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Validation of a novel imaging-guided and anatomy-based classification system for anorectal fistulas: a retrospective clinical evaluation study

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Purpose: This study was conducted to evaluate the validity of a new imaging-guided, anatomy-based classification of anorectal fistulas in defining disease severity and predicting surgical outcomes.

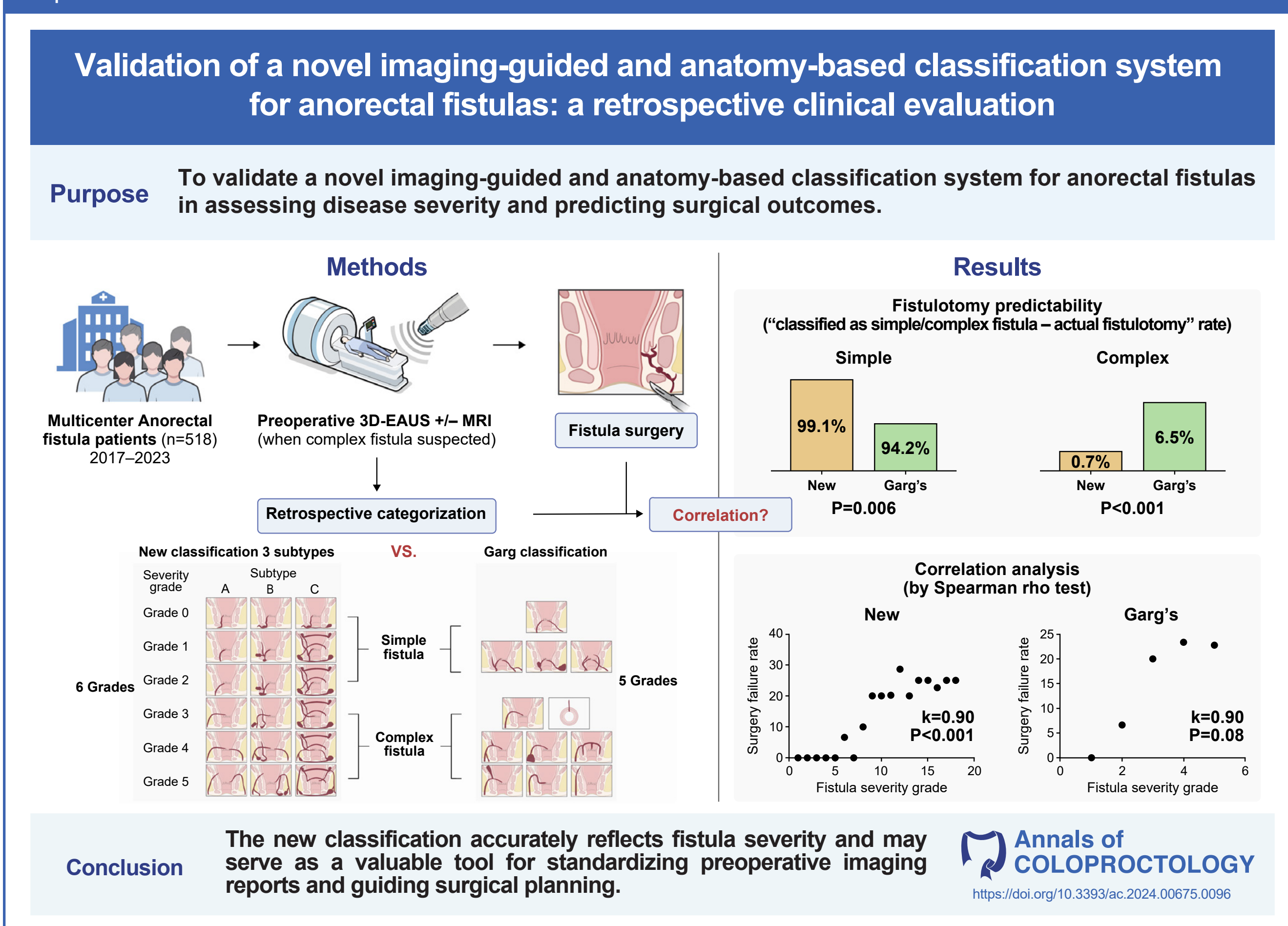
Methods: This multicenter, retrospective cohort study analyzed data from patients with perianal fistulas who underwent surgery between 2017 and 2023. All patients underwent preoperative 3-dimensional endoanal ultrasound, with adjunctive magnetic resonance imaging performed if ultrasound indicated a complex fistula. Imaging examinations were retrospectively evaluated to categorize fistulas according to the Garg classification and the newly proposed classification system. The new classification included 6 severity grades based on the characteristics of the primary tract: submucosal, intersphincteric, low transsphincteric, high transsphincteric, multiple, and suprasphincteric/extrasphincteric. Each grade was further subdivided into 3 subtypes (A, B, C) based on the extension of secondary tracts.

Results: When compared with the new classification, the Garg classification demonstrated a slightly lower ability to predict the feasibility of fistulotomy in simple fistulas (94.2% vs 99.1%; Fisher exact test, $P=0.006$). A strong positive correlation was found between the surgery failure rate and the severity grade of the new classification (Spearman rho, 0.90; $P<0.001$), whereas the Garg classification showed a nonsignificant positive correlation with surgical failure rate (Spearman rho, 0.90; $P=0.08$).

Conclusion: The new imaging-guided, anatomy-based classification of anorectal fistulas demonstrates high accuracy in defining disease severity. It represents a valuable tool for preoperative grading of anal fistulas, standardizing the reporting of diagnostic imaging, and improving the communication of findings among healthcare professionals.

Keywords: Anal fistula; Anal fistula classification; Fistulotomy; Sphincter-saving procedure; Magnetic resonance imaging

Graphical abstract



INTRODUCTION

Anorectal fistulas, particularly anorectocutaneous fistulas, are characterized by an internal anal or rectal opening, a perineal external orifice, and a primary tract that connects these 2 openings. Additionally, there may be secondary tracts, also known as secondary extensions, which branch off from the primary tract and extend into the perianal spaces as fistulous branches or fluid collections [1–4].

These anatomical characteristics can be accurately evaluated preoperatively using imaging diagnostic techniques such as 3-dimensional endoanal ultrasound (3D-EAUS) [5–7] or magnetic resonance imaging (MRI) [8]. These modalities provide a precise definition of the extent of perianal sepsis, aiding surgeons in selecting the most appropriate treatment strategy [9].

The severity of fistula-related disease is influenced by several anatomical factors, including the relationship between the primary tract and the anal sphincters, the number of primary tracts, and the presence and extent of secondary tracts. However, current classification systems for fistulas do not adequately consider these critical anatomical aspects of perianal sepsis. This oversight leads to an incomplete evaluation of disease severity and the use of vague terminology, which often results in confusion, especially between radiologists and surgeons, when classifying fistulas. For example, the Parks classification [10], which relies solely on clinical observations, overlooks important factors such as the height of transsphincteric primary tracts and the existence of secondary extensions. Consequently, it demonstrates a weak correlation with the actual severity of the condition [11]. Similarly, the St. James's University Hospital classification [12], although it incorporates MRI evaluations, suffers from the same deficiencies as the Parks classification [11].

