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REVIEW

European Hernia Society guidelines on prevention and treatment of parastomal hernias

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Abstract

Background International guidelines on the prevention and treatment of parastomal hernias are lacking. The European Hernia Society therefore implemented a Clinical Practice Guideline development project.

Methods The guidelines development group consisted of general, hernia and colorectal surgeons, a biostatistician and a biologist, from 14 European countries. These guidelines conformed to the AGREE II standards and the GRADE methodology. The databases of MEDLINE, CINAHL, CENTRAL and the gray literature through OpenGrey were searched. Quality assessment was performed using Scottish Intercollegiate Guidelines Network checklists. The guidelines were presented at the 38th European Hernia Society Congress and each key question was evaluated in a consensus voting of congress participants.

Results End colostomy is associated with a higher incidence of parastomal hernia, compared to other types of stomas. Clinical examination is necessary for the diagnosis of parastomal hernia, whereas computed tomography scan or ultrasonography may be performed in cases of diagnostic uncertainty. Currently available classifications are not validated; however, we suggest the use of the European Hernia Society classification for uniform research reporting. There is insufficient evidence on the policy of watchful waiting, the route and location of stoma construction, and the size of the aperture. The use of a prophylactic synthetic non-absorbable mesh upon construction of an end colostomy is strongly recommended. No such recommendation can be made for other types of stomas at present. It is strongly recommended to avoid performing a suture repair for elective parastomal hernia. So far, there is no sufficient comparative evidence on specific techniques, open or laparoscopic surgery and

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The complete lists of excluded articles for each introductory question and each key question are available from the corresponding author.

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specific mesh types. However, a mesh without a hole is suggested in preference to a keyhole mesh when laparoscopic repair is performed.

Conclusion An evidence-based approach to the diagnosis and management of parastomal hernias reveals the lack of evidence on several topics, which need to be addressed by multicenter trials. Parastomal hernia prevention using a prophylactic mesh for end colostomies reduces parastomal herniation. Clinical outcomes should be audited and adverse events must be reported.

keywords Parastomal hernia · Stoma · Ostomy · Prevention · Treatment · Recurrence

Introduction

The European Hernia Society (EHS) has decided to implement a Clinical Practice Guideline development project on the prevention and treatment of parastomal hernias, in view of the lack of relevant summarized evidence and recommendations. The present guideline is based on a systematic and comprehensive literature review and takes into account both expected benefits and potential harms of prevention and treatment strategies. It applies to health-care professionals (surgeons, general practitioners, stoma care nurses, physiotherapists), patients with a temporary or a permanent stoma, or patients expected to have a stoma, and policymakers. The target users of this guideline are health-care professionals and policymakers within the European region, although with some limitations because the feasibility of application in different countries may vary.

Clinical decisions are based not only on research evidence, but also on individual patients' preferences, specific characteristics, the clinician's perspective, available resources and special circumstances. The present guideline should be viewed as a guide for clinical practice. However, clinical decision making is a much more complex process and cannot rely only on guidelines [1]. It is suggested that users of this guideline also inform their decisions through the aforementioned pathways, as well as from the current literature.

Methods

The coordinator and the supervisor of the project invited individuals from 14 European countries in December 2015 to participate, based on their published experience with the subject. Invited individuals and the steering committee, which consisted of members of the European Hernia

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Society, composed the guideline development group, which included general, hernia and colorectal surgeons, a biostatistician and a biologist. The group agreed on three introductory and nine key questions, which were determined and refined through e-mail communication. The guideline development protocol was formed by the coordinator and the supervisor in January 2016 (Appendix I). Every effort was made to conform to the AGREE II standards (Appraisal of Guidelines for Research and Evaluation) and the methodology proposed by the GRADE working group [2, 3].

In brief, the key words for each question were defined by each subgroup in collaboration with the coordinator. The coordinator and a clinical librarian developed the search strategy (Appendix II) and the results of the first-level screening of titles and abstracts were distributed to the subgroups in February 2016. A member of each subgroup cross-checked the first-level search for potential omissions and all members scrutinized the search results to identify any missing articles. The search included the databases of MEDLINE (through PubMed), CINAHL (through OpenAthens) and CENTRAL (through Wiley Online Library), with no date or language restrictions. The gray literature was searched through OpenGrey (Exalead).

The second-level screening was conducted by at least two members of each subgroup and included the full texts of articles retrieved at the first-level screening. Relevant articles entered the quality assessment and grading of evidence process. These articles were assessed for their quality by at least two members of each subgroup, using the Scottish Intercollegiate Guidelines Network (SIGN) checklists [4]. Articles of unacceptable quality were discarded. Study data of acceptable quality articles were tabulated in summary of evidence tables. The quality of the evidence for each question was rated according to the GRADE approach (Fig. 1) [3]. Based on this assessment, each subgroup proposed a statement and recommendation for each question. Recommendations were classified as strong or weak, in line with the GRADE methodology; if there was no evidence on a key question, or if it was of inadequate quality, no recommendation was made (Fig. 2) [3]. In a consensus meeting in Brussels in April 2016, the guidelines development group reviewed, modified, refined and approved the statements and recommendations. A summary of the guideline development process is presented in Fig. 3.

The guideline was presented in a session of the European Hernia Society Congress on June 8, 2016 in Rotterdam and each key question was evaluated in a consensus voting of congress participants. The results of the voting procedure are provided in Appendix III. The guideline manuscript was drafted in August 2016 and it was peer reviewed by two external reviewers, who assessed its methodological soundness according to the AGREE II instrument.

Results

The summary of statements and recommendations can be found in Table 1.

Introductory question 1

What is the incidence of parastomal hernias?

