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REVIEW

Italian guidelines for the surgical management of enteral stomas in adults

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Abstract

Background Worldwide, stomas represent a medical and social problem. Data from the literature on stoma management are extensive but not homogeneous. In Italy, no guidelines exist for this topic. Thus, clear and comprehensive clinical guidelines based on evidence-based data and best practice are need. In 2018, the Multidisciplinary Italian Study group for STOmas, called MISSTO, was founded. The aim was to elaborate guidelines for practice management of enteral and urinary stomas in adults.

Methods A systematic review of the literature was performed using PubMed, National Guideline Clearinghouse, and other databases. The research included guidelines, systematic reviews, meta-analyses, randomized clinical trials, cohort studies, and case reports. Five main topics were identified: "stoma preparation", "stoma creation", "stoma complications", "stoma care", and "stoma reversal". The systematic review was performed for each topic, and studies were evaluated according to the GRADE system, AGREE II tool.

Results Recommendations were elaborated in the form of statements with an established grade of recommendation for each statement. For low levels of scientific evidence statements, a consensus conference composed of expert members of the major Italian scientific societies in the field of stoma management and care was held. After discussing, correcting, validating, or eliminating the statements by the experts, the final version of the guidelines was elaborated and prepared for publication. This manuscript is focused on statements on the surgical management of enteral stomas.

Conclusions These guidelines are the first Italian guidelines on multidisciplinary management of enteral stomas with the aim of assisting surgeons during stoma management and care.

Keywords Stoma · Ostomy · Enterostomy · Ileostomy · Colostomy · Surgery

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Introduction

Worldwide, a stoma is a medical and social problem. In the United States, approximately 100,000 patients each year undergo operations with stoma creation [1]. Italian data on enteral or urological ostomy creation are not available; to date, a national registry does not currently exist but the Italian Government is working to create it [2]. In 2004, ALSI (Associazione Lombarda Stomizzati e Incontinenti–Lombardy Association of Ostomy and Incontinent People) performed a regional survey: the general population was 9,246,796, and there were 11,305 ostomates (urostomy 25.89%, colostomy 42.06%, ileostomy 10.69%, and non-specified enterostomy 21.36%) with a mean population prevalence of 0.122%. Based on these regional data, it has been estimated that in Italy, there are 74,000 individuals with an ostomy [3]. The creation of an enteral stoma in adults may be indicated in the management of several conditions, including cancer, inflammatory disease, and trauma. Despite improvements in both surgical techniques and quality of disposable products for ostomy management, operations with enteral stoma creation, though common, still have complication rates up to 70% [4]. Thirty-day morbidity rates, excluding stoma specific complications such as dehydration, skin problems, and prolapse, range from 33 to 48%; risk-adjusted morbidity rates may vary significantly ranging from 31 to 61% [5]. Moreover, some studies show that adequate stoma care significantly improves outcomes and may decrease hospital readmission and emergency surgery rates [6]. However, data from the literature on several aspects of stoma management are extensive but extremely nonhomogeneous. Therefore, in this field, the scientific community has emphasized the necessity of clear and comprehensive clinical guidelines based on evidence-based data, if available, and on best practice, through the experience of expert stoma surgeons and nurses.

The aim of the Multidisciplinary Italian Study group for STOmas (MISSTO) was to elaborate guidelines for practice management of enteral and urinary stoma in adults [7].

Materials and methods

The aim of these guidelines is to provide practice recommendations for the surgical and nursing aspects of management and care of enteral and urinary stomas. For journal publication purposes, the original project was divided into three parts; this manuscript focusses on the surgical management of enteral stomas.

The statements contained in this article, including several recommendations about preparation, creation, complications, postoperative care, and reversal of stoma, should assist surgeons to manage adult patients with enteral stomas during preoperative, intraoperative, and postoperative phases. These guidelines do not provide indications about clinical circumstances when an ostomy should or should not be created or reversed.

The project began on January 2018 with the creation of MISSTO, a multisociety and multidisciplinary research group including components of the main Italian societies of surgeons (both general surgeons and urologists expert in the field of ostomy creation and care), stoma-therapy nurses, experts in scientific methodology, and patient's associations focused on stoma management and care. The work began with the identification of the main topics of the guidelines: "stoma preparation", "stoma creation", "stoma complications", "stoma care", and "stoma reversal" (only for enteral stomas). While the topics "stoma preparation" and "stoma care" were comprehensive of indications for both enteral and urinary stomas, the topics "stoma creation" and "stoma complications" were discussed separately for enteral and urinary stomas, respectively. A systematic review of the literature was performed by two members at a time (updated March 31, 2018) with the keywords "ostomy", "stoma", "enteral ostomy", "colostomy", "ileostomy", and "urostomy", and with the specific terms for each topic. The research included every type of study, including previous guidelines, systematic reviews, meta-analysis, randomized clinical trials, cohort studies, and case reports. The research was first performed in PubMed, National Guideline Clearinghouse, and CINAHL and then extended to the following international and national databases: Cochrane Database of Collected Reviews, SIGN (Scottish Intercollegiate Guidelines Network), NICE (National Institute For Clinical Excellence Guideline), Johanna Briggs Institute, RNAO (Registered Nurses' Association of Ontario), WOCN (Wound Ostomy and Continence Nurses) Society, BSG (British Society of Gastroenterology), AASTN (Australian Association of Stomal Therapy Nurses Inc), ACGBI (Association of Coloproctology of Great Britain and Ireland), ASCRS (American Society of Colon and Rectal Surgeons), CAET (Canadian Association for Enterostomal Therapy), ERAS (Enhanced Recovery After Surgery) Society, EAUN (European Association of Urology Nurses), and WCET (World Council of Enterostomal Therapists). The inclusion criteria were adult patients, articles published in English or Italian, and with complete text available. Previous existing guidelines were evaluated with the Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool [8]. The other studies were assessed using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system [9]. For each topic, every identified article was analyzed, and the evidence and biases were reported on a specific table for analysis according to the GRADE system.

All the evidence found in the individual articles was then examined, and the group elaborated recommendations in the form of statements. The final grade of recommendation for each statement was established using the GRADE system (Table 1) and shared by the group. For some statements, the level of scientific evidence was low (GRADE 2C or NO GRADE), because no experimental or analytical clinical studies were performed. For these statements, a consensus conference was held (Bologna, December 3rd 2018) composed of expert members (surgeons, urologists, nurses, and patient's associations) of the major Italian scientific societies [Italian Association of Stoma Care Operators (AIOSS); Italian Society of Surgery (SIC); Italian Association of Hospital Surgeons (ACOI); Italian Society of Colorectal Surgery(SICCR); Italian Society of Surgical Oncology (SICO); Italian Unitary Society of Coloproctology (SIUCP); Italian Society of Urology (SIU); Italian Association of Urologic Nurses (AIURO)] and patient's associations [Association of Inflammatory Bowel Diseases (AMICI); Federativion of Associations of Incontinent and Stoma Patients (FAIS); Italian Association of Stoma Patients (AISTOM)] in the field of stoma management and care. Each society appointed a single expert to evaluate each statement not supported by a sufficient level of scientific evidence. During the consensus conference, each recommendation not supported by sufficient levels of scientific evidence was discussed, corrected, validated, or eliminated by the experts. Moreover, the expert members selected additional topics that were subsequently elaborated by the group and submitted to the experts for final validation if no sufficient GRADE was reached. The complete guidelines were then checked by the group, which evaluated the relevance, clarity, accuracy, comprehensiveness, organization, and consistency with current research, best practice, and usefulness to the target population. This last check was accomplished with the help of the AGREE II tool [8]. The working group decided to include in this manuscript GRADE 2C and NO GRADE statements, because they were considered to be relevant aspects of the guidelines discussed and approved by the expert members of all contributing scientific societies.

Stoma preparation

Preoperative discussion and informed consent

Statement Preoperative education of patients and their families improves postoperative quality of life and stoma management, and reduces the average hospital stay. (Strong recommendation based on moderate quality evidence, GRADE 1B).

Preoperative and postoperative recovery programs represent a challenge for the stoma specialists (especially nurses), who have to prepare stoma patients or caregivers for self-care in a short amount of time, and for the patients, who have to quickly comprehend stoma-care information and practical and manual management [10]. As suggested by the guidelines of the American Society of Colon and Rectal Surgeons (ASCRS) and by the Scottish Intercollegiate Guidelines Network (SIGN), preoperative and postoperative education should be provided by professional figures, such as nurses specialized in stoma care [11, 12]. Because the preoperative time available for patient education is limited, patient education has to be effective, addressed with a multidisciplinary approach and planned by trained educators; information must to be repeated and reinforced with written advice, DVDs, or other multimedia aids [13]. In a randomized-controlled trial (RCT) with 54 patients, Lo et al. analyzed the cost-effectiveness of a multimedia learning educational program, compared to the conventional program. The authors found that the multimedia group had better outcomes in terms of knowledge of self-care, attitude of self-care, and behavior of self-care, with a final better result in total social costs [14]. Several studies analyzed the role of preoperative education in different postoperative outcomes (stoma complications and length of hospital stay), the level of self-efficacy in stoma management, the degree of adaptation to the presence of the stoma, and the quality of life (QoL). Table 2 reports data from randomized-controlled trials that evaluated the role of preoperative and postoperative stoma education [10, 14–16]. Educational preoperative programs focused on stoma appear to positively influence the rate of postoperative complications, the length of hospital stay, and the QoL of stoma patients, improving the ability of patients in stoma care with consequent cost-effectiveness [15, 17–20].

Stoma siting

Statement Preoperative detection of the stoma site, both in elective and emergency surgery, promotes self-care, reduces stoma complications and improves postoperative quality of life. (Strong recommendation based on moderate quality evidence, GRADE 1B).

Table 3 shows the main comparative studies that analyzed the role of stoma siting in improving postoperative outcome and QoL of stoma patients [18, 21–28]. Except for the study of Carlsson (that has the bias of high discrepancy in sample size of IG and CG), all of the studies emphasized the importance of preoperative stoma siting in preventing postoperative stoma-related problems and improving the QoL of stoma patients [18, 21–33]. The American Society of Colon

Table 1 *GRADE* Grades of recommendation, assessment, development, and evaluation[5]

	Description	Benefits vs. risks and burdens	Methodological quality of supporting evidence	Implications
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, low- or very-low-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances, or patient's or societal values
2B	Weak recommendations, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances, or patients' or societal values
2C	Weak recommendation, low- or very-low-quality evidence	Uncertainty in the estimates of benefits, risks and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

RCT randomized-controlled trial

Table 2 Preoperative stoma education and postoperative stoma-related outcomes: randomized-controlled trials

Study	Patients	Outcomes analyzed	Follow-up data points	Main results
Chaudhri [15]	IG: 21 CG: 21	Time to stoma proficiency Postop hospital stay, unplanned stoma-related interventions Cost-effectiveness	6 weeks preop 6 weeks postop	IG group was significantly better than CG in: Stoma proficiency Postoperative hospital stay Unplanned stoma-related intervention Cost-effectiveness
Lo [14]	IG: 27 CG: 27	Stoma knowledge Self-care attitude and behavior Cost-effectiveness	1 week preop Day 1–3–5–7 postop	IG group was significantly better than CG in: Stoma knowledge (at day 7 postop) Self-care attitude and behavior (at day 7 postop) Cost-effectiveness
Zhang [16]	IG: 52 CG: 51	Ostomy adjustment Stoma self-efficacy Satisfaction with care Stoma complications	3 months preop 1–2 days preop 1 month postop 3 months postop	At 1 month IG was significantly better than CG in: Satisfaction with care Stoma complications At 3 months IG was significantly better than CG in: Ostomy adjustment Stoma self-efficacy Satisfaction with care Stoma complications
Forsmo [10]	IG: 61 CG: 61	Postop hospital stay Early stoma-related complications Minor morbidity Major morbidity Mortality Readmission rate	1 month preop 10 and 30 days postop	IG group was significantly better than CG in: Postoperative hospital stay

IG interventional group (preoperative educational program), *CG* control group

and Rectal Surgeons (ASCRS), the American Urological Association (AUA), and the Wound Ostomy and Continence Nurses (WOCN) Society strongly recommended the preoperative stoma siting for people who will undergo a surgical procedure with the creation of a stoma, both enteral and urological [34]. Moreover, both the ASCRS guidelines and the Scottish Intercollegiate Guidelines Network (SIGN) strongly recommended the presence of trained staff (stoma specialist nurse) to perform the preoperative stoma siting and for the postoperative care of the stoma [11, 12]. In Italy, an agreement was signed between the Italian Society of Surgery (SIC) and the Italian Association of Stoma Care Operators (AIOSS) in 2016 to strongly recommend preoperative stoma siting [35].

Stoma creation

Table 4 reports common surgical indications for enteral stomas.

Loop choice

Statement Despite heterogeneity regarding stoma creation techniques, some tenets are universal: in general, the bowel for the ostomy should be well vascularized and sufficiently mobilized to minimize tension. (NO GRADE–Experts' opinion).

Surgical approach: open versus laparoscopy

Statement 1 Laparoscopic stoma creation, if feasible, should be preferred to an open approach. (Strong recommendation based on low quality evidence, GRADE 1C).

No randomized study exists comparing the traditional open to the minimally invasive laparoscopic approaches [36–44]. Laparoscopic stoma creation appears to be a feasible and safe procedure. The conversion rate ranged from 0 to 15.8%, and the most frequent cause of conversion was adhesions. The rate of intraoperative complications (different from adhesions) during the laparoscopic approach varied between 0 and 3.1%. The risk of postoperative complications within 30 days after laparoscopic stoma creation varies between 4.2 and 17.5%. However, all of the comparative series considered in this study report a significantly lower rate of postoperative morbidity in the laparoscopic group than the open group. The 30-day mortality rate in the laparoscopic group ranged between 0 and 4.8%; for this outcome, the laparoscopic group had a lower risk than the open group. The advantage of the laparoscopic approach also influenced the postoperative

Table 3 Preoperative stoma siting and postoperative outcome: main studies

Study	Patients	Outcomes analyzed	Main results
Bass [21]	IG: 292 CG: 301	Early and late postoperative complications	IG was significantly better than CG in: Overall postop complications Early postop complications Late postop complications
Mahjoubi [22]	IG: 174 CG: 174	Postoperative Quality of Life (EORTC-QLQ C30 and CR38)	IG was significantly better than CG in: Sexual enjoyment, physical and role functioning Micturation, gastrointestinal problems, weight loss, dyspnea, pain, fatigue, vomiting Overall QoL score
Nastro [23]	IG: 1087 CG: 129	Postoperative stoma complications	IG was associated with a significantly lower risk of postoperative stoma complications than CG
Person [24]	IG: 52 CG: 53	Postoperative complications Independence of patients in stoma care Quality of life	IG was significantly better than CG in: Rate of postop complications Better independence of patients in stoma care Better QoL
Millan [18]	IG: 123 CG: 147	Early skin irritation Anxiety about stoma	IG was associated with a significantly lower risk of early skin irritation and a lower rate of anxiety about stoma than CG
Baykara [25]	IG: 287 CG: 461	Postoperative stoma complications Peristomal skin problem Mucocutaneous separation Stomal retraction	IG group showed a significantly: Lower rate of overall complications Lower rate of peristomal skin problems Lower rate of mucocutaneous separation Lower rate of stomal retraction
Jayarajah [26]	IG: 146 CG: 46	Postoperative stoma complications (stoma prolapse, skin ulceration, and parastomal hernia)	IG was associated with a significantly lower risk of postoperative stoma complications (prolapse, skin ulceration, and parastomal hernia) than CG
Mckenna [27]	IG: 35 CG: 24	Quality of life	Overall score of QoL was significantly better in IG than CG
Carlsson [28]	IG: 182 CG: 25	Postoperative stoma complications	No significant differences between IG and CG

IG interventional group (preoperative stoma siting), *CG* control group

hospital stay, which appeared to be significantly shorter than after an open approach.

Various pitfalls can occur in a laparoscopically created defunctioning ileostomy, especially the correct orientation of the bowel. Measures can be taken to minimize these technical errors. All of the authors underlined that when performing laparoscopic stoma, care should be taken to avoid twisting of the exteriorized bowel (for a loop ostomy) or kinking of the mesentery (for an end ostomy). Some procedures, such as marking proximal or distal ends and laparoscopic visualization of the intestinal loop after it passes through the fascia, help the surgeon to confirm the correct orientation of the bowel and should be always performed. However, obstructive complications occur in approximately 5% of laparoscopically created stoma. Early recognition of this ileostomy complication is important, as prompt operative intervention can reduce postoperative morbidity [45].

Statement 2 Laparoscopic-created stomas appear to be easier to reverse. (Weak recommendation based on low quality evidence, GRADE 2C).

Hiranyakas et al. compared 352 stoma closures, 145 after laparoscopic stoma creation, and 206 after open creation. The laparoscopic group had a significantly shorter operative time and postoperative hospital stay than the open group. Moreover, the rate of postoperative morbidity was significantly higher in the open group than in the laparoscopic group [46].

Temporary stoma creation

Statement 1 Loop ileostomy is associated with reduced risk of prolapse and infectious complications compared with those of loop colostomy for temporary fecal diversion (Weak recommendations based on high-quality evidence, GRADE 2A).

At least five RCTs, five meta-analyses and several observational studies have been performed on this topic [47–56]. In one trial, no significant differences were found [48]; two studies found significant differences only in favor of ileostomy [47, 50], and one study only in favor of colostomy

Table 4 Indications for enterostomy

Obstruction	Congenital malformation Neoplasm (colorectal or abdominal cancer) Hernia Inflammation Endometriosis Ischemia Radiation
Complications of inflammatory disease (Diverticular disease, Crohn's disease, and ulcerative colitis)	Perforation Fistula Obstruction
Diversion (covering stoma proximal to the anastomosis or the lesion)	Colorectal or coloanal anastomoses Ileal pouch-anal anastomoses Anal disease or perineal infections Decubitus ulcers Burns
Injury	Iatrogenic Penetrating trauma Blunt trauma Foreign bodies
Miscellaneous	Constipation or colonic dysmotility Fecal Incontinence Hepatico-cutaneous jejunostomy Feeding tube Antegrade colonic enema

[51]. One trial found significant differences both in favor of colostomy and ileostomy [49]. These RCTs were small and analyzed different outcomes, so their heterogeneity was significant.

Several meta-analyses have also been performed [52–56]. In 2007, a Cochrane comparative analysis of the 5 RCTs on temporary ileostomy and colostomy was published [53]. The main result of this Cochrane analysis and the only significant difference between the two types of stoma was the higher rate of stoma prolapse in the colostomy group (19% vs 2% in ileostomy group). However, a trend (not statistically significant) in favor of ileostomy was found for the rate of wound infection (8% vs 14%) and the rate of incisional hernia after stoma closure (0% vs 10%). After this Cochrane study, three other meta-analyses were published [54–56]. In an Italian meta-analysis, 20 studies were analyzed (1529 patients), including the 5 RCTs [54]. Patients with ileostomy experienced fewer overall complications after stoma creation, fewer infectious complications, and less stoma prolapse; however, ileostomy patients experienced more frequent dehydration and intestinal obstruction after stoma closure. The last, more recent meta-analyses established the greater safety of ileostomy in terms of prolapse risk and wound infection after closure, postoperative sepsis, hernia, and overall morbidity [55, 56]. Dehydration was one of the main causes of hospital readmission for patients undergoing loop ileostomy construction (from 38.3 to 43.1% in the literature); sometimes, the severity of this complication led to renal failure. No consistent data exist to determine predictive factors for dehydration. Among the retrospective studies, age > 65 years, perioperative complications, and chemo-radiotherapy appeared to increase the risk of dehydration, while only age > 50 years appeared to be linked to the risk of renal failure. All of the studies agreed that nurse counseling and home-care appeared to reduce readmission due to dehydration [57–63].

Statement 2 Loop ileostomy appears to favor better quality of life than loop colostomy. (Weak recommendation based on low quality evidence, GRADE 2C).

