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REVIEW

Critical appraisal of international guidelines for the management of fecal incontinence in adults: is it possible to define what to do in different clinical scenarios?

A. Muñoz-Duyos[1] · L. Lagares-Tena[1] · Y. Ribas[2] · J. C. Baanante[1] · A. Navarro-Luna[1]

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Abstract
Fecal incontinence (FI) is a complex often multifactorial functional disorder which is associated with a significant impact on patients' quality of life. There is a broad spectrum of symptoms, and degrees of severity and diverse patient backgrounds. Several treatment algorithms from different professional societies and experts are available in the literature. However, no consensus has been reached on several aspects of FI management. We performed a critical review of the most recently published guidelines on FI, emphasising the lack of consensus, highlighting specific topics mentioned in each of the guidelines that are not covered in the others and defining the treatment proposed in different clinical scenarios.

Keywords Faecal incontinence · Treatment algorithm · Guidelines · Review

Introduction

Faecal incontinence (FI) is a complex often multifactorial functional disorder, which is associated with a significant impact on patients' quality of life (QoL). The true prevalence of FI is unknown and is probably underestimated because patients are too embarrassed to disclose it and the condition is often not reported [1, 2]. In an up-to-date systematic review, the prevalence in adults varied from 1.4 to 19.5%. However, when clear definitions were used, prevalence was 8.3–8.4% for face-to-face or telephone interviews and 11.2–12.4% for postal surveys [3].

As multiple etiological factors are involved and no two patients are alike, treatment may be challenging and needs to be individualised [4, 5].During the past 20 years, new therapeutic options have been developed but their specific roles in the management of FI have not been fully defined to date.

✉ A. Muñoz-Duyos
amduyos@gmail.com

[1] Unit of Colorectal Surgery. Department of General Surgery. Hospital, Universitari Mútua Terrassa, Universitat de Barcelona, Plaça Dr.Robert, 5, 08221 Terrassa, Barcelona, Spain

[2] Department of Surgery, Consorci Sanitari de Terrassa, Terrassa, Barcelona, Spain

Several treatment algorithms from different societies and experts may be found in the literature. However, no consensus has been reached on several aspects of FI. Our aim was to perform a critical review of the most recently published guidelines on FI, emphasising the lack of consensus and highlighting the specific topics mentioned in each of the guidelines and defining the treatment proposed in different clinical scenarios.

International guidelines on faecal incontinence

The International Continence Society (ICS) guidelines

An international expert committee responsible for updating a list of recommendations on many topics on both urinary and fecal incontinence. They define the specific statements that the recommendations are supposed to address and analyse and rate (with level of evidence) the relevant papers published in the literature [6].

The last edition, published in 2016, includes several subclassifications on FI including aspects on basic sciences, patient's evaluation, education and lifestyle changes and how to specifically treat patients with neurological or congenital alterations, frail older individuals or children.

Moreover, there is an extensive section reviewing the qualitative research on the experience of FI and QoL.

Regarding treatment, these guidelines develop a clear algorithm mainly focused on three levels of complexity and recommend which professionals and centres should treat patients, which is an aspect not as clearly mentioned in other guidelines (Table 1).

The first step is to improve stool consistency, and the need for assessing and treating the etiology of diarrhea is emphasized. Soluble dietary fiber with moderate fermentability such as psyllium is recommended, rather than adjuvant to antimotility medication as their effects may be similar. Starting with a lower fiber amount and assessing its effect then increasing to a higher amount, if needed, is suggested.

Emphasis is placed on the importance of a multi-component conservative treatment, the application of different measures such as pelvic floor muscle exercises, an increase of dietary fibre and fluids, optimisation of bowel habits, and the use of barrier creams. Another important aspect is to provide patients with practical advice for coping with FI, such as locating toilets and others, also mentioned in the National Institute for Health and Care Excellence (NICE) guidelines, but not in the others. A specific section is also devoted to the recent literature regarding the use of probiotics, prebiotics and symbiotics, not mentioned in other guidelines.

They propose that general practitioners or surgeons working in non-specialised centres should implement the first-line treatment following a basic evaluation. As a second step, they recommend referring patients to an incontinence

Table 1 Specific questions not addressed in all guidelines

ICS	Develop three progressive levels of complexity for FI patients with different health professionals, examinations and treatments on each level:
	1.General practitioners or surgeons working in non-specialized centres: anamnesis, examination, QOL assessment; 2. incontinence specialist: EUS, manometry, other; 3.referral centres: to apply second or third-line specific surgical treatments once the others fail, managed by gastroenterologists, colorectal surgeons, urogynaecologists, and/or a multi-disciplinary team
	There is a specific section on the recent literature about the use of probiotics, prebiotics and synbiotics
	Divide the indications of different treatments in three patient groups: 1. spinal cord; 2. structural defects[a]; 3. all the others: based on EAS integrity
	State IAS and EAS should be repaired separately
NICE	Suggest that when assessing FI healthcare professionals should avoid making simplistic assumptions that causation is related to a single primary diagnosis ('diagnostic overshadowing')
	Contain concrete measures for specific patient groups not treated in other guidelines: patients with learning disabilities, terminally ill, using enteral tube feeding, or with cognitive impairment
	Enhance the importance to exclude and treat concomitant conditions to FI not mentioned on the other guidelines as third-degree haemorrhoids, acute disc prolapse or cauda equina syndrome
	Suggest using a food and fluid diary to help establish baseline habits and potential improvements
	Base the indications for different treatments on EAS defects and patient willingness to undergo a more aggressive treatment
	State the importance of full-length EAS defects in the indication for sphincteroplasty
ASCRS	Enhance the importance of using a self-directed evaluation of the patients' habits using defecation diaries or repeated questionnaires to identify triggering or aggravating factors
	Suggest the use of clonidine as medical treatment because it reduces rectal sensation, urgency and improves stool consistency
	State the indication of biofeedback just for patients with incontinence and some preserved voluntary sphincter contraction
	State that the posterior plication of the EAS; Parks postanal repair, is not recommended
French	State clearly that biofeedback it is not indicated initially for patients with significant and recent sphincter tear; External rectal prolapse or neurological disease
	Mentions the topic of subclinical sphincter defects and declares that in the case of a minimal subclinical defect, e.g. one seen by endoanal ultrasonography, sacral nerve modulation may be preferred to sphincter repair
	Use the concept of RECENT lesion in the indication of sphincteroplasty
	Recommend the use of SNM in all patients after a first-line treatment of patients divided into four groups: 1. significant and recent sphincter tear; 2. external rectal prolapse; 3. neurological disease 4. ALL OTHER PATIENTS (use of biofeedback recommended)
Italian	There is an extensive section about the correction of structural defects
	Describe two different sphincter repair options: 1. sphincteroplasty (without overlapping) in the case of limited sphincter damage by preserving the scars; and 2. anterior overlapping sphincteroplasty, combined with a modified lotus petal flap, that may significantly improve results in the delayed repair of traumatic cloaca