> ***Statement:*** *The overall incidence of parastomal hernia is unknown, but is estimated to be over 30% by 12 months, 40% by 2 years and 50% or higher at longer duration of follow up.*

The incidence of parastomal hernia varies widely in the literature, as it depends on the duration of follow-up, the type of stoma, patient characteristics and the definition of occurrence. Two randomized controlled trials (RCTs) reported on incidences of 32 and 44% at a median follow-up of 12 months [5, 6]. Two other case series and an RCT reported on incidences between 30 and 46% at 29–36 months follow-up [7–9]. However, it should be noted that this evidence comes from studies of patients with colostomy and no robust evidence on the incidence of hernia in other types of stomas exists. An incidence of parastomal hernia (excluding stoma prolapse) of up to 58% has been reported by systematic reviews with a maximum follow-up of 7 years [10–13].

Introductory question 2

Is there a difference in the incidence of parastomal hernia for colostomy, ileostomy or ileal conduit?

> ***Statement:*** *End colostomy is reported to be associated with a higher incidence of parastomal hernia, compared to loop colostomy and loop ileostomy. The incidence of parastomal hernia in the setting of ileal conduit or end ileostomy is unknown.*

Direct comparative data between types of stoma do not exist. Matched cohort studies and multivariate analyses would provide information on the relative risk of parastomal hernia between different types of stoma; these would however require large sample sizes. An overview of the literature suggests that end colostomy is associated with the highest incidence of parastomal hernia. Loop ileostomy was associated with a parastomal hernia incidence of 16% at 4 months in an RCT, where diagnosis was established during surgery for continuity restoration [14]. A similar incidence was reported in a case series with a clinical diagnosis of parastomal hernia at a mean follow-up of 9 years [15].

Underlying methodology	Quality rating	Definitions
Randomised trials or double-downgraded observational studies	High	Further research is unlikely to change our confidence in the estimate of effect.
Downgraded randomised trials or important upgraded observational studies	Moderate	Further research is likely to have an impact on our confidence in the estimate of effect and may change the estimate.
Double-downgraded randomised 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 randomised 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

Type of evidence	*Randomised trial = high* *Observational study = low* *Any other evidence = very low*
Decrease* grade if:	• Serious (− 1) or very serious (− 2) limitation to study quality • Important inconsistency (− 1) • Some (− 1) or major (− 2) uncertainty about directness • Imprecise or sparse data (− 1) • High probability of reporting bias (− 1)
Increase 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) • 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, if very serious, by two levels.

Fig. 1 Criteria for assigning grade of evidence

Strong recommendation	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.
Weak recommendation	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.
No recommendation	If based on the literature research no evidence could be found, no recommendation can be made.

