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Garg scoring system to predict long-term healing in cryptoglandular anal fistulas: a prospective validation study

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Purpose: Complex anal fistulas can recur after clinical healing, even after a long interval which leads to significant anxiety. Also, ascertaining the efficacy of any new treatment procedure becomes difficult and takes several years. We prospectively analyzed the validity of Garg scoring system (GSS) to predict long-term fistula healing.

Methods: In patients operated for cryptoglandular anal fistulas, magnetic resonance imaging was performed preoperatively and at 3 months postoperatively to assess fistula healing. Scores as per the GSS were calculated for each patient at 3 months postoperatively and correlated with long-term healing to check the accuracy of the scoring system.

Results: Fifty-seven patients were enrolled, but 50 were finally included (7 were excluded). These 50 patients (age, 41.2 ± 12.4 years; 46 men) were followed up for 12 to 20 months (median, 17 months). Forty-seven patients (94.0%) had complex fistulas, 28 (56.0%) had recurrent fistulas, 48 (96.0%) had multiple tracts, 20 (40.0%) had horseshoe tracts, 15 (32.0%) had associated abscesses, 5 (10.0%) were suprasphincteric, and 8 (16.0%) were supralevator fistulas. The GSS could accurately predict long-term healing (high positive predictive value, 31 of 31 [100%]) but was not very accurate in predicting nonhealing (negative predictive value, 15 of 19 [78.9%]). The sensitivity in predicting healing was 31 of 35 (88.6%).

Conclusion: GSS accurately predicts long-term fistula with a high positive predictive value (100%) but is less accurate in predicting nonhealing. This scoring system can help allay anxiety in patients and facilitate the early validation of innovative procedures for anal fistulas.

Keywords: Rectal fistula; Fecal incontinence; Magnetic resonance imaging; Recurrence

INTRODUCTION

Anal fistulas, especially the complex variants, are challenging to treat [1]. One of the main issues is the high recurrence rate associated with complex fistulas [2, 3]. Apart from the high rate, the other problem with recurrence is a high level of unpredictability

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associated with recurrence [4]. A fistula that may appear clinically well healed (cessation of all pus discharge and absence of any swelling or pain in the perianal region) can still recur months and even years after surgery [4]. This causes a lot of anxiety and frustration in patients' minds as even a clinical cure provides little reassurance, and the fear of recurrence looms large for several years [5]. Another problem with unpredictability is that it becomes quite difficult to ascertain the efficacy of any procedure utilized for anal fistulas [4]. It is not uncommon that a new procedure innovated for anal fistulas seems effective initially, but with the passage of time (when long-term follow-up becomes available), the success rate drops dramatically [6–8]. Therefore, a scoring system that could accurately predict long-term fistula healing would greatly help surgeons and patients.

Garg et al. [5] proposed a new scoring system (Garg scoring system, GSS) which was shown to be effective in predicting long-term healing in cryptoglandular anal fistulas with a positive predictive value (PPV) of 98.2%. This was the first scoring system described for cryptoglandular anal fistulas. However, that was a retrospective study. The validity of the new scoring system (GSS) is evaluated prospectively in this study.

METHODS

Ethics statement

The study was conducted at a referral center in India, which deals exclusively with anal fistulas. The study was conducted in accordance with the Declaration of Helsinki, and written informed consent was obtained from all the patients. Ethical approval was obtained from the Ethics Committee of the Indus International Hospital (No. EC/IIH-IEC/SP6).

Study design and setting

In a prospective study, all consecutive patients operated for anal fistula over 8 months from July 2020 to February 2021, and who had preoperative and postoperative magnetic resonance imaging (MRI) to assess fistula healing at 3 months postoperatively, were included. Only patients with cryptoglandular fistulas were included, and patients with Crohn disease were excluded. Long-term clinical healing was defined as complete healing of all the fistula tracts (complete cessation of pus discharge from the anus as well as all the external openings) with a minimum follow-up of at least 1 year. If there was pus discharge from even a single tract, then the fistula was considered nonhealing. All the MRI scans were interpreted independently by 2 experts who had extensive experience in analyzing fistula MRI scans, including the MRI done in the postoperative period [9]. The MRI of every patient was then discussed to reach a consensus. Cases in which no consensus could be reached were excluded from the analysis.

