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Design and psychometric evaluation of the ‘Quality of Life in patients with Anal Fistula Questionnaire’ (QoLAF-Q).

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Abstract

Background: Quality of life is often considered when deciding and evaluating the treatment strategy for patients diagnosed with anal fistula.

Objective: To develop and psychometrically test the 'Quality of Life in patients with Anal Fistula Questionnaire'.

Design: Observational cross-sectional study for the development and validation of a psychometric tool.

Setting: General hospital in the southeast of Spain.

Patients: Convenience sample of 54 patients diagnosed with anal fistula.

Main outcomes measures: The tool's reliability was assessed through its internal consistency (Cronbach's α) and temporal stability (Spearman's correlation coefficient (r) between test-retest). The content validity index of the items and the scale was calculated. Correlation analysis and an ordinal regression analysis between the developed tool and the SF-12 examined its concurrent validity. Principal component analysis and known-group analysis using Kruskal-Wallis Test examined its construct validity.

Results: The reliability of the developed questionnaire was very high ($\alpha=0.908$; $r=0.861$; $p<0.01$). Its content validity was excellent (all items' *content validity index*=0.79–1; *scale's validity index*=0.92). Evidence of its concurrent validity includes: [1] strong correlation between the developed tool and SF-12 ($r=0.734$; $p<0.001$), and [2] participants' scores on the developed tool explained approximately 46.2% of the between-subject variation for the participants' scores on the SF-12 (Nagelkerke- $R^2=0.462$). Confirming its construct validity, principal component analysis revealed that two factors explained 81.63% of the total variance found. Known-group analysis evidenced the questionnaire's ability to detect expected differences in patients presenting with different symptomatology.

Limitations: The major limitations of this study were: using a small sample of Spanish-speaking patients, not including patients in the initial development of the questionnaire, and developing the scoring system using a summation method.

Conclusion: The ‘Quality of Life in patients with Anal Fistula Questionnaire’ has proven to be a valid, reliable and concise tool that could contribute to the evaluation of quality of life amongst patients with an anal fistula.

Keywords

Quality of life; anal fistula; psychometrics; validity; reliability.

Introduction

An anal fistula (AF) is an abnormal tract or cavity communicating with the rectum or anal canal by an identifiable internal opening.¹⁻² Most anal fistulae are believed to arise as a result of a cryptoglandular infection and are more frequent amongst adults between 30-60 years old.²⁻³ Although the actual incidence of AF remains unknown and there is high geographical variability reported in the literature (from 0.86 per 10,000/year in Helsinki to 2.32 per 10,000/year in Italy), this is generally considered an uncommon disease.³⁻⁴ Nonetheless, the management of anal fistulae is often the focus in international literature on coloproctology. The symptomatology most frequently associated with an AF includes suppuration, bleeding and/or pain, which are often preceded by the drainage of a perianal abscess and can severely affect patients’ quality of life (QoL).^{2,5-6} The curative treatment for anal fistulae can be costly and always require a surgical intervention.^{3,7-8} Indeed, it is suggested that between 10-30% of the total surgical procedures performed by coloproctology specialists could be related to the management of anal fistulae.⁷

Although the aim of undertaking surgery on these patients is clearly directed towards removing the fistula, alleviating its symptoms, preventing its recurrence, and preserving the sphincter’s function, its effectiveness can be variable.⁷ For example, in patients

presented with non-complex, primary fistulae (i.e. intersphincteric and low transsphincteric), fistulotomy is usually the surgical procedure of choice and is believed to be useful in around 90% of the cases.^{7,9-10} However, in patients presented with complex anal fistulae, the results from performing different surgical procedures (i.e. mucosal advancement flap, seton placement, LIFT procedure, plugs and adhesives, etc) remain unclear and are somewhat controversial.¹¹⁻¹⁴ Consequently, a risk of recurrence of approximately 10-60%, and complications such as incontinence due to undergoing numerous unsuccessful surgical interventions can also contribute to negatively affect patients' QoL.^{4,13-15}

In the light of this, patient QoL emerges as an important indicator that is often taken into consideration by coloproctology specialists when making individualised decisions on the treatment strategy to be followed for each patient and the posterior evaluation of its success.¹⁶⁻²¹ However, to the best of our knowledge, no instrument to specifically assess QoL in patients diagnosed with AF has been developed, validated and published. In fact, our literature review evidenced that the tools used to evaluate QoL amongst patients diagnosed with AF were initially designed for measuring either general health-related QoL (SF-12, SF-36)¹⁶⁻¹⁹ or other constructs related to patients' incontinence (St Mark's Incontinence Score, Cleveland Incontinence Score, Wexner Score and FIQL).¹⁶⁻²¹ In this context, the design of a valid and reliable instrument that aims to evaluate QoL amongst patients with AF could help to provide more specific and better-fitted information about this particular population.

The aim of this study is to develop and evaluate the psychometric properties of a questionnaire to assess QoL in patients diagnosed with AF.

Methods

Study design and participants

In this study, an observational cross-sectional design was used for the development and validation of the ‘Quality of Life in patients with Anal Fistula Questionnaire’ (QoLAF-Q). Following a convenience sampling technique, patients attending the coloproctology clinic in a general hospital in the southeast of Spain between March 2015 and June 2016 were recruited for the study. The inclusion criteria for participation were: to be ≥ 18 years old and to have been diagnosed with a cryptoglandular AF. The exclusion criteria for participation were: to suffer any cognitive impairment that could interfere with understanding and completing the questionnaire, to suffer from inflammatory bowel disease or any other medical condition that could affect QoL (i.e. COPD, fibromyalgia...), and to present with an AF secondary to carcinoma, radiation therapy, obstetric damage or any other primary cause that could affect QoL. Eighty participants were eligible for inclusion and 54 volunteered to participate. Patient demographic characteristics, past medical history and information about the AF were collected.