Fig. 2 Criteria for assigning strength of recommendation

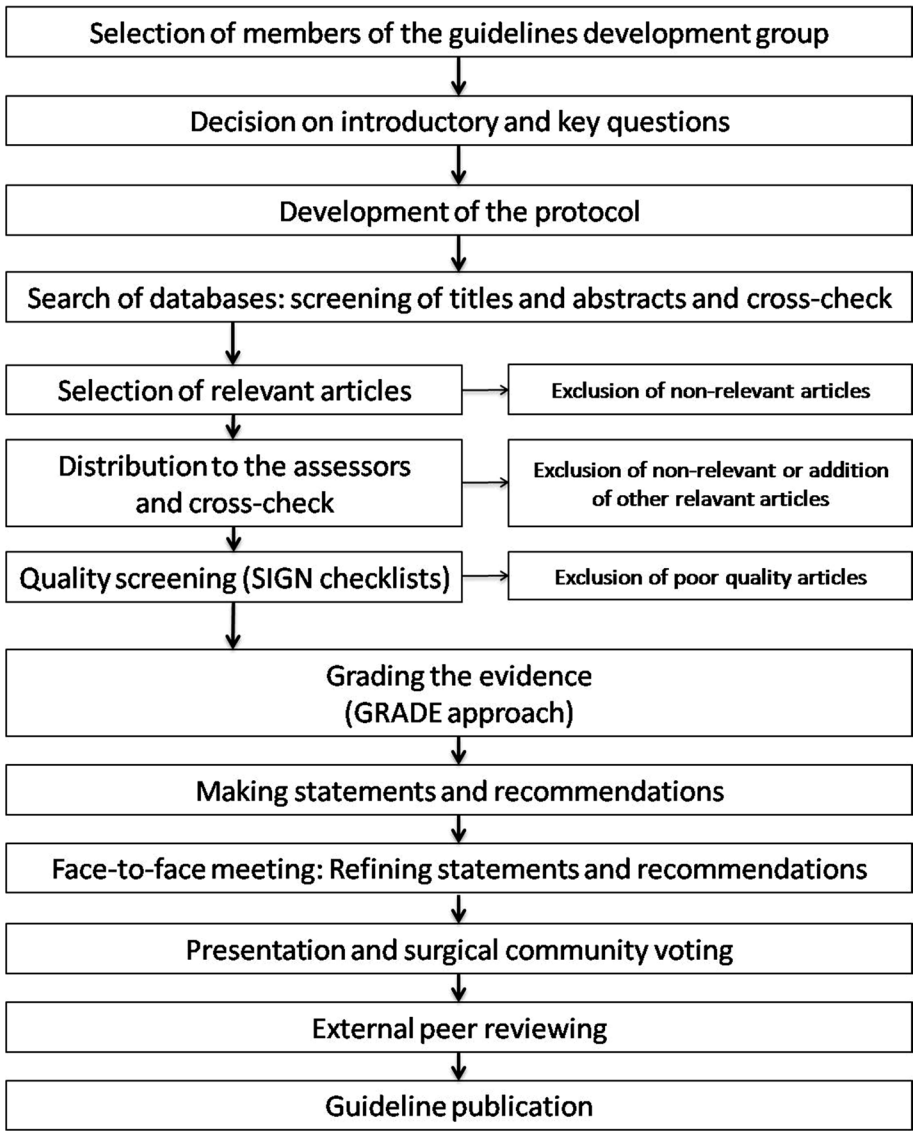

Fig. 3 Flowchart of guidelines development summary

Table 1 Summary of statements and recommendations

	Statements and recommendations	Quality of evidence[a]/strength of recommendation
Incidence	Statement: The overall incidence of parastomal hernia is unknown, but is estimated to be over 30% by 12 months, 40% by 2 years and 50% or higher at longer duration of follow-up	–
	Statement: End colostomy is reported to be associated with a higher incidence of parastomal hernia, compared to loop colostomy and loop ileostomy. The incidence of parastomal hernia in the setting of ileal conduit or end ileostomy is unknown	–
Classification	Statement: There are 5 classifications on parastomal hernias at the moment, including the European Hernia Society classification proposed in 2014. No classification has been subject to validation Recommendation: There is insufficient evidence to favour one classification over another. We suggest the use of the European Hernia Society classification for uniform research reporting	☒☐☐☐ Weak recommendation
Diagnostics	Statement: The sensitivity of clinical examination against CT scan as reference study for the diagnosis of parastomal hernia ranges between 66 and 100% and the negative predictive value between 75 and 100%. However, CT scan seems to also result in false positive diagnoses. More studies are needed to clarify the clinical relevance of ultrasonography in the diagnosis of PSH Recommendation: Clinical examination in supine/erect position and using the Valsalva maneuver is necessary for the diagnosis of parastomal hernia, whereas CT scan or ultrasonography may be performed in uncertain cases	☒☐☐☐ Weak recommendation
Watchful waiting	Statement: There is no evidence on the comparative outcome of the benefit of watchful waiting versus surgery for patients with a parastomal hernia Recommendation: No recommendation can be made on the policy of watchful waiting for patients with a non-incarcerated parastomal hernia	☒☐☐☐ No recommendation
Specific techniques	Statement: There is insufficient evidence on the comparative risk of parastomal hernia development after construction of a stoma via the extraperitoneal or the transperitoneal route Recommendation: No recommendation can be made in preference of stoma construction through the extraperitoneal over the transperitoneal route	☒☐☐☐ No recommendation
	Statement: There is insufficient evidence on the comparative risk of parastomal hernia development after construction of the stoma at a lateral pararectus location or a transrectus location Recommendation: No recommendation can be made in preference of stoma construction at a lateral pararectus location over a transrectus location	☒☐☐☐ No recommendation
	Statement: There is insufficient evidence on the ideal size of the fascial aperture when constructing a stoma Recommendation: We suggest keeping the size of the fascial aperture as small as possible to allow passage of the intestine through the abdominal wall without causing ischemia	☒☐☐☐ Weak recommendation
Prophylactic mesh	Statements: High quality evidence supports the use of a prophylactic mesh during construction of a permanent end colostomy in elective surgery in reducing the incidence of parastomal hernia development Recommendation: It is recommended to use a prophylactic synthetic non-absorbable mesh when constructing an elective permanent end colostomy to reduce the parastomal hernia rate	☒☒☒☒ Strong recommendation
	Recommendation: No recommendation to use a prophylactic mesh can be made for ileostomies or ileal conduit stomas, nor for the use of synthetic absorbable or biological meshes	☒☒☐☐ No recommendation
Non-mesh repair	Statements: There is no high quality evidence on the comparative risk of recurrence following parastomal hernia repair with mesh, stoma relocation or suture repair. There is, however, evidence suggestive of a high risk of recurrence following suture repair There is insufficient evidence on the comparative risk of morbidity following mesh repair, stoma relocation or suture parastomal hernia repair. There is, however, evidence suggestive of a low rate of infectious complications for parastomal hernia repair with a synthetic mesh Recommendation: It is recommended not to perform a suture repair for elective parastomal hernia surgery because of a high risk of recurrence	☒☒☐☐ Strong recommendation

Table 1 (continued)

	Statements and recommendations	Quality of evidence[a]/strength of recommendation
Laparoscopic repair	Statements: There is insufficient evidence on the risk of recurrence following laparoscopic versus open parastomal hernia repair with a mesh There is insufficient evidence on the morbidity following laparoscopic versus open parastomal hernia repair with a mesh Recommendation: No recommendation can be made in favour of laparoscopic or open parastomal hernia repair with a mesh in elective surgery	☒☐☐☐ No recommendation
Open techniques	Statements: There is insufficient evidence on the optimal technique for open parastomal hernia repair with regard to morbidity or recurrence Recommendation: No recommendation can be made in favour of any open parastomal hernia repair with mesh.	☒☐☐☐ No recommendation
Laparoscopic techniques	Statements: There is evidence favouring the use of a mesh without a hole in preference to a keyhole mesh for laparoscopic parastomal hernia repair in terms of recurrence There is insufficient evidence on the safest laparoscopic technique for parastomal hernia repair with regard to morbidity Recommendation: For laparoscopic parastomal hernia repair, a mesh without a hole is suggested in preference to a keyhole mesh	☒☐☐☐ Weak recommendation
Mesh types	Statements: There is insufficient evidence on the most effective mesh for parastomal hernia repair with regard to recurrence or morbidity There is no evidence supporting superiority of biological over synthetic meshes with regard to recurrence or morbidity Recommendation: No recommendation can be made on the use of specific mesh material for parastomal hernia repair	☒☐☐☐ No recommendation

[a]Grading of quality of evidence

☒☐☐☐ very low

☒☒☐☐ low

☒☒☒☐ moderate

☒☒☒☒ high

Introductory question 3

Which classifications of parastomal hernias have been published and what is their use in the literature on parastomal hernias?