The fistulas were classified under the Parks classification and St James's University Hospital (SJUH) classification. The fistulas in early grades (Parks I or SJUH I–II) were classified as simple fistulas and higher grades (Parks II or SJUH III–V) were categorized as complex fistulas. Fistulotomy was performed for simple fistulas, and transanal opening of intersphincteric space (TROPIS) was performed for complex fistulas [10–12]. The TROPIS procedure is a modification of ligation of intersphincteric fistula tract (LIFT) in which the fistula tract in the intersphincteric space is not ligated but laid open into the anal canal through the transanal route. The intention is that the fistula tract in the intersphincteric space heals by secondary intention because, in the presence of sepsis, healing by secondary intention is better than by primary intention [10].

Garg scoring system

Six parameters were assessed as per the GSS postoperatively 3 months after surgery. Out of 6, 4 parameters were MRI-based (to be assessed on postoperative MRI), and 2 were clinical (Table 1) [5]. Each parameter was allotted a score of 0 or 1. Then, as per the importance of each parameter in the healing process, a definite weight was assigned to each parameter which was then utilized to get a minimum and a maximum possible score for each parameter.

The MRI-based parameters were healing of the internal (primary) opening (healed, 0; not healed, 4), healing of the fistula tract in the intersphincteric space (healed, 0; not healed, 4), healing of the external tracts in the ischiorectal fossa (healed, 0; not healed, 1), and development of a new abscess in intersphincteric space in the postoperative period (on MRI) (absent, 0; present, 4). The 2 clinical parameters were passage of flatus from any of the external openings (clinical) (absent, 0; present, 4) and persistent discharge (pus or serous) from any external opening or anus (clinical) (no discharge, 0; serous discharge, 1; purulent but $<50\%$ of preoperative level, 2; purulent but $>50\%$ of preoperative level, 3) (Table 1) [5]. Thus, the minimum possible score was 0, and the maximum possible score was 20. The cutoff score was 8. A GSS score of <8 indicated that the fistula had healed at 3 months and would remain healed on a long-term basis. On the other hand, a weighted score of ≥ 8 implied that the fistula had not healed at 3 months and would not heal after that.

Statistical analysis

The StatsDirect software for statistics (StatsDirect Ltd) was used. The categorical variables were compared using Fisher test or chi-

Table 1. Garg scoring system to predict long-term anal fistula healing

No.	Parameter	Scoring	Weight	Weighted score possible range
Magnetic resonance imaging assessment 3 mo after surgery				
1	Healing of internal (primary) opening	Healed, 0 Not healed, 1	4	0–4
2	Healing of fistula tract in the intersphincteric space	Healed, 0 Not healed, 1	4	0–4
3	Healing of external tracts in ischiorectal fossa	Healed, 0 Not healed, 1	1	0–1
4	Development of a new abscess in intersphincteric space in the postoperative period	No, 0 Yes, 1	4	0–4
Clinical assessment 3 mo after surgery				
5	Flatus passage from any of the external openings (even occasionally)	No, 0 Yes, 1	4	0–4
6	Discharge from any external opening or anus	No, 0 Serous, 1 Purulent (less amount, < 50% of preoperative quantity), 2 Purulent (high amount, > 50% of preoperative quantity), 3	1	0–3
		Total		0–20

Total weighted score of < 8 indicates healing; total weighted score of ≥ 8 indicates nonhealing.
Adapted from Garg et al. [5], available under the Creative Commons License.

square analysis. When the data were normally distributed, the continuous variables were analyzed by t-test when there were 2-sampled or analysis of variance test when there were more than 2 samples. If the data were not distributed normally, Wilcoxon signed rank test was applied for paired samples, and the Mann-Whitney U-test was performed for unpaired samples. The significant cutoff point was set at $P < 0.05$.

RESULTS

A total of 57 patients were enrolled in the study. Out of these, 50 patients were included in the final analysis, and 7 patients were excluded (4 patients were lost to follow up and postoperative MRI could not be done at 3 months postoperatively in 3 patients). The patients (age, 41.2 ± 12.4 years; 46 men) were operated on with a follow-up of 12 to 20 months (median, 17 months). In the cohort, most of the fistulas, 47 of 50 (94.0%), were complex fistulas (Parks grade II–IV or SJUH grade III–V). In the study, 28 (56.0%) had recurrent fistulas, 48 (96.0%) had multiple tracts, 20 (40.0%) had horseshoe tracts, 15 (32.0%) had associated abscesses, 5 (10.0%) were suprasphincteric, and 8 (16.0%) were supralevator fistulas (Table 2).

