



Colon/Rectum/Anus

FISSIT (Fistula Surgery in Italy) study: A retrospective survey on the surgical management of anal fistulas in Italy over the last 15 years



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ABSTRACT

Background: Surgical treatment of anal fistulas is still a challenge. The aims of this study were to evaluate the adoption and healing rates for the different surgical techniques used in Italy over the past 15 years.

Methods: This was a multicenter retrospective observational study of patients affected by simple and complex anal fistulas of cryptoglandular origin who were surgically treated in the period 2003–2017. Surgical techniques were grouped as sphincter-cutting or sphincter-sparing and as technology-assisted or techno-free. All patients included in the study were followed for at least 12 months.

Results: A total of 9,536 patients (5,520 simple; 4,016 complex fistulas) entered the study. For simple fistulas, fistulotomy was the most frequently used procedure, although its adoption significantly decreased over the years ($P < .0005$), with an increase in sphincter-sparing approaches; the overall healing rate in simple fistulas was 81.1%, with a significant difference between sphincter-cutting (91.9%) and sphincter-sparing (65.1%) techniques ($P = .001$). For complex fistulas, the adoption of

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sphincter-cutting approaches decreased, while sphincter-sparing techniques were mildly preferred ($P < .0005$). Moreover, there was a significant trend toward the use of technology-assisted procedures. The overall healing rate for complex fistulas was 69.0%, with a measurable difference between sphincter-cutting (81.1%) and sphincter-sparing (61.4%; $P = .001$) techniques and between techno-free and technology-assisted techniques (72.5% and 55.0%, respectively; $P = .001$).

Conclusion: Surgical treatment of anal fistulas has changed, with a trend toward the use of sphincter-sparing techniques. The overall cure rate has remained stable, even if the most innovative procedures have achieved a lower success rate.

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Introduction

Surgical treatment of anal fistulas (AFs) is still a challenge for surgeons due to the need to balance the success rate with the risk of postoperative continence impairment.¹ Anal fistulotomy is associated with a higher healing rate but, at the same time, is associated with a non-negligible risk of altered continence, especially in the case of complex fistulas (CFs).^{2–4}

The rectal advancement flap was described just over 100 years ago by John Elting, and since then, it represents one of the most adopted techniques for the treatment of CFs, even if it is also associated with a not negligible (approximately 10%) risk of postoperative fecal incontinence.^{4,5}

In the last 15 years, in an attempt to maintain good success rates and guarantee the patient a better functional outcome, numerous "minimally invasive" techniques have been introduced.⁶ In this context, the contribution of Italian proctologic surgery has always been relevant; in fact, many techniques were born or have been developed and disseminated in this country.^{7–11} However, to date, no surgical procedure can be considered the "gold standard". Most likely, the reason for this is the poor quality of the studies, the small sample size, the short duration of the follow-up (FU), and the different selections of patients.⁶

Therefore, the effectiveness of these techniques in long-term FU has been questioned recently, leading clinicians and researchers to wonder whether it would be more useful to rethink the "traditional" techniques, not abandoning them but using them with appropriate variations and with optimized indications.^{12–14} This line of thought has influenced the most recent international guidelines on the topic.^{4,15–17}

The primary aim of this study was to evaluate the variation in the adoption of different surgical techniques (both "traditional" and "minimally invasive") used in Italy for the treatment of AFs over the past 15 years. The secondary aims of the study were to investigate the healing rates in patients per year; finally, the adherence of "real surgical practice" with the indications set by some of the international Guidelines^{4,15–17} will also be discussed.

Methods

This was a multicenter retrospective observational study of patients affected by AFs of cryptoglandular origin who underwent surgery between January 2003 and December 2017. This study was conducted on behalf of the Italian Society of Colorectal Surgery (SICCR): any Italian center in which at least 30 surgeries/year for AFs were performed was able to join the study. Each center (including the coordinating center) identified a study manager and obtained approval from its local ethics committee (Prot. 10797/19, ID: 2483). Patients selected for the study were informed and gave written informed consent.