ICS International Continence Society, *NICE* National Institute for Health and Care Excellence, *ASCRS* American Society of Colon and Rectal Surgeons, *FI* Fecal Incontinence, *QOL* Quality of Life, *EUS* Endoanal Ultrasound, *EAS* External Anal Sphincter, *IAS* Internal Anal Sphincter, *FI* Fecal Incontinence, *SNM* Sacral Neuromodulation

[a]Rectal prolapse, anal cloaca

specialist to perform specific tests and propose a combination of conservative treatments, biofeedback, pelvic floor muscle exercises, transanal irrigation (TAI) and anal plugs (Table 2).

The third level of treatment is reserved for patients whose condition remains unsolved. These are referred to a gastroenterologist, colorectal surgeon, urogynaecologist, and/or a multi-disciplinary team. They divide the population into three groups: (1) patients with severe spinal cord injury who should be treated with the Malone anterograde continence enemas (MACE), retrograde irrigations or colostomy; (2) those with rectal prolapse, rectovaginal fistula or cloacal malformation who must be treated with reconstructive surgery, and (3) the remaining patients are classified according to the integrity of the external anal sphincter (EAS): (a) those without defect may receive sacral neuromodulation (SNM), followed by biomaterial injection if SNM fails; (b) those with a defect < 120° should be treated with SNM, followed by sphincteroplasty, then biomaterial injection in case of remaining minimal defect; (c) patients with a sphincter defect between 120 and 180 degrees are advised to initially be treated with sphincteroplasty, followed by SNM; and (d) patients with EAS injuries > 180° or an important tissue loss should be treated with sphincteroplasty and vaginal reconstruction, and may be treated with SNM as second line in case of failure. In this group, stimulated graciloplasty (SG) or artificial bowel sphincter (ABS) are also considered as treatment options. Colostomy is mentioned as the last treatment option.

Regarding sphincteroplasty, they advocate repairing the internal and EAS separately when possible, which is not mentioned in other guidelines. Moreover, in case of failure, they recommend reassessing the integrity of the repair by endoanal ultrasound and consider repeating sphincteroplasty in patients with a remaining defect and a poor continence outcome. These guidelines also recommend considering the patient's opinion when deciding whether to surgically repair a damaged sphincter or not. Patients are invited to fill in a written table with pros and cons for each option.

Several procedures of neosphincter surgery are discussed: (1) unstimulated graciloplasty that should not be routinely offered; (2) SG; (3) ABS; and (4) magnetic anal sphincter (MAS). MAS was considered as an alternative at the time the guidelines were written because of the promising results. However, it is important to remark that MAS is not on the market at the moment.

ABS was recommended when other treatments nave failed but the guidelines point out potential problems such as obstructed defecation and device erosion. Moreover, it is no longer commercially available. SG should be offered to selected patients who do not respond to other treatments, particularly when there is loss of native sphincter tissue.

Colostomy is recommended for patients with congenital malformations. A substantial part is dedicated to FI in neurological patients, mainly insisting on an extensive evaluation and complete conservative treatment including measures for faecal disimpaction. Second-line options mentioned are SNM, TAI, ABS, sacral anterior root stimulation and botulinum toxin for anal sphincter spasticity. The authors mention the successful results obtained with the Malone antegrade continence enema procedure via appendicostomy (MACE) and point out the risk of complications such as stoma stenosis (20%), or significant stomal leakage (28%). These complications cause 10–33% of patients to undergo revision of the appendicostomy. Stomal prolapse, pressure sore, wound infection, anastomotic leak, stomal granulation, caecal-flap necrosis and caecal volvulus are uncommon complications reported after MACE.

Finally, the authors mention several novel therapies that should be considered under protocol: posterior tibial nerve stimulation (PTNS), MAS, puborectalis sling, radiofrequency energy (Secca System [SECCA]), vaginal bowel control system and stem cell therapy.

National Institute for Health and Care Excellence (NICE) guidelines

These are extensive guidelines made up of several documents, elaborated by a multi-disciplinary guidelines development group with the support of expert advisors and a guidelines review panel.

A list of clinical questions was developed to guide the literature searching process and facilitate the development of graded recommendations. The first version was published in 2007, with some parts reviewed in 2014. In 2018, the guidelines were checked by an extensive experts' group but were not updated since no new evidence affecting the recommendations was found, although some aspects were revised [7].