The new scoring system could accurately predict long-term healing (specificity and high PPV, 31 of 31 [100%]) but was not very accurate in predicting nonhealing (negative predictive value [NPV], 15 of 19 [78.9%]). The sensitivity in predicting healing was 88.6% (31 of 35) (Table 3).

Table 2. Patient characteristics

Characteristic	Value (n = 50)
Follow-up (mo)	17 (12–20)
Age (yr)	41.2 ± 12.4
Sex	
Male	46 (92.0)
Female	4 (8.0)
Recurrent	28 (56.0)
Abscess	15 (32.0)
Multiple tracts	48 (96.0)
Horseshoe	20 (40.0)
Supralevator	8 (16.0)
Suprasphincteric	5 (10.0)
Simple fistulas (lower grades[a])	3 (6.0)
Complex fistulas (higher grades[b])	47 (94.0)

Values are presented as median (range), mean ± standard deviation, or number (%).
[a]Parks classification grade I or St James's University Hospital (SJUH) classification grade I–II. [b]Parks grade II–IV or SJUH grade III–V.

In the subset in whom GSS predicted healing and the fistula remained healed on long-term (true positive, n = 31) (Fig. 1), the mean weighted scores were 2.2 ± 2.5 (median, 2) (Table 4). While, in the subset in whom GSS predicted nonhealing and the fistula remained nonhealed on long-term (true negative, n = 15) (Fig. 2), the mean weighted scores were 10.9 ± 0.5 (median, 10) whereas the patients in whom the scoring system predicted nonhealing but the fistula healed on long-term (false negative, n = 4) (Fig. 3), the mean weighted scores were 9.6 ± 0.9 (median, 10) (Table 4,

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Table 3. Accuracy of scoring system in predicting long-term healing

Scoring system	Fistula on long-term		Predictive value
	Healed	Not healed	
Predicted healing (weighted score, < 8)	31 (True positive)	0 (False positive)	PPV, 100% (31/31)
Predicted nonhealing (weighted score, ≥ 8)	4 (False negative)	15 (True negative)	NPV, 78.9% (15/19)
	Sensitivity, 88.6% (31/35)	Specificity, 100% (15/15)	Total = 50

PPV, positive predictive value; NPV, negative predictive value.