In 2000, Gooszen et al. published a prospective clinical trial analyzing 37 patients with temporary loop ileostomy and 39 patients with temporary loop colostomy (randomly assigned comparison). The authors did not find a significant correlation between stoma type and QoL [64]. In 2003, Silva et al. used a questionnaire and compared the QoL of 25 patients with an ileostomy to the QoL of 25 patients with a colostomy. Both ileostomy and colostomy resulted in significant QoL impairment. However, with ileostomy, the effluent was more tolerable, and the appetite was preserved compared with colostomy. No differences regarding travel, dress, daily chores, or sexual activity were found between the two groups [65].

Statement 3 Temporary loop colostomy produces a lower rate of complications than end-colostomy in stoma closure. (NO GRADE – Experts' opinion).

Few studies analyze this topic. Bruns et al. compared loop with end temporary colostomy (58 vs. 160 cases) in emergency and traumatic surgery (retrospective study). Patients with end-colostomy were more likely to require midline laparotomy, and had greater intraoperative blood loss, longer hospital stay, and more overall complications than patients with loop colostomy [66].

Temporary tube stoma is a feasible and effective alternative to conventional loop stoma in selected cases. The *T*-tube ileostomy was first reported at Texas Children's Hospital in 1959, and several investigators reported successful outcomes in neonates with unresolved uncomplicated meconium ileus unrelieved by contrast enema [67, 68]. Use of tube ileostomy in adults is reported by Hojo in seven young patients treated for familial polyposis coli [69]. The main advantage is that it effectively diverts the bowel contents and avoids the need for a second surgery and its related complications. In 2016, a meta-analysis of four studies analyzed the role of tube stoma for the protection of a low anastomosis in colorectal surgery in adults [70]: 332 patients with tube stoma and 310 with conventional loop stoma. No differences were found regarding the incidence of anastomotic leakage. However, in

comparison with conventional loop stoma, temporary tube stoma was associated with significantly fewer stoma-related complications, shorter operative time, and hospital stay and shorter time to stoma closure. In special circumstances, such as complex traumatic, malignant, or inflammatory anorectal conditions, the formation of a proximal "trephine" sigmoid (or transverse) colostomy may avoid the need for a formal laparotomy with the consequent associated morbidity. This technique was first described by R. Phillips and A. Senapati from St Mark's Hospital in London [71]. The creation of a diverting 'trephine' colostomy through a 'keyhole' incision may be associated with technical pitfalls including difficulty in identifying the correct intestinal segment, and difficulty in distinguishing between the proximal (afferent) and distal (efferent) bowel segments. Potential complications are inadvertent creation of a transverse colostomy instead of the intended sigmoid one, maturation to skin of the distal bowel opening, and closure of the proximal bowel segment, resulting in complete colonic obstruction. To avoid these pitfalls, a colonoscopy-assisted technique to perform a "trephine" sigmoid colostomy was described [72]. Currently, there is too little evidence to establish the effectiveness of this technique for stoma creation.

Technical aspects

Statement 1 The use of a rod or bridge for the loop ostomy does not reduce the stoma retraction rate and increases the incidence of complications (necrosis, infection, dermatitis) for both ileostomy and colostomy. The routine use of a rod for loop ostomy is not recommended (Strong recommendations based on high-quality evidence, GRADE 1A).

Surgical literature and technique text books advocate the use of a stoma rod to support loop ileostomy and colostomy and to prevent stoma retraction [73]. Before 2016, only a small randomized-controlled trial compared early retraction rates in loop ileostomy, which demonstrated no significant difference between rigid bridge or no bridge at all [74]. More recently, three RCTs (two for ileostomy and one for colostomy) and one prospective observational study confirmed that use of a rod does not reduce the stoma retraction rate, but, at the same time, can increase the incidence of postoperative complications (bowel necrosis, edema, peri-stoma dermatitis, and surgical site infection) [75–78].

Zindel et al., in a multicenter RCT that included 78 patients, showed a lower rate of stoma necrosis in the group without rod for loop ileostomy (2.9% vs 29.5% in rod group—p 0.002). They elaborated a Stoma Specific Morbidity Score (SSMS), including all possible stoma-related complications, and demonstrated no significant difference in score between the two groups of patients. The authors reported that high body mass index (BMI) was the only variable significantly related to higher incidence of complications, independent of the rod use [74]. Huchino et al., in a single-center RCT, randomized 257 patients who underwent loop ileostomy during proctocolectomy for ulcerative colitis. They demonstrated a lower rate of peri-stoma dermatitis in the group without a rod (28.1% vs 54.1% in rod group—$p < 0.01$), while the surgical site infection rate was similar [76]. Franklyn et al. in a single-center RCT, analyzed the complication rate in 151 loop colostomy patients and its relationship with the use of a plastic rod. The rate of stoma edema, congestion, and necrosis was significantly lower in the group without a rod (respectively, 3.9% vs 23%, $p < 0.001$, 2.6% vs 20.3%, $p < 0.001$ and 1.3% vs 10.7%, $p = 0.018$). Moreover, the hospital readmission rate was also lower in the group without a rod (0% vs 8.5%, $p = 0.027$), while the rate of parastomal abscess was similar (1.3% in group without rod vs 4.2% in rod group, $p = 0.360$) [77]. Whiteley et al., in a prospective, observational, single-center study, compared the 30-day complication rate in 515 enterostomy patients and its correlation with the use of a rod. The group without a rod had a significantly lower rate of postoperative complications (14.4% vs 28.7% in the rod group, $p < 0.001$) [78].

Statement 2 When using a rod or bridge, a flexible or rigid rod can be used, as well as a skin bridge (Weak recommendation based on low quality evidence, GRADE 2C).

Several studies have attempted to demonstrate which type of supporting rod or bridge should be used for loop ostomy [79–82]. Although there are no RCTs comparing different rods, a small, single-center, retrospective study compared the use of a plastic rod with skin bridge for loop ileostomy (20 patients in each arm) [79]. Authors showed a higher rate of surgical site infection in the plastic rod group (25% vs 5%) as well as a higher incidence of peristomal dermatitis (90% vs 0%). In the skin bridge group, the numbers of change per week for stoma appliance were lower than in the plastic rod group, until the plastic rod was removed. Other small, observational studies recommended the use of flexible rods, while rigid supports appeared to have a role only if the stoma is under tension [80–82].

Statement 3 A stoma protrusion of at least 1 cm above skin level reduces the complication rate. (Strong recommendation based on low quality evidence, GRADE 1C).

Literature has demonstrated that surgical technique can influence the incidence of stomacomplications [83]. Many technical aspects can contribute to poor ostomy outcomes and difficulties in stoma care (see Table 5). Among surgical features, the height or protrusion of the ostomy above skin level appears to be an important detail. In a high-quality, multicenter, observational study, the authors precisely

Table 5 Complication preventions in stoma surgery

Complication	Definition	General measure of prevention	Specific measures
Mucocutaneous Separation	Detachment/separation of the bowel part of the stoma from the skin	a) Avoiding/managing risk factor for poor healing (smoking, malnutrition, immunosuppression, obesity) b) Preoperative marking of the stoma site c) Avoiding tension during stoma creation, preserving vascularization d) Encouraging weight loss in obese patients prior to surgery and long-term weight management after surgery	a) Avoid use of convexity at early stage b) Ileostomy and colostomy should be fashioned to protrude over the skin surface (at least 2 cm for ileostomy and 1 cm for colostomy) c) Use of rod does not prevent retraction d) Use of rod may increase the risk of necrosis See points b), c) and d)
Retraction	Upper border of a stoma sitting flush or below the skin level		
Ischemia/necrosis	Death of stoma tissue due to inadequate blood flow		
Stenosis	Narrowing of stoma opening making difficult the exit of stools. Can be the later stage of a mucocutaneous separation or stoma ischemia		
Leakage/chemical irritation	Cutaneous lesions as consequence of stoma disfunction		See point b)
Prolapse	Protrusion of full thickness length of bowel through an ostomy		See text for specific statement

measured ostomy protrusion and demonstrated its strong association with patient competence in stoma care [83]. In another study, authors showed an inverse relationship between height of stoma protrusion and the risk of having stoma complications [84]. As general principle, a well-done ileostomy should protrude at least 2 cm over the skin surface, while colostomy should protrude at least 1 cm. Obviously, this is not always possible because of a thick abdominal wall or short mesentery, as seen in obese patients or for Crohn's disease, carcinoid tumors, and desmoid tumors. However, the surgeon should not make an ostomy at the skin level if technically possible. To increase ostomy length, technical tips that may be used are selective mesenteric vessel ligation, "end- loop" ostomies, and choosing upper abdominal sites in patients who are obese [11].

Statement 4 No recommendation can be made regarding stoma fixation to the fascia or techniques for muco-cutaneous suture (NO GRADE–Experts opinion).

Several surgical atlases and books describe techniques for ileostomy and colostomy, but there are no high-quality studies exploring technical details. In general, fixation to the fascia is not considered mandatory, but is suggested for terminal ostomy, without complete agreement among authors. Mucocutaneous suture is preferable using absorbable suture in a simple, interrupted fashion to circumferentially secure the edges of the ostomy to the skin, normally with an everting technique [85–91].

Parastomal hernia prevention

Statement 1 Regarding parastomal hernia prevention, the size of the fascial aperture should be as small as possible without affecting stoma perfusion; the general consensus is that an aperture size that accommodates two fingers(approximately 3 cm) is necessary. (NO GRADE–Experts' opinion).

There is evidence regarding the correlation between the size of the fascial aperture and the risk of developing parastomal hernia. There is general consensus among surgeons about a standardized size of two fingers (approximately 3 cm) or trephine size [92]. In the European Hernia Society (EHS) guidelines, the authors' unanimously agreed that the size of fascial aperture should be as small as possible, without compromising the stoma perfusion [93].

Statement 2 The stoma site should not be used for specimen extraction or in conjunction with other techniques to reduce parastomal hernia risk in patients requiring a terminal stoma. (Weak recommendation based on moderate quality evidence, GRADE 2B).

The use of the stoma aperture as a site for specimen extraction appeared to increase the clinically detectable parastomal hernia rate. The increase of parastomal hernia rates is likely due to the enlargement of the stoma site for extraction. Li et al., in 2017, retrospectively compared 738 consecutive patients: 139 with stoma site extraction and 599 with no stoma site extraction. In patients with stoma site used for specimen extraction, the risk of parastomal hernia was significantly higher (10.1% vs 4.2% in control group, $p < 0.05$) [94].

Statement 3 Lateral pararectus or transrectus location of stoma are comparable techniques in relation to parastomal hernia prevention (Weak recommendations based on moderate quality evidence, GRADE 2B).

Stoma can be constructed either at the lateral pararectus or transrectus location. The lateral pararectus location has been proposed to reduce the risk of parastomal hernia due to the preservation of abdominal rectus muscular fibers [93]. A Cochrane review showed no difference between the two techniques, but this result may be linked to the poor quality of the included studies (lack of standardization of the surgical procedure and absence of a uniform definition and detection method for parastomal hernia) [95]. In addition, a recent pilot, single-center, randomized trial, the PATRASTOM trial, did not demonstrate superiority of one technique over the other in terms of parastomal hernia prevention: 60 randomized patients underwent elective temporary loop ileostomy, and the incidence of parastomal herniation did not significantly differ between the lateral pararectal (18.5%) and trans-rectal groups (13.8%; $p = 0.725$) [92].

Statement 4 Use of prophylactic non-absorbable synthetic mesh in permanent stoma, when not contraindicated, decreases the rate of parastomal hernia. (Weak recommendation based on high quality evidence, GRADE 2A).

In recent years, several reports evaluated the use of prophylactic mesh for prevention of parastomal hernia. A general consensus exists about the use of prophylactic mesh in the case of end-colostomy, with high-quality level of studies, including RCTs, systematic reviews, and meta-analysis of RCTs, as well as the recent EHS guidelines [93, 96–104]. The positioning of prophylactic mesh can be achieved by several approaches, but the more efficient approaches appear to be the "keyhole" and the "modified Sugarbaker" techniques. In the first case, the mesh can be positioned onlay, inlay, or sublay among the anterior abdominal wall by open approach. The second technique is performed by laparoscopy and is comparable to the first in terms of efficacy and hernia prevention. There is also general consensus about the use of synthetic non-absorbable mesh if compared with the use of other types of meshes. Only one study, the STOMAMESH trial, found no difference in parastomal hernia rates between procedures including a prophylactic mesh and those without mesh. This study can be considered the largest RCT to date, with relatively little bias and findings of lack of effect [105]. A recent meta-analysis of 11 RCTs involving 907 patients has been addressed to assess the cost-effectiveness of using mesh for the prevention of parastomal hernia. The study found no significant increase in operative time, with significant cost savings for synthetic meshes. The evidence was of lower quality for composite and biological meshes, with extra costs appearing to dissolve potential savings. However, even this study had limitations, including study heterogeneity, bias, and methodology differences (impossibility of meta-regression due to different individual study quality, and evaluating the utility of mesh in stomas different from end-colostomy) [106]. In contrast, the study of Odensten et al. found a longer operative time (median 38 min more) in the mesh group [105].

Statement 5 Due to the poor evidence, no recommendation can be made about the use of alternative mesh types. (NO GRADE–Experts' opinion).

The use of funnel-shaped meshes is currently under validation and has been validated only in small case series or retrospective studies, with low reported rates of parastomal hernia and complications [107–109]. SMART (Stapled Mesh stomA Reinforcement Technique) and modified SMART techniques have been proposed as alternatives to reduce parastomal hernia rates. The first was first described in 2011 using circular stapling gun and biologic mesh to reinforce the stoma trephine [110]. The second is a modification of the original technique with the use of standard polypropylene mesh fixed with a circular stapler in the retro-muscular position [111]. The use of a stomaplasty ring, called KORING, has been proposed for the prevention of parastomal hernia and investigated in a prospective, multicenter, observational trial, with promising results [112]. However, for these alternative approaches, further investigation is needed and no recommendation can be made.

Statement 6 Prophylactic mesh in the emergency setting is not recommended. (Strong recommendation based on low quality evidence, GRADE 1C).

Only 1 study addresses the use of prophylactic parastomal mesh during emergency surgery [113]. In previous papers, the analysis of single cases underlined that even in the emergency setting, patients may benefit from prophylactic parastomal mesh [114–117]. In the cohort study by Lykke et al., a slowly re-absorbable synthetic lightweight mesh was placed on the anterior surface of the posterior rectus sheath dorsal

to the rectus muscle to reduce the risk of bacterial contamination in the case of ileostomy or colostomy construction. The study analyzed 109 patients in the mesh group and 117 in the reference group with no mesh. Median operative time was 37 min shorter in the reference group ($p < 0.0005$). At 1 year, no difference in terms of parastomal hernia, peristomal bulging, prolapse, stoma reversal, and mortality was found between the two groups, and no clinical mesh infections were registered in the mesh group [113]. Therefore, on the basis of these results, the use of synthetic mesh during emergency stoma creation showed no significant preventive effect on the formation of parastomal hernia.

Statement 7 The use of biologic mesh for the prevention of parastomal hernia is not recommended outside clinical studies. (Strong recommendation based on low quality evidence, GRADE 1C).

A recent systematic review conducted by a group of hernia experts (BioMesh Study Group) was performed to analyze the current evidence in different clinical situations. In this study, only two RCTs and two case-controlled studies focusing on the use of biologic mesh were considered. In one RCT and two case-controlled studies, there was a lower incidence of parastomal hernia in the mesh group and a similar complication rate compared to the no-mesh group. In one RCT, no significant differences in the incidence of parastomal hernia and complication rates were found [118]. However, the quality of data was very poor. Thus, the use of biologic mesh for the prevention of parastomal hernia is not recommended outside clinical studies [119]. The EHS guidelines agree with this statement [92].

Statement 8 Extraperitoneal tunneling is comparable to transperitoneal tunneling to prevent parastomal hernia. Some evidence demonstrates a slight advantage of extraperitoneal tunneling. (Weak recommendation based on moderate quality evidence, GRADE 2B).

Extraperitoneal versus transperitoneal tunneling are two different techniques without the use of prophylactic mesh for end-colostomies. Although there is not sufficient evidence to establish the superiority of one technique over the other, extraperitoneal tunneling has been proposed to reduce the risk of parastomal hernia [93, 99]. Different studies have focused on the role of stoma tunneling, but the quality of the evidence is too poor to allow a robust conclusion. A meta-analysis of nine retrospective studies concluded that the extraperitoneal route reduced the risk of parastomal herniation, but all of the studies analyzed were retrospective cohort studies with high risk of bias [95]. Therefore, no recommendation can be made on the basis of such incomplete and inconclusive evidence. A recent review and meta-analysis of two RCT and eight retrospective studies found a lower rate of parastomal hernia in the extraperitoneal group (6.3% vs 17.8% in transperitoneal group; $p < 0.001$). However, only two RCTs were included in this meta-analysis, and the authors considered a large period of time (1974–2014), in which different changes were introduced in operative and perioperative care. Moreover, with the increased use of laparoscopy in colorectal surgery, the extraperitoneal route was considered impractical for this approach, even if this aspect was not specifically investigated in the study [120].

Stoma prolapse prevention

Statement 1 To prevent stoma prolapse in temporary fecal diversion, loop ileostomy is preferable to loop colostomy. (Strong recommendation based on high-quality evidence, GRADE 1A).

Loop ileostomy, compared to loop colostomy, has a reduced incidence of stoma prolapse. Four meta-analyses were performed on this subject [53–56]. In 2007, a Cochrane comparative analysis of five RCTs between temporary ileostomy and colostomy was published. The only significant difference between the two types of stoma was the higher rate of stoma prolapse in the colostomy group (19% vs 2% in ileostomy group) [53]. An Italian meta-analysis analyzed 12 studies (1529 patients): patients with ileostomy experienced a lower rate of overall complications, infectious complications, and stoma prolapse [54]. Moreover, the two most recent meta-analyses confirmed that ileostomy was better than colostomy in terms of risk of prolapse [55, 56].

Statement 2 In terminal colostomy, the extraperitoneal approach has a reduced incidence of stoma prolapse compared to the transperitoneal approach. (Weak recommendation based on moderate quality evidence, GRADE 2B).

In terminal colostomy creation, transperitoneal and extraperitoneal techniques appear to have a different incidence of prolapse. Two meta-analyses attempted to analyze the differences between these two techniques. In 2012, Lian et al. showed, in a meta-analysis (on 1071 patients), similar incidence of prolapse, but the study considered only seven retrospectives studies [121]. A more recent meta-analysis (analyzing data from 10 studies, 2 randomized, on 1048 patients) demonstrated a lower rate of stoma prolapse after the extraperitoneal approach [120].

Ghost ileostomy

Statement Ghost ileostomy (GI) may avoid stoma creation in select patients, but no clear indication exists on the timing and clinical circumstances of GI conversion. GI should

not be recommended as a routine technique to avoid loop ileostomy. (Weak recommendation based on low quality evidence, GRADE 2C).

GI is a prestage ileostomy that can be performed to avoid stoma creation in patients with relative risk of colorectal anastomotic leakage [122]. GI can be easily performed in both open and laparoscopic surgeries by creation of a window in the terminal ileum mesentery to pass in a vessel loop or a drainage, exteriorizing it through a small incision in the right flank and fixing it to the skin or to a gauze above the skin. If anastomotic leakage occurs in the postoperative period, GI can be easily converted into loop ileostomy under local anesthesia at either the bedside or in the operating room, avoiding the need for relaparotomy or relaparoscopy under general anesthesia. If no complication occurs, then the exterior loop can be removed and the loop dropped back into the abdominal cavity. GI appears to be a useful technique that adds no complications to the surgical procedure and creates a stoma only in patients who truly need it, with generally reduced numbers of stoma-related complications. However, only six reports in the literature described the GI construction technique and its clinical application, and all of them are from Italian institutions [122–127]. No clear indications exist about the clinical circumstances in which GI should be converted into loop ileostomy. Moreover, it is not clear if the diagnosis of anastomotic leakage must be clinical or radiological, and no indications are reported about the adequacy in terms of timing and surgical resolution of converting GI in any case of anastomotic dehiscence. In conclusion, further research is needed to assess the clinical usefulness of GI. For these reasons, GI should not be recommended as a routine technique to avoid loop ileostomy.

Stoma complications

Prevention of stoma complications

In Table 5, definitions and measures suggested to prevent complications in stoma surgery are reported. Many of these measures are not supported by high-level evidence, but they refer to basic principles of any correct surgical techniques. The recommendations supported by evidence in the literature (e.g., not routine use of a rod) are extensively discussed in the guidelines.