Ethical considerations

The institutional ‘Ethics in Research Board’ granted ethical approval. Patients meeting the eligibility criteria were invited to participate in the study by their surgeon and received a written document with information about their rights, the study’s aim and the research plan. Patients who volunteered to participate signed an informed consent form before enrolling in the study. All data collected were treated in accordance with the European legislation on data protection.²²

Initial development of the questionnaire

The researchers developed the QoLAF-Q based on their experiences with patients, the most frequent clinical manifestations of anal fistulae,² and the domains included in the WHOQOL.²³ The initial version of the QoLAF-Q (i-QoLAF-Q) was developed in Spanish and comprised of 17 items, which response options followed a 5-point Likert-type format.

Before its administration to the study participants, the i-QoLAF-Q was critically revised by a panel of 14 independent experts in coloproctology and colorectal surgery from different institutions. In order to calculate the content validity index (CVI) of the i-QoLAF-Q, these experts were requested to score each item as 1='not relevant', 2='somewhat relevant', 3='quite relevant' or 4='highly relevant' for measuring QoL in patients diagnosed with AF.²⁴ Each individual item's CVI (I-CVI) was estimated by summing the number of experts rating the item as either 'quite relevant' or 'highly relevant' and dividing it by the total number of experts in the panel.²⁴ For a panel of 14 experts, an I-CVI \geq 0.78 is acceptable as it shows a high degree of agreement about its relevance.²⁴ Table 1 shows that the experts considered items 3, 4 and 16 not to be relevant for measuring QoL in patients diagnosed with AF (I-CVI<0.78) and they were removed from the QoLAF-Q (see Appendix 1 for further information on the questions and response options for the QoLAF-Q).

Data analysis of the final version of the QoLAF-Q

The 14-item version of the QoLAF-Q was tested amongst the study sample and psychometrically evaluated following other authors' guidelines and recommendations.²⁴⁻²⁸ The QoLAF-Q was originally developed and tested in Spanish. The forward-backward translation procedure recommended by the 'European Organisation for Research and Treatment of Cancer' was used to translate the QoLAF-Q to English.²⁹ IBM® SPSS® v.21 was used to perform the data analysis.

Readability and understandability

The readability and grade level of the QoLAF-Q was assessed using the Flesch-Kincaid tool in Microsoft Word[®]. To evaluate its understandability, ten independent native Spanish-speakers and five independent non-native, non-proficient Spanish-speakers were asked to comment on the difficulties they might have found when reading and completing the QoLAF-Q. Using feedback from non-native, non-proficient Spanish-speakers can give directions to further simplify the readability of the tool and improve its understandability.²⁵⁻²⁶ The completion time for the instrument was recorded.

Reliability

To evaluate the reliability of the QoLAF-Q, its internal consistency and temporal stability were investigated. The internal consistency of the QoLAF-Q was evaluated using the following three estimators: [1] Cronbach's coefficient alpha for the overall tool, [2] estimated Cronbach's alpha of the overall tool if a particular item was removed, [3] corrected item-total correlation (C-ITC). Items were considered to positively contribute to increase the internal consistency of the QoLAF-Q if their item's corrected C-ITC > 0.3, and the tool's Cronbach's alpha coefficient did not significantly increase after removing that particular item. To assess the QoLAF-Q's temporal stability, participants completed the questionnaire in two occasions separated by a 4-week interval using an identical data collection procedure for the test and retest. The Spearman's correlation coefficient (r) and the weighted Cohen's kappa (k) were calculated. In this 4-week interval, participants underwent further diagnostic tests and did not receive any treatment; they were recommended to maintain good hygiene of the perianal area.

Validity

The content, criterion and construct validity of the QoLAF-Q were examined. For the assessment of the QoLAF-Q's content validity, the average CVI of the overall questionnaire (S-CVI/Ave) was calculated; the data obtained from the critical review procedure performed by the aforementioned panel of experts were used for its calculation. A S-CVI/Ave > 0.90 was considered as evidence of the instrument's content validity.²⁴ For the assessment of the QoLAF-Q's criterion validity, its concurrent validity was studied and the SF-12 Health-Survey (SF-12) was used as the criterion of reference for comparisons.³⁰ The decision to use the SF-12 for comparisons was based on the following criteria: [1] it measures all the domains comprising the construct 'health-related QoL',^{23,30} [2] it is a widely used instrument that has shown excellent psychometric properties in its Spanish version,³⁰ and [3] it is short, easy to understand and simple to complete by the participants. The Spearman's correlation coefficient (r) between patients' results on the QoLAF-Q and their results on the Spanish version of the SF-12 was calculated. Additionally, we conducted an ordinal logistic regression analysis in which the associations between the participants' scores in the QoLAF-Q and the SF-12 were explored. Lastly, for the assessment of the QoLAF-Q's construct validity, principal component analysis (PCA) and known-groups analysis were performed.