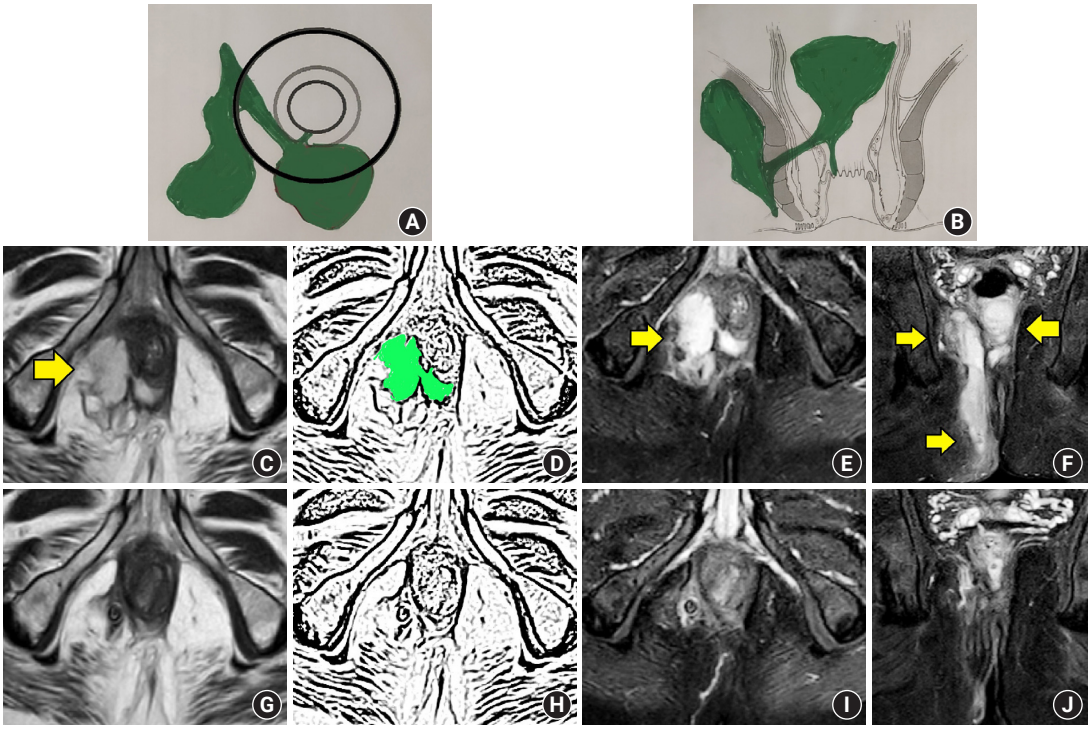

Fig. 1. A 52-year-old male patient was operated for right-sided high transsphincteric abscess with supralevator extension. The fistula healed completely on clinical examination at postoperative 3 months with no symptoms or signs. Magnetic resonance imaging (MRI) done at that time showed healed tracts with weighted score of 0 (as per Garg scoring system). The patient is asymptomatic 22 months after surgery. (A) Axial section (schematic diagram). (B) Coronal section (schematic diagram). (C) Preoperative axial T2-weighted MRI. (D) Sketch of Fig. 1C highlighting transsphincteric abscess in green. (E) Preoperative axial short tau inversion recovery (STIR) MRI. (F) Preoperative coronal STIR MRI. (G) Postoperative 3-month axial T2-weighted MRI. (H) Sketch of Fig. 1G. (I) Postoperative 3-month axial STIR MRI. (J) Postoperative 3-month coronal STIR MRI. Arrows indicate fistula location.

Table 4. Weighted scores in each group

Score	True positive[a] (n = 31)	False positive[b] (n = 0)	False negative[c] (n = 4)	True negative[d] (n = 15)
Mean ± SD	2.2 ± 2.5	0	9.6 ± 0.9	10.9 ± 0.5
Range	0–7	0	8–10	10–12
Median	2	0	10	10

SD, standard deviation.
Scoring system predicted [a]healing and fistula healed on long-term; [b]healing and fistula not healed on long-term; [c]nonhealing and fistula healed on long-term; and [d]nonhealing and fistula not healed on long-term.

Fig. 3). The details of 4 patients with false-negative result have been tabulated in Table 5.

DISCUSSION

The study corroborates and validates the efficacy of the GSS. The study's main strength is that it evaluated the scoring system pro-

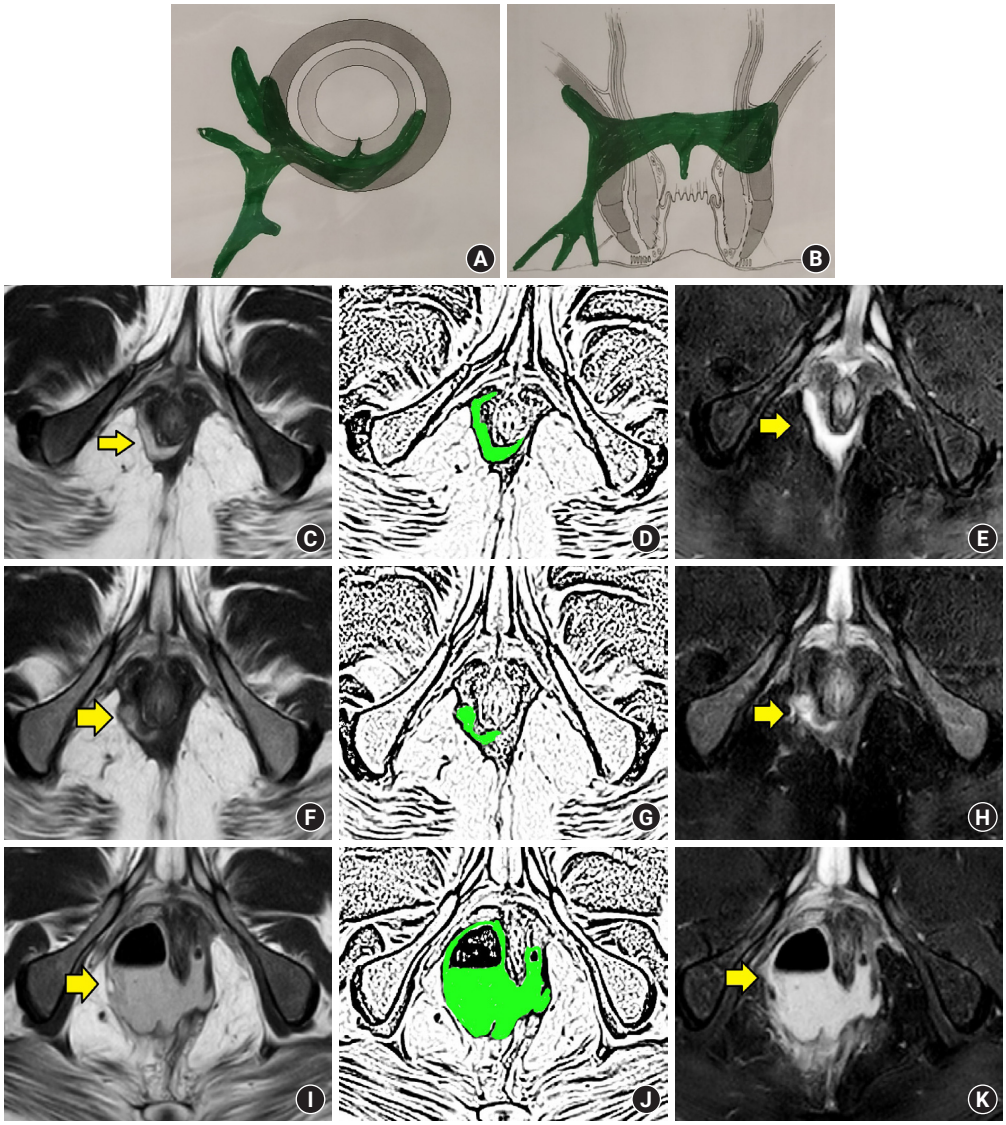

Fig. 2. A 45-year-old male patient was operated for right-sided high transsphincteric horseshoe fistula. The fistula healed completely on clinical examination at postoperative 3 months with no symptoms or signs. However, magnetic resonance imaging (MRI) done at that time showed a residual intersphincteric tract with weighted score of 9 (as per Garg scoring system). The patient was informed about the possibility of recurrence. The patient presented again 20 months after the operation with a large posterior horseshoe abscess. (A) Axial section (schematic diagram). (B) Coronal section (schematic diagram). (C) Preoperative axial T2-weighted MRI showing posterior horseshoe fistula tract. (D) Sketch of Fig. 2C highlighting posterior horseshoe fistula tract in green. (E) Preoperative axial short tau inversion recovery (STIR) MRI showing posterior horseshoe fistula tract. (F) Postoperative 3-month axial T2-weighted MRI showing residual intersphincteric fistula tract. (G) Sketch of Fig. 3F showing residual intersphincteric fistula tract in green. (H) Postoperative 3-month axial STIR MRI showing residual intersphincteric fistula tract. (I) Postoperative 20-month axial T2-weighted MRI showing large posterior horseshoe abscess. (J) Sketch of Fig. 2I showing large posterior horseshoe abscess in green. (K) Postoperative 20-month axial STIR MRI showing large posterior horseshoe abscess. Arrows indicate fistula location.

spectively. It demonstrated that GSS had a high PPV (100%), though the NPV was not that high (78.9%). This indicates that once the fistula is healed as per GSS (score, <8) done 3 months after surgery, then the chances of fistula recurrence are quite low. This is creditable because it would provide significant reassurance to the patients and the operating surgeon. Also, as discussed above, it happens not uncommonly that a new procedure innovated for anal fistulas looks effective initially, but as the long-term follow-up becomes available, the success rate drops down significantly. This leads to significant waste of time and resources and adds to patient morbidity. The availability of an effective scoring system would facilitate the rapid evaluation of newer surgical procedures.

The reasons for the lower NPV are not difficult to understand.

