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Quality of life in 1870 patients with constipation and/or fecal incontinence : constipation should not be underestimated

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ABSTRACT

Background: Quality of life is increasingly seen as important, but remains difficult to assess in patients with functional anorectal complaints.

Objective: We aimed to quantify quality of life and to analyse the symptomatic descriptors associated with a poor outcome in patients with faecal incontinence (FI) and/or constipation.

Methods: The characteristics of the patients, data from self-administered questionnaires and from physical examinations were evaluated prospectively for all cases of functional anorectal disease over a period of thirteen years. Functional anorectal disease included faecal incontinence (FI) and/or constipation. Patients with scores in the lowest quartile of the Gastrointestinal Quality of Life Index (GIQLI) were considered to have suffered severe alterations to their quality of life, and were compared with the other patients.

Results: In total, 1870 patients with functional anorectal disease were included (470 with a severely altered quality of life (GIQLI<70)). Constipation predominated (1212/1870; 65.1%) and severe FI was frequent (761/1870; 40.9%). Severely altered quality of life was significantly associated with constipation ($p= 0.0001$), urinary urgency and incontinence ($p=0.0001$), depression ($p=0.001$), diabetes ($p=0.0224$), severe FI ($p= 0.0001$), neurological disease ($p= 0.0138$) and liquid stools ($p= 0.0002$) in multivariate analysis.

Conclusion: Several treatable factors are associated to an impaired quality of life in patients with functional anorectal disorders. Intervention studies are mandatory (stool consistency and frequency).

Keywords: quality of life, faecal incontinence, constipation

INTRODUCTION

Health-related quality-of-life (HRQoL) studies have come to the fore in recent years, and provide a new dimension for analysing the impact of both disease and treatment. In cases of functional disease, it is particularly difficult to evaluate quality of life, because the dysfunction relates partly to social and psychological factors. Constipation and faecal incontinence (FI) were found to have a negative impact on quality of life [1,2]. Many studies have evaluated the impact of FI on quality of life [3-8], but fewer data are available concerning the impact of constipation on quality of life [2,9-12]. FI and constipation frequently occur together, but the association of these two conditions is rarely considered [2].

The Gastrointestinal Quality of Life Index (GIQLI) [13] is a validated tool for assessing HRQoL in clinical studies of patients with gastrointestinal disease. of its principal strength is that can be used to evaluate HRQoL in different types of functional digestive complaints. It is easy to perform and yields a quantified global score. This tool has already been used in patients with anorectal disorders [2,6,14,16].

The aims of this study were: (i) to describe the characteristics and quality of life of patients with functional anorectal disease (faecal incontinence (FI) and/or constipation) and (ii) to identify the factors associated with changes to HRQoL in this population.

MATERIALS AND METHODS

Study Population

All patients referred to our tertiary unit (Rennes University Hospital, France) for an anorectal complaint between 2005 and 2016 were consecutively recruited and prospectively included in a registry (*Fondamentum,* CNIL no. 1412467).

The patients included in this registry were excluded from the study if they were pregnant or had a history of colon, rectal or anal cancer, or of anal or rectal stricture. Self-administered questionnaires and physical examination data were prospectively recorded in a database. Age, sex, height, weight, medical history (including diabetes, neurological disease and depression) and surgical history (including haemorrhoidectomy, anal surgery, cholecystectomy, and surgery for anterior or posterior colopocele) were recorded. Symptoms were recorded as previously described [17]. The questionnaire focused on the main anorectal complaints (incontinence, constipation, dyschezia, Bristol stool scale, number of stools per week, symptom duration). Dyschezia was defined by sensation of blockage at defecation, sensation of incomplete evacuation or straining during defecation. Urge and passive FI were differentiated. Urgency was associated with a perceived urge to defaecate and passive FI with the stool loss without being aware of it. FI was evaluated with the validated Cleveland Clinic Incontinence Score (CCIS 0–20) [18]. Constipation was assessed with the validated Knowles-Eccersley-Scott Symptom Constipation Score (KESS) [19]. Quality of life was quantified with a validated scale for gastrointestinal complaints (Gastrointestinal Quality of Life Index (GIQLI)) [13] and the Urinary Distress Inventory scale (UDI) for urinary incontinence, as previously descrived in studies of faecal incontinence cohorts [20]. Functional anorectal disease included faecal incontinence (FI) and/or constipation in this study.

Clinical dyssynergic defaecation and pelvic floor disorders were assessed by physical

examination. Internal intussusception and high-grade prolapse were defined as an intra-anal or exteriorised intussusception of the rectal wall during straining.

Until 2016, French legislation does not require the written consent for this type of study and the CNIL declaration was sufficient.

Definitions

FI was defined as a CCIS > 5 and severe FI was defined as a CCIS ≥ 9 [15,21]. Significant constipation was defined as a KESS ