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**Original Article**

# Use of sponge-assisted endoluminal vacuum therapy for the treatment of colorectal anastomotic leaks: expert panel consensus

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## Abstract

**Background:** Anastomotic leaks represent one of the most significant complications of colorectal surgery and are the primary cause of postoperative mortality and morbidity. Sponge-assisted endoluminal vacuum therapy (EVT) has emerged as a minimally invasive technique for the management of anastomotic leaks; however, there are questions regarding patient selection due to the heterogeneous nature of anastomotic leaks and the application of sponge-assisted EVT by surgeons.

**Method:** Seven colorectal surgical experts participated in a modified nominal group technique to establish consensus regarding key questions that arose from existing gaps in scientific evidence and the variability in clinical practice. After a bibliographic search to identify the available evidence and sequential meetings with participants, a series of recommendations and statements were formulated and agreed upon.

**Results:** Thirty-seven recommendations and statements on the optimal use of sponge-assisted EVT were elaborated on and unanimously agreed upon by the group of experts. The statements and recommendations answer 10 key questions about the indications, benefits, and definition of the success rate of sponge-assisted EVT for the management of anastomotic leaks.

**Conclusion:** Although further research is needed to resolve clinical and technical issues associated with sponge-assisted EVT, the recommendations and statements produced from this project summarize critical aspects to consider when using sponge-assisted EVT and to assist those involved in the management of patients with colorectal anastomotic leaks.

## Introduction

Despite advances in surgical techniques and stapling devices, the incidence of anastomotic leaks (ALs) has not substantially decreased over the past decades[1], and low colorectal or coloanal anastomoses are still prone to leakage. ALs represent one of the most significant and feared complications of colorectal surgery[2]. They can occur in up to 24 per cent of patients and are the primary cause of postoperative mortality and morbidity, with a mortality rate of up to 4 per cent[3].

Management of ALs depends on several factors, including age, co-morbidity, clinical manifestations, and patient stability. Traditionally, the low anastomosis is de-functioned or 'taken down', and the abscess is drained either percutaneously or transanally; however, this strategy might result in the formation of a presacral sinus, leading to a permanent stoma and, if it remains unresolved or symptomatic, to extensive surgical intervention[4]. Other approaches for treating ALs include salvage methods, such as fibrin glue, endoscopic clips, or self-expanding metal stents[5], all of them with little data yet to assist the physician in the most convenient selection of patients for each one.

In recent years, the sponge-assisted EVT (Endo-SPONGE®; B. Braun Surgical SAU, Rubí, Spain), an endoscopic vacuum system, has emerged as an attractive minimally invasive technique to potentially manage ALs[6] as an alternative to major surgery. Sponge-assisted EVT is indicated for extraperitoneal ALs following colorectal surgery and extraperitoneal Hartmann's stump leaks[7]. It consists of an open-cell polyurethane sponge connected to an evacuation tube applied endoscopically to drain the cavity and promote granulation through negative pressure, closing the defect[8] (*Fig. 1*).

Weidenhagen first described EVT in 2008[6]. Since then, several retrospective and prospective cohort studies have shown

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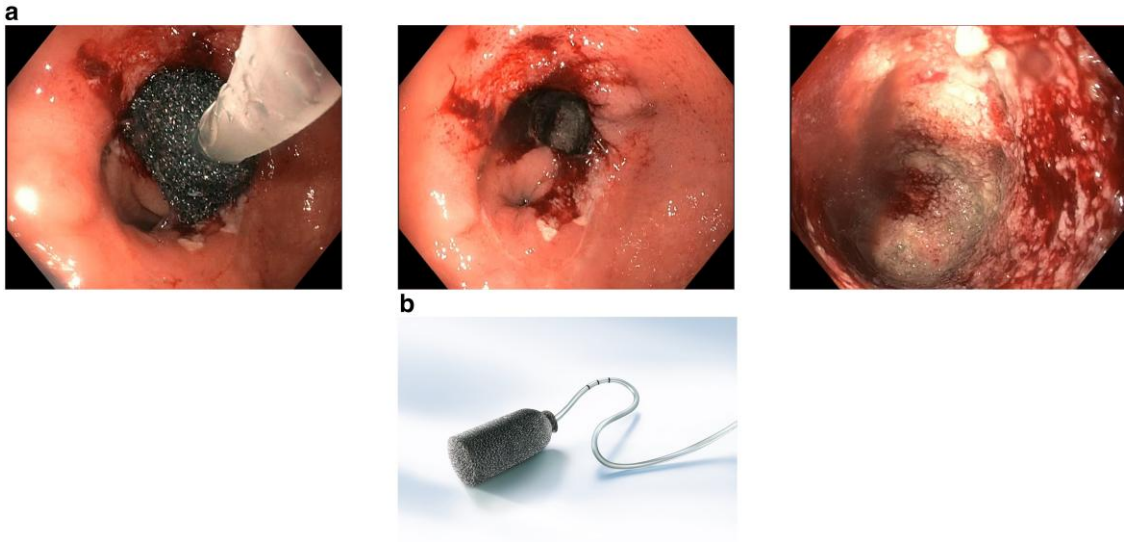


**Fig. 1** **a** Image of an anastomotic leakage, showing the correct placement of the Endo-SPONGE in the cavity and the evolution of the cavity after applying negative pressure, showing a clean cavity with granulation tissue in the last image. **b** Image of the Endo-SPONGE device for sponge-assisted vacuum therapy.

sponge-assisted EVT to have a high success rate in the treatment of AL[9–12]. Nevertheless, the lack of randomized clinical trials (RCTs) and the diverse and limited data of the available studies make it difficult to draw firm conclusions on the indications, clinical application, and effectiveness. Therefore, it is now crucial to provide better orientation and guidance to healthcare professionals who might wish to consider utilizing sponge-assisted EVT in the management of patients with colorectal ALs.

Based on a review of relevant evidence and expert advice, this document aims to deliver expert recommendations and statements to optimize and guide the appropriate use of sponge-assisted EVT to treat patients with colorectal ALs, standardizing indications for use and the definitions of success.

## Methods

### The expert group

The coordinator (W.B.) was appointed based on his expertise in the management of colorectal ALs and the use of sponge-assisted EVT and the methodology of the project was conceptualized and agreed with him. A scientific committee was established, consisting of seven specialists with proven interest and expertise of more than 14 years on average in the management of anastomosis after colorectal surgery and at least four years of experience in the use of sponge-assisted EVT. The seven participants were from five different countries within the EU and have each authored between 40 and 250 relevant research publications in the field of colorectal surgery. B. Braun had no role in the design, conception, execution, analyses of data, elaboration of statements, or decision to submit the results.

### Workflow

This document has been developed using a modified nominal group technique (NGT)[9]. The thematic index with the key questions (KQs) to address was discussed and agreed upon by the scientific committee in a virtual meeting in March 2020, based on the gaps in scientific evidence and variability in clinical practice.

Based on the thematic index, a bibliographic search was performed to extract relevant scientific evidence that could provide answers to the KQs. PubMed was used, the only limitation being the inclusion of articles in the English language published since the introduction of sponge-assisted EVT up to the search date (2008–2019). Titles and abstracts were reviewed, full articles of all relevant studies were retrieved, and current publications were prioritized following appraisal criteria. The experts validated the selected publications and added some more references based on their expertise and any updated bibliography relevant to the consensus meeting. The list and a brief description of the publications used for the key questions are shown in the supplementary materials (*Table S1*).

An evidence document was developed and shared with the participants. A virtual brainstorming session was held in January 2021, where the experts shared the key points that, in their opinion, should be considered in response to each question. The results of the brainstorming were compiled and distributed to the experts, who worked in pairs to provide evidence-based responses or clinical expert opinions as statements or recommendations for the KQs. All the responses were compiled and shared with the experts' group before the virtual consensus meeting. In this meeting, held in February 2021, the experts discussed and gave their opinions on the adequacy and suitability of the statements and recommendations. These were edited and revised as needed and voted on using the Zoom polling facility. The consensus was considered when a percentage of agreement of more than 80 per cent was achieved. A percentage of less than 80 per cent consensus agreement was considered disagreement. During the meeting, some new recommendations based on the reviewed evidence and the clinical experience of the experts were formulated after discussion among the whole group. All seven experts were present in all the meetings and voted on the statements without absence or abstentions.

The statements and recommendations covered the most relevant and controversial areas of Endo-SPONGE® therapy in the management of colorectal ALs and answered 10 KQs about the indications, benefits, and definition of the success rate of

Endo-SPONGE® for the management of ALs. After the final meeting, a unanimous consensus was achieved for all statements.

## Results

Thirty-seven statements and recommendations were formulated by a steering committee.

### When to use sponge-assisted endoluminal vacuum therapy

Sponge-assisted EVT is indicated for the treatment of anastomotic leakage or Hartmann's stump leakages following colorectal surgery in the lower pelvic area (extraperitoneal) by means of negative pressure[4,9,13–17], for which it has been previously shown to be an option[10,11].

Studies show that sponge-assisted EVT is more suitable for stable patients with early leaks[11,12,18] and that the earlier the treatment starts, the greater the success rate: an 89 per cent (9 of 10) overall success rate was shown for acute leaks (less than 60 days) whereas in chronic leaks (more than 60 days), the overall success rate was 50 per cent (two of four)[10].

In terms of how to complete sponge-assisted EVT, two different techniques have been described. In the Weidenhagen technique[13], the sponge is downsized gradually and replaced as many times as necessary until the cavity is small enough to close by itself. In the early surgical closure technique, after preconditioning with sponge-assisted EVT[14], the cavity is closed surgically under general anaesthesia. Both have been reported as successful in the treatment of AL, and the reasons for selecting one or the other seem to depend on the surgeon's practice and experience.

Considering a combination of the above evidence and expert opinion, the following statements, and recommendations on the indications for sponge-assisted EVT were provided and unanimously agreed upon (*Table 1*).

### When to end treatment with sponge-assisted EVT

The optimal time to stop sponge-assisted EVT might depend on whether early closure or the Weidenhagen technique is used. In studies using the early closure technique, sponge-assisted EVT was stopped when the abscess cavity was considered clean and the bowel edges were mobile[4,15]. In contrast, in studies using the Weidenhagen technique, the treatment was completed either when the cavity was covered with sufficient granulation tissue[8,16,17] or when it was too small to place another sponge[8,17,19,20]. In addition, Verra *et al.*[8] also proposed an endoscopic examination of the walls of the cavity to exclude the presence of fistulas before completing the treatment. In any case, when the sponge is removed, endoscopic follow-up should be performed until complete healing is achieved[8].

As the cavity is not closed surgically with the Weidenhagen technique, a small sinus might persist after the sponge is removed. Whether it should be treated or left to close spontaneously is debated and depends on different factors related to both the patient and the surgeon's preference. Several approaches have been described—to use a small aspiration drain connected to a negative pressure bottle[16], to leave the cavity to close by itself[20], or to apply fibrin glue to close the defect[12,20]—but no comparative studies have been conducted.

Considering the above evidence and the expert opinion, the following statements, and recommendations on when to end the treatment with sponge-assisted EVT were provided and unanimously agreed (*Table 2*).

**Table 1 Recommendations on when to use sponge-assisted endoluminal vacuum therapy**

| Key questions and recommendations | Percentage of agreement (%) |
|---|---|
| **KQ1: Which indications should be treated with sponge-assisted EVT?** | |
| 1. All leaks in pelvic extraperitoneal anastomoses with no connection to the peritoneal cavity are potentially suitable for sponge-assisted EVT. | 100 |
| 2. Rectal stump dehiscence, ensuring that the sponge is not in contact with the small bowel. | 100 |
| 3. Off-label application of sponge-assisted EVT should only be used in expert centres with appropriate expertise. Examples are intraperitoneal anastomoses, perianal fistulae and drainage of abscesses following abdominoperineal resection. | 100 |
| **KQ2: Which type of anastomotic leak should be treated with sponge-assisted EVT?** | |
| 1. Sponge-assisted EVT is recommended for early leaks, but this does not preclude attempted therapy for late leaks. | 100 |
| 2. Sponge-assisted EVT is not recommended for complete anastomotic dehiscence. | 100 |
| 3. Sponge-assisted EVT can be considered for chronic leaks, although it is accepted that there is a lower chance of success. | 100 |
| 4. It is advisable to defunction the anastomosis when using sponge-assisted EVT. | 100 |
| **KQ3: What is the optimal timing for the commencement of sponge-assisted EVT?** | |
| 1. Early treatment with sponge-assisted EVT of the leak is associated with increased healing rates. | 100 |
| 2. Early treatment with sponge-assisted EVT facilitates the early closure technique. | 100 |
| 3. Early detection of leaks (for example using a protocol) is essential for the timely initiation of sponge-assisted EVT | 100 |
| 4. Once anastomotic leakage is detected, sponge-assisted EVT should be started as soon as possible, with regular assessment of the vitality of anastomosis. | 100 |
| 5. In the presence of a defunctioned anastomosis, surgeons should have increased suspicion of silent leaks. | 100 |
| 6. The use of protocols based on biochemical markers followed by imaging has been demonstrated to increase rates of early detection of anastomotic leaks. | 100 |
| **KQ4: Regarding the use of sponge-assisted EVT when would you use the Weidenhagen technique, and when would you use the early closure technique?** | |
| 1. Sponge-assisted EVT can be considered for the treatment of a leak with a confined extraluminal cavity or as an alternative means to control local sepsis. | 100 |
| 2. There is general agreement to attempt to close the defect when local conditions allow it. | 100 |

EVT, endoluminal vacuum therapy; KQ, key question.

### Benefits of sponge-assisted EVT

Sponge-assisted EVT has been shown to have some potential benefits. First, it is reported to probably improve patients' quality of life, as it might prevent a permanent stoma and preserve bowel continuity[4,10,12,16–18]. Furthermore, it is a

minimally invasive procedure that ensures continuous drainage[18,21], limits pelvic sepsis[15,19], promotes granulation[22], and reduces the size of the abscess cavity, thus reducing the risk of permanent stoma[18,19]. EVT has also been associated with improved outcomes, as it reduces morbidity, mortality, and the hospitalization rate among a study of 14 patients[21]. Whether its usage reduces healthcare costs remains unknown, but some studies suggest that costs associated with major reoperative surgery, recovery, complications of surgery and permanent stoma might be considerably reduced[23,24].

Considering the above evidence and the experts' opinions, the following statements, and recommendations on the benefits of sponge-assisted EVT were provided and unanimously agreed (*Table 3*).

## The success rate of sponge-assisted EVT

The success rate of sponge-assisted EVT is not defined consistently in the literature, and different endpoints should be considered, including technical, clinical, and long-term outcomes. While some studies used endoscopy to determine the cavity closure[4,15,16,21], others considered a therapeutic success to have occurred when no subsequent pelvic abscess developed during follow-up[8], when the intestinal continuity was restored[18], or when the cavity was covered with granulation tissue[17].

As stated in the National Institute for Health and Care Excellence (NICE) guidelines[23], there is a lack of good-quality studies assessing the effectiveness of Endo-SPONGE® (sponge-assisted EVT) *versus* conventional treatment. NICE acknowledges that anastomotic leak is a rare occurrence; therefore, the study sample sizes are small. While this methodologically impacts the quality of the studies, it should be highlighted that larger study sample sizes would not be achievable in this patient group; however, two comparative studies have been conducted, both showing a clinical success rate of 100 per cent and 95.2 per cent in patients treated with Endo-SPONGE®, compared with 52 per cent and 65.9 per cent respectively, in the conventional treatment group[12,15]. Data from pooled analyses demonstrate high clinical and technical success rates after sponge-assisted EVT[25], and three literature reviews[8,18,20] report sponge-assisted EVT success rates of 85.5 per cent (ranges between 25 per cent and 100 per cent), 85.4 per cent (ranges between 80 per cent and 91 per cent), and 82.6 per cent respectively. Wasmann *et al.* demonstrated that in patients treated with endoscopic vacuum-assisted surgical closure the long-term pouch function was preserved, and the leak was not associated with future increased pouch failure rates[26].

Considering the above evidence and expert opinions, the following statements and recommendations on the success rate of sponge-assisted EVT were provided and unanimously agreed (*Table 4*).

**Table 2 Recommendations about when to end treatment with endoluminal vacuum therapy**

| Key questions and recommendations | Percentage of agreement (%) |
|---|---|
| **KQ1: What is the optimal time to stop sponge-assisted EVT?** | |
| In early closure technique | |
| 1. Closure of the defect should be attempted when the cavity is healthy, and the tissue edges are compliant. | 100 |
| In the Weidenhagen technique | |
| 2. Sponge-assisted EVT should be stopped when the cavity is healthy but too small to hold a new sponge. | 100 |
| 3. Sponge-assisted EVT should be stopped when there is no local progression (shrinking of the cavity) after several sponge replacements[3]. | 100 |
| **KQ2: What should be done with the remaining small sinus when applying the Weidenhagen technique?** | |
| 1. There is no evidence or consensus related to the treatment of the remaining sinus. | 100 |
| 2. Different treatments can be attempted for the remaining sinus: aspiration drains, irrigations (iodine, Microdacyn, Granudacyn, or others), growth factors, fibrin glue, closure of the sinus and/or de-roofing. | 100 |
| 3. The use of intraluminal sponge therapy is a potential option in lower gastrointestinal leaks, but requires more research. | 100 |

EVT, endoluminal vacuum therapy; KQ, key question.

**Table 3 Recommendations on the benefits of endoluminal vacuum therapy**

| Key questions and recommendations | Percentage of agreement (%) |
|---|---|
| **KQ1: What are the benefits of sponge-assisted EVT for patients?** | |
| 1. There is evidence to suggest that the use of sponge-assisted EVT can reduce the rate of permanent stoma after an anastomotic leak. | 100 |
| 2. The use of sponge-assisted EVT in managing anastomotic leaks can reduce the incidence of reoperation and associated complications. | 100 |
| 3. Sponge-assisted EVT provides the possibility of undergoing therapy after an anastomotic leak as an outpatient, and potentially reducing inpatient stay. | 100 |
| 4. Local control of sepsis with the use of sponge-assisted EVT in acute anastomotic leaks can result in a reduction of the use of antibiotics and other more invasive interventions. | 100 |
| **KQ2: What are the benefits of sponge-assisted EVT for surgeons?** | |
| 1. The use of sponge-assisted EVT in the management of acute anastomotic leak is associated with a reduction in the need for major reoperative surgery. | 100 |
| 2. The acute use of sponge-assisted EVT can potentially be used as a bridging measure to control local sepsis associated with anastomotic leaks and allow time for the patient to be stabilized/optimized, undergo further diagnostic tests to be performed or be transferred to a specialist centre. | 100 |
| 3. The use of sponge-assisted EVT may be associated with a reduction in healthcare costs associated with major reoperative surgery, recovery, complications of surgery and permanent stoma. | 100 |

EVT, endoluminal vacuum therapy; KQ, key question.

## Discussion

Sponge-assisted EVT has been introduced in recent years as a potential treatment for the management of ALs; however, due

**Table 4 Recommendations on the success rate of sponge-assisted endoluminal vacuum therapy**

| Key questions and recommendations | Percentage of agreement (%) |
|---|---|
| **KQ1: How would you define the success of sponge-assisted EVT?** | |
| 1. Sponge-assisted EVT may provide the possibility to achieve optimal control of local sepsis (and avoid other major interventions required for the control of sepsis after starting sponge-assisted EVT). | 100 |
| 2. The use of sponge-assisted EVT may provide the possibility to achieve 'technical success' (radiological and/or endoscopic evidence of closure of the anastomotic defect after starting sponge-assisted EVT). | 100 |
| 3. The use of sponge-assisted EVT may provide the possibility to achieve 'clinical success' (the presence of intestinal tract continuity with no evidence of anastomotic leak after starting sponge-assisted EVT). | 100 |
| 4. The use of sponge-assisted EVT may provide the possibility to achieve 'long-term success' (satisfactory functional outcomes and the survival of the anastomosis/continuity of the intestinal tract at 2 years). Secondary measures of long-term success may involve the absence of cancer recurrence, anastomotic stenosis, and satisfactory quality of life scores. | 100 |
| **KQ2: What is the success rate of sponge-assisted EVT *versus* conventional treatment in terms of anastomotic integrity and stoma closure?** | |
| 1. Sponge-assisted EVT is associated with increased anastomotic closure rates compared with conventional therapy. | 100 |
| 2. There is evidence from the results of a pooled analysis of a large number of case series that demonstrate high rates of early sepsis control following sponge-assisted EVT but there is a large variation in individual studies. | 100 |
| 3. There is evidence from the results of a pooled analysis from a large number of case series that demonstrate high rates of technical success (radiological and/or endoscopic evidence of closure of the anastomotic defect) following sponge-assisted EVT but there is a large variation in individual studies. | 100 |
| 4. There is evidence from the results of a pooled analysis of a large number of case series trials that demonstrate that clinical success (reversal of stoma and restoration of bowel continuity) rates following sponge-assisted EVT treatment can be more than 75% but there is a large variation in individual studies (38–92%). | 100 |
| 5. There is a paucity of evidence reporting long-term success rates for sponge-assisted EVT. | 100 |

EVT, endoluminal vacuum therapy; KQ, key question.

to the paucity of robust data on its clinical effectiveness[23], there are still many questions and heterogeneity in practice with respect to its use. In 2021, the UK NICE published a review[23] of the use of Endo-SPONGE® for treating low rectal ALs but claimed that there are not enough robust studies on its clinical effectiveness[23]. This project aimed at gathering a series of recommendations and statements from renowned experts in the field to assist in the effective and safe use of sponge-assisted EVT.

Sponge-assisted EVT is indicated for the treatment of anastomotic leakage or Hartmann's stump leakages following colorectal surgery in the lower pelvic area (extraperitoneal) by means of negative pressure[7]; however, there are potential off-label colorectal applications, including rectal perforations[12] and management of some types of fistulae[27,28]. Not all extraperitoneal ALs after colorectal surgery are suitable for EVT and should be assessed with a personalized approach to each patient. This tailored approach will consider factors such as the anatomic location of the leak and the type of anastomosis (side-to-end or end-to-end).

It is crucial to identify ALs as early as possible as EVT success rates are improved the earlier the treatment is initiated[4,10,15,29]. Although there is evidence that sponge-assisted EVT can be safely performed in patients even without a diverting stoma, it is recommended to defunction the anastomosis before starting the treatment[19].

Two strategies have been described for cessation of sponge-assisted EVT: the early closure technique as proposed by the Amsterdam group[14,15] and the Weidenhagen technique[13]. Presently, this decision is made by the surgeon; however, proposals have been made to develop treatment algorithms to help. In the early closure technique, sponge-assisted EVT is stopped when the cavity is clean, but in the Weidenhagen technique a small sinus might persist. Although there is no reported evidence on how to manage it, several methods were proposed during the meeting, including aspiration drains, iodine/antiseptic solutions, growth factors, fibrin glue, or a conservative approach in asymptomatic patients.

The experts highlighted the importance of establishing a standard definition for sponge-assisted EVT success, which is currently lacking. They agreed on differentiating between technical, clinical, and long-term outcomes. Technical success is determined by radiological and/or endoscopic evidence of anastomosis closure; clinical success when the intestinal tract is restored with no evidence of anastomotic leak; long-term success is considered in the case of satisfactory functional outcomes and the presence of intestinal continuity at 2 years. The influence of neoadjuvant chemotherapy on treatment outcome has been reported in a recent systematic review. It is associated with larger cavity sizes, longer treatment duration and a higher number of sponge exchanges. The effect on the success of the treatment with sponge-assisted EVT has shown diverging results[30]. Results from another study consistently reported longer duration of treatment with no difference in mortality, success rate, and long-term preservation of continuity[31].

Functional outcomes after treatment with sponge-assisted EVT require further investigation[32]. Some studies have reported low anterior resection syndrome (LARS) in all or most patients, with a high percentage experiencing major LARS[4,17]. There is evidence that sponge-assisted EVT can be used in patients with AL following pouch surgery for ulcerative colitis. Eighteen patients with AL were treated with sponge-assisted EVT and 22 with conventional treatment and were compared with a control group (ileoanal pouch without AL). Similar pouch function and pouch failure rates were observed in patients undergoing sponge-assisted EVT compared with control patients. Patients undergoing conventional management had worse pouch function and higher pouch failure rates[26]. Another study reported a 93 per cent functional pouch rate in patients with anastomotic leakage after ileal pouch-anal anastomosis (IPAA)

treated with sponge-assisted EVT compared with 86 per cent with conventional treatment[15].

Given the low rates of ALs and even lower number of patients treated with sponge-assisted EVT, an RCT may not be feasible to conduct; however, an international multicentre registry of patients would probably provide valuable insights to further guide clinical practice and help improve patient lives.

One of the limitations in developing these recommendations was the lack of high-level evidence, as there are no RCTs, and the retrospective study design and small sample sizes represent a risk of bias. As the available evidence is limited, no exhaustive systematic literature review was performed, and the level of evidence was not assessed, which is a clear limitation.

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All the authors of this document made substantial contributions to conception and design. W.B. contributed to drafting, and all authors revised the manuscript critically for important intellectual content; gave final approval of the version to be published; and agreed to be accountable for all aspects of the work.

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## Supplementary material

Supplementary material is available at *BJS Open* online.

## Data availability

The data that support the findings of this study are available from the corresponding author, W.B., upon reasonable request.

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