Statement: *There are 5 classifications on parastomal hernias at the moment, including the European Hernia Society classification proposed in 2014. No classification has been subject to validation.*
Recommendation: *There is insufficient evidence to favour one classification over another. We suggest the use of the European Hernia Society classification for uniform research reporting.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *Weak*

The value of classifications of parastomal hernia lies on assessment of the risk of stoma complications, defining the indication for surgical intervention and uniform research reporting to allow comparability and synthesis of outcomes. Five classifications have been published to date. These are heterogeneous and based on clinical examination [16, 17], perioperative assessment [18] or clinical imaging [19–21]. The use of these classifications has been very limited and they have not been validated to date.

The classification proposed by the EHS [21] shares some features with the one described by Szczepkowski [17] and takes into account both the size of the defect and the presence of a concomitant incisional hernia. In view of the lack of validation, the guidelines development group proposes the use of the EHS classification, as it is the result of a multinational collaboration, reflecting the views and expectations of surgeons from several European countries. Furthermore, this classification provides an unambiguous definition of the different types of hernia and specifies the presence of a primary or recurrent parastomal hernia.

Endoscopic ultrasound (EUS) with 3D reconstruction has been recently proposed as a tool for classification of parastomal hernias. EUS was associated with a fair inter-observer and intra-observer reliability and may become a low-cost method for assessment of parastomal hernias [22].

Key question 1

What is the diagnostic accuracy of the clinical diagnosis of parastomal hernias versus a diagnosis by medical imaging?

Statement: *The sensitivity of clinical examination against CT scan as reference study for the diagnosis of parastomal hernia ranges between 66 and 100% and the negative predictive value between 75 and 100%. However, CT scan seems to also result in false positive diagnoses. More studies are needed to clarify the clinical relevance of ultrasonography in the diagnosis of PSH.*
Recommendation: *Clinical examination in supine/erect position and using the Valsalva maneuver is necessary for the diagnosis of parastomal hernia, whereas CT scan or ultrasonography may be performed in uncertain cases.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *Weak*

There is currently no gold standard examination for the detection of parastomal hernias. These are evident at clinical examination in a large proportion of patients, with reported sensitivity rates between 66 and 94%, whereas specificity rates are reported to be as high as 100%. Some cases of parastomal hernia are, however, not detected on clinical examination, with reported negative predictive values ranging from 63 to 96% [5, 7, 19]. Furthermore, clinical diagnosis of parastomal hernia has been considered challenging, as it is characterized by poor inter-observer reliability [23]. These estimations are based upon abdominal computed tomography scan (CT) as a reference study; however, even this examination may fail to detect cases in 7% of patients [24]. CT examination with the patient in the prone position seems to be associated with a strong inter-observer reliability, whereas CT examination in the supine position may not be as reliable [25].

The clinical significance of parastomal hernias that are evident on CT, but not on clinical examination is unknown. Although there is no gold standard diagnostic method, CT scan has been the traditional imaging modality to confirm the diagnosis or obtain better characterization of parastomal hernia. The correlation between hernia rates diagnosed with clinical examination and by CT scan is poor [5, 7, 24]. There is also evidence suggesting that CT scan may also result in false positive diagnoses when surgical diagnosis is considered the reference diagnostic method [24], relevant data are, however, scarce.

Intra-stomal 3-D ultrasonography is a new imaging modality to confirm the diagnosis of parastomal hernia [22, 23, 25, 26, 27]. Dynamic ultrasound examination may be performed without the necessity of the patient lying in the supine position and without the use of radiation. More studies are needed before ultrasonography may be considered a routine imaging technique for the diagnosis of parastomal hernia, according to the currently available evidence. Furthermore, relevant experience may not be available in every institution; therefore, CT scan has, at this point in time, the predominant role in cases of diagnostic uncertainty. Nevertheless, the clinical value of the imaging diagnosis of parastomal hernias and their correlation with patient symptoms has been insufficiently investigated.

Key question 2

Is there a place for watchful waiting in patients with a parastomal hernia?

Statement: *There is no evidence on the comparative outcome of the benefit of watchful waiting versus surgery for patients with a parastomal hernia.*
Recommendation: *No recommendation can be made on the policy of watchful waiting for patients with a non-incarcerated parastomal hernia.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *No*

Watchful waiting for patients with parastomal hernias is a common practice, although relevant evidence is scarce. High recurrence rates following parastomal hernia repair and the lack of symptoms in a considerable proportion of patients make conservative approach an attractive option. Risks associated with watchful waiting, such as the risk of strangulation, the potential enlargement of the hernia and the development of comorbidities, which may increase the difficulty and risks of subsequent surgery, the increased incidence of perioperative complications following emergency surgery, as well as quality of life parameters, need to be taken into account when making clinical decisions. Although the size of the hernia orifice has been identified as an independent risk factor for postoperative complications in incisional hernia, such an association has not been investigated for parastomal hernias [28, 29]. One relevant retrospective analysis of 16 patients with parastomal hernia was found in the literature, which was considered to be outdated and of insufficient quality [30]. In the absence of adequate evidence, no recommendation on the policy of watchful waiting could be made. Support garments may improve symptoms and could be of benefit with regard to the risk of hernia enlargement and strangulation. However, there is little evidence to support this hypothesis. Undoubtedly, strangulation of a parastomal hernia during a course of watchful waiting requires emergency surgery.