They initially state that when assessing FI, healthcare professionals should be aware that it is a symptom, often with multiple contributory factors, and advise avoiding making the simplistic assumption that causation is related to a single primary diagnosis with a term not mentioned in other guidelines: 'diagnostic overshadowing'.

The authors also state that concomitant reversible conditions, commonly related to these patients, such as fecal loading, potentially treatable causes of diarrhoea, rectal prolapse or third-degree hemorrhoids, and acute disc prolapse or cauda equina syndrome, should be evaluated and addressed. Some of these considerations are not mentioned in other guidelines.

The treatment algorithm proposed by the NICE also focuses on several initial conservative management options including coping strategies, diet modifications, bowel habits

Table 2 Conservative Treatment Recommendations for Fecal Incontinence in Different Guidelines

	ICS	NICE	ASCRS	Italian	French
Dietary advice	Control the diet to have ideal stool consistency. Attention to the effects of **lactose, yogurt, sorbitol, fructose, caffeine and alcohol**	List of food and drinks that may exacerbate FI: excessive doses **of vitamin C, magnesium, phosphorus, lactose, chilli, alcohol (stout, beers and ales), artificial sweeteners, olestra fat substitute**	Recommends use of a **diary** to detect triggering factors Attention to the effects of **caffeine**, **sugar replacements, lactose**, and other dietary components that may result in fecal urgency or diarrhea	Not mentioned	Recommends asking about eating habits, or any dietary triggers
Stool bulking agents	Fiber Psyllum (moderately fermentable soluble fiber) Probiotics: initial short evidence	Fiber	Kaopectate Fiber	Polycarbophil calcium Fiber	Dietary fibre Mucilage (not for patients with hard or normal consistency stools)
Anti-diarrheal medication	**Loperamide** Diphenoxylate	**Loperamide** Codein phosphate Co-phenotrope when intolerant	**Loperamide** Diphenoxylate Atropine	**Loperamide** Codeine Amitriptyline Atropine Diphenoxylate	**Loperamide** Codeine
Laxatives	Not enough evidence to recommend them	For people with faecal loading	Not enough evidence to recommend them	In incontinent patients with faecal impaction	Laxatives, rectal suppositories or enemas to control incontinent episodes associated with constipation
Cholestyramine	Not enough evidence to recommend it	Not mentioned	Particularly in patients with a **history of cholecystectomy or ileocolonic resection**	Not mentioned	**Recommended**
Antidepressant drugs	Recommends them for patients with stress UI or bladder pain associated to FI	Not mentioned	Benefits and risks must **be weighed on an individual basis** (tricyclic antidepressants and opioids)	Limited evidence	Amitryptyline is **not recommended**
Other drugs	**Sodium valproate:** may have a modest role in postsurgical faecal incontinence	Attention to **Drugs that may exacerbate FI**: some antibiotics, metformine, calcium channel antagonists	**Clonidine** to manage urgency and reduce rectal sensibility		**Oral valproate, diazepam not** recommended General or local **hormone replacement** therapy in postmenopausal women not recommended
Perianal skin care	Topical phenylephrine, zinc–aluminum ointment, estrogen creams (insufficient evidence), for elderly and frail patients	Products for containment and skin care advice should also be available for initial treatment. Recommended both **cleansing** and using **barrier products**	Protective ointments (eg, zinc oxide based), gentle soaps and wipes, as well as deodorants and pads	Not mentioned	Topical phenylephrine, zinc, and aluminium are **not recommended**

Table 2 (continued)

	ICS	NICE	ASCRS	Italian	French
Posterior Tibial Nerve Stimulation	Remains an investigational treatment protocol which cannot currently be recommended for clinical practice	If conservative management failures	Weak recommendation	It could offer a relatively affordable treatment in patients who have failed conservative treatment	Weakly recommended after SNM fails in the algorithm. Also stated as a potential alternative to be use with the same indications as SNM being a less invasive option

ICS International Continence Society, *NICE* National Institute for Health and Care Excellence, *ASCRS* American Society of Colon and Rectal Surgeons, *FI* Fecal Incontinence, *UI* Urinary Incontinence

and medication. An extensive list of food, drinks, and drugs which may exacerbate FI is drawn up (Table 2).

In agreement with the ICS guidelines, the authors state that patients with persistent episodes of FI after initial management should be considered for specialised management. This may involve referral to a specialist continence service, which can include pelvic floor muscle exercises, bowel retraining, biofeedback, and electrical stimulation.

In line with other guidelines, TAI is also indicated before surgery, but only depending on personal preferences, and is especially useful in patients with fecal loading and those with neurological or spinal disease or injury. The use of plugs is recommended as part of other coping strategies.

A specific section in these guidelines is dedicated to the follow-up of patients with FI. It includes different aspects such as psychological and emotional support, fostering acceptance and positive attitudes and counselling on how to talk to friends and family about FI and its management.

For further managing strategies, they identify specific groups of patients who require specialised care and surgery: patients with fecal loading, people with limited mobility, persons using enteral tube feeding, those with severe cognitive impairment, patients with neurological or spinal disease or injury, people with learning disabilities and, finally, severely or terminally ill patients. Some of these specific groups are not addressed in other guidelines (Table 1).

Pelvic floor muscle exercises, biofeedback and electrical stimulation were noted to have limited evidence and the authors only recommend them for patients not responding to initial management.

The authors state that all patients considered for surgery should be referred to a specialist surgeon. Surgical treatment is based on EAS defect and patient preference. The procedures accepted in the United Kingdom are sphincter repair, SNM and anterograde irrigation as first-line options.