Patients' selection

Patients were enrolled as follows. Inclusion criteria: primary or recurrent cryptoglandular AFs; simple and complex AFs; age between 18 and 85 years. Exclusion criteria: subcutaneous AFs; AFs related to Crohn's disease or UC (ulcerative colitis); ano-vaginal or recto-vaginal fistula; pouch-related AFs; AFs related to cancer/radiotherapy. Simple fistulas were defined as follows: low inter-sphincteric; low trans-sphincteric; <30% of the internal and/or external anal sphincter crossed by the primary tract (as assessed by preoperative endoanal ultrasound or pelvic MRI, or after evaluation under anesthesia); no preoperative continence impairment; not anterior in women; complex fistulas were defined as follows: medium or high inter-sphincteric; medium or high trans-sphincteric; supra- or extra-sphincteric; $\geq 30\%$ of the internal and/or external anal sphincter crossed by the primary tract (as assessed by preoperative endoanal ultrasound or pelvic MRI, or after evaluation under anesthesia); preoperative fecal incontinence; anterior in women.

Surgical techniques

The following surgical techniques were considered: placement of loose seton (considered as definitive treatment and then removed); cutting seton; complete fistulotomy or fistulectomy; fistulotomy with immediate sphincter reconstruction; flaps; glues/pastes; anal fistula plugs; LIFT (ligation of the intersphincteric fistula tract); laser; VAAFT (video-assisted anal fistula treatment); other techniques (only if used with frequency ≥ 10 cases/y).

For the analysis of this study, the surgical techniques were grouped as follows: "sphincter-cutting" procedures (including cutting seton; complete fistulotomy or fistulectomy; fistulotomy with immediate sphincter reconstruction) or "sphincter-sparing" procedures (loose seton, flaps, glues/pastes, anal fistula plugs, LIFT, laser, VAAFT, other techniques); in addition, the techniques were categorized as "technology-assisted" (glues/pastes, plugs, laser, VAAFT, other techniques) or "techno-free" procedures (loose seton, cutting seton, fistulotomy or fistulectomy; fistulotomy with immediate sphincter reconstruction, flaps, LIFT).

Follow-up

In each participating center, the same data collection sheet was used. Information regarding the outcome was obtained from electronic databases, telephone/email surveys, and outpatient clinical visits. Fistula healing was defined by clinical evaluation (eg, closure of the external orifices and wound, absence of secretions) and/or imaging (MRI or endoanal ultrasound). All patients included in the study were followed for at least 12 months.

Table I
Patients and healing rates per procedure

Procedures	Overall (8,469 patients)		Simple fistula (5,064 patients)		Complex fistula (3,405 patients)	
	Patients, no. (%)	Healing rate	Patients, no. (%)	Healing rate	Patients, no. (%)	Healing rate
Fistulotomy/fistulectomy	4,542 (53.6%)	90.0%	3511 (69.3)	92.4%	1,031 (30.3)	81.9%
Flap	989 (11.7%)	68.9%	199 (3.8)	69.3%	790 (23.2)	68.7%
Cutting setons	877 (10.3%)	91.5%	776 (15.3)	93.8%	101 (3.0)	74.3%
FIPS	870 (10.3%)	82.9%	443 (8.7)	84.7%	427 (12.5)	81.0%
Plugs	314 (3.7%)	55.1%	45 (0.9)	57.8%	269 (7.9)	54.6%
LIFT	290 (3.4%)	71.0%	37 (0.7)	62.2%	253 (7.4)	72.3%
VAAFT	267 (3.2%)	67.8%	16 (0.3)	56.3%	251 (7.4)	68.5%
Glues/paste	93 (1.1%)	49.5%	10 (0.2)	50.0%	83 (2.4)	49.4%
Laser	30 (0.4%)	50.0%	/	/	30 (0.9)	50.0%
Other	197 (2.3%)	36.0%	27 (0.5)	29.6%	170 (5.0)	39.4%

FIPS, fistulotomy and primary sphincteroplasty; LIFT, ligation of intersphincteric fistula tract; VAAFT, video-assisted anal fistula treatment. A total of 1,067 patients (simple: 456; complex: 611) underwent only loose setons placement.

Statistical analysis

A descriptive analysis of the results was conducted, and the temporal trends of the adoption and healing percentages (of each technique) were determined. Trends in adoption rates and healing rates were investigated both with fixed-base indexes and with a linear regression model where the slope indicated the inclination of the regression line. Fixed-base indexes were extensively adopted when dealing with temporal comparisons involving long time series. In more detail, each year was compared with the base year, and the ratio's results highlighted an increase or a decrease in the considered quantity. The comparisons between groups of surgical techniques were performed with either the χ^2 test or Wilcoxon test; a value of $P < .05$ was considered significant. Statistical analyses were performed using SPSS version 21.0 for Windows software (SPSS, Chicago, IL).