PCA. This analysis aimed to identify the principal components of the QoLAF-Q and the items that should be retained as part of the instrument. Before investigating the structure of the QoLAF-Q, the appropriateness to perform PCA was tested by carrying out the Kaiser-Meyer-Olkin Measure of Sampling Adequacy and the Bartlett's Test of Sphericity. Then, an unlimited factor analysis test with Varimax rotation was computed. Factors were retained as part of the QoLAF-Q if they met the following criteria: [1]

factors' eigenvalues ≥ 1 , [2] presence of a clear graphic representation of the factor on the plot of eigenvalues, and [3] its items' factor-loading value ≥ 0.45 .³¹

Known-group analysis. The total sample ($N=54$) was divided in groups depending on the participants' scores on the following clinical manifestations: frequency of suppuration, amount of suppuration, frequency of pain, and intensity of pain. Based on this categorisation, between-groups differences in individuals' QoLAF-Q scores were expected and Kruskal-Wallis H Test was carried out to explore them.

Development of a scoring and interpretation system for the QoLAF-Q

Participants' score on the QoLAF-Q could range from 14 (minimum score) to 70 (maximum score). Using a summation method,³² the following five-category scoring and interpretation system was developed: 'zero impact'=14 points, 'limited impact'=15-28 points, 'moderate impact'=29-42 points, 'high impact'=43-56, and very 'high impact'=57-70 points.

A panel of 20 experts were asked to score their degree of agreement with the appropriateness and usefulness of the aforementioned scoring and interpretation system using a 5-point Likert scale (1=strongly agree, 2=agree, 3=neither agree or disagree, 4=disagree, 5=strongly disagree). Furthermore, the experts were asked to provide any feedback they considered appropriate about the scoring and interpretation system proposed by the researchers.

Results

There were not any missing values in the dataset used in this study.

Description of the main sample

The main sample's mean age was 46.7 years ($SD=11.60$; range=24-70) and it was comprised of 74.1% male participants. Table 2 presents detailed information about patients' demographics, past medical history and specific characteristics of their AF.

Readability and understandability

The reading level of the QoLAF-Q corresponds to 4th grade, so it can be read by a schooled ten-year-old individual. Neither the independent native Spanish-speakers, nor the independent non-native, non-proficient Spanish-speakers reported any difficulties when reading and completing the QoLAF-Q. Furthermore, mean completion time was less than 5 minutes (range=4-6 minutes).

Reliability

Table 1 presents detailed results of the internal consistency analysis for the QoLAF-Q ($N=54$). The QoLAF-Q's Cronbach's $\alpha=0.908$, which would not have significantly increased after removing any of the items. The C-ITC for the items ranged from 0.35-0.83. Regarding the analysis of the tool's temporal stability, the Spearman's correlation coefficient between the test and the 4-week retest was very high ($r=0.861$; $p<0.001$). Additionally, the weighted Cohen's kappa was very good when unequal distance between the response options was assumed (quadratic $k=0.82$; 95% CI=0.735-0.906), and good when equal distance between the response options was assumed (linear $k=0.72$; 95% CI=0.593-0.847) (see Table 3).

Validity

Regarding content validity, the I-CVI for the 14 items comprising the QoLAF-Q ranged from 0.79-1 (see Table 1) and the QoLAF-Q's S-CVI/Ave=0.92. In terms of concurrent validity, the QoLAF-Q showed a strong, significant correlation with the SF-12 ($r=0.734$; $p<0.001$). Moreover, ordinal logistic regression analysis suggested that participants' scores on the QoLAF-Q explained approximately 46.2% of the between-subject variation for the participants' scores on the SF-12 (Nagelkerke- $R^2=0.462$). However, those patients in whom the AF has a limited or moderate impact over their QoL (based on their scores on the QoLAF-Q) had statistically significant higher odds of

scoring among the groups with worse health-related QoL (based on their results on the SF-12), with an odds ratio (OR) of 0.020 [95% CI=0.04-0.95] and an OR of 0.124 [95% CI=0.032-0.485], respectively (see Table 4 for a summary of the interactions between participants' results on the SF-12 and the QoLAF-Q). Results for construct validity analysis are presented below.

PCA

The Barlett's Test of Sphericity was significant ($\chi^2=450.32$; $p<0.01$) and the Kaiser-Meyer-Olkin measure of sampling adequacy was 0.764; thus, PCA was carried out. Table 5 presents the results of the PCA on the 14-item QoLAF-Q. Two factors showed eigenvalues ≥ 1 , a clear graphic representation on the plot of eigenvalues, and all their loading items with a factor-loading coefficient ≥ 0.45 . These two factors accounted for 81.63% of the total variance found and refer to the physical (Factor 1) and biopsychosocial (Factor 2) impact of the AF (see Table 5).

Known-groups analysis

Known-groups analysis results are shown in Table 6. In summary, the Kruskal-Wallis H Test showed that the participants' scores on the total QoLAF-Q and its two subscales are significantly different ($p<0.05$) depending on their self-reported frequency of suppuration, amount of suppuration, frequency of pain, and intensity of pain.

Scoring and interpretation system for the QoLAF-Q

The 20 experts revising the scoring and interpretation system proposed by the researchers either strongly agreed (n=17) or agreed (n=3) with its appropriateness. No further changes were required.

Discussion

Our literature review suggested that QoL is an essential indicator to be taken into consideration when deciding the strategy to be followed in the treatment of patients

diagnosed with AF.¹⁴⁻²¹ However, previously published studies exploring QoL amongst these patients have always used instruments that were initially designed for the evaluation of more generic populations' QoL.¹⁶⁻²¹ To the best of our knowledge, no specific tools for the assessment of QoL in patients with AF have been previously designed, validated and published; hence why this study aimed to develop and evaluate the psychometric properties of the 'Quality of Life in patients with Anal Fistula Questionnaire' (QoLAF-Q).

The psychometric evaluation of the QoLAF-Q intended to find an evidence-based answer to the following three questions: [1] does the tool measure accurately? [2] what does the tool actually measure? and [3] is the tool actually usable? Whilst questions one and two refer to the reliability and validity of the QoLAF-Q, question three concerns the tool's readability, understandability and applicability.²⁷⁻²⁸

Regarding the first question, the psychometric analysis performed demonstrated the excellent internal consistency and temporal stability of the QoLAF-Q among the study sample. These qualities could be considered proof of the tool's reliability, repeatability and reproducibility.²⁷⁻²⁸

In order to answer the second question, content, criterion and construct validity of the QoLAF-Q were explored. Firstly, the QoLAF-Q's content validity analysis included a process of critical review by a panel of 14 experts and evidenced that all the items included in the final 14-item version of the QoLAF-Q contributed to the operationalization of 'quality of life in patients with AF' as a measurable concept.^{24,27-28} Secondly, in relation to criterion validity, the QoLAF-Q's concurrent validity was assessed by exploring its ability to correlate and converge with patients' score on the SF-12, which measures individuals' health-related QoL. Evidence has shown that the QoLAF-Q does not only correlate very strongly with this previously-validated and

widely-used tool, but is also able to make similar decisions about patients' QoL. These results could be interpreted as an indicator of the QoLAF-Q's ability to provide valid information about the QoL of patients diagnosed with AF.²⁷⁻²⁸ Furthermore, regarding the tool's construct validity, evidence from the PCA suggests that the QoLAF-Q has two clearly-defined subscales, which evaluate the extent in which the AF impacts the patient's physical and biopsychosocial domains of QoL. Corroborating the confirmatory evidence of the instrument's construct validity, results from the known-group analysis showed the QoLAF-Q's ability to detect expected differences between individuals depending on their symptomatology.

Lastly, concerning the usability of the instrument, results have shown that the QoLAF-Q is an easily understandable and applicable tool which can be completed in less than 5 minutes and provide immediate information about the impact that the AF has on patients' QoL.

Although the QoLAF-Q could be used in research (e.g. experimental designs comparing the efficacy of different treatment approaches on patients' QoL), and in clinical practice (e.g. as part of the initial assessment of patients with AF), some limitations must be highlighted. Firstly, the small size of the main sample, which could have affected the validity of our PCA and known-groups analysis, together with the use of a convenience sampling method does not allow for the generalisation of the results. As the participants were a relatively small group of patients with specific characteristics (for example, all patients presented with a cryptoglandular AF and the majority were males), those willing to use the QoLAF-Q amongst different populations should conduct a validation study before doing so. Secondly, although the participants were encouraged to make comments on how they would improve the QoLAF-Q once they had completed it, this study did not include them in the discussion that led to the initial

development of the questionnaire. We suggest that future validation and adaptation studies of the QoLAF-Q conduct in-depth interviews and/or focus groups in which patients have the opportunity to be more actively involved with the process of deciding which items are included in the questionnaire and how these items are worded. Thirdly, our scoring system for the QoLAF-Q does not take into account that some items may be more important than others for measuring the underlying construct and may potentially lead to a cancellation effect.³² We recommend that future studies develop scoring systems using other approaches and compare them to the one presented in this manuscript. Lastly, as the QoLAF-Q was created and psychometrically tested in Spanish, its use in other languages must be preceded by an appropriate translation and validation process.

Conclusions

The QoLAF-Q has shown excellent psychometric properties after being subjected to a rigorous testing process. The QoLAF-Q has proven to be a valid, reliable and concise tool that could contribute to the evaluation of quality of life amongst patients with anal fistula. Additionally, its easy and rapid applicability could facilitate its use and contribute to informing the physician in the decision-making process in which the most suitable treatment for each particular case is usually discussed. It is suggested that future studies focus on assessing the QoLAF-Q's psychometric properties after translating it into different languages and validating its usability on larger randomised samples of patients.

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Table 1.

Results of the content validity ($N=14$) and internal consistency analysis of the QoLAF-Q ($N=54$).

		I-CVI [†]	QoLAF-Q's Cronbach alpha if item deleted	Corrected ITC [‡]
1.	How often do you experience discharge (suppuration) from the fistula?	.93	.910	.42
2.	How much discharge (suppuration) from the fistula do you experience?	.93	.910	.35
3.	How often do you bleed from the fistula?	.21	Removed from QoLAF-Q before testing it with patients (I-CVI<0.78)	
4.	How much bleeding from the fistula do you experience?	.14	Removed from QoLAF-Q before testing it with patients (I-CVI<0.78)	
5.	How often do you experience uncontrollable flatulence (farting) since having the fistula?	1	.908	.44
6.	How often do you experience unintentional loss of stools since having the fistula?	1	.907	.44
7.	What is the amount of unintentional stool loss that you usually experience since having the fistula?	.93	.908	.40
8.	How often do you experience pain in the anal area as a consequence of the fistula?	.93	.897	.72
9.	What is the intensity of the pain that you experience as a consequence of the anal fistula?	.86	.902	.59
10.	Since suffering the symptoms of the anal fistula, how would you say your health is?	1	.901	.64
11.	How much does the anal fistula affect your physical health? (e.g. energy and activity levels, sleeping pattern, general well-being...)	.86	.892	.81
12.	How much does the anal fistula affect your psychological health? (e.g. your body image, self-esteem, state of mind, ability to focus on a particular task...)	.93	.896	.73
13.	How much does the anal fistula affect your independence level? (e.g. mobility, ability to work, daily activities...)	.86	.897	.71
14.	How much does the anal fistula affect your social relationships and interactions with others? (e.g. your relationships with friends, family, partner...)	.93	.893	.80
15.	How much does the anal fistula affect your sexual relationships?	.93	.898	.69
16.	How much does the anal fistula affect your beliefs, values and attitudes? (e.g. your religious practices, your eating and drinking practices, your general beliefs...)	.29	Removed from QoLAF-Q before testing it with patients (I-CVI<0.78)	
17.	How much does the anal fistula affect other aspects of your life? (e.g. your freedom, your economic income, your free time...)	.79	.891	.83