The Standard Practice Task Force classification [13], initially linking disease severity to the extent of external sphincter involvement, effectively identifies simple fistulas that are appropriate for fistulotomy. However, it seems to lack precision in predicting complex fistulas [11] and fails to include results from diagnostic imaging evaluations.

Recently, Garg [14] proposed a new MRI-based classification for fistulas. Although this classification has proven to be more accurate in defining disease severity than all previous systems, it relies solely on MRI findings and lacks a detailed topographic mapping of sepsis anatomy. This limitation could result in potential misunderstandings, especially when categorizing fistulas with distant secondary extensions.

In light of these considerations, the aim of this study was to evaluate the validity of a new imaging-guided, anatomy-based classification system for anorectal fistulas. Specifically, we assessed its effectiveness in grading disease severity and predicting surgical outcomes, comparing it with the Garg classification.

METHODS

Ethics statement

The study's protocol and methodology were approved by the Institutional Board of the Italian Unitary Society of Colon-Proctology (No. 0003/2023). Written informed consent was secured from all participants for both the surgical procedures and the use of their personal data for scientific research, which included collection, processing, storage, and utilization. The study was conducted in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for cohort studies [15] and adhered to the principles of the Declaration of Helsinki.

Study design

This research was a multicenter, retrospective cohort study that analyzed data from patients with perianal fistulas who underwent surgical treatment between 2017 and 2023. The study involved 6 European colorectal centers: "A. Cardarelli" Hospital, Naples, Italy; "Madonna del Buon Consiglio Fatebenefratelli" Hospital, Naples, Italy; University of Campania "Luigi Vanvitelli," Naples, Italy; the Department of Surgery, Pelvic Floor Center, AUSL-IRCCS Reggio Emilia, Reggio Emilia, Italy; Academy of Applied Medical and Social Sciences (AMiSNS), Elbląg, Poland; and the Unit of Proctology and Pelvic Surgery, "Città di Pavia" Clinic, Pavia, Italy.

Patient selection

All patients referred to the participating centers for perianal sepsis treatment during the study period were evaluated for eligibility to participate in this study. Before undergoing surgery, each patient received clinical and instrumental assessments, which included rectosigmoidoscopy, 3D-EAUS, and MRI in selected cases.

Based on this diagnostic work-up, the study included patients who met the following criteria: age over 18 years, availability for preoperative diagnostic imaging evaluation, confirmed diagnosis of anorectal fistulas based on imaging investigations, fitness for surgery, and at least a 1-year clinical follow-up after surgery. The exclusion criteria were as follows: anorectal cancer, prior radiation therapy, isolated perianal abscess, anal stenosis that precluded the execution of 3D-EAUS, absolute contraindications to MRI, and unavailability for the scheduled clinical follow-up.

Clinical examination

The clinical examination included a comprehensive patient history alongside an assessment of the frequency and severity of fecal incontinence, utilizing both the Cleveland Clinic Incontinence Score (CCIS) [16] and the Vaizey score [17]. A thorough general and anoperineal physical examination was performed, which included inspection and palpation of the perineal area and a digital anorectal examination to check for swellings, tenderness, and potential external and internal openings. To prevent the formation of additional tracts, fistula probes were not employed during the examination. After the physical assessment, anorectosigmoidoscopy was carried out to rule out any malignancies.

3D-EAUS

The first-line diagnostic tool for all patients was 3D-EAUS [9]. The endosonographic evaluation was conducted with patients in the left-lateral position using the anorectal transducer (BK Medical 2052, BK Medical). This transducer is equipped with a 360° rotating head and operates within a frequency range of 6 to 16 MHz. After applying lubricant to the probe, it was inserted through the anus into the lower rectum. The transducer head was then automatically advanced in a caudal direction to the anal verge, generating 3D images of the distal rectum and anus, which were displayed as a cube. Fistulas and abscesses were visible as hypoechoic tracts or masses, occasionally containing focal hyperechoic areas indicative of gas. During hydrogen peroxide (H_2O_2)-enhanced 3D-EAUS, the introduction of H_2O_2 produced small air bubbles that improved visualization. Internal openings were visible as hyperechoic breaches, and fistula tracts appeared as hyperechoic pathways.

Magnetic resonance imaging

MRI was performed as an adjunctive diagnostic examination in cases where 3D-EAUS indicated high primary tracts and/or suspected secondary extensions [9]. All MRI studies were conducted using a 1.5-T closed magnet system (Signa Explorer, GE Healthcare) equipped with a body phased-array receiver coil. The protocol began with initial localizer images obtained in 3 planes, followed by sequences that encompassed the small pelvis, perineum, and gluteal regions: axial TSE T1-weighted, axial TSE T2-weighted, and sagittal TSE T2-weighted. The sagittal sequence was crucial for assessing the orientation of the anal canal, which facilitated the accurate alignment of true axial and coronal images along the long axis of the anal canal. The imaging sequences included high-resolution T2-weighted fat-saturated images. Additionally, sagittal TSE T2-weighted fat-saturated sequences were acquired in some cases, depending on the location and tract of the fistula. The use of T2-weighted fat-saturated sequences largely eliminated the need for intravenous contrast agents, as active fistula tracts were naturally hyperintense. This approach enabled a detailed evaluation of the fistula anatomy [18, 19]. The entire examination typically required about 20 minutes to complete.

In a minority of cases, the MRI protocol included multiplanar T1-weighted fat-saturated sequences following the administration of a gadolinium-based intravenous contrast agent. This adjustment was made at the radiologist's discretion, based on real-time evaluation and specific diagnostic needs.

Surgical procedure

Surgery was performed under subarachnoid anesthesia with patients placed in the lithotomy position. When external orifices were suspected, Lockhart-Mummery fistula probes and H_2O_2 were utilized to delineate fistula tracts and pinpoint internal openings. The relationship of the primary tract to the anal sphincters was meticulously evaluated according to Parks classification, including the degree of external sphincter involvement.

The surgical approach was tailored to the fistula type: (1) submucosal fistulas, lay-open procedure; (2) intersphincteric fistulas, lay-open procedure with internal sphincterotomy; (3) low transsphincteric fistulas (involving less than one-third of the external sphincter), fistulotomy with internal and external sphincterotomy; and (4) high transsphincteric, suprasphincteric, and extrasphincteric fistulas (involving more than one-third of the external sphincter), sphincter-saving procedures. All secondary extensions, including abscesses and fistulous branches, were identified, drained, and dissected, and the affected perianal spaces were surgically opened.

Follow-up

All patients underwent clinical follow-up, which included physical examinations and evaluations of anal continence using the CCIS and Vaizey scores at postoperative 6 and 12 months. Surgical success was defined as complete healing of the anal wound without any residual tracts, external or internal openings, or perianal discharge. Surgical failure was defined as either incomplete healing of the anal fistula within postoperative 6 months, suggesting a persistent fistula, or the clinical recurrence of the fistula after the surgical wound had completely healed, occurring within postoperative 12 months, indicating a recurrent fistula [20].

Imaging analysis and fistula classifications

For the purpose of this study, all 3D-EAUS cubes and MRI examinations were evaluated retrospectively in consensus. The 3D-EAUS images were reviewed jointly by a surgeon and a radiologist, while the MRI studies were assessed by 2 radiologists, each with over 10 years of experience in pelvic imaging. Fistulas were classified as non-anorectal if the imaging showed no morphological connection to the anorectal musculature and subepithelial tissue. The anatomical characteristics of the fistulas were examined as follows, based on previous studies [5–9], a previously published MRI template [21], and a recently established expert consensus [22]:

(1) Internal orifice: The number and location on a clock-face dial, with the patient in the lithotomy position.
(2) Primary tract: The number, location on a clock-face dial, and classification according to the Parks classification, based on the relationship with the anal sphincters (intersphincteric, transsphincteric, suprasphincteric, or extrasphincteric) [10]. For transsphincteric fistulas, the position of the primary tract relative to the external sphincter was evaluated, distinguishing between low and high transsphincteric fistulas. Low transsphincteric fistulas involve less than one-third of the external anal sphincter, whereas high transsphincteric fistulas involve more than one-third [13].
(3) Possible secondary extensions: The number and location of branches and/or abscesses in relation to perianal spaces, which include the submucosal, superficial/perianal, postanal, intersphincteric, ischioanal, supraelevator, retrorectal, and intramural rectal spaces. The intramural rectal space is defined as the area between the rectal muscular layers, continuing into the space between the conjoint longitudinal muscle and the internal anal sphincter. The "outersphincteric" space is defined as the area between the external anal sphincter and the surrounding lateral fascia [23]. A horseshoe tract is defined as a secondary extension that involves at least half of the anal circumference, whether anteriorly, posteriorly, or laterally [22].

Based on these imaging analyses, all included examinations were evaluated according to the described anatomical characteristics of the fistulas and categorized using a new classification system (Table 1, Fig. 1). This system identifies 6 main severity grades, ranging from 0 to 5, which reflect the progression of the primary tract through various anatomical zones: submucosal, intersphincteric, low transsphincteric, high transsphincteric, multiple (including at least 1 transsphincteric tract), and suprasphincteric/extrasphincteric. Each grade is further divided into 3 subtypes (A, B, C) to denote increasing severity based on the presence and location of secondary extensions, resulting in a total of 18 severity levels. Specifically, subtype A includes an isolated primary tract; subtype B includes secondary extensions adjacent to the primary tract, located in the submucosal, superficial, postanal, ischioanal, or intersphincteric spaces; and subtype C includes secondary extensions that are more distant from the primary tract, located in the outersphincteric space, supraelevator space, retrorectal space, intrarectal space, or involving horseshoe abscesses.

According to this classification, fistulas classified as grades 0 to 2 were categorized as simple and amenable to fistulotomy, whereas those classified as grades 3 to 5 were categorized as complex, not amenable to fistulotomy, and requiring sphincter-saving procedures. Additionally, all fistulas were retrospectively categorized according to the Garg classification (Table 2) [14].

Outcome measures

The primary objective of this study was to assess the predictive accuracy of a newly proposed classification system for determining the feasibility of safe fistulotomy, in comparison to the Garg

Table 1. Imaging-guided and anatomy-based classification of anorectal fistulas

Classification	Fistula typology	Subtype		
		A	B	C
Grade 0	Submucosal	Isolated primary tract	Secondary extensions adjacent to the primary tract[a]	Secondary extensions distant from the primary tract[b]
Grade 1	Intersphincteric	Isolated primary tract	Secondary extensions adjacent to the primary tract[a]	Secondary extensions distant from the primary tract[b]
Grade 2	Low transsphincteric	Isolated primary tract	Secondary extensions adjacent to the primary tract[a]	Secondary extensions distant from the primary tract[b]
Grade 3	High transsphincteric, anterior in women, anal incontinence	Isolated primary tract	Secondary extensions adjacent to the primary tract[a]	Secondary extensions distant from the primary tract[b]
Grade 4	Multiple tracts (grade > 0) with at least 1 transsphincteric	Isolated primary tract	Secondary extensions adjacent to the primary tract[a]	Secondary extensions distant from the primary tract[b]
Grade 5	Suprasphincteric/extrasphincteric	Isolated primary tract	Secondary extensions adjacent to the primary tract[a]	Secondary extensions distant from the primary tract[b]

[a]In the submucosal, superficial perianal, postanal, ischioanal, and intersphincteric space. [b]In the outersphincteric, supraelevator, retrorectal, and intramural rectal space, and horseshoe abscesses.

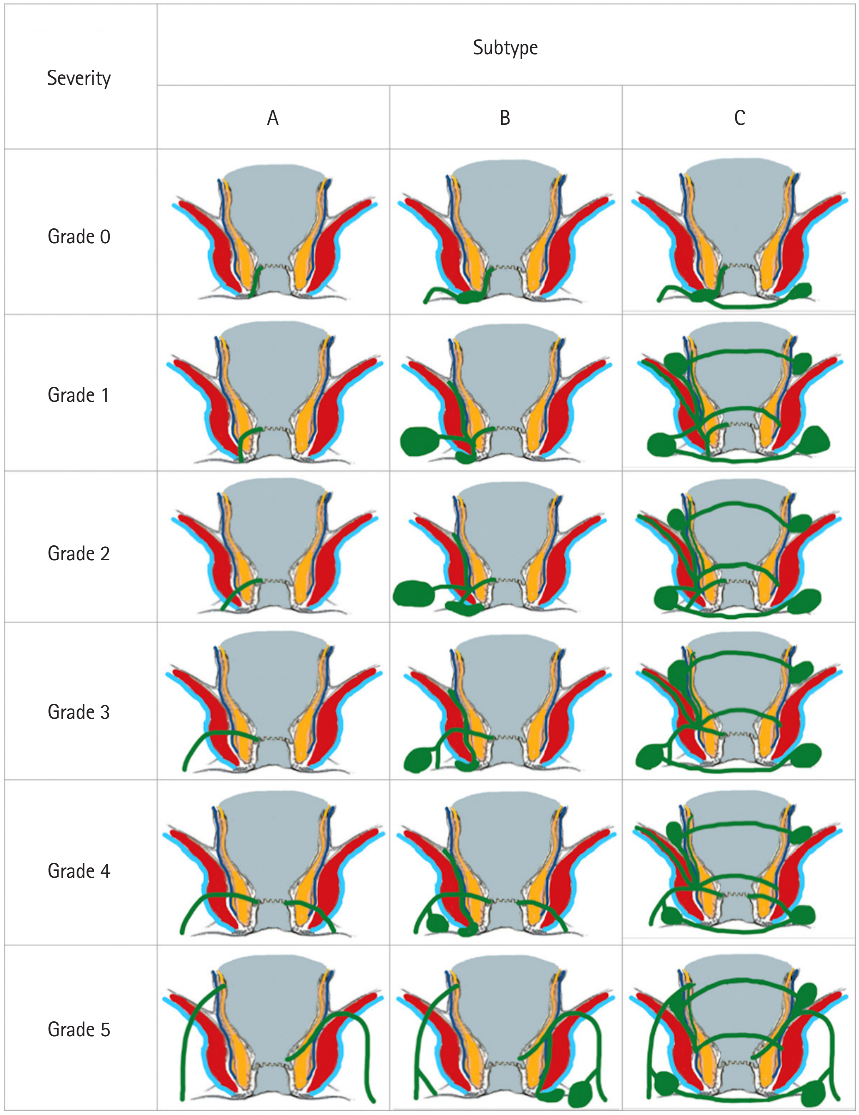


Fig. 1. Schematic diagram of fistula severity grades according to the new classification.