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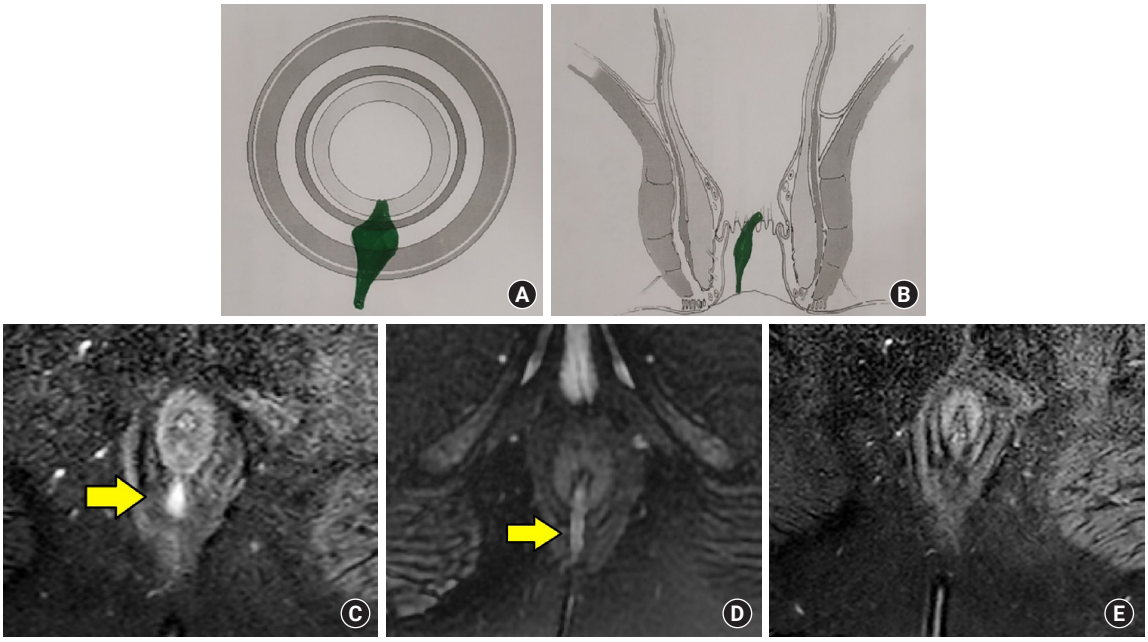

Fig. 3. A 33-year-old male patient was operated for a right posterior small intersphincteric abscess and fistula. Magnetic resonance imaging (MRI) done at 3 months after surgery showed a residual intersphincteric tract with weighted score of 10 (as per Garg scoring system). The patient was followed up. At postoperative 12 months, the fistula healed completely clinically as well as on MRI. (A) Axial section (schematic diagram). (B) Coronal section (schematic diagram). (C) Preoperative axial short tau inversion recovery (STIR) MRI showing right posterior intersphincteric fistula. (D) Postoperative 3-month axial STIR MRI showing residual intersphincteric fistula tract. (E) Postoperative 12-month axial STIR MRI showing complete fistula healing. Arrows indicate fistula location.

Table 5. Male patients with false-negative results (scoring system at 3 months predicted nonhealing of fistulas [Garg score of ≥8] but the fistulas healed nonetheless)

Variable	Patient 1[a]	Patient 2	Patient 3	Patient 4
Age (yr)	33	52	35	53
Body mass index (kg/m^2)	35.8	31.3	19.5	25.2
Fistula classification	Parks I SJUH II	Parks II SJUH IV	Parks II SJUH IV	Parks III SJUH V
No. of tracts	2	4	2	3
Horseshoe	No	No	No	No
Suprasphincteric	No	No	No	Yes
Tract[b]	Low	High	High	High
Procedure	Fistulotomy	TROPIS	TROPIS	TROPIS
Garg scores at postoperative 3 mos	10	10	10	11
Fistula status at postoperative 3 mo	Not healed	Not healed	Not healed	Not healed
Final status of fistula, long-term follow-up	Healed	Healed	Healed	Healed
Time taken for complete fistula healing (mo)	5	7	6	7
Total follow-up available (mo)	13	15	15	18

SJUH, St James's University Hospital classification; TROPIS, transanal opening of intersphincteric space procedure [10–12].
[a]Fig. 3. [b]High, fistula tract involving >1/3 of external anal sphincter; low, fistula tract involving <1/3 of external anal sphincter.

The complexity of fistulas, including the number and width of tracts and infection magnitude, can vary significantly. So, it is probable that all fistulas would not heal 3 months after surgery. Therefore, in 4 patients, the GSS score was ≥8 (predicting that the fistula would not heal) but the fistula still healed.