[†] I-CVI = Item Content Validity Index[‡] ITC = Item-total Correlation

Table 2.

Demographic characteristics of main sample

	Main Sample
	(N=54)
	M ± S.D.
Age (years)	46.9 ± 11.60
	n (%)
Gender	
Female	14 (25.9)
Male	40 (74.1)
Comorbidities	
Hypertension	12 (22.2)
Diabetes Mellitus Type I	3 (5.6)
Diabetes Mellitus Type II	4 (7.4)
Obstetric damage	
Yes	0 (0)
No	54 (100)
Previous anal surgery	
No previous anal surgery	17 (31.5)
One previous anal surgery	15 (27.8)
More than one anal surgery	22 (40.7)
Clinical manifestations	
Suppuration	45 (83.3)
Bleeding	26 (48.1)
Pain	31 (57.4)
Incontinence	0 (0)
Main symptomatology	
Suppuration	38 (70.4)
Bleeding	3 (5.6)
Pain	13 (24.1)
Incontinence	0 (0)

Location of EFO (based on physical anamnesis*)	
Unidentified EFO	0 (0)
Anterior	8 (14.8)
Posterior	14 (25.9)
Right lateral	18 (33.3)
Left lateral	14 (25.9)
Location of IFO (based on digital rectal examination*)	
Unidentified IFO	25 (46.3)
Anterior	7 (13.0)
Posterior	15 (27.8)
Right lateral	5 (9.3)
Left lateral	2 (3.7)
Type of anal fistula (based on findings from physical anamnesis*, and/or digital rectal examination*, and/or injection of hydrogen peroxide + saline solution*, and/or MRI**, and/or anoscopy**)	
Intersphincteric	18 (33.3)
Transsphincteric	27 (50)
Suprasphincteric	0 (0)
Extrasphincteric	3 (5.6)
Undetermined	6 (11.1)

* The physical anamnesis, the digital rectal examination and the injection of hydrogen peroxide were performed during the patients' visit to the outpatient coloproctology clinic.

** The MRI and anoscopy were requested in order to confirm diagnosis of the anal fistula and determine its classification after the first visit to the outpatient coloproctology clinic.

Table 3.

Results of the weighted Cohen's kappa analysis for the assessment of the QoLAF-Q's temporal stability at 4-week retest ($N=54$).¹

		Impact of the anal fistula on the participants' QoL at initial test ($N=54$)					Relative frequency n/N (%)
		Zero Impact Frequency (n)	Limited Impact Frequency (n)	Moderate Impact Frequency (n)	High Impact Frequency (n)	Very High Impact Frequency (n)	
Impact of the anal fistula on the participants' QoL at 4-week re-test ($N=54$)	Zero impact Frequency (n)	0	0	0	0	0	0/0 (0%)
	Limited impact Frequency (n)	0	16	2	0	0	18/54 (33.3%)
	Moderate Impact Frequency (n)	0	4	12	2	0	18/54 (33.3%)
	High Impact Frequency (n)	0	0	4	12	2	18/54 (33.3%)
	Very High Impact Frequency (n)	0	0	0	0	0	0/0 (0%)
Relative frequency n/N (%)		0/0 (0%)	20/54 (37%)	18/54 (33.3%)	14/54 (25.9%)	2/54 (3.7%)	54/54 (100%)

	Equal distance between response options assumed (Linear weighted Cohen's kappa)	Unequal distance between response options assumed (Quadratic weighted Cohen's kappa)
Weighted kappa (k)	0.720	0.821
Standard error	0.065	0.044
95% CI	0.593 – 0.847	0.735 – 0.906

¹ Categorisation was made on the basis of participants' scores on the QoLAF-Q following the scoring system presented in this manuscript.

Table 4.

Simplified summary of the interactions between participants' scores on the QoLAF-Q and SF-12. (N=54)

		Participants' general health-related QoL ¹				
		(N=54)				
		Very good health-related QoL (n=15)	Good health-related QoL (n=10)	Fair health-related QoL (n=15)	Poor health-related QoL (n=12)	Very poor health-related QoL (n=2)
Impact of the anal fistula on the participants' QoL ² (N=54)	Zero impact (n=0)	0	0	0	0	0
	Limited impact (n=20)	11	5	4	0	0
	Moderate impact (n=17)	4	4	5	4	0
	High impact (n=15)	0	1	6	6	2
	Very high impact (n=2)	0	0	0	2	0

¹Health-related QoL categorisation was made on the basis of participants' scores on the SF-12 Health-Survey.