Table 2. Garg classification of anorectal fistulas

Classification	Fistula typology
Grade I	Low linear intersphincteric or transsphincteric
Grade II	Low or high intersphincteric or low transsphincteric with abscess, multiple or horseshoe abscess
Grade III	High linear transsphincteric or with associated comorbidities
Grade IV	High transsphincteric with abscess, multiple or horseshoe abscess
Grade V	Supraelevator, suprasphincteric, extrasphincteric

Adapted from Garg [14], available under the Creative Commons License.

classification. This was achieved by analyzing and comparing the prevalence of fistulotomies performed on fistulas deemed simple and complex by both classification systems, along with the corresponding continence scores at 12 months.

The secondary outcome focused on evaluating the predictive capability of 2 grading systems regarding surgical outcomes. This involved analyzing and comparing how well the severity grades assigned by each system correlated with the rates of surgical failure.

Sample size

A retrospective analysis of patients who underwent surgery for anal fistulas, classified as simple according to the Garg classification, showed a 94.2% prevalence of fistulotomy within this group. We hypothesized that using the new classification system could achieve a corresponding prevalence of 99.1%. Based on this hypothesis, we estimated that enrolling at least 500 patients would provide a statistical power of 99% to detect a 5% difference in the prevalence of fistulotomies between fistulas classified as simple by the Garg classification and those classified as simple by the new classification, with a significance level (α) of 0.05 (2-tailed).

Statistical analysis

Statistical analysis was performed using Microsoft Excel 2011 (Microsoft Corp) and InStat GraphPad Prism 9 (GraphPad Software). Categorical data were presented as raw numbers and percentages in parentheses, or vice versa, depending on the data distribution. Continuous data were reported as medians with ranges in parentheses.

Differences between results were analyzed using the Fisher exact test for categorical data or the Mann-Whitney U-test for continuous data, as appropriate. Correlations between variables were assessed using the Spearman rank correlation coefficient (rho). The concordance between imaging investigations and surgical findings was evaluated using the simple kappa coefficient (κ). A P-value of less than 0.05 was considered statistically significant.

RESULTS

Study population

During the study period, 625 patients referred for treatment of perianal sepsis were evaluated for enrollment. Of these, 85 patients (13.6%) were excluded due to reasons including isolated abscesses, prior radiation therapy, cancer, contraindications to imaging investigations, or the absence of imaging confirmation of an anorectal origin of the sepsis. Among the remaining 540 patients, 22 (4.1%) were lost to follow-up. Therefore, 518 patients (250 men, 268 women; median age, 49 years [range, 18–72 years]) met the selection criteria and were included in the study (Fig. 2).

Surgery

Based on intraoperative findings, 500 out of 518 patients (96.5%) presented with a single primary tract, while 18 patients (3.5%) had multiple primary tracts, totaling 536 fistulous primary tracts. Of the 500 single primary tracts, 221 (44.2%) were classified as simple and treated with fistulotomy. These included 41 submucosal fistulas (18.6%), 82 intersphincteric fistulas (37.1%), and 98 low transsphincteric fistulas (44.3%). The remaining 279 (55.8%) were categorized as complex and required sphincter-saving procedures. These procedures were applied to 216 high transsphincteric fistulas or those associated with Crohn disease (77.4%), 36 suprasphincteric fistulas (12.9%), and 2 extrasphincteric fistulas (0.7%). Additionally, 20 low anterior transsphincteric fistulas (7.2%) in female patients and 5 low transsphincteric fistulas (1.8%) in patients with anal sphincter lesions and impaired fecal continence were treated with sphincter-saving procedures. Among these 254 cases, the most commonly performed techniques were the endoanal advancement flap in 120 patients (47.2%), ligation of the intersphincteric fistula tract (LIFT) in 76 patients (29.9%), and fistula-tract laser closure (FiLaC) in 46 patients (18.1%). These procedures often followed the placement of a draining seton, which was used in 60% of cases. Twelve patients (4.7%) achieved healing solely with the use of a loose seton. For very high fistulous tracts, such as suprasphincteric and extrasphincteric fistulas, where flap or LIFT procedures were not feasible, treatment involved the placement of a draining seton followed by curettage of the fistulous tract and either cauterization or suturing of the internal opening.

In cases involving multiple primary tracts, 18 patients presented with 2 primary tracts extending into different quadrants of the anal circumference. This group comprised 6 patients with double high transsphincteric tracts, 10 with double low transsphincteric tracts, and 2 with 1 low transsphincteric tract and 1 intersphincteric tract. All patients underwent sphincter-saving treatments, which began with the insertion of a draining seton, followed by either an endoanal advancement flap or LIFT procedures.

Secondary extensions were identified intraoperatively in 115 out of 518 patients (22.2%). These extensions were located in various perianal spaces: the ischioanal space (27 of 115, 23.5%), intersphincteric space (26 of 115, 22.6%), perianal superficial space (9 of 115, 7.8%), postanal space (2 of 115, 1.7%), supraelevator space (30 of 115, 26.1%), outersphincteric space (5 of 115, 4.4%), and intramural rectal space (4 of 115, 3.5%). Horseshoe abscesses were present in 17 (14.8%), with associated secondary extensions found in the intersphincteric space (3 of 17, 17.6%), ischioanal space (9 of 17, 52.9%), and supraelevator space (5 of 17, 29.4%). In all cas-

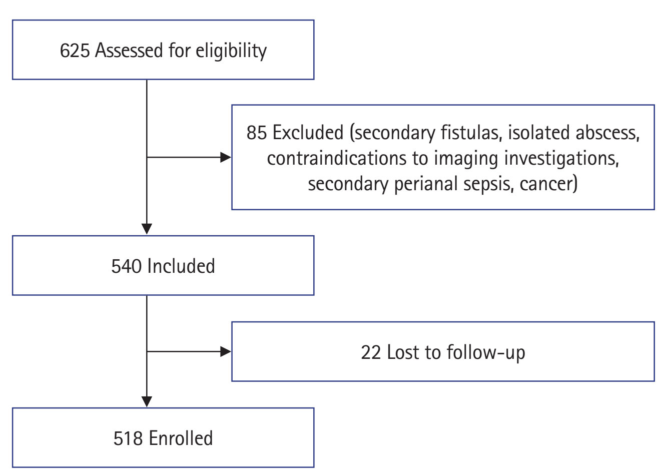


Fig. 2. Flowchart of patient selection.