Statement Identifying the risk factors for stomal and peristomal complications can prevent them. (Strong recommendation based on low quality evidence, GRADE 1C).

Several studies have identified many factors, some potentially modifiable, associated with an increased incidence of stoma and peristomal complications. Studies from the last decade have emphasized, with moderate evidence, risk factors such as obesity, sex, emergency surgery, type and height of the stoma, as well as other factors associated with the age of the patient and his or her clinical history.

Obesity: Obesity, defined as a BMI > 30 kg/m^2, was the most statistically associated risk factor for some stoma complications (parastomal hernia and retraction) and peristomal skin complications. High BMI or severe obesity was a major risk factor for parastomal hernia in several studies involving patients with both urinary derivations and enteral stomas, particularly with colostomies [126–131].

Donahue et al., in a retrospective study involving 386 patients with urinary ileal conduits, identified BMI, together with female gender and preoperative albumin level, as risk factors for development of parastomal hernia [128]. Analyzing a population of 516 people with the same type of urinary derivation, Liu et al. highlighted as risk factors for a parastomal hernia a BMI > 40 kg/m^2 and a clinical history of previous laparotomies [129]. Funahashi et al. found a 27.5% incidence of parastomal hernia in patients with a permanent colostomy. The only risk factor linked to the patient was a high BMI [131]. De Raet et al., in a small cohort of patients with permanent colostomy, pointed out that the risk factor for a parastomal hernia was not BMI, but waist circumference > 100 cm [132]. The studies of Harilingam et al. [133] and Nybaek et al. [134] showed that BMI > 30 kg/m^2 was a risk factor for stoma retraction and peristomal skin complications, respectively. The retrospective data analysis from 1170 patients with enterostomy led Sung et al. to confirm that a high BMI was significantly associated with peristomal cutaneous complications, parastomal hernia, stoma retraction, and flush stoma that can impede correct adhesion of the stoma appliance and thus predispose to irritant contact dermatitis [135].

Sex: Some studies found that female sex was a risk factor for parastomal hernia and stoma retraction. In the previously mentioned retrospective study of Sung et al., female patients had a significantly higher incidence of parastomal hernia and retraction compared to the male population [135]. In addition, the study of Donahue et al. confirmed female sex as one of the risk factors statistically associated with parastomal hernia development in a population with Ureteral-Ileal-Cutaneous-Stoma (UICS) [128]. A recent retrospective study by Jayarajah et al. found that parastomal hernia was significantly more common in female patients with enterostomy than in male patients (OR = 3.845; 95% CI 1.853–7.976; $p = 0.0001$) [26].

Stoma performed in emergency setting without preoperative stoma siting: The evidence in the last 10 years concerning the effect of emergency surgery compared to elective surgery on stoma complications is controversial. The multicenter prospective study of Parmar et al., which involved

192 patients with enterostomies, found a higher incidence of early stoma complications in emergency patients compared to those who underwent elective surgery (46.4% vs. 22.0%; $p = 0.002$). The preoperative stoma siting also reduced the risk of complications (20% vs. 42.9%, $p < 0.001$) [83]. Nastro et al., in a retrospective study involving 1216 patients with enterostomies, showed that preoperative stoma siting is associated with a reduction of risk of stoma complications (OR 0.59, 0.39–0.90; $p = 0.014$) [23]. Caricato et al. had different results: emergency surgery and the lack of preoperative stoma siting were not risk factors for the onset of stoma complications [136].

Type and height of the stoma: The study by Cottam et al. with a population of 3970 people with enterostomy identified an association between the height of the ostomy and the probability of developing complications. The average height of the ostomies that did not present complications was 15 mm compared to the average of 11.3 mm for those with complications. A logistic regression model of stoma height as a predictor of stoma problems established that the height of less than 10 mm is associated with a 35% complication rate in stoma care [84]. Nybaek et al., in a transversal study involving 199 people, demonstrated a higher frequency of peristomal skin complications in patients with ileostomy than patients with colostomy (OR = 2.34; CI 95% 1.28–4.26; $p = 0.0052$) [134]. This association was also confirmed by the studies of Persson [137] and Parmar [83]. In the prospective study of Persson et al., 53% of patients with colostomy, 79% of patients with loop ileostomy, and 70% of patients with end ileostomy had one or more stoma complications (the most frequent complication involved peristomal skin). The ileostomies with height < 20 mm were more susceptible to detachment of the stoma appliance and, therefore, at a higher risk of peristomal skin complications [137]. The study by Parmar et al., unlike the previous study, found a higher incidence of early stoma complications in people with colostomy compared to people with ileostomy (31.7% vs. 18.3%, $p < 0.05$). Above all, the complications taken into account were retraction and mucocutaneous separation. The authors agree with the previous study regarding stoma height as a risk factor: the average stoma height was significantly lower in patients with complications than in those with no complications (10.6 ± 14.9 vs 17.17 ± 14.2 mm; $p = 0.006$) [83]. The retrospective study by Jayarajah et al. showed a higher incidence of parastomal hernia in patients with end-colostomy than in other types of enterostomies (OR = 6.333; 95% CI 1.986–20.195; $p = 0.001$) [26].

Preexisting conditions and comorbidity: Preoperative clinical conditions (such as preoperative hypoalbuminemia) and previous laparotomies may be risk factors for parastomal hernia in patients with UICS [128, 129]. Patients with enteral stoma operated for complications of inflammatory bowel diseases are particularly susceptible to develop a peristomal gangrenous pyoderma, especially if they are female, if they have a BMI > 26.6 kg/m^2 and if they have other autoimmune diseases [138].

Stoma reversal

Timing of stoma reversal

Statement 1 Early timing of loop ostomy closure, defined as closure within 2 weeks from the index surgery, in patients with an uneventful recovery and no evidence of anastomotic leak may be considered feasible and safe. (Weak recommendations based on high-quality evidence, GRADE 2A).