Results

Twenty Italian centers joined the study, with an equal geographic distribution: 6 centers were from northern, 7 from central and 7 from southern regions. Concerning the setting, 10 centers were university teaching hospitals, and 6 were public hospitals; the remaining 4 centers were private hospitals.

A total of 9,536 patients affected by cryptoglandular anal fistulas (5,520 simple fistulas; 4,016 complex fistulas) underwent surgery between January 2003 and December 2017 and entered the study. The mean number of patients treated in each center was 476.8 (range, 79–1218 patients) (Table I).

Overall, the most adopted technique, both for simple and complex fistulas, was fistulotomy/fistulectomy (4,542 patients, 53.6%), followed by flaps (989 patients, 11.7%) and cutting setons (877 patients, 10.3%), although the latter 2 methods were mostly used for complex or simple fistulas, respectively. Eight hundred seventy patients (10.3%) underwent fistulotomy with immediate sphincter reconstruction, with a similar adoption rate between simple and complex fistulas. The remaining techniques, mainly technology-assisted, were used in 1,191 patients (14.1%) (Table I).

The overall healing rate was 80.1%. Specifically, it was 62.3% if sphincter-saving procedures were used and 89.2% when sphincter-cutting techniques were adopted; when a techno-free operation was chosen, the healing rate was 82.7%, while it was 54.4% in the case of technology-assisted procedures.

Simple fistulas

The number of patients treated increased during the study period, and this was due to the progressive increase per year in

both the number of recruiting centers and the patients treated in each center. Fig S1 shows the trend of using each single technique during the study period. Fistulotomy/fistulectomy was consistently the most frequently used procedure, although its adoption significantly decreased over the years (slope = -1.28, $P < .0005$, $R^2 = .695$); however, the addition of a sphincter reconstruction to the fistulotomy was more frequently used over time (slope = 1.03, $P < .0005$, $R^2 = .805$) (Table S1). Overall, an increase in the adoption of sphincter-sparing approaches was detected, mainly after 2010 (Table S2, Fig 1a, 1b). Moreover, there has been a progressively increasing use of technology-assisted procedures, rising from 0% in 2003 to 3.2% in 2017 (Table S2).

For simple fistulas, the overall healing rate was 81.1%; a statistically significant difference between sphincter-cutting (91.9%) and sphincter-sparing (65.1%) techniques ($P = .001$) was maintained over time (Fig 1c). Among the procedures, cutting setons and fistulotomy/fistulectomy (with or without sphincter reconstruction) achieved the highest cure rates (Table I).

Complex fistulas

Additionally, for complex fistulas, a progressive increase in patient surgical procedures was registered during the study period; again, this was due to the progressive increase in both the number of recruiting centers and the patients treated in each center (Fig S2).

The adoption of a flap-construction, fistulotomy/fistulectomy and loose seton was the prevalent preference at the beginning of the study period and remained that at the end but with the rates almost halved (Table S3, Fig S2). The adoption of sphincter-cutting techniques decreased over the years (Tables S3 and S4, Fig 2a). Consequently, the analysis of fixed-base indexes derived from adoption rates highlights that «sphincter-sparing» techniques have been mildly preferred to «sphincter-cutting» techniques ($P < .0005$). Moreover, there was a statistically significant trend toward the use of technology-assisted procedures, rising from 2.6% in 2003 to 31.7% in 2017 ($P = .0001$) (Table S4, Fig 2c).

The overall healing rate for complex fistulas was 69.0%. Among the procedures, fistulotomy/fistulectomy, with or without sphincter reconstruction, achieved the highest cure rates (Table I), again with a statistically significant difference between sphincter-cutting (81.1%) and sphincter-sparing (61.4%) interventions ($P = .001$) (Fig 2b). A statistically significant difference in healing rates was found between techno-free and technology-assisted techniques (72.5% and 55.0%, respectively; $P = .001$) (Fig 2d).