²Impact of the anal fistula on the patient's QoL was categorised according to the scoring system proposed in manuscript.

Table 5.

Factor loadings and total variance explained from the rotated factor structure of the QoLAF-Q ($N=54$).

Item by Factor	Factor	
	1	2
Physical impact of the anal fistula		
1. How often do you experience discharge (suppuration) from the fistula?	.671	
2. How much discharge (suppuration) from the fistula do you experience?	.628	
3. How often do you experience uncontrollable flatulence (farting) since having the fistula?	.484	
4. How often do you experience unintentional loss of stools since having the fistula?	.784	
5. What is the amount of unintentional stool loss that you usually experience since having the fistula?	.754	
6. How often do you experience pain in the anal area as a consequence of the fistula?	.757	
7. What is the intensity of the pain that you experience as a consequence of the anal fistula?	.676	
Biopsychosocial impact of the anal fistula		
8. Since suffering the symptoms of the anal fistula, how would you say your health is?	.636	
9. How much does the anal fistula affect your physical health? (e.g. energy and activity levels, sleeping pattern, general well-being...)	.672	
10. How much does the anal fistula affect your psychological health? (e.g. your body image, self-esteem, state of mind, ability to focus on a particular task...)	.644	
11. How much does the anal fistula affect your independence level? (e.g. mobility, ability to work, daily activities...)	.653	
12. How much does the anal fistula affect your social relationships and interactions with others? (e.g. your relationships with friends, family, partner...)	.649	
13. How much does the anal fistula affect your sexual relationships?	.672	
14. How much does the anal fistula affect other aspects of your life? (e.g. your freedom, your economic income, your free time...)	.637	
% of variance	45.16	36.47
Cumulative % of variance	45.16	81.63

Table 6.
Results of the known-groups analysis.¹ (N=54)

	Frequency of suppuration				Amount of suppuration				Frequency of pain				Intensity of pain			
	Never or rarely (n=14)	Sometimes (n=9)	Very often or always (n=31)	Between-groups differences ²	None or limited (n=23)	Moderate (n=16)	High or very high (n=15)	Between-groups differences ²	Never or rarely (n=20)	Sometimes (n=9)	Very often or always (n=25)	Between-groups differences ²	None or limited (n=17)	Moderate (n=24)	High or very high (n=13)	Between-groups differences ²
	<i>Mean Rank</i>	<i>Mean Rank</i>	<i>Mean Rank</i>	<i>p-value</i> ³	<i>Mean Rank</i>	<i>Mean Rank</i>	<i>Mean Rank</i>	<i>p-value</i> ³	<i>Mean Rank</i>	<i>Mean Rank</i>	<i>Mean Rank</i>	<i>p-value</i> ³	<i>Mean Rank</i>	<i>Mean Rank</i>	<i>Mean Rank</i>	<i>p-value</i> ³
Physical impact	14.82	24.44	34.11	<0.001	20.54	31.56	33.83	0.009	13.13	32.50	37.20	<0.001	15.00	28.54	41.92	<0.001
Biopsychological impact	20.36	20.83	32.66	0.015	22.59	29.44	32.97	0.048	15.80	25.61	37.54	<0.001	16.56	28.65	39.69	<0.001
Total QoLAF-Q	17.21	21.56	33.89	<0.001	22.02	28.63	34.70	0.034	14.00	25.50	39.02	<0.001	14.79	29.75	39.96	<0.001

¹Known-groups categorisation was made on the basis of participants' self-reported suppuration (frequency and amount) and pain (frequency and intensity).

²Between-groups differences were analysed using Kruskal-Wallis H Test.

³Significance level when p-value≤0.05

APPENDIX 1

Quality of Life in patients with Anal Fistula Questionnaire[©]

QoLAF-Q[©]

Spanish and English versions

Manuel Ferrer-Marquez
Natalia Espínola-Cortés
Angel Reina-Duarte
José Granero-Molina
Cayetano Fernández-Sola
José Manuel Hernández-Padilla

Código de identificación		Iniciales del paciente (si el paciente acepta)	
Edad		Nivel de estudios	
Sexo		Fecha	
Ingresos familiares medios (euros/mes)			

Cuestionario de calidad de vida en pacientes con fistula anal (QoLAF-Q)[©]

Hemos creado este cuestionario con la intención de conocer mejor cómo afecta la fistula anal en su calidad de vida.

Como puede ver más abajo, cada pregunta tiene cinco opciones de respuesta. Cada una de estas opciones ha sido numerada del 1 al 5.

Para responder a cada pregunta solo tiene que redondear el número correspondiente a la respuesta que quiere dar. Si lo prefiere, puede marcar con una cruz la casilla que encontrará al lado de cada número.

Si tiene alguna duda o necesita ayuda para rellenar este cuestionario, no dude en preguntar a su médico y este le ayudará encantado.

Por último, recuerde que su información será tratada con total confidencialidad.

1. ¿Con qué frecuencia le sale pus de la fístula anal?				
1 <input type="checkbox"/> Nunca	2 <input type="checkbox"/> Rara vez (pasan semanas sin que supure)	3 <input type="checkbox"/> A veces o de vez en cuando (alguna vez todas las semanas)	4 <input type="checkbox"/> Frecuentemente (casi todos los días)	5 <input type="checkbox"/> Siempre o de manera continua (todos los días)

2. ¿Qué cantidad de pus le sale de la fístula?				
1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Escasa (mancho ligeramente la ropa interior)	3 <input type="checkbox"/> Moderada (mancho bastante la ropa interior y necesito 1 gasa diaria)	4 <input type="checkbox"/> Alta (tengo que usar varias gasas simultáneamente o una compresa diaria)	5 <input type="checkbox"/> Extrema (tengo que usar más de 4 compresas o paquetes de gasas diarias)

3. ¿Con que frecuencia se le escapan gases desde que tiene la fístula?