The main indications for SNM and sphincter repair are listed in Table 3. The use of SNM is recommended on the basis of patients' response to percutaneous nerve evaluation (test phase). Regarding the indication for sphincteroplasty, these are the only guidelines that consider not only the circumferential but also the longitudinal extent of the EAS defect, as described in the Starcks and Norderval scores [8, 9]. They recommend it for patients with full-length EAS defect of 90° or greater (with or without an associated internal anal sphincter defect) (Table 3).

The next line of treatment is neosphincter surgery, including SG and ABS, indicated when SNM is unsuccessful and other situations shown in Table 3. The authors state that the SG evidence is limited but seems sufficient to support its use for carefully selected patients in whom other treatments have failed or are contraindicated. However, the recommendation for ABS is lower, as they declare that current evidence does not appear adequate for this procedure

Table 3 Summary of the main indications and recommendations for different surgical treatments for fecal incontinence in the analysed guidelines

	ICS	NICE	ASCRS	Italian	French
Treatment indication is based on:	Three groups: 1. spinal cord; 2. structural defects; 3. all the others: based on EAS integrity	EAS defect and patient willingness	No algorithm defined	No algorithm defined	Four groups: 1. significant and recent sphincter tear; 2. external rectal prolapse; 3. neurological disease 4. all other patients
SNM indications	Patients **without defect**; or < **120°** defect; **second line if sphincteroplasty fails**	When **sphincter surgery is deemed inappropriate**: no defect, sphincter disruption, or sphincter defect + atrophy, denervation, a small defect, absence of voluntary contraction, fragmentation of the sphincter or a poor-quality muscle	First-line surgical option for FI **with and without sphincter defects**	**Intact but weak** anal sphincter; Sphincter disruption **up to 120 degrees**; **After rectal surgery or rectal prolapse surgery**; **Double incontinence**; Selected patients with **neurogenic FI**	**In the algorithm: all patients** after the specific treatment failure: 1. sphincteroplasty in recent sphincter tear; 2. rectopexy in rectal prolapse; 3. TAI for neurologic patients, or 4.-biofeedback for the rest of patients **Inclusion criteria:** idiopathic anal incontinence; old sphincter defect even when extensive; scleroderma; central or incomplete peripheral non-progressive neurological lesion;, concomitant urinary incontinence with overactive bladder **It is not recommended** in patients with Crohn's disease owing to the paucity of published data
Sphincter repair indications	Symptomatic patients with a defined defect in the EAS: **first option if lesion 120–180°**; after SNM if lesion < 120°; adding vaginoplasty if lesion > 180° Patients option when deciding whether sphincter repair vs SNM	**Full-length** EAS defect that **is 90° or greater** (with or without an associated internal anal sphincter defect)	**Symptomatic** patients with a **defined defect of the EAS**	**Highly symptomatic** patients with **a defect of the EAS**	Defect of **60° to 120°** and is **especially recommended if the lesion is recent**
Redo-sphincteroplasty	**Recommended** after an EUS that confirms the lesion	Not mentioned	**No recommended** unless other treatment modalities are not possible or have failed	**Recommended** for persistent or relapsing EAS defect	Not mentioned

Table 3 (continued)

	ICS	NICE	ASCRS	Italian	French
Biomaterial injection (bulking agents) indications	After sphincteroplasty or SNM **when minimal defect remains**	No consistent results**. Just used in the context of a clinical trial** or formal audit protocol	They state that may help to decrease episodes of **passive FI**	**Passive FI, post-defecatory leakage and involuntary gas escape**. It can be used in **damaged or degenerated IAS** with very limited evidence	Weakly recommended **when SNM fails, at the same level than ABS of PTNS**
Stimulated Graciloplasty (SG) indications	Selected patients who have failed other modalities of treatment particularly where there has been **loss of native sphincter tissue**	For carefully selected patients in whom other treatments have failed or are contraindicated. Should be performed in by **clinicians with specific training and experience**	Not mentioned	To replace the anal sphincter **when extensive sphincter damage, muscle loss and pudendal neuropathy are involved**. **Final rescue solution** before colostomy	It is not possible to make specific recommendations
Artificial Bowel Sphincter (ABS) indications	For patients who have **failed other modalities of treatment**. **Neurological** patients after failure of TAI	For carefully selected patients in whom other treatments have failed or are contraindicated. **Less recommended than SG**	In patients in whom **all other treatments have failed**, or those with **extensive sphincter destruction** (> 180 degrees), **congenital malformations**, neurogenic incontinence from **spinal cord injury**, or **postsurgical significant bowel dysfunction with intact anal canal anatomy**	**Same indications as graciloplasty**	Weakly recommended as a third-line treatment once SNM fails, at the same level as bulking agents or PTNS

Table 3 (continued)

	ICS	NICE	ASCRS	Italian	French
Other treatment indications	**PTNS:** remains an investigational treatment protocol which cannot currently be recommended for clinical practice **MAS**: a novel treatment for patients who have failed other modalities of treatment **Puborectal sling** remains unproven but may be of value in selected patients **Vaginal bowel control system** remains to be established **Secca:** long-term results are disappointing **Stem cell therapy** remains experimental and should only be offered as part of a well-designed research trial	**PTNS:** if conservative management failures **MAS:** limited evidence **MACE, neo-appendicostomy or continent colonic conduit**: in selected people with constipation and colonic motility disorders associated with FI **Other novel treatments** with limited evidence: Transabdominal artificial bowel sphincter implantation; Endoscopic radiofrequency of the anal sphincter	**PTNS, SECCA and MAS:** weak recommendation	**PTNS:** it could offer a relatively affordable treatment in patients who have failed conservative treatment **SECCA:** not recommended **MAS:** limited evidence **MALONE*:** considered to give pseudocontinence in selected patients with associated constipation or neurogenic bowel	**PTNS:** weakly recommended after SNM fails in the algorithm. Also stated as a potential alternative to be use with the same indications as SNM being a less invasive option **SECCA:** not recommended **MAS:** it is not possible to make specific recommendations **MALONE*:** in case of TAI failure

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to be used without special arrangements for consent and for audit or research. Moreover, they state that patients being considered for neosphincter surgery should be assessed and managed at a centre with experience in performing these procedures. Patients with an implanted SNM device, SG or an ABS should be offered training and ongoing support, be monitored and have regular reviews at a specialist centre.