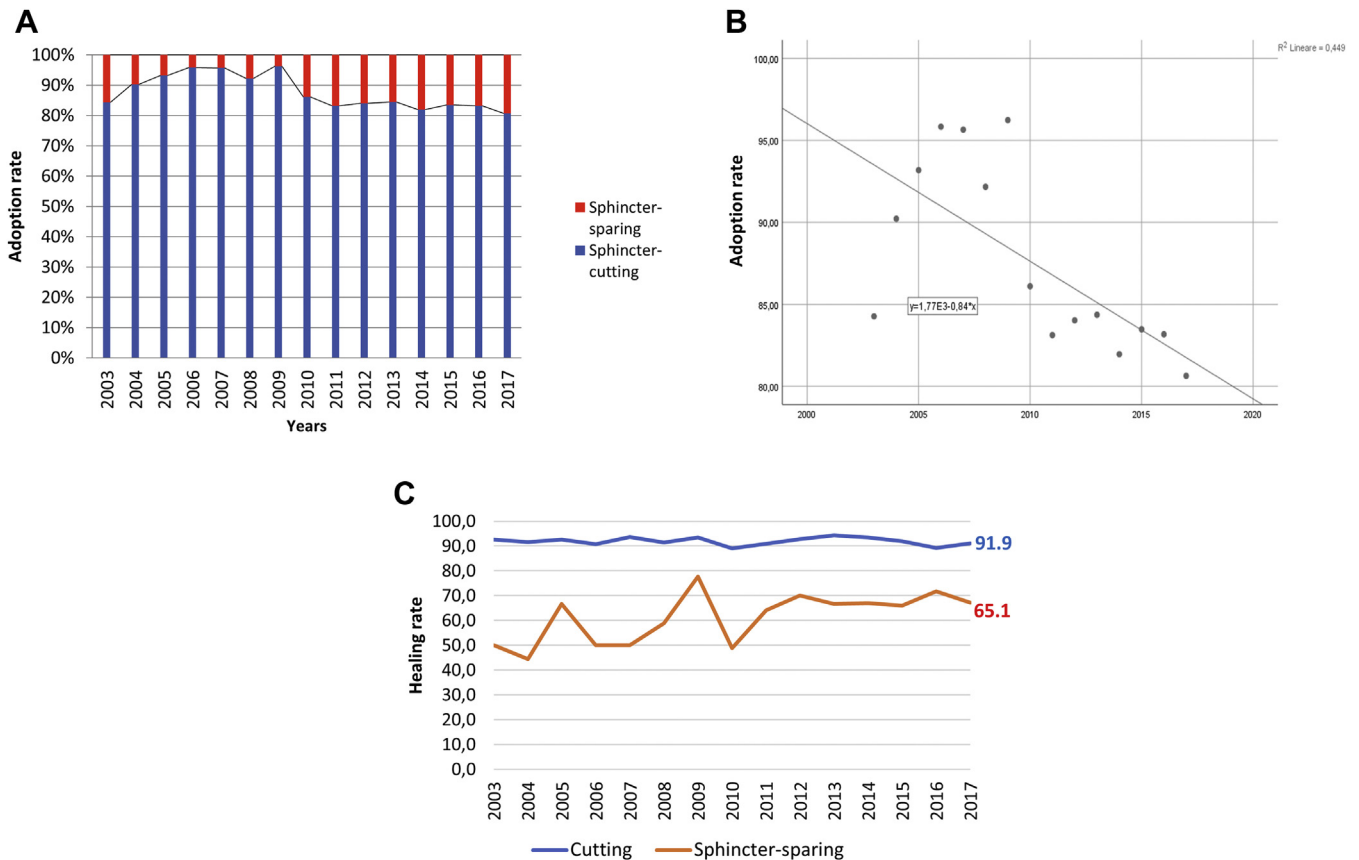


Fig. 1. Simple fistulas: (a) adoption rates per year of «sphincter-cutting» and «sphincter-sparing» techniques; (b) linear regression model showing a significant decrease in the adoption of «sphincter-cutting procedures» over the years (slope = -0.839 , $R^2 = 0.449$, $P = .006$); different healing rates of «sphincter-cutting» and «sphincter-sparing» techniques ($P = .001$).