1 <input type="checkbox"/> Nunca	2 <input type="checkbox"/> Rara vez (pasan semanas sin que me pase)	3 <input type="checkbox"/> A veces o de vez en cuando (alguna vez todas las semanas)	4 <input type="checkbox"/> Frecuentemente (casi todos los días)	5 <input type="checkbox"/> Siempre o de manera continua (todos los días)
-------------------------------------	---	--	---	--

4. ¿ Con que frecuencia se le escapan heces desde que tiene la fístula?

1 <input type="checkbox"/> Nunca	2 <input type="checkbox"/> Rara vez (pasan semanas sin que me pase)	3 <input type="checkbox"/> A veces o de vez en cuando (alguna vez todas las semanas)	4 <input type="checkbox"/> Frecuentemente (casi todos los días)	5 <input type="checkbox"/> Siempre o de manera continua (todos los días)
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5. ¿Qué cantidad de heces se le escapa desde que tiene la fístula?

1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Escasa (mancho ligeramente la ropa interior)	3 <input type="checkbox"/> Moderada (mancho bastante la ropa interior y necesito 1 gasa diaria)	4 <input type="checkbox"/> Alta (tengo que usar varias gasas a la vez o una compresa diaria)	5 <input type="checkbox"/> Extrema (tengo que usar más de 4 compresas o paquetes de gasas diarias)
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6. ¿Con qué frecuencia le duele la zona de la fístula?

1 <input type="checkbox"/> Nunca	2 <input type="checkbox"/> Rara vez (pasan semanas sin que me duela)	3 <input type="checkbox"/> A veces o de vez en cuando (alguna vez todas las semanas)	4 <input type="checkbox"/> Frecuentemente (casi todos los días)	5 <input type="checkbox"/> Siempre o de manera continua (todos los días)
-------------------------------------	--	--	---	--

7. ¿Cuál es la intensidad del dolor que le provoca la fístula?

1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Escaso	3 <input type="checkbox"/> Moderado	4 <input type="checkbox"/> Alto	5 <input type="checkbox"/> Extremo o el peor imaginable
------------------------------------	--------------------------------------	--	------------------------------------	--

8. Desde que sufre los síntomas que le provoca la fístula, ¿cómo diría que es su salud?				
1 <input type="checkbox"/> Excelente	2 <input type="checkbox"/> Buena	3 <input type="checkbox"/> Regular o aceptable	4 <input type="checkbox"/> Mala	5 <input type="checkbox"/> Horrible

9. ¿Cuánto afecta la fistula anal a su salud física? (por ejemplo: a su nivel de energía, patrón de sueño, bienestar general...).				
1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Poco	3 <input type="checkbox"/> Ni poco ni mucho	4 <input type="checkbox"/> Bastante	5 <input type="checkbox"/> Mucho

10. Por favor, díganos cuánto afecta la fistula a su salud psicológica (por ejemplo: a su imagen corporal, su estado de ánimo, su autoestima, su capacidad de concentración...).				
1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Poco	3 <input type="checkbox"/> Ni poco ni mucho	4 <input type="checkbox"/> Bastante	5 <input type="checkbox"/> Mucho

11. ¿Cuánto afecta la fistula anal a su nivel de independencia? (por ejemplo: a su movilidad, a su capacidad de trabajar, a sus actividades de la vida diaria...).				
1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Poco	3 <input type="checkbox"/> Ni poco ni mucho	4 <input type="checkbox"/> Bastante	5 <input type="checkbox"/> Mucho

12. ¿Cuánto afecta la fistula anal a sus relaciones sociales? (por ejemplo: a sus relaciones con amigos/pareja/familia...).				
1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Poco	3 <input type="checkbox"/> Ni poco ni mucho	4 <input type="checkbox"/> Bastante	5 <input type="checkbox"/> Mucho

13. ¿Cuánto afecta la fistula anal a sus relaciones sexuales?				
1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Poco	3 <input type="checkbox"/> Ni poco ni mucho	4 <input type="checkbox"/> Bastante	5 <input type="checkbox"/> Mucho

14. ¿Cuánto afecta la fistula anal a otros aspectos de su vida? (por ejemplo: a su libertad, a su tiempo libre, a sus recursos económicos...).				
1 <input type="checkbox"/> Nada	2 <input type="checkbox"/> Poco	3 <input type="checkbox"/> Ni poco ni mucho	4 <input type="checkbox"/> Bastante	5 <input type="checkbox"/> Mucho

Por favor use el siguiente recuadro para añadir cualquier comentario que desee sobre el cuestionario.

Gracias por su colaboración.

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Participant's code		Participants' initial (if willing to share them)	
Age		Educational level	
Gender		Date	
Family income (net per month)			

Quality of Life in patients with Anal Fistula Questionnaire (QoLAF-Q)[©]

We have created this questionnaire to better understand how your anal fistula affects your quality of life.

As you can see below, each question we ask has 5 possible response-options. Each one of these options has been numbered from 1 to 5.

In order to respond to each question you only need to circle the number that corresponds with the answer you want to give. You can also tick the box next to the number if you prefer doing so.