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es, secondary extensions were managed by dissecting, opening, and draining the affected perianal spaces.

Agreement between imaging investigations and surgery

Almost perfect agreement (κ = 0.97) was observed between imaging investigations and surgical findings in defining the primary tracts of fistulas. Discrepancies occurred in only 4 cases, including 2 high transsphincteric fistulas that were classified as low during surgery and 2 low transsphincteric fistulas that were categorized as high during surgery. Perfect agreement (κ = 1) was achieved between imaging investigations and surgical findings in identifying the presence and location of secondary extensions.

Validity of the new classification

Based on imaging findings and in accordance with the new classification system, 518 fistulas were categorized into 6 grades: submucosal (grade 0), intersphincteric (grade 1), low transsphincteric (grade 2), high transsphincteric, anterior fistulas in women, or fistulas in patients with comorbidities (grade 3), multiple (grade 4), and suprasphincteric/extrasphincteric (grade 5). The distribution of these grades was as follows: grade 0 was found in 39 cases (7.5%), grade 1 in 84 (16.2%), grade 2 in 98 (18.9%), grade 3 in 241 (46.5%), grade 4 in 18 (3.5%), and grade 5 in 38 (7.3%) (Table 3, Figs. 3, 4).

In summary, the new classification system categorized 42.7% (221 of 518) of anorectal fistulas as simple and 57.3% (297 of 518) as complex. This system proved highly accurate in grading fistula severity, as evidenced by surgical outcomes. Specifically, fistulotomy was performed in only 0.7% (2 of 297) of the fistulas classified as complex by imaging diagnostics, according to the new classification, while 99.1% (219 of 221) of those classified as simple were successfully treated with fistulotomy. Notably, there was no significant change in the median CCIS at the 1-year follow-up (1 [range, 0–5] preoperatively vs. 1 [range, 0–5] postoperatively; Mann-Whitney U-test, $P = 0.48$).

Table 4 presents the 1-year surgical success and failure rates for each fistula grade according to the new classification, demonstrating its reliability in predicting surgical outcomes. A strong positive correlation was found between the surgery failure rate and the severity grade (Spearman rho, 0.90; $P < 0.001$; 95% confidence interval, 0.748–0.964) (Fig. 5).

According to the new classification, the 30 fistulas with secondary extensions into the supralevator space were distributed as follows: 10 (33.3%) in group 1C, 8 (26.7%) in group 2C, 10 (33.3%) in group 3C, and 2 (6.7%) in group 5C. The success rates for each group were 100%, 75%, 60%, and 50%, respectively, resulting in an overall success rate of 76.7% (Figs. 6, 7). Interestingly, in 2 cases (6.7%), the supralevator collection ruptured into the rectum, leading to the formation of a secondary rectal internal orifice.

Validity of the Garg classification

Based on imaging findings and according to the Garg classification, a total of 479 patients with anorectal fistulas were identified, as the 39 submucosal fistulas detected by 3D-EAUS were not included in this classification. The 479 fistulas were categorized as follows: grade I in 142 (29.6%), grade II in 30 (6.3%), grade III in 198 (41.3%), grade IV in 43 (9.0%), and grade V in 66 (13.8%) (Table 5).

In summary, the Garg classification categorized anorectal fistulas as simple in 35.9% (172 of 479) of cases and complex in 64.1% (307 of 479). This classification demonstrated high accuracy in grading fistula severity, as evidenced by its alignment with surgical outcomes. During surgery, fistulotomy was performed on 6.5% (20 of 307) of the fistulas deemed complex and on 94.2% (162 of 172) of those classified as simple according to the Garg classification. There was no significant change in the median CCIS at the 1-year follow-up, with scores remaining stable from preoperative

Table 3. Prevalence of fistula severity grades in the study population according to the new classification (n = 518)

Classification	No. of patients (%)
Grade 0	39 (7.5)
0A	31/39
0B	8/39
0C	0/39
Grade 1	84 (16.2)
1A	64/84
1B	5/84
1C	15/84
Grade 2	98 (18.9)
2A	78/98
2B	10/98
2C	10/98
Grade 3	241 (46.5)
3A	198/241
3B	29/241
3C	14/241
Grade 4	18 (3.5)
4A	10/18
4B	4/18
4C	4/18
Grade 5	38 (7.3)
5A	22/38
5B	8/38
5C	8/38

Percentages may not total 100 due to rounding.

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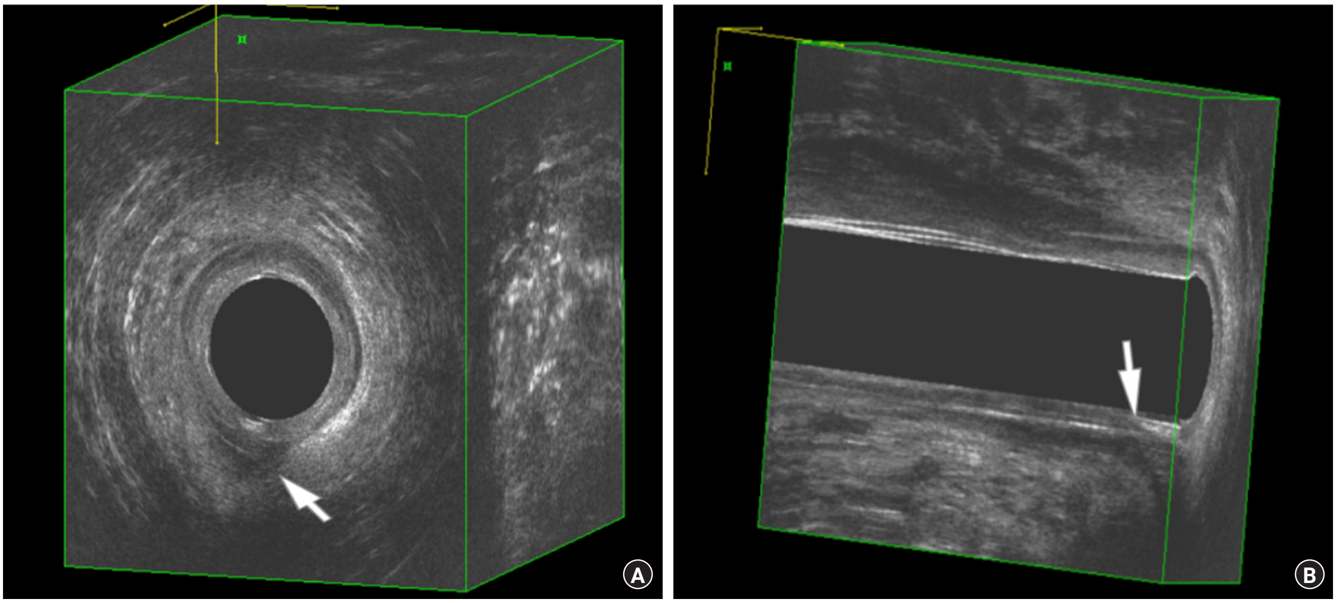

Fig. 3. The 3-dimensional endoanal ultrasound images of a posterior submucosal fistula (arrows). (A) Axial plane. (B) Sagittal plane. Submucosal fistulas were categorized exclusively by the new classification.