Key question 3

Are there techniques for stoma creation without prophylactic mesh use that result in fewer parastomal hernias?

a. Extraperitoneal versus transperitoneal stoma construction

Statement: *There is insufficient evidence on the comparative risk of parastomal hernia development after construction of a stoma* via *the extraperitoneal or the transperitoneal route.*
Recommendation: *No recommendation can be made in preference of stoma construction through the extraperitoneal over the transperitoneal route.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *No*

b. Stoma construction at a lateral pararectus location versus a transrectus location

Statement: *There is insufficient evidence on the comparative risk of parastomal hernia development after construction of the stoma at a lateral pararectus location or a transrectus location.*
Recommendation: *No recommendation can be made in preference of stoma construction at a lateral pararectus location over a transrectus location.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *No*

c. Size of the fascial aperture

Statement: *There is insufficient evidence on the ideal size of the fascial aperture when constructing a stoma.*
Recommendation: *We suggest keeping the size of the fascial aperture as small as possible to allow passage of the intestine through the abdominal wall without causing ischemia.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *Weak*

Specific operative techniques for stoma construction may result in decreased risk of parastomal hernia. Placing of the stoma through the extraperitoneal route has been hypothesized to reduce the risk of herniation [31]. A meta-analysis has synthesized the results of seven retrospective studies. The pooled estimate of treatment effect was in favor of the extraperitoneal route (odds ratio 0.41; 95% confidence interval, 0.23–0.73, $p = 0.002$). Again, the non-randomized design of the included studies limits our confidence on the reported results. The extraperitoneal route of stoma placement warrants further investigation.

Location of the stoma at a lateral pararectus versus a transrectus location has been also suggested to reduce the risk of parastomal hernia. Proponents of the first technique argue that the integrity of the rectus muscle and sheaths is preserved with minimization of the anterior abdominal wall disruptions and a consequent reduction of the risk of hernias at a lateral position of the stoma. A Cochrane systematic review encompassing nine retrospective studies of 761 patients has tested the hypothesis of a different risk for parastomal herniation following stoma construction at a transrectus or a pararectus location [31]. Although the risk of herniation and stoma prolapse was not statistically different, the low quality of the included studies challenges the internal validity of the pooled outcome. Recently, a pilot RCT failed to demonstrate significant treatment

effects of either technique; it was however underpowered [14].

There is some evidence suggesting that the size of the aperture is associated with the risk of parastomal herniation. Logistic regression analyses of retrospective data from 108 patients identified trephine size as an independent risk factor for parastomal herniation, although the selected cutoff value was not reported [32]. There was unanimous consensus among the guidelines development group that the size of the aperture should be as small as possible, but without challenging perfusion of the stoma.

Key question 4

Does the use of a prophylactic mesh during stoma construction reduce the incidence of parastomal hernias?

Statements: *High quality evidence supports the use of a prophylactic mesh during construction of a permanent end colostomy in elective surgery in reducing the incidence of parastomal hernia development.*
Recommendation: *It is recommended to use a prophylactic synthetic non-absorbable mesh when constructing an elective permanent end colostomy to reduce the parastomal hernia rate.*
Quality of evidence: ☒☒☒☒
Strength of recommendation: *Strong*
Recommendation: *No recommendation to use a prophylactic mesh can be made for ileostomies or ileal conduit stomas, nor for the use of synthetic absorbable or biological meshes.*
Quality of evidence: ☒☒☐☐
Strength of recommendation: *No*

High parastomal hernia rates prompted surgeons to use meshes upon stoma construction as a prophylactic measure. The same three randomized clinical trials published before 2012 [6, 7, 33, 34] were analyzed in four meta-analyses [10, 12, 13, 35]. Since then, six other RCTs have been published [5, 24, 36–40]. Most of the studies used the open surgical approach with a retromuscular mesh with a hole in the center of the prosthesis [6, 7, 24, 34, 38, 39]. Three studies used a laparoscopic approach either by placing a keyhole mesh [5, 36] or using a modified Sugarbaker technique [37]. In most studies a synthetic non-absorbable mesh [5–7, 24, 36, 37, 39] and in two studies a biological mesh [34, 38] was used.

The magnitude of comparative treatment effects, the consistency of outcomes, the low comparative risk of adverse events and the low cost of synthetic meshes prompted the guidelines development group to unanimously support a strong recommendation.

It may be expected that a decrease in the risk of parastomal herniation will improve the quality of life and reduce human and material resources associated with stoma care and surgery for hernia repair, thereby outweighing the required additional resources. Two cost-effectiveness studies were published suggesting that mesh prophylaxis may be a cost-effective strategy [40, 41], although future research is expected to further address these issues. The use of funnel-shaped meshes in the context of parastomal hernia prevention is a further subject of research [42, 43].

Most trials have applied open retromuscular position of a synthetic non-absorbable mesh in patients operated on for rectal cancer and subjected to end colostomy. No recommendation could be made with regard to the use of biological or synthetic absorbable meshes and on the application of prophylactic mesh for the construction of loop colostomies, ileostomies or ileal conduits. Future trials are expected to address the clinical effectiveness of absorbable meshes and of mesh application in stomas other than end colostomy.

Key question 5

Is a suture repair for elective parastomal hernia repair an option?

Statements: *There is no high quality evidence on the comparative risk of recurrence following parastomal hernia repair with mesh, stoma relocation or suture repair. There is, however, evidence suggestive of a high risk of recurrence following suture repair. There is insufficient evidence on the comparative risk of morbidity following mesh repair, stoma relocation or suture parastomal hernia repair. There is, however, evidence suggestive of a low rate of infectious complications for parastomal hernia repair with a synthetic mesh.*
Recommendation: *It is recommended not to perform a suture repair for elective parastomal hernia surgery because of a high risk of recurrence.*
Quality of evidence: ☒☒☐☐
Strength of recommendation: *Strong*

There are no high-quality studies comparing different techniques of elective open parastomal hernia repair. In a retrospective observational study of 50 patients with recurrent parastomal hernia, in which stoma relocation was compared with suture repair, the authors have found similar complication rates between the two groups after a mean follow-up of 2 years [44]. Same side relocation was associated with recurrence in 4 out of 5 patients, whereas contralateral side relocation was associated with recurrence in 7 out of 18 patients. Comparison of direct suture repair versus contralateral side relocation demonstrated a lower recurrence rate for the latter approach ($p = 0.021$). The validity of this study is limited by the source patient population, which had recurrent parastomal hernias, s larger proportion of patients with an ileostomy in the suture repair group and a low power to detect potential pragmatic differences.

