenter</th>
<th>Country</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodological introduction</td>
<td>Filip Muysoms</td>
<td>Belgium</td>
<td>5 min</td>
</tr>
<tr>
<td>Incidence of parastomal hernias</td>
<td>Cesare Stabilini</td>
<td>Italy</td>
<td>5 min</td>
</tr>
<tr>
<td>Diagnosis of parastomal hernias</td>
<td>Tero Rautio</td>
<td>Finland</td>
<td>5 min</td>
</tr>
<tr>
<td>Classification of parastomal hernias</td>
<td>Kamil Bury</td>
<td>Poland</td>
<td>5 min</td>
</tr>
<tr>
<td>Indications for parastomal hernia repair</td>
<td>Frederik Helgstrand</td>
<td>Denmark</td>
<td>5 min</td>
</tr>
<tr>
<td>Prevention of parastomal hernia without mesh</td>
<td>Alexander Hotouras</td>
<td>United Kingdom</td>
<td>5 min</td>
</tr>
<tr>
<td>Prevention of parastomal hernia with mesh</td>
<td>Léon Maggiori</td>
<td>France</td>
<td>5 min</td>
</tr>
<tr>
<td>Treatment of parastomal hernias</td>
<td>Stavros A. Antoniou</td>
<td>Greece</td>
<td>5 min</td>
</tr>
<tr>
<td>Selection of parastomal hernia repair technique</td>
<td>Cornelia Frei-Lanter</td>
<td>Switzerland</td>
<td>5 min</td>
</tr>
<tr>
<td>Consensus voting on the statements</td>
<td>Leonard Kroese</td>
<td>The Netherlands</td>
<td>45 min</td>
</tr>
</tbody>
</table>
7. External peer review and Publication of the Guidelines

The Guidelines manuscript will be drafted by the coordinator and the supervisor of the project in Summer 2016. A short manuscript will be preferred to achieve clarity of presentation, supplemented by several addenda reporting on components of the methodology, the search process and the search results. The manuscript will conform to reporting standards suggested by the AGREE Next Steps consortium (3). The manuscript will be peer-reviewed by all members of the GDG and an external reviewer. The decision on the selection of the external reviewer will be made during the Guidelines Development Meeting in Brussels.

The European Ostomy Association and the European Council of Enterostomal Therapist will be contacted and will be asked to provide their input on the final product. The manuscript will be potentially further revised, if one or more components will need to be highlighted in the discussion.

The manuscript will be linguistically corrected by a native English-speaking co-author and will be submitted to Hernia, official journal of the EHS. The coordinator will serve as the primary author, the supervisor as the senior author and the GDG members will co-author the manuscript in alphabetical order.

Suggestions for an update of the Guidelines will be made during the Guidelines Development Meeting in Brussels. These will be forwarded to the Board of Governors of the EHS and documented in the Guidelines manuscript.
References