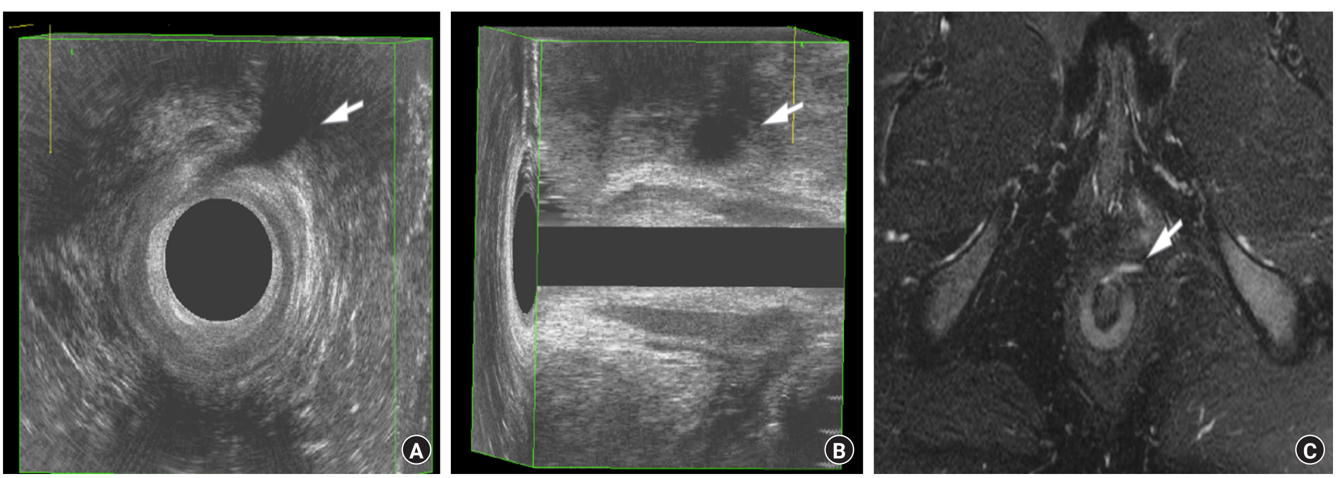

Fig. 4. The imaging findings of a high anterior transsphincteric fistula (arrows). The 3-dimensional endoanal ultrasound images in (A) the axial plane and (B) the sagittal plane. (C) The magnetic resonance imaging T2-weighted fat-saturated high-resolution sequence in the axial plane. This fistula was categorized as grade 3A by the new classification.

to postoperative assessments (1 [range, 0–5] preoperatively vs. 1 [range, 0–5] postoperatively; Mann-Whitney U-test, P = 0.48).

When compared with the new classification, the Garg classification was significantly less accurate in predicting the feasibility of fistulotomy for both simple (94.2% vs. 99.1%; Fisher exact test, P = 0.006) and complex fistulas (6.5% vs. 0.7%; Fisher exact test, P < 0.001).

If submucosal fistulas were categorized with intersphincteric fistulas in the Garg classification, the rate of fistulotomies performed on fistulas deemed simple by the Garg classification would be 95.3% (201 of 211). This rate is significantly lower than the 99.1% observed under the new classification (Fisher exact test, P = 0.010).

Table 5 displays the 1-year surgical success and failure rates for each fistula grade according to the Garg classification. A nonsignificant positive correlation was observed between the surgery failure rate and the severity grade (Spearman rho, 0.90; P = 0.080) (Fig. 8).

Table 4. Success and failure rates in each fistula severity grade according to the new classification (n = 518)

Classification	No. of cases (%)	
	Success	Failure
Grade 0 (n = 39)		
0A (n = 31)	31 (100)	0 (0)
0B (n = 8)	8 (100)	0 (0)
0C (n = 0)	0 (0)	0 (0)
Grade 1 (n = 84)		
1A (n = 64)	64 (100)	0 (0)
1B (n = 5)	5 (100)	0 (0)
1C (n = 15)	14 (93.3)	1 (6.7)
Grade 2 (n = 98)		
2A (n = 78)	78 (100)	0 (0)
2B (n = 10)	9 (90.0)	1 (10.0)
2C (n = 10)	8 (80.0)	2 (20.0)
Grade 3 (n = 241)		
3A (n = 198)	158 (79.8)	40 (20.2)
3B (n = 29)	23 (79.3)	6 (20.7)
3C (n = 14)	10 (71.4)	4 (28.6)
Grade 4 (n = 18)		
4A (n = 10)	8 (80.0)	2 (20.0)
4B (n = 4)	3 (75.0)	1 (25.0)
4C (n = 4)	3 (75.0)	1 (25.0)
Grade 5 (n = 38)		
5A (n = 22)	17 (77.3)	5 (22.7)
5B (n = 8)	6 (75.0)	2 (25.0)
5C (n = 8)	6 (75.0)	2 (25.0)

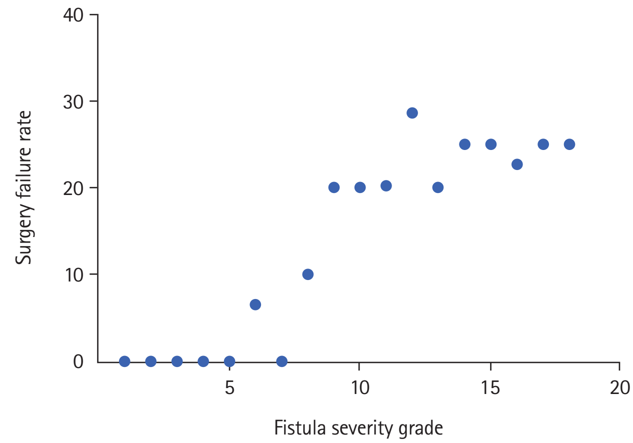

Fig. 5. The correlation between the surgery failure rate and severity grades in the new classification. A strong positive correlation was found between the surgery failure rate and severity grade (Spearman rho, 0.90; P < 0.001).

DISCUSSION

The results of this study indicate that both the proposed new classification and the Garg classification serve as effective tools for grading the severity of anorectal fistulas. Each scoring system demonstrates high accuracy in assessing the viability of a safe fistulotomy, clearly differentiating between fistulas suitable for a lay-open procedure and those that necessitate a sphincter-saving approach. Specifically, the new classification appears to be slightly more effective in predicting a safe fistulotomy and surgical outcomes. This may be attributed to its congruence with the typical anatomy of fistulas and its capacity to articulate the anatomical-topographic complexity of perianal sepsis, which may subsequently influence therapeutic strategies and surgical results.