In a retrospective study comparing relocation versus suture repair with and without the use of mesh and including both primary and recurrent parastomal hernias, the authors have found significantly less recurrences in the stoma

relocation group (11 of 25 versus 29 of 36, $p < 0.01$) [45]. However, no summative data on complications and effect sizes were provided.

Hansson and colleagues performed a systematic review of case series, in which they reported on various techniques for parastomal hernia repair [46]. Applying logistic regression analyses, the authors have identified cohorts of studies on suture repair to be at higher risk for recurrence, compared with mesh repair ($p < 0.0001$). Furthermore, wound infection was higher in suture repair than in the other techniques (odds ratio 4.0, 95% confidence interval 1.7–9.5). Due to the considerable heterogeneity among and within studies with regard to operative techniques, mesh materials and patient characteristics, our confidence on these outcomes is limited. Available evidence, however, is suggestive of a high risk of recurrence following suture repair. The guidelines development group agreed that alternate techniques to suture repair of parastomal hernias should be strongly considered, although evidence to recommend a particular technique is inadequate. However, it recognizes that suture repair may pose less risks compared to mesh repair on specific patient groups, such as those subjected to surgery for strangulated parastomal hernia or in contaminated cases, although no relevant data exist to date. Without doubt, however, suture repair remains the technically simplest method of surgical management of parastomal hernia.

Key question 6

Is a laparoscopic approach equivalent to an open approach for parastomal hernia mesh repair in elective surgery?

Statements: *There is insufficient evidence on the risk of recurrence following laparoscopic versus open parastomal hernia repair with a mesh.*
There is insufficient evidence on the morbidity following laparoscopic versus open parastomal hernia repair with a mesh.
Recommendation: *No recommendation can be made in favor of laparoscopic or open parastomal hernia repair with a mesh in elective surgery.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *No*

Laparoscopic repair of parastomal hernia has emerged as an alternative to open repair. The keyhole technique involves placement of a mesh with a central hole or a slit around the bowel loop forming the stoma. In the laparoscopic modified Sugarbaker technique, the mesh covers the bowel loop, which lies in a side-to-side fashion onto the abdominal wall. The sandwich technique is a combination of the former two.

There are no high-quality studies comparing laparoscopic versus open parastomal hernia surgery. In a data analysis of more than 2000 patients from the American College of Surgeons–National Quality Improvement Program database, the authors have compared laparoscopic with open parastomal hernia repair after adjusting for age, gender, American Society of Anesthesiologists score, emergency designation of the operation, hernia type and wound class [47]. They found that patients subjected to laparoscopy had approximately 60% lower odds of morbidity (odds ratio 0.42, 95% confidence interval 0.27–0.64) and operative time reduced by 13 min (mean difference − 13.24, 95% confidence interval − 24 to − 3). The retrospective design and limitations associated with the database query do not allow for sufficient assessment of the comparative outcomes of laparoscopic versus open parastomal hernia repair. Pastor and colleagues retrospectively analyzed their data of a cohort of 25 patients and did not find any difference in outcomes of interest in this underpowered study [48]. In the systematic review of case series by Hansson and colleagues, various techniques of parastomal hernia repair were reported [46]. The cumulative laparoscopic and open study populations consisted of more than 300 patients each. Applying logistic regression analyses, the authors have found laparoscopic parastomal hernia repair to be associated with lower odds of recurrence when compared with open suture repair, but to be equally effective to open intraperitoneal and open retromuscular repair. Furthermore, the odds of mesh infection and morbidity did not differ significantly between laparoscopic and open parastomal hernia repair. The evidence deriving from these data is limited, due to the considerable heterogeneity among and within studies. The heterogeneity of procedures and patient cohorts did not allow for drawing definite conclusions. Clinical decision making should depend on local resources, patient preferences, surgical experience and on specific patient conditions, such as comorbidities, previous surgeries, intraperitoneal adhesions and the size of the hernia.

Key question 7

Is there an optimal open parastomal hernia mesh repair technique?

Statements: *There is insufficient evidence on the optimal technique for open parastomal hernia repair with regard to morbidity or recurrence.*
Recommendation: *No recommendation can be made in favour of any open parastomal hernia repair with mesh.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *No*

Parastomal hernia repairs using a mesh include the onlay (fixation onto the fascia of anterior rectus sheath and the aponeurosis of the external oblique muscle), the retromuscular (dorsally to the rectus muscle and anteriorly to

the posterior rectus sheath) and the intraperitoneal (intra-abdominal fixation onto the peritoneum) techniques. There is a paucity of comparative evidence, although several case series and two systematic reviews have been published [46, 49].

In the systematic review and synthesis of outcomes of open mesh repair by Hansson and colleagues, the onlay, retromuscular, Sugarbaker and keyhole techniques were associated with recurrence rates of 17.2% (95% confidence interval, 11.9–23.4%), 6.9% (95% confidence interval, 1.1–17.2%), 11.6% (95% confidence interval, 6.4–18.0%) and 34.6% (95% confidence interval, 13.1–60.3%), respectively, with mesh infection rates not exceeding 2.6% [46]. Direct comparison of these pooled outcomes is not justified, due to the heterogeneity of patient characteristics, surgical techniques and mesh materials.