If you have got any questions, do not understand something or need help to complete this questionnaire, please do not hesitate to ask your doctor. He will happily help you.

Lastly, please remember that the information you provide us will be treated with the strictest confidentiality.

1. How often do you experience discharge (suppuration) from the fistula?				
1 <input type="checkbox"/> Never	2 <input type="checkbox"/> Rarely (Weeks go by without having any discharge)	3 <input type="checkbox"/> Sometimes (I have some discharge every week)	4 <input type="checkbox"/> Often (I have discharge almost every day)	5 <input type="checkbox"/> Always or continuously (I have discharge every day)

2. How much discharge (suppuration) from the fistula do you experience?				
1 <input type="checkbox"/> None	2 <input type="checkbox"/> Limited (I very slightly stain my underwear)	3 <input type="checkbox"/> Some (I get visible stains on my underwear)	4 <input type="checkbox"/> Quite a lot (I have to use sanitary towels)	5 <input type="checkbox"/> An extreme amount (I have to use sanitary towels and change them various times a day)

3. How often do you experience uncontrollable flatulence (farting) since having the fistula?				
1 <input type="checkbox"/> Never	2 <input type="checkbox"/> Rarely (Weeks go by without having any uncontrollable flatulence)	3 <input type="checkbox"/> Sometimes (I have some uncontrollable flatulence every week)	4 <input type="checkbox"/> Often (I have uncontrollable flatulence almost every day)	5 <input type="checkbox"/> Always or continuously (I have uncontrollable flatulence every day)

4. How often do you experience an unintentional loss of stools since having the fistula?				
1 <input type="checkbox"/> Never	2 <input type="checkbox"/> Rarely (Weeks go by without having any unintentional loss of stools)	3 <input type="checkbox"/> Sometimes (I have some unintentional loss of stools every week)	4 <input type="checkbox"/> Often (I have unintentional loss of stools almost every day)	5 <input type="checkbox"/> Always or continuously (I have unintentional loss of stools every day)

5. What is the amount of unintentional stool loss that you usually experience since having the fistula?				
1 <input type="checkbox"/> None	2 <input type="checkbox"/> Limited (I very slightly stain my underwear)	3 <input type="checkbox"/> Some (I get visible stains on my underwear)	4 <input type="checkbox"/> Quite a lot (I have to use sanitary towels)	5 <input type="checkbox"/> An extreme amount (I have to use sanitary towels and change them various times a day)

6. How often do you experience pain in the anal area as a consequence of the fistula?				
1 <input type="checkbox"/> Never	2 <input type="checkbox"/> Rarely (Weeks go by without experiencing any pain)	3 <input type="checkbox"/> Sometimes (I experience some pain every week)	4 <input type="checkbox"/> Often (I experience pain almost every day)	5 <input type="checkbox"/> Always or continuously (I experience pain every day)

7. What is the intensity of the pain that you experience as a consequence of the anal fistula?				
1 <input type="checkbox"/> No pain	2 <input type="checkbox"/> Mild pain	3 <input type="checkbox"/> Moderate pain	4 <input type="checkbox"/> Severe pain	5 <input type="checkbox"/> Extreme or the worst imaginable pain

8. Since suffering the symptoms of the anal fistula, how would you say your health is?				
1 <input type="checkbox"/> Excellent	2 <input type="checkbox"/> Good	3 <input type="checkbox"/> Acceptable (it is not too bad)	4 <input type="checkbox"/> Bad	5 <input type="checkbox"/> Horrible

9. How much does the anal fistula affect your physical health? (e.g. energy and activity levels, sleeping pattern, general well-being...)				
1 <input type="checkbox"/> Not much	2 <input type="checkbox"/> Little	3 <input type="checkbox"/> Somewhat	4 <input type="checkbox"/> Much	5 <input type="checkbox"/> A great deal

10. How much does the anal fistula affect your psychological health? (e.g. your body image, self-esteem, state of mind, ability to focus on a particular task...)				
1 <input type="checkbox"/> Not much	2 <input type="checkbox"/> Little	3 <input type="checkbox"/> Somewhat	4 <input type="checkbox"/> Much	5 <input type="checkbox"/> A great deal

11. How much does the anal fistula affect your independence level? (e.g. mobility, ability to work, daily life activities...)				
1 <input type="checkbox"/> Not much	2 <input type="checkbox"/> Little	3 <input type="checkbox"/> Somewhat	4 <input type="checkbox"/> Much	5 <input type="checkbox"/> A great deal

12. How much does the anal fistula affect your social relationships and interactions with others? (e.g. your relationships with friends, family, partner...)				
1 <input type="checkbox"/> Not much	2 <input type="checkbox"/> Little	3 <input type="checkbox"/> Somewhat	4 <input type="checkbox"/> Much	5 <input type="checkbox"/> A great deal

13. How much does the anal fistula affect your sexual relationships?				
1 <input type="checkbox"/> Not much	2 <input type="checkbox"/> Little	3 <input type="checkbox"/> Somewhat	4 <input type="checkbox"/> Much	5 <input type="checkbox"/> A great deal

14. How much does the anal fistula affect other aspects of your life? (e.g. your freedom, your economic income, your free time...)				
1 <input type="checkbox"/> Not much	2 <input type="checkbox"/> Little	3 <input type="checkbox"/> Somewhat	4 <input type="checkbox"/> Much	5 <input type="checkbox"/> A great deal

Please, use the box below to add any comments you wish about this questionnaire.

Thanks for your cooperation.

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