Anorectal fistulas originate from a septic source, typically an anal or rectal orifice, and include a primary tract that connects the internal opening to the perineum, along with potential secondary extensions. These extensions can be additional tracts or abscesses that branch off from the primary tract and spread into the perianal spaces. The complexity of treatment and the prognosis worsen as the involvement of the anal sphincter by the primary tract increases and as the secondary tracts become more extensive and distant from the origin of sepsis. Furthermore, the presence of multiple detectable primary tracts can complicate surgical intervention and increase the risk of damage.

The new classification was developed with specific considerations to more accurately align with the anatomical structure of anorectal fistulas, as well as to encapsulate the severity of the condition and the complexity of its treatment. This classification comprises 6 grades, each determined by the height and number of primary tracts. These grades are further divided into 3 subtypes, which escalate in severity based on the presence and extent of secondary tracts.

In our opinion, this severity score for anorectal fistulas is straightforward and easy to remember. It aids in reducing confusion when interpreting radiological and clinical fistula topography, facilitating the standardization of radiological reports and enabling a more detailed categorization of specific fistula types. Notably, this includes those classified in the Garg classification as high intersphincteric fistulas and supraelevator fistulas.

Indeed, high intersphincteric fistulas are specifically defined by their anatomy, characterized by a primary tract that exclusively crosses the internal sphincter and a secondary tract that extends upward into the intersphincteric space [10, 23]. These fistulas can be treated effectively and safely using a lay-open procedure. This involves a limited internal sphincterotomy, extending up to the internal orifice, coupled with meticulous dissection and drainage of the proximal intersphincteric space.

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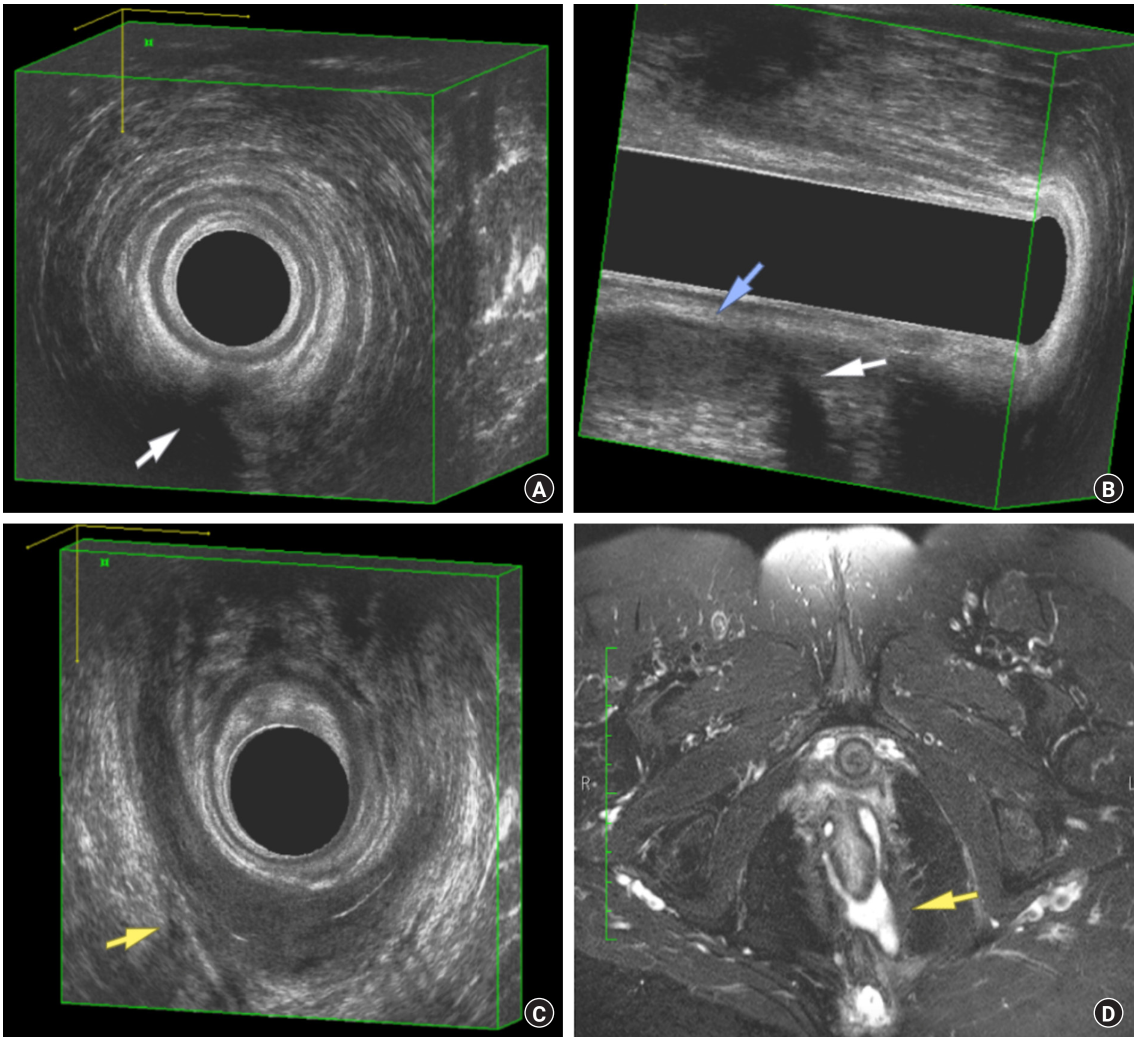

Fig. 6. The imaging findings of a posterior transsphincteric fistula (white arrows) with a secondary tract extending via the intersphincteric route (blue arrow) into the supraelevator space, forming a horseshoe abscess (yellow arrows). The 3-dimensional endoanal ultrasound images in (A) the axial plane and (B) the sagittal plane. (C) The axial 3-dimensional endoanal ultrasound image shows the posterior horseshoe abscess (yellow arrow) extending laterally in the supraelevator space. (D) The magnetic resonance imaging T2-weighted fat-saturated high-resolution sequence in the axial plane. This fistula was categorized as grade 3C by the new classification.

Similarly, "supraelevator fistulas" are accurately categorized in the new classification as intersphincteric, low transsphincteric, or high transsphincteric fistulas, each with a secondary tract that extends through the intersphincteric route into the supraelevator space. These fistulas present a diverse range of characteristics, making it challenging to classify them as a uniform group. The complexity of treatment and the severity of the disease largely depend on the anatomical features of the primary tract. In cases involving intersphincteric and low transsphincteric fistulas classified under this category, a lay-open technique can be employed. This method may include a limited internal and possibly external sphincterotomy extending to the internal orifice, coupled with the dissection and drainage of the supraelevator space through the intersphincteric route. This surgical approach effectively removes the source of the infection and creates an open space below that promotes ongoing drainage of any residual fluid collections. This, in turn, supports and hastens the healing process. Due to these characteristics, these fistulas are designated as simple fistulas in the new classification. The surgical success rate for these procedures is nearly 90%, with no significant impact on the postoperative anal continence score. High transsphincteric fistulas are managed with sphincter-saving procedures and drainage of the supralevator space. Consequently, these fistulas are categorized as complex fistulas in the new classification, aligning with the Garg classification.