Discussion

The main purpose of the FISSIT study in terms of presenting the trend of surgical treatment in Italy over the last 15 years was reached due to the accrual of the largest patient population followed for the longest period ever published, to our knowledge. Although this study provided a significant interpretative contribution, drawing definitive conclusions about the ideal surgical treatment of anal fistulas is still not possible today.

In fact, the dual aims of surgery, that is, fistula healing and full continence preservation, can be difficult to achieve in some conditions. The advantages and limitations of "traditional" surgical options should be regarded in relation not only to the potential for fistula healing but also to the impact on anorectal function and further patient quality of life (QoL). In the present study, although the information concerning fistula healing was perfectly accurate, the complete assessment of continence impairments was not possible; this represents the main limitation of the present study. We can borrow from Visscher et al's study that the risk of continence impairment increases with fistula complexity, especially after a lay-open fistulotomy, and this has an impact on the patient's QoL.¹⁸ On the other hand, it should be considered that even the persistence of the disease has a clear effect on QoL.¹⁹ For these reasons, new therapeutic approaches to the disease have been introduced during the last 15 to 20 years, thanks to the support of industry and technology, to both improve the healing rates and preserve anal continence.

In this study, both traditional and new surgical procedures were evaluated. It has been noted that, for both simple and complex

fistulas, the adoption rate of fistulotomy/fistulectomy decreased significantly over the study period, although it showed the best healing rates. It could be inferred that the surgeons' choice has been conditioned by the risk of further anal continence impairment more than by the potential of cure, particularly in complex fistulas. Therefore, some surgeons have appreciated the possibility of minimizing the risk of continence impairments (due to fistula lay-open) by immediate sphincter repair. This is confirmed by the significant increase in its adoption rate for all types of fistula. On the other hand, the availability of new sphincter-sparing procedures (some of them technology-assisted) might have encouraged attempts to change the approach. However, this had a minimal role in simple fistulas, where flap construction was progressively reduced (in up to 4.1% of patients in 2017), and only loose setons showed increased adoption (in up to 11.4% of patients in 2017). On the other hand, the use of technology-assisted procedures accounted for a cumulative adoption rate of less than 5% of patients. More frequent was the adoption of sphincter-saving operations in complex fistulas, including flaps and loose setons (but with a downward slope compared with that in the past, up to 19.1% and 9.9%, respectively, in 2017) and technology-assisted procedures (almost 30% in 2017).

The assessment of healing rates obtained by different procedures showed that in both simple and complex fistulas, traditional surgical techniques requiring fistulotomy/fistulectomy achieved the highest cure rates; these data are consistent with those in the available literature. It must be emphasized that, especially in complex fistulas, the healing rate of sphincter-cutting procedures was approximately 80%, which is probably slightly inferior to the expected rate. Among the sphincter-sparing