The timing of stoma closure is still debated. In the last decade, there were at least four RCTs and two meta-analyses comparing the conventional timing (from 8 to 12 weeks from index surgery) with early timing (within 4 weeks from the index surgery) [139–144]. The majority of the data are from patients with loop ileostomy undergone rectal surgery for cancer. All studies agree that there are no significant differences in terms of anastomotic leaks in relation to time of ostomy closure. All patients enrolled in the studies had an uneventful recovery from the index operation and no evidence of anastomotic leak following investigation with a water-soluble contrast enema. In one RCT, the early ileostomy closure (on postoperative day 8) resulted in better outcomes, with fewer small bowel obstructions (SBO), lower medical complication rates, and shorter hospital stay, while there were lower wound complication rates in the late closure arm (more than 12 weeks from index surgery) [139]. The EASY trial found a lower rate of complications after index surgery with a 12-month follow-up in the early group (ileostomy closure performed between 8 and 13 days from index surgery) [140]. Another RCT analyzed a very small number of patients and found that early ileostomy closure (before postoperative day 6 after index surgery) resulted in better outcomes in terms of easiness of abdominal wall closure, easiness of reversal, duration of operation, and obviously lower cost of stoma care [141]. The fourth RCT recorded data of patients who underwent heterogeneous ostomy surgery (colostomy or ileostomy, performed in elective or emergency settings). The early ostomy closure (between 14 and 28 days from index surgery) resulted in a better quality of life and in a lower cost of stoma care [142]. The results of the two meta-analyses found no more evidence than the previous RCTs. In 2017, Farag et al. compared four RCTs, finding no differences in terms of anastomotic leak or stenosis, postoperative complications, length of hospital stay, and duration of operation [143]. Menahem et al. in 2018 compared six studies, four of which were RCTs, and

reported fewer stoma-related complications and SBO in the early closure arm (within 14 days from the index operations), while there was a lower infection rate of the stoma site with the conventional timing of ostomy closure [144].

Statement 2 Hartmann's reversal should be performed at least 3 months after the index surgery. (Weak recommendation based on low-quality evidence, GRADE 2C).

The timing of Hartmann's reversal is still debated. There are few data in the literature concerning the correct delay from index surgery.

Several authors suggest delaying reversal by 3 months, reporting only mild adhesions at 3 months following Hartmann's procedure [145, 146], while other authors recommend waiting at least 6 months to allow adhesion density to decrease and pelvic inflammation to resolve [147, 148].

Technical aspects

Statement 1 Stapled technique for loop ileostomy closure is better than hand-sewn closure in terms of a reduced early postoperative SBO rate and a shorter operative time, without any difference in anastomotic leak rate. (Strong recommendation based on high-quality evidence, GRADE 1A).

Anastomosis in loop ileostomy closure can be performed using stapled or hand-sewn techniques. Many studies collected data from patients undergoing loop ileostomy closure after diverted rectal surgery for cancer [149–152]. In all RCTs, a shorter operative time was reported in the stapler arm. In 1 RCT, despite the heterogeneous type of index surgery requiring a temporary ileostomy, a lower SBO rate was found in the stapler arm; the anastomotic leak rate was higher in the hand-sewn arm (2/70 vs 0/71), but without statistical significance ($p = 0.2447$) [152]. In 2010, Shelygin et al. reported a lower overall morbidity rate in the stapled technique arm, but they did not analyze the anastomotic leak rate [150]. All of the meta-analyses agree with the reduction of SBO rate in the stapled technique, while three (except Madani et al. [153]) also reported the significant reduction of operative time in the stapler arm. No difference was found in terms of anastomotic leakage [153–156].

Statement 2 Hartmann's laparoscopic reversal appears to be a safe and feasible technique, although it should be performed by expert laparoscopic surgeons due to the high reported conversion rate. (Weak recommendation based on moderate quality evidence, GRADE 2B).

As minimally invasive techniques have evolved, they have increasingly been applied to colorectal procedures, including Hartmann's reversal, with demonstrated success in small series [157, 158].

Two meta-analyses compared laparoscopic and open Hartmann's reversal. In 2010, Siddiqui et al. compared eight studies, reporting advantages in the laparoscopic arm in terms of lower complication rates and shortening of hospital stay [158]. More recently, in 2015, Celentano et al. reported no significant differences after analyzing 13 studies between the laparoscopic and open approaches [157].

Skin closure

Statement Purse-string closure in stoma reversal should be the preferred skin closure technique because it is associated with lower surgical site infection rates in comparison with other techniques. (Strong recommendation based on high quality evidence, GRADE 1A).

Stoma reversal is associated with a significant morbidity, with an overall complication rate of 17% and an overall mortality rate of 0.4% [159]. Surgical site infection (SSI) is one of the most common complications, and can increase costs and length of hospital stay. The purse-string closure method was first described by Banerjee in 1997 with the aim of reducing the wound infection rate in stoma reversal in a simple, effective way with good cosmetic results [160]. A recent meta-analysis including 5 RCTs compared purse-string closure with conventional closure technique in stoma reversal surgery for a total of 385 patients. Three of these included only ileostomy, while two included both colostomy and ileostomy. Purse-string closure was significantly associated with a lower rate of SSIs [161]. Similar conclusions have been reported in three previous meta-analyses comparing purse-string closure with primary closure techniques [162–164]. In 2013, Li et al. performed a network meta-analysis comparing six closure techniques in stoma reversal. Fifteen studies with a total of 2921 patients were included. Although the overall quality of these studies was judged to be low, purse-string suture was associated with the lowest SSI risk (OR 0.12; 95% CI 0.02–0.40) among all six closure techniques analyzed [165]. Similar findings were reported by a retrospective study analyzing 4 closure techniques in 146 patients from a single institution: purse-string closure was associated with the lowest risk of developing SSI [0.07 (0.01-0.63), $p = 0.02$] [166]. Although it has also been claimed that purse-string closure is a more cosmetic with better results regarding wound healing and patient satisfaction, data are still controversial. Two RCTs showed that purse-string closure was associated with greater patient satisfaction [167, 168]. However, the "STOMA" trial, an RCT involving 61 patients undergoing ileostomy reversal, did not show any difference in patient satisfaction compared to linear closure [169]. Two RCTs looking at the incisional hernia

rate and intestinal obstruction as secondary outcomes failed to demonstrate any differences, but the follow-up duration was not adequate (1 and 3 months, respectively) [168, 170]. Recently, a single-center, retrospective study specifically looking at incidence of incisional hernia (detected by CT scan) after ileostomy reversal showed a significantly lower rate in the purse-string closure group compared to the conventional closure group (12.9% vs 35.2%, $p=0.017$) [171].

Antibiotic prophylaxis

Statement All patients undergoing enterostomy closure should receive antibiotic prophylaxis. (Strong recommendation based on low quality evidence, GRADE 1C).

The use of prophylactic antibiotics appeared to reduce infection rates [172, 173]. Various regimens have been described, including intravenous second-generation cephalosporin and metronidazole [171, 173]. Oral preoperative antibiotics appeared to be associated with less morbidity than parenteral antibiotics [174]. Prophylactic use of triple-agent antibiotics appears to have a protective effect against infection [175]. Implantation of local antibiotics provides no clinically relevant reduction of the wound infection rate [176].

Conclusions

These guidelines were developed from a collaboration of Italian colorectal surgeons and stoma-care nurses with the involvement of the major Italian scientific societies and stoma patients' associations. They are the first Italian guidelines for the management and care of enteral stoma, with the aim to assist surgeons and stoma-care nurses during the creation, management and closure, when possible, of an enteral stoma. For the statements with low or no scientific evidence, MISSTO will propose further studies to investigate the specific topics.

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Compliance with ethical standard

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

Informed consent No need of informed consent since no human subject was included in the study.

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