Interestingly, the new fistula scoring system classifies all multi-

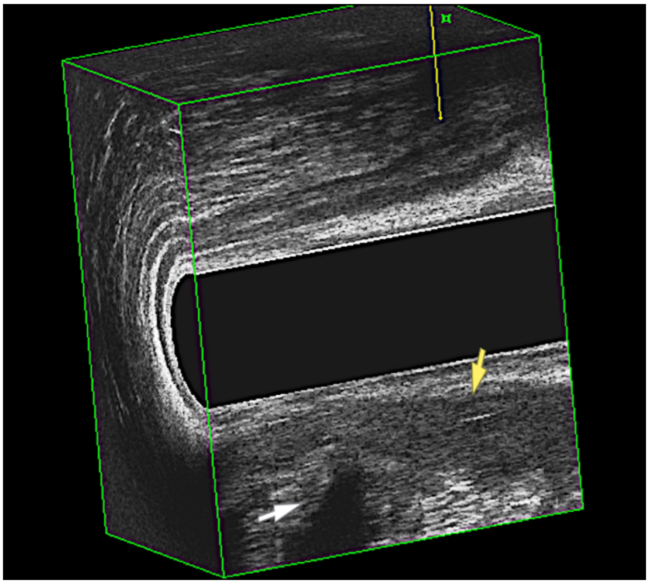

Fig. 7. The 3-dimensional endoanal ultrasound image in the sagittal plane of a posterior transsphincteric fistula (white arrow) with a secondary tract extending into the supraelevator space (yellow arrow) via the intersphincteric route. This fistula was categorized as grade 3C by the new classification.

Table 5. Success and failure rates in each fistula severity grade according to the Garg classification

Classification	No. of patients (%)		
	Total (n = 479)	Treatment outcome	
		Success	Failure
Grade I	142 (29.6)	142 (100)	0 (0)
Grade II	30 (6.3)	28 (93.3)	2 (6.7)
Grade III	198 (41.3)	158 (79.8)	40 (20.2)
Grade IV	43 (9.0)	33 (76.7)	10 (23.3)
Grade V	66 (13.8)	51 (77.3)	15 (22.7)

ple fistulous tracts that extend into different quadrants of the anal circumference and include at least 1 transsphincteric tract as complex. This classification applies regardless of the extent of external sphincter involvement. This approach differs from the Garg classification and aligns with the significant risk of anal incontinence associated with patients undergoing a double lay-open procedure. This procedure involves a combined external and internal sphincterotomy extended across 2 different quadrants of the anus. Consequently, in our series, all such fistulas were managed with sphincter-saving techniques, resulting in a perfect match between the surgical approach and the new classification for this specific group of fistulas.

A further point of discussion concerns the inclusion of submucosal fistulas in the new classification, which are not present in the

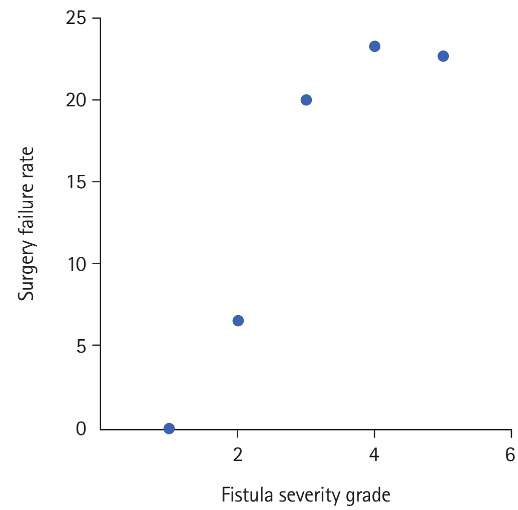

Fig. 8. The correlation between the surgery failure rate and severity grades in the Garg classification. A nonsignificant positive correlation between surgery failure rate and severity grade was found (Spearman rho, 0.90; P = 0.080).

Garg classification. These fistulas often develop from anal fissures that have become complicated by abscesses, leading to fistulization due to local infection. Typically, they feature an internal orifice situated between the pectinate line and the anal verge, along with a submucosal primary tract. Occasionally, these fistulas may also have secondary extensions, such as fluid collections in the superficial perianal or ischioanal spaces, which complicates the differential diagnosis with other types of fistulas

Submucosal fistulas are frequently encountered in clinical practice and can be readily diagnosed with 3D-EAUS in patients suspected of having complicated chronic anal fissures. This imaging method provides a precise assessment of the presence and extent of associated occult anal sepsis, thereby aiding surgeons in choosing the most suitable surgical intervention [24–29]. In our study, the application of 3D-EAUS as the initial diagnostic tool likely facilitated the identification of submucosal anal fistulas, enabling their incorporation into the newly proposed classification.

Ultimately, unlike the Garg severity score, the new classification incorporated both 3D-EAUS and MRI in preoperative evaluations. The 3D-EAUS served as the primary diagnostic tool for all patients, with MRI employed as a supplementary tool in instances where 3D-EAUS revealed high primary tracts or secondary extensions.

Limitations

The use of different diagnostic imaging methods for simple and complex fistulas may represent a limitation of the study, potential-

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ly weakening the formulation of the new classification. However, a previous study comparing the accuracy of 3D-EAUS and MRI in preoperative fistula assessment found no significant differences between the 2 techniques when examining simple fistulas. For complex fistulas, the combined use of 3D-EAUS and MRI yielded the best results in terms of diagnostic accuracy [9]. Therefore, the methodology used in the current study for preoperative assessment and severity score formulation is considered reasonable and adequate, supporting the validity of the proposed new classification. The primary limitations of this study include its retrospective design and the relatively small sample size for certain fistula subtypes. To confirm the validity of the new classification, further prospective studies with larger sample sizes are necessary. Additionally, the analysis of the relationship between classification severity and outcomes may have been constrained by the absence of multivariate analysis that considers factors such as patient age, sex, and comorbidities. Lastly, the variability in the surgical treatment of complex anal fistulas presents a challenge in evaluating postoperative outcomes.

Conclusions

The newly proposed imaging-guided, anatomy-based classification of anorectal fistulas shows high accuracy in determining the severity of fistulas, especially in relation to the feasibility of fistulotomy and surgical outcomes. This model may be viewed as a novel categorization derived from the Garg classification, offering comparable effectiveness. It aims to provide a more precise description and categorization of anorectal fistulas into various severity grades and subtypes, based on the anatomical characteristics of primary and secondary tracts.

This new classification system holds promise as a valuable tool for the preoperative grading of anal fistulas. It standardizes the interpretation of fistula anatomy and complexity, thereby reducing misunderstandings in fistula definitions. This facilitates a "common language" between radiologists and surgeons, enhancing communication and collaborative decision-making.

ARTICLE INFORMATION

Conflict of interest

Antonio Brillantino, Luigi Marano, and Pasquale Talento are editorial board members of this journal, but were not involved in the peer reviewer selection, evaluation, or decision process of this article. No other potential conflict of interest relevant to this article was reported.

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Author contributions

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