Key question 8

Is there an optimal laparoscopic parastomal hernia mesh repair technique?

Statements: *There is evidence favouring the use of a mesh without a hole in preference to a keyhole mesh for laparoscopic parastomal hernia repair in terms of recurrence.*
There is insufficient evidence on the safest laparoscopic technique for parastomal hernia repair with regard to morbidity.
Recommendation: *For laparoscopic parastomal hernia repair, a mesh without a hole is suggested in preference to a keyhole mesh.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *Weak*

Techniques of laparoscopic parastomal hernia repair have not been comparatively evaluated to date. Relevant evidence derives from case series and small retrospective cohort studies, which have been synthesized by two systematic reviews. The meta-synthesis with logistic regression analyses by Hansson et al. suggests that the laparoscopic Sugarbaker technique is associated with a lower recurrence rate (pooled recurrence rate 11.6%, 95% confidence interval 6.4–18.0%), compared to laparoscopic hernia repair using a keyhole mesh (pooled recurrence rate 34.6%, 95% confidence interval 13.1–60.3%; odds ratio for the comparison 2.3, 95% confidence interval 1.2–4.6) [46]. In another recent meta-analysis of case series, the pooled recurrence rates of the laparoscopic Sugarbaker technique and of the laparoscopic keyhole mesh repair were 10% (95% confidence interval 4–19%) and 28% (95% confidence interval 12–47%), respectively [50]. Perhaps, the largest case series on the laparoscopic Sugarbaker technique reported a recurrence in 4 out of 61 patients at a mean follow-up of 26 months [51]. Although available data suggest that the laparoscopic Sugarbaker technique may be associated with lower recurrence rates compared to the laparoscopic keyhole mesh repair, our confidence on these outcomes is limited, due to the retrospective study designs, heterogeneity in patient characteristics, definition of recurrence and types of stoma, both within and across studies. The sandwich technique, which may be considered a combination of the Sugarbaker and the keyhole technique, was associated with one recurrence in 47 parastomal hernia repairs in a prospective cohort study, at a median follow-up of 20 months [52]. The hybrid parastomal endoscopic re-do (HyPER) technique combines open and laparoscopic repair using a funnel-shaped mesh. No recurrence was observed at the 6-month follow-up in a prospective study of 12 patients [53]. The latter two techniques have not been well established in the literature; comparative studies are awaited to assess their relative effectiveness. It should be noted that most laparoscopic techniques require a level of expertise and may have a significant learning curve.

Key question 9

Which meshes are the most effective?

Statements: *There is insufficient evidence on the most effective mesh for parastomal hernia repair with regard to recurrence or morbidity.*
There is no evidence supporting superiority of biological over synthetic meshes with regard to recurrence or morbidity.
Recommendation: *No recommendation can be made on the use of specific mesh material for parastomal hernia repair.*
Quality of evidence: ☒☐☐☐
Strength of recommendation: *No*

There is a lack of comparative evidence on different meshes for parastomal hernia repair. Available data come from retrospective case series of patients subjected to parastomal hernia repair with polypropylene, expanded polytetrafluoroethylene (ePTFE), polyvinylidene fluoride (PVDF), polyester or biological meshes. Evidence provided by retrospective case series suggests that biological meshes are associated with high recurrence rates (ranging between 16 and 90%) and may demonstrate some benefit in terms of mesh infection [54, 55]. Current data are, however, of low quality and the guidelines development group could not make a relevant recommendation. Nevertheless, synthetic uncoated meshes are generally not considered for intraperitoneal use, due to the risk of adhesions, bowel erosion and stricture. A recent retrospective cohort study has demonstrated a significantly higher incidence of intestinal obstruction secondary to adhesions when using PVDF versus a composite coated polyester mesh (11.5% versus 0%, $p = 0.006$) [56].

Comments

This is the first international guideline focusing on parastomal hernias. The major limitation in making recommendations was related to the scarcity of evidence. This is associated with the fact that patients subjected to permanent stoma construction are few in an average tertiary care center and around 30–50% of those patients will present with parastomal hernia in the long term. It is imperative that future trials be based on power size calculations, to provide more precise treatment effect estimates. Multi-institutional design and adequate outcome reporting are essential for future studies to achieve this goal. This approach will allow performing subgroup analyses, which may reveal distinct effects in different patient populations (for example, terminal ileostomy in young patients with Crohn's disease versus terminal colostomy in older patients with colorectal malignancy). The available evidence was insufficient to allow for making distinct recommendations for specific patient subgroups. Clinical decision making should take into account patient characteristics and specific preferences, along with the present recommendations.

Another shortcoming was the retrospective study design of the majority of relevant studies. This is of specific importance for outcome assessment in patients with parastomal hernia, because attrition bias (due to loss at follow-up) and detection bias (due to CT and magnetic resonance imaging examinations performed for indications other than diagnosing a parastomal hernia, such as postoperative cancer surveillance) limit our confidence on the true epidemiological and clinical outcome data.

As suggested by the GRADE methodology, this guideline was conservative in making recommendations based on experts' opinion in the absence of relevant research evidence. Our literature review and study assessment suggest that there is ample room for future research on several topics, including the use of classifications for parastomal hernias, the policy of watchful waiting, specific techniques for stoma construction, the use of mesh for construction of end ileostomy, the use of mesh for parastomal hernia repair and the application of laparoscopic surgery. There was no substantial evidence to support recommendations for these subjects. The results of the consensus conference presented in the appendix suggests that, although the scientific community agrees with the statement that relevant evidence is scarce, there is need for recommendations on numerous key subjects. Until new research output is available, clinical decision making on these subjects must rely on surgeons' discretion and knowledge, patient preference and local resources. Management and treatment strategy options need to be adequately discussed with patients to assist them with making informed decisions and understanding as much as possible about the procedures they are agreeing to.