A stoma is proposed as a final option when other approaches have failed. The use of a synthetic or biological mesh to prevent a parastomal hernia is specifically not recommended. Other alternatives with low recommendation grade are listed in Table 3.

The American Society of Colon and Rectal Surgeons (ASCRS) guidelines

These are Clinical Practice Guidelines elaborated by a committee of FI experts, members of the ASCRS. An organised literature search was performed in March 2014. A list of therapeutic options and their recommendations grade based on the evidence-based medicine and the opinion of the experts was formulated by the primary authors and reviewed by the entire committee [10].

Initially, there is an extensive section regarding patient evaluation and risks factors. The authors mention the importance of using a self-directed evaluation of the patients' habits using a diary or repeated questionnaires to identify triggering or aggravating factors in their daily routine. They state that these habits may be difficult to detect in the short span of an interview during a physician's evaluation. They also consider that clinicians' assessments of patients' outcomes often underestimate the degree of bother perceived by patients and focus on issues less important for patients. Consequently, they stress the need to use patient self-completed questionnaires or patient-reported outcomes.

Different treatments are categorised as strongly and weakly recommended, non-operative and surgical management options. Among the non-operative treatment options, the ASCRS strongly recommends dietary and medical management (Tables 1 and 2). The use of clonidine in urge incontinence is a special recommendation of these guidelines even though evidence is limited to date [11–13].

Furthermore, the authors state that bowel management programmes to help with rectal evacuation are useful in selected patients and recommend the use of enemas or suppositories at convenient times to reduce rectal stool volume and help mitigate the risk of incontinence episodes. However, the use of TAI or anal plugs as a conservative or palliative treatment is not mentioned in these guidelines.

Biofeedback is reserved for patients with some preserved voluntary sphincter contraction, a question not specifically stated in other guidelines. The NICE guidelines mention that patients with neurological or spinal disease should have some residual motor function to be candidates for biofeedback.

Regarding surgical treatments, they recommend SNM as first-line surgical treatment for patients with or without sphincter defects. Sphincter repair may be offered to symptomatic patients with a defined EAS defect. However, nothing is said about the degrees and/or length of sphincter defect to consider sphincteroplasty. Repeat anal sphincter reconstruction after a failed overlapping sphincteroplasty should generally be avoided unless other treatment modalities are not possible or have failed, and the plication of the external anal sphincter (Park's postanal repair) is no longer recommended.

These guidelines also stand out because they recommend the correction of other anatomical pathologies (e.g. rectovaginal fistula, rectal prolapse, cloaca) that may lead to FI, before any other intervention.

Regarding sphincter replacement strategies, there is no mention of SG which was initiated in the United States but is no longer permitted by the Food and Drug Administration (FDA). In contrast, ABS is strongly recommended and due to the high success rates and safety profiles of other treatments such as SNM, is generally reserved for a specific group of patients shown in Table 3.

SECCA is weakly recommended because of the limitations of available data, while the injection of bulking agents is only suggested for patients with passive FI. The authors also point out that PTNS and MAS are not approved by the FDA and are weakly recommended (Table 3).

Finally, as in the other guidelines, colostomy is the last option considered an excellent surgical option for patients who have failed other treatments or do not wish to pursue other therapies for FI.

The Italian guidelines

An expert committee nominated by the Italian Society of Colorectal Surgery (SICCR) and the Italian Association of Hospital Gastroenterologists developed a consensus on the diagnostic and therapeutic aspects of FI in adults. As their American colleagues, they elaborated a list of therapeutic options and their recommendations grade based on the evidence-based medicine [14]. Conservative medical treatments are strongly recommended (antidiarrheal or laxative agents as appropriate), as well as biofeedback, pelvic floor exercises and TAI. Interestingly. The authors comment on the use of amitriptyline to improve symptoms in patients with idiopathic FI and irritable bowel syndrome, due to its effect in prolonging colonic transit timeand improving stool consistency. However, they point out that stronger evidence is needed to administer it routinely. Nothing is stated about diet management, protective anal creams, or the use of coping strategies.

A specific section on the reconstruction of structural defects such as rectal prolapse is included in these guidelines, as well as some considerations regarding neurological patients for whom they recommend the use of TAI.

Strongly recommended surgical procedures are sphincter repair, SNM and MACE. An extensive list of indications for SNM is provided (Table 3). Nevertheless, the authors point out that there is no evidence about which patients are the best candidates for SNM. Sphincter repair is indicated in highly symptomatic patients with EAS defect, and two different types of sphincter repair are described (Table 1). Moreover, repeat overlapping sphincteroplasty is recommended for persistent EAS defects (grade C) as the results are stable over time, based on two studies with 36 and 21 patients (Table 3) [15, 16].