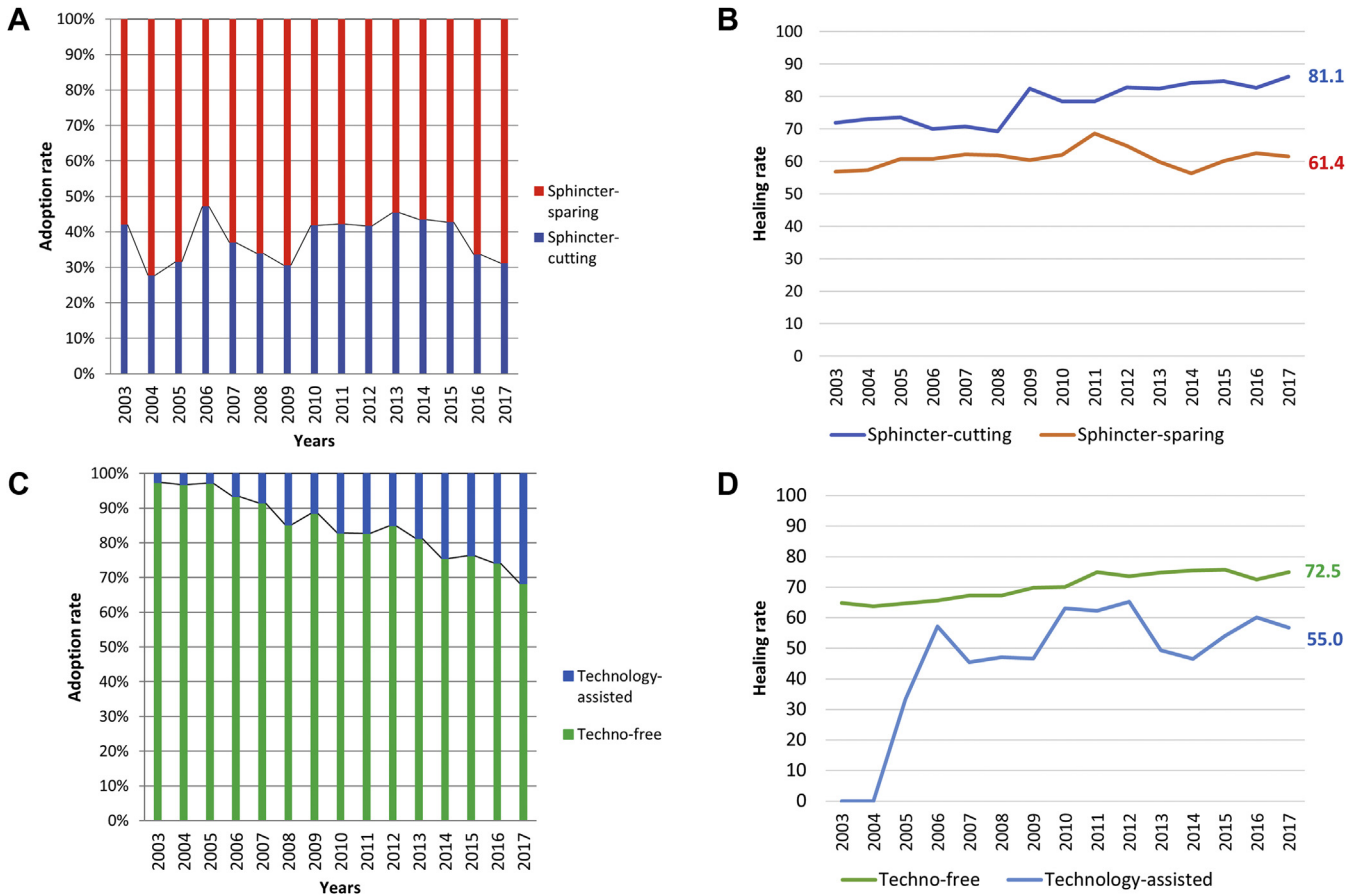


Fig. 2. Complex fistulas: (a) adoption rates per year of «sphincter-cutting» and «sphincter-sparing» techniques; (b) different healing rates of «sphincter-cutting» and «sphincter-sparing» techniques ($P = .001$); (c) the adoption rates of «techno-free» and «technology-assisted» procedures significantly changed over the years ($P = .0001$); (d) different healing rates of «techno-free» and «technology-assisted» procedures ($P = .001$).

techniques, techno-free surgical procedures, especially flap and LIFT, have achieved the best results. This study confirms what emerged in a brilliant study by Sugrue et al: patients treated by flaps or LIFT were less likely to have a recurrence than patients treated by glues or plugs.¹⁴ The researchers found that the cure rate had increased over the years, with a return to the use of

techno-free procedures. In the FISSIT study, we observed that the overall healing rate remained stable over the study period: approximately 1,000 patients were treated with endorectal flaps, with a healing rate of 68.9%. For this reason, given the good sample size, we can reasonably confirm that this "traditional" sphincter-saving therapy could cure fistulas in two-thirds of

Procedure	USA 2016*		GERMANY 2017**		GB 2018***		ITALY 2020*	
Fistulotomy	● (in simple fistula)	1B	● ●	2b	●	III-C	● ● (in simple fistula)	1B
Cutting setons	●	2B	●	2a	●	III-B	ND	ND
Flap	●	1B	●	1b	●	III-B	●	1B
LIFT	●	1B	●	1b	●	III-B	●	1B
Plugs	● ●	2B	● ●	1b	● ●	I-C	● ●	2B
Glues	● ●	2B	●	1b	● ●	I-C	● ●	2B/2C
VAAFT	ND	ND	●	5	?	II/III-C	●	2C
Laser	ND	ND	?	?	?	II/III-C	●	2C

Fig. 3. Surgical procedures: guideline statements with grade of recommendation and/or levels of evidence. * = GRADE system-grading recommendations²²; ** = Oxford Centre for evidence-based-medicine-levels of evidence²³; *** = NICE/SIGN recommendation or Rapid Technology Appraisal²⁴; ND = not discussed. Symbols: green = recommended; yellow = debated, no full agreement; red = not recommended.

patients. Similar results emerged in 290 patients treated by LIFT, where a 71.0% cure rate was achieved. These data approximately coincide with those reported by a recent meta-analysis of these above-mentioned procedures.²⁰ On the other hand, technology-assisted procedures provided significantly lower cure rates than techno-free procedures, particularly when used in the most appropriate field of application, that is, complex fistulas.