An important feature of this guideline is the high level of consensus between the guidelines development group and the scientific community. The latter was represented by attendees of the 38th International Congress of the EHS, which are primarily hernia surgeons or general surgeons with a specific interest in hernia surgery. The views and preferences of a wide spectrum of European countries have been reflected in the consensus conference, resulting in wide agreement. This manuscript was assessed by two external reviewers using the AGREE II instrument. The outcome of this assessment is presented in Appendix IV.

Nevertheless, it should be noted that limitations might be imposed for several recommendations of these guidelines by local resources and health-care policies. This is of specific importance in the context of social and economic circumstances, which vary across countries. It is recommended that national health-care authorities evaluate the capacity of health-care resources to implement a policy of routine prophylactic mesh in end colostomies.

There are two parameters of these guidelines, which might have at least short-term direct financial implications. First is the policy of performing CT scan in uncertain cases of parastomal hernias. Particularly, the differential diagnosis between parastomal hernia and stoma prolapse may require CT imaging. Relevant financial implications are not expected to be significant, because the diagnosis of parastomal hernia is unclear in a minority of patients. Nevertheless, if the cost of such an approach is anticipated to be significant, ultrasonography examination is proposed. Second, the recommendation to routinely use a prophylactic mesh in the construction of end colostomy is also not expected to carry a significant financial burden, provided that conventional synthetic non-absorbable meshes are used exclusively for these very indications.

The impact of these guidelines on clinical practice is planned to be assessed through a Web-based survey to be completed by members of the EHS, 2 years after publication of this manuscript. Partial or complete adherence to these guidelines by at least 70% of the participants will be considered suggestive of adequate implementation. Participants will be invited to submit comments and suggestions for the planned update of these guidelines. The results of this survey will be made publicly available. A 2-year interval for repeated assessment is considered adequate to monitor the level of implementation.

An update of the guidelines is intended to take place in 2021, to be presented in the World Conference on Abdominal Wall Hernia Surgery. The rationale behind this intention is that the guidelines development group is not aware of planned or ongoing trials that would address major key points in the field of parastomal hernia surgery. The UK NIHR CIPHER Study will prospectively evaluate the surgical and patient risk factors for 4000 patients having stoma

formation with a median follow-up of 3 years. Patient recruitment is planned to open in April 2017. This study will provide longitudinal epidemiological evidence on the incidence and prevalence of different types of stomas, examine the validity of the EHS classification, determine symptomatic questionnaires that will guide when to assess and treat parastomal hernias, quality of life follow-up and health economic analyses among others. The methodology for the update of these guidelines is planned to be similar to the present guidelines, with the search strategy including articles published from February 2016 upward. Further key topics, such as the assessment of risk factors of parastomal hernia and associated complications, the effects and risks of supportive girdles, and the role of abdominal exercise in the prevention of parastomal hernia will be addressed in this update.

Conclusion

The present guidelines provide an evidence-based approach to the diagnosis and management of parastomal hernias. There is a lack of evidence on several topics that are expected to be addressed by future trials. These will ideally be based on multicenter collaborations. The main feature of these guidelines is the recommendation to use a prophylactic mesh for end colostomies. Although there is robust evidence to support this policy, the clinical outcomes should be audited and reporting of adverse events is strongly suggested.

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Compliance with ethical standards

Conflicts of interest SAA declares no conflict of interest. FA declares no conflict of interest. JGA declares no conflict of interest. DB declares no conflict of interest. FB declares no conflict of interest. HTB declares no conflict of interest. KB declares no conflict of interest. JC declares conflict of interest not directly related to the submitted work (personal fees from Johnson & Johnson Ethicon, personal fees from BARD Davol). DC declares conflict of interest not directly related to the submitted work (grants and personal fees from W.L. Gore, personal fees from BARD Davol, personal fees from Johnson & Johnson and personal fees from MSD). UAD declares no conflict of interest. RHF declares no conflict of interest. CFL declares no conflict of interest. BH declares no conflict of interest. FH declares no conflict of interest. AH declares no conflict of interest. AJ declares no conflict of interest. LFK declares no conflict of interest. JRL declares no conflict of interest. IKL declares no conflict of interest. MLC declares conflict of interest not directly related to the submitted work (personal fees from Johnson & Johnson and personal fees from BARD Davol). MM declares conflict of interest not directly related to the submitted work (personal fees from Springer, personal fees from Aspide, grants and personal fees from Bard, personal fees from Braun, personal fees from Cook, grants and personal fees from Covidien, personal fees from Ethicon and personal fees from W.L. Gore) and he serves as co-editor of *Hernia*. AM serves as executive editor of *Hernia*. SMC declares conflict of interest not directly related to the submitted work (personal fees from Bard, personal fees from Gore, personal fees from Medtronic and personal fees from Olympus). MP declares no conflict of interest. TR declares no conflict of interest. NS declares conflict of interest not directly related to the submitted work (grants and personal fees from Medtronic). MS declares no conflict of interest. MS declares no conflict of interest. CS declares no conflict of interest. FEM declares conflict of interest not directly related to the submitted work (grants, personal fees and non-financial support from Medtronic, grants and personal fees from Johnson & Johnson, grants and personal fees from Dynamesh, personal fees from Cousin Biotech and personal fees from BARD Davol).

Ethical approval For this type of study formal consent is not required.

Human and animal rights This article does not contain any studies with animals performed by any of the authors.

Informed consent This article does not require informed consent due to the lack of human participants.

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