Therefore, in more complex fistulas, it is prudent to get a postoperative MRI and evaluate GSS at a later interval (4–6 months after surgery) rather than at 3 months. This would reduce the chances of false negatives. The point of time to calculate GSS was chosen at 3 months postoperatively because most fistulas heal

clinically and radiologically by 3 months. Before 3 months, it is difficult to differentiate between postoperative tissue inflammation, healing granulation tissue, and active fistula tract [9, 13]. Expectedly, delaying the point of time (4–6 months) would decrease the NPV, but it was practically difficult to make all patients wait for that long.

The main utility of GSS in clinical practice would be in high complex cryptoglandular fistulas, which have already recurred a few times. Preoperative MRI is usually done anyway in such cases, and along with that, if a postoperative MRI is also done, then GSS evaluation and long-term healing can be predicted.

Due to logistic reasons, it was easier to conduct a validation study of GSS at our center. Apart from the high incidence of fistulas in India, the main reason was the availability of very economical MRI scan facilities. Unlike North America and Europe, where MRI scan is costly, in India, the MRI scan costs the patient only US $60 to $80. Therefore, most patients with complex fistulas do not mind getting repeat postoperative MRI scans. Since the initial study was retrospective, we were keen to check the validity of GSS in a prospective study.

GSS was the first scoring system published to predict long-term healing in cryptoglandular anal fistulas. However, a few scoring systems had earlier been proposed for Crohn perianal fistulas like Van Assche scores, MAGNIFI-CD scores, and modified Van Assche scores [14–16]. The first scoring system was published by Van Assche et al. [14] to check the effects of infliximab on perianal Crohn disease in 18 patients. This scoring system was modified by Samaan et al. [15] in 2017 who analyzed it in a cohort of 50 patients with Crohn disease. In 2019, Hindryckx et al. [16] proposed MAGNIFI-CD scores to assess the response of Crohn fistulas to stem cell treatment. All these scoring systems evaluated the response of Crohn anal fistulas to medical treatment only, and none of these assessed healing after surgery [14–16]. Also, these scoring systems did not correlate accurately with postoperative healing [16, 17]. There were a few possible reasons for this. These scoring systems did not utilize any clinical parameters and were based on MRI-evaluated parameters only [14–16]. This was perhaps a mistake as anal fistula healing is a clinical phenomenon, and for the prediction of a scoring system to be accurate, clinical assessment parameters should be included in the scoring system. This could possibly explain that GSS was more accurate because, unlike previous scoring systems, GSS includes both clinical and MRI parameters. Another reason could be that the earlier scoring systems described for Crohn disease included preoperative features of fistula complexity like an associated abscess, multiple tracts, supralevator extension, etc., as their scoring parameters [14–16]. No doubt, these features that make a fistula complex preoperatively may decrease the chances of postoperative healing, but these parameters are not necessarily the markers of fistula nonhealing in the postoperative period [18–20]. They are therefore confounding parameters and may not accurately correlate with post-treatment healing. Hence, these preoperative features were not included in GSS. The higher accuracy of GSS as compared to previous scoring systems further corroborates this point.

This study had some limitations. The sample size was small. Including Crohn fistulas would have added more value to the study. Though GSS was described for cryptoglandular anal fistulas, it would be interesting to evaluate its accuracy for Crohn fistulas.

To conclude, the newly described GSS accurately predicts fistula healing with a high PPV indicating that a fistula deemed healed by GSS would have an extremely low chance of recurrence. However, the NPV is not that high, indicating that a fistula predicted not to heal still has more than a 20% chance of healing. Further studies are needed to corroborate the findings of this study.

ARTICLE INFORMATION

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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Author contributions

Conceptualization: SD, PG, VDY; Data curation: BK, GRM, VDY; Formal analysis: PG, GRM, SD; Investigation: SD, PG, VDY, BK; Methodology: SD, PG, VDY; Project administration: SD, VDY; Resources: VDY, SD, GRM; Software: PG, GRM; Supervision: SD, VDY; Validation: PG, SD, VDY; Visualization: VDY, PG, SD; Writing–original draft: SD, PG; Writing–review & editing: all authors. All authors read and approved the final manuscript.

Additional information

This manuscript has been presented at the annual meeting of the American Society of Colon and Rectal Surgeons (ASCRS) in the Best Paper Category on May 1, 2022, in Tampa, Florida, USA.

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