Data from this study have raised some urgent questions. The first addresses the role played by patients' opinions on multiple aspects of surgical management of anal fistulas: a study by Ellis clearly showed that the majority of patients selected a sphincter-sparing procedure when they were faced with the possibility of choosing between various therapeutic scenarios that considered both the success rate and the risk of postoperative incontinence.²¹ Consequently, other "ethical" aspects could involve the adequacy of the proposed treatment, which should concern not only fistula healing but also functional sequelae. This topic will be specifically addressed in an ongoing study. Moreover, adequate assessment of the cost/efficacy balance should primarily concern the decision-making process for treatment. In this field, of course, the new, techno-assisted options could contribute in some regards, especially in preserving sphincter integrity; however, their exaggerated and non-justified use should be avoided. These considerations should take place in the creation of future general guidelines for clinical practice and have already produced important changes in the available documents drawn up by prominent scientific societies (Fig 3).^{4,15–17} Data from the present study seem to demonstrate good adherence to the above-mentioned guidelines, mainly concerning the use of fistulotomy in simple fistulas; on the other hand, approximately one-third of FISSIT study patients with complex fistulas have been treated with this sphincter-cutting procedure. In accordance with the guidelines, the use of "cutting setons" has been reduced in Italy over time, especially for complex fistulas; however, approximately 10% of patients with simple fistulas have been treated in this way even in the last years of this study. In the guideline documents, the 2 techniques with the highest grade of recommendation are the flap and the LIFT; from the analysis of our study, an increasing (even if relatively poor) adoption of LIFT emerged, while the flap tended to decrease. One possible reason could be that, sometimes, new technologic procedures may seem simpler and therefore more attractive, while the flap is technically demanding.

Finally, a word of caution is expressed by the published guidelines concerning the newest and most technologic procedures due to higher costs and the relatively low success rate. In contrast, from our data, it seems that the adoption of these techniques has progressively increased; to explain this apparent contrast, it is necessary to consider that Italy has always had a pioneering and widespread role in these techniques and that some of them have been developed here.^{7–11} For this reason, we believe that it would be especially useful to repeat our study in other countries to evaluate the global performance of the newest therapeutic options.

Some additional limitations of this study should be considered. The retrospective and observational nature of the present investigation may have introduced an unavoidable selection bias, even if the high number of patients and centers included should have reduced it. Moreover, a detailed analysis of the recurrence time, the mean number of operations for simple and complex fistulas and the outcome of reoperations was not carried out.

In conclusion, surgical treatment of anal fistulas in Italy has changed over the last 15 years, especially for complex fistulas where the use of sphincter-sparing techniques supported by technology or industry has progressively increased. Despite this fact, the overall cure rate has remained stable; unfortunately, the most innovative procedures have achieved a lower success rate.

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Conflict of interest/Disclosure

None of the authors have any conflicts of interest to disclose.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.surg.2021.02.055>.