Sphincter replacement strategies with autologous muscle or prosthesis are considered as a final rescue option before colostomy (Table 3). Authors state that bulking agents such as injectable dextranomer, elastomer, porcine dermal collagen, carbo-coated zirconium oxide beads or hydrogel cross-linked with polyacrylamide are mainly indicated for passive FI, post-defecatory leakage and involuntary gas escape. They also suggest them in patients with damaged or degenerated IAS with very limited evidence. PTNS is considered as an alternative but there are different protocols, the quality of the studies is poor, and no studies supporting the long-term benefits of PTNS have been published to date [17, 18]. Nevertheless, given a cheaper initial outlay, PTNS could be an affordable treatment in comparison with SNM in patients who have failed conservative treatment [19]. Other developing alternatives are also described (Table 3).

The French National Society of Coloproctology (SNFCP) guidelines

An organising committee, a working and a reading group, representing several professional subdisciplines, were appointed by the SNFCP. A systematic search was conducted, and the working group proposed recommendations graded from A to C depending on the level of evidence. In the absence of sufficient scientific data, recommendations were made by the working group based on consensus [20].

The guidelines propose a therapeutic algorithm that can be followed step by step. After an initial symptom assessment, extensive advice on dietary measures and medical treatment, essentially based on antidiarrheal medication (Table 2), they recommend adopting different approaches depending on four clinical situations, on the basis of their structural features or background. Thus, (1) sphincter repair is pointed as the treatment option for patients with significant recent sphincter tear; at the same level, (2) ventral mesh rectopexy is recommended for those with external rectal prolapse, and (3) TAI for patients with FI due to a neurological disease. Finally, (4) for all other patients, they recommend biofeedback. Specific aspects of this approach are shown in Table 1.

In case of failure, the authors suggest SNM as a common third-line treatment for all patients, an aspect not established as clearly in other guidelines (Table 3). If the percutaneous nerve evaluation (PNE) phase proves to be inefficient, they propose bulking agent injection, PTNS or ABS as alternatives. However, they point out that based on the current knowledge and devices available in France, it is not possible to make specific recommendations regarding ABS, SG or MAS.

Different rehabilitation strategies such as pelvic floor exercises and biofeedback, in cycles of at least ten sessions, are recommended by these authors, specifying that they should involve the retraining of the perineal sphincters and abdominal muscles. The use of electrostimulation is not recommended due to its low evidence.

They state that the type of technique used for sphincter repair (direct or overlapping sphincter repair) does not influence the success rate. However, they insist that the procedure must be associated with improvement of bowel habits and regular bowel motions with normal stool consistency to obtain better functional outcomes. These are the only guidelines that mention subclinical sphincter defects and declare that in cases with a minimal defect e.g. one seen by endoanal ultrasonography, and very mild symptoms, SNM may be preferred to sphincter repair (Table 1). There are no comments on repeat sphincteroplasty.

Critical appraisal

There is a lack of consensus on definitions, assessments and treatments of FI which affects essential aspects of research studies about FI. In this line, Vaizey [21] criticised the variety of unscientific scoring systems used in the studies, the small numbers of patients included and the short follow-ups. The ICS experts committee also advised on the need to standardise definitions of FI and [6].

Regarding definitions, in our opinion, the terms “passive incontinence” and “soiling”, are often mixed up in the literature. In 2017, the ICS Experts Committee published a terminology report to assist clinical practice and research [22]. Passive fecal incontinence was defined as the “involuntary soiling of liquid or solid stool without sensation or warning or difficulty wiping clean”. In a foot note, they added that soiling “is a bothersome disorder characterized by continuous or intermittent liquid anal discharge” and that “it should be differentiated from discharge due to fistulae, proctitis, hemorrhoids, and prolapse. Patients complain about staining of underwear and often wear protection. The discharge may cause inflammation of the perineal skin with excoriation,

perianal discomfort, burning sensation, and itching. It often indicates the presence of an impaired internal sphincter function or a solid fecal mass in the rectum but could also be due to the inability to maintain hygiene due to hemorrhoids". In our opinion, the fact that the word "soiling" is included in the definition of "passive incontinence" shows that these two different concepts are mixed in the definition. We would define "passive incontinence episodes" as the passive leakage of a fairly large amount of faeces, often a complete bowel movement, which are common in neurological patients; and "soiling" as the episodes of leakage of a small amount of liquid staining the underwear which is common in patients with impaired internal sphincter function as may happen after proctologic surgery. The fact that these two very different clinical situations may be included under the same definition in a study may raise questions about the outcome of a particular treatment.

Another controversial topic is the frequency and amount of leakage to include a patient in therapeutic studies. Several studies include patients based on scores, and some patients may therefore be excluded from treatment. Furthermore, included patients might have different amounts and types of leakage although they have the same score. A recent study with the Rome IV FI criteria [23], using an internet survey of 6300 subjects determined that although 16.1% of patients reported at least one episode of FI in the last 3 months, only 3.3% met the Rome IV criteria. However, all of them had impaired QoL. The authors call for diagnosing FI in all patients with two or more episodes in 3 months and providing additional information on frequency, duration and amount of stool loss to assist clinicians in decision making [24].

Similar controversies arose over classification of the etiology of FI. Often the inclusion criteria "Patients with more than one episode a week of FI" or simply "Patients with FI" are used in many studies, with very limited specification about patients' background. This might mislead clinicians when interpreting the efficacy of treatments such as SNM for FI with different etiologies. Overall treatment efficacy may mask the specific therapeutic results in the different etiology subgroups [25–29].

All guidelines thoroughly cover different modalities of conservative treatment with common aspects such as the use of fibre and loperamide. However, there are differences between guidelines regarding a wide range of other treatments (Table 2). Different options of conservative treatment and rehabilitation have frequently been used in combination, such as biofeedback which is usually combined with pelvic floor muscle training and sensory training with a rectal balloon, that is recommended in the ICS guidelines with a recommendation Grade A [6]. In a crossover study, Sjodhal et al. [30] discussed the usefulness of combining biofeedback with loperamide and stool bulking agents, with the result that the combined treatment was associated with significant improvement compared to baseline when using one of the two options alone.

Common aspects in the different guidelines include the use of biofeedback as second line in conservative treatment, the correction of other anatomical pathologies that may lead to FI (e.g. rectovaginal fistula, rectal prolapse, cloaca) and colostomy as the last step in patients not responding to other options. SNM and sphincteroplasty are commonly recommended in all guidelines but indications vary (Table 3).

The ICS and the French guidelines propose a clear pathway for patients with FI based on different criteria, and the NICE guidelines also provide some flowcharts. However, a thorough analysis of these guidelines shows that there is no consensus on the pathway, a fact which is evident if different clinical scenarios are presented (Table 4). Taking sphincter repair as an example, the three guidelines differ in the degree of EAS injury that is an indication for surgery. Moreover, while the French Guidelines consider time since sphincter tear an important factor, the NICE guidelines focuses on length of the lesion. The other two guidelines (ASCRS and Italian) provide information about the recommendation grade of different treatment options without proposing any algorithm.

Regarding the length of the EAS lesion, the NICE guidelines only indicate sphincteroplasty for full-length lesions. However, in our opinion patients with partial-length obstetric injuries should also be considered for reconstruction, especially if they are recent. Obstetric trauma occurs in a longitudinal direction from the higher part of the anal canal towards the skin, and a very thin portion of the EAS often remains in the lower part of the anal canal. Young symptomatic patients may benefit from an overlapping sphincteroplasty, preserving and plicating the remaining EAS band to lengthen the anal canal.

The French guidelines briefly mention the controversial topic of what to do in case of a subclinical sphincter defect and state that SNM may be preferred to sphincter repair. Patients with minor defects and very mild symptoms may benefit from initial less invasive surgery [31, 32]. We would like to address the need for sphincter repair in young patients with mild symptoms after a recent obstetric injury as two meta-analyses have determined that a significant number will develop FI during their life [33, 34]. Even if symptoms are mild, patients need to be properly informed of the risks of developing FI and the potential benefit of early sphincter repair.

Over ten different materials for biomaterial injection have been reported in the literature [35–38], since the first use of polytetrafluoroethylene paste into the anal submucosa by Shafik in 1993 [39]. Despite being a minimally invasive treatment, the evidence is inconsistent, weak and long-term follow-up is lacking. Some treatments for FI fail to withstand

Table 4 Therapeutic options for different clinical scenarios in different guidelines

	ICS	NICE	ASCRS	Italian	French
First surgical treatment in **a young patient with a recent obstetric 100° EAS lesion** and FI	SNM	Sphincteroplasty (if full-length lesion, no atrophy, no denervation, and with good voluntary contraction) SNM in the rest	SNM/Sphincteroplasty (not clear)	SNM/Sphincteroplasty (it is not clear)	Sphincteroplasty
First surgical treatment in a **young patient with a recent obstetric > 120° EAS lesion** and FI	Sphincteroplasty	Idem as previous scenario	SNM/Sphincteroplasty (not clear)	Sphincteroplasty	Not mentioned
Young patient with a recent obstetric EAS 90° lesion **without FI: subclinical sphincter defect**	Not mentioned	Not mentioned	Not mentioned	Not mentioned	SNM better than sphincteroplasty
-First surgical treatment in a **≥ 50 y.o. woman with FI and old 100° EAS lesion**	SNM	Probably SNM due to atrophy or absence of voluntary contraction	SNM/Sphincteroplasty (not clear)	SNM	SNM
First surgical treatment in the **idiopathic FI without EAS lesion**	SNM	SNM	SNM	SNM	SNM
Second step after conservative treatment failure in **Congenital FI in an adult patient**	MACE (poor outcome) Colostomy preferred	ABS	ABS	Not mentioned	Not mentioned
Management of **neurological patients with FI** after conservative treatment	TAI MACE (If TAI failure) In some selected patients: ABS, SNM, SARS	TAI	ABS	TAI SNM in certain neurologyc patients	TAI MACE (if TAI failure) SNM if central or incomplete peripheral non-progressive neurological lesion
Management of **traumatic FI with > 180° and/or multiple sphincteric disruption**	Vaginal reconstruction SG ABS SNM	SG ABS (less recommended)	ABS	Gluteoplasty graciloplasty or ABS	Not mentioned
FI **without EAS lesion but** post-hemorrhoidectomy and/or with IAS lesion postanal surgery	Bulking agents? (Not clearly stated in this clinical scenario but recommended when minimal defect remains)	Not mentioned	Bulking agents? (Not clearly stated in this clinical scenario but declared to possibly help decrease episodes of passive FI)	Bulking agents? (Can be used in patients with damaged or degenerated IAS with very limited evidence)	Not mentioned

Table 4 (continued)

	ICS	NICE	ASCRS	Italian	French
Ultimate options **after previous treatment failures: SNM, sphincter repair, bulking agents**	ABS	SG	ABS	Gluteoplasty	PTNS
	SG	ABS	Stoma (last option)	Graciloplasty	ABS
	Stoma (last option)	Stoma (last option)		ABS	Bulking agents
				Stoma (last option)	Stoma (last option)

ICS International Continence Society, *NICE* National Institute for Health and Care Excellence, *ASCRS* American Society of Colon and Rectal Surgeons, *FI* Fecal Incontinence, *EAS* External Anal Sphincter, *SNM* Sacral Neuromodulation, *MACE* Malone Antegrade Continence Enema, *ABS* Artificial Bowel Sphincter, *TAI* Transanal Irrigation, *SARS* Sacral Anterior Root Stimulation, *SG* Stimulated Graciloplasty, *PTNS* Posterior Tibial Nerve Stimulation

the test of time, which has to be taken into account when analysing all emerging therapies. This may explain why indications and recommendations are different in each of the guidelines (Table 3). In 2011, Ratto et al. described the Gatekeeper™, self-expandable polyacrylonitrile prostheses implanted into the upper-middle intersphincteric space of the anal canal, with promising results [40–46]. The same authors evolved this treatment to a new generation of prostheses named Sphinkeeper™, which are longer and thicker, and they propose the implantation of ten prostheses, rather than six [47–49]. This is a relatively new treatment which explains why it is only briefly mentioned in the guidelines. In our opinion, the main advantage of these prostheses is that they are implanted under endoanal ultrasound control, and not injected as other bulking agents. When prostheses are correctly placed, the results seem to be encouraging [50].

Regarding neosphincter surgery, SG and ABS are the oldest alternatives, with more accumulated evidence. Nevertheless, indications and recommendations vary among the different guidelines and are weak in some of them (Table 3). Since the first report of SG by Baeten in 1995 [51], some case series and three multicentre non-randomised studies which bring together the results of several centres with very few cases [52–54]. Efficacy was around 70% but morbidity was high in most series, and better results were reported in centres with significant prior experience of the procedure [52]. In the long-term follow-up, results seemed to be better in trauma patients [55].

Alongside the development of SNS, various types of ABS were designed to treat severely incontinent patients. In a recent long-term follow-up study, one of the most expert centres in ABS, reported their results using the Acticon device, and continence was restored in 35% of patients. However, at 5-year follow-up, 80% of the cohort experienced a complication requiring surgery. The device was explanted in 31 out of 62 patients, and a total of 101 reoperations were conducted. The main reasons for revision were device failure and infection [57]. These results are similar to those previously reported [58–60].

The ICS experts committee declares that "ABS alternatives frequently derive from innovations and experiments of other specialties such as urology or upper gastrointestinal surgery; their development is associated with significant efforts from companies that invest heavily to establish them in the market; they are not yet universally approved and have to be regarded as investigational/experimental in many ways as strong evidence is still missing in terms of feasibility, cost-effectiveness, durability and reproducibility" [6]. In our opinion, introducing any prosthetic material into the perineum is always worse in terms of potential morbidity than using a transposed muscle. Moreover, MAS and ABS in its original trademark are not in the market anymore, so neosphincter surgery options are limited to SG.

High morbidity rates and the introduction of SMN as much less invasive treatment reduced the use of SG. However, a subsequent single-centre study proposed its use as the final option before stoma in selected patients [56]. The procedure requires significant surgical skills and must be performed in centres with high volume of patients with FI. In our opinion, is the only option for patients with large perineal trauma or congenital malformations when minimal EAS encircles the anal canal. SG electrodes are no longer manufactured, but our group has adapted other electrodes with very good outcome.

Common clinical scenarios in clinical practice were correlated with the treatment approaches of the different guidelines (Table 4), showing that there is no agreement about the choices, except for SNM after conservative treatment failure in idiopathic FI without an EAS lesion. For instance, there is no consensus on the first surgical treatment for a young woman with a recent 100º obstetric EAS lesion: while the ICS clearly opts to start with SNM, the French guideline recommends starting with sphincteroplasty, NICE advocates using sphincteroplasty but only if it is a full-length lesion, whereas there is no clear statement in the ASCRS and the Italian guidelines. Moreover, some scenarios are not clearly covered by some guidelines. Nevertheless, it is important to note that each of the guidelines includes specific questions not mentioned by the others, which should be considered if a consensus is reached (Table 1).

We previously emphasised the importance of clinical relevance as many FI studies yield results with statistical significance that may not have an impact on clinical outcome [61]. Several examples can be found in publications about radiofrequency, where very small changes in the Cleveland Clinic Score (< 3 points) were reported as statistically significant improvement, although most patients remained in the moderate incontinence category [62–64]. The actual importance of these changes is yet to be determined, as pointed out by other authors [65, 66].

We strongly believe that it would be useful to unify the criteria to select patients based on their background, clinical symptoms, impact on their QoL and sphincter integrity, and to propose a tailored approach if the first option fails. The term FI includes patients with a spectrum of symptoms and different pathophysiologies, which implies that patients with soiling, gas incontinence or urge incontinence may require different approaches. Other patients who should be considered differently are those with low anterior resection syndrome, who present an even broader spectrum of symptoms. Patients with congenital FI are also a particular group, since some present with combined obstructed defecation and overflowing FI, and others with severe passive incontinence. Moreover, the level of coping strategies varies significantly and should be taken into consideration when deciding on the best approach. As FI can be one of the numerous symptoms of functional bowel disorders [67], treatment should be tailored to the individual patient and aimed at treating the most bothersome symptom.

A review of the literature shows a lack of consensus and evidence of good quality data. Guidelines should be developed by professionals, not only experts in analysing the literature but also with experience with a high volume of patients. The recent initiative of the European Society of Coloproctology to analyse scoring systems in detail [21] is very encouraging.

Finally, as in other pathologies, complex cases should only be treated in specialised units, but even then, the best approach may be difficult to identify. We believe that the creation of an international chat with clinical experts would contribute to overcome these difficulties and allow discussing complex cases that should be managed in an individualised manner.

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Declarations

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Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study formal consent is not required.

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