References

1. Westerterp M, Volkers NA, Poolman RW, van Tets WF. Anal fistulotomy between Skylla and Charybdis. *Colorectal Dis.* 2003;5:549–551.
2. Göttgens KWA, Janssen PT, Heemskerk J, et al. Long-term outcome of low perianal fistulas treated by fistulotomy: A multicenter study. *Int J Colorectal Dis.* 2015;30:213–219.
3. Tozer P, Sala S, Ciandi V, et al. Fistulotomy in the tertiary setting can achieve high rates of fistula cure with an acceptable risk of deterioration in continence. *J Gastrointest Surg.* 2013;17:1960–1965.
4. Vogel JD, Johnson EK, Morris AM, et al. Clinical practice guideline for the management of anorectal abscess, fistula-in-ano, and rectovaginal fistula. *Dis Colon Rectum.* 2016;59:1117–1133.
5. Soltani A, Kaiser AM. Endorectal advancement flap for cryptoglandular or Crohn's fistula-in-ano. *Dis Colon Rectum.* 2010;5:486–495.
6. Göttgens KW, Smeets RR, Stassen LPS, Beets G, Breukink SO. Systematic review and meta-analysis of surgical interventions for high cryptoglandular perianal fistula. *Int J Colorectal Dis.* 2015;30:583–593.
7. Altomare DF, Greco VJ, Tricomi N, et al. Seton or glue for trans-sphincteric anal fistulae: A prospective randomized crossover clinical trial. *Colorectal Dis.* 2011;13:82–86.
8. Meinerio P, Mori L. Video-assisted anal fistula treatment (VAAFT): A novel sphincter-saving procedure for treating complex anal fistulas. *Tech Coloproctol.* 2011;15:417–422.
9. Giamundo P, Geraci M, Tibaldi L, Valente M. Closure of fistula-in-ano with laser-FiLaC™: An effective novel sphincter-saving procedure for complex disease. *Colorectal Dis.* 2014;16:110–115.
10. Ratto C, Litta F, Donisi L, Parello A. Prospective evaluation of a new device for the treatment of anal fistulas. *World J Gastroenterol.* 2016;22:6936–6943.
11. Fabiani B, Menconi C, Martellucci J, Giani I, Toniolo G, Naldini G. Permacol™ collagen paste injection for the treatment of complex anal fistula: 1-year follow-up. *Tech Coloproctol.* 2017;21:211–215.
12. Wallin UG, Mellgren AF, Madoff RD, Goldberg SM. Does ligation of the intersphincteric fistula tract raise the bar in fistula surgery? *Dis Colon Rectum.* 2012;55:1173–1178.
13. Sileri P, Cadeddu F, D'Ugo S, Franceschilli L, et al. Surgery for fistula-in-ano in a specialist colorectal unit: A critical appraisal. *BMC Gastroenterol.* 2011;11:120.
14. Sugrue J, Mantilla N, Abcarian A, et al. Sphincter-sparing anal fistula repair: Are we getting better? *Dis Colon Rectum.* 2017;60:1071–1077.
15. Williams G, Williams A, Tozer P, Phillips R, Ahmad A, Jayne D, Maxwell-Armstrong C. The treatment of anal fistula: Second ACPGBI Position Statement – 2018. *Colorectal Dis.* 2018;20(Suppl 3):5–31.

16. Amato A, Bottini C, De Nardi P, et al. Evaluation and management of perianal abscess and anal fistula: SICCR position statement. *Tech Coloproctol.* 2020;24:127–143.
17. Ommer A, Herold A, Berg E, et al. German S3 guidelines: Anal abscess and fistula (second revised version). *Langenbecks Arch Surg.* 2017;402:191–201.
18. Visscher AP, Schuur D, Roos R, Van der Mijnsbrugge GJH, Meijerink WJHJ, Felt-Bersma RJF. Long-term follow-up after surgery for simple and complex cryptoglandular fistulas: Fecal incontinence and impact on quality of life. *Dis Colon Rectum.* 2015;58:533–539.
19. Owen HA, Buchanan GN, Schizas A, Cohen R, Williams AB. Quality of life with anal fistula. *Ann R Coll Surg Engl.* 2016;98:334–338.
20. Stellingwerf ME, van Praag EM, Tozer PJ, Bemelman WA, Buskens CJ. Systematic review and meta-analysis of endorectal advancement flap and ligation of the intersphincteric fistula tract for cryptoglandular and Crohn's high perianal fistulas. *BJs Open.* 2019;3:231–241.
21. Ellis CN. Sphincter-preserving fistula management: What patients want. *Dis Colon Rectum.* 2010;53:1355–1652.
22. Guyatt G, Gutterman D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an american college of chest physicians task force. *Chest.* 2006;129:174–181.
23. CEBM (Centre for Evidence-Based Medicine), Oxford Centre for Evidence-based Medicine—Levels of Evidence (March 2009); 2009, Available from: <http://www.cebm.net/index.aspx?o=1025>, Accessed January 11, 2021.
24. Eccles M, Mason J. How to develop cost-conscious guidelines. *Health Technol Assess.* 2001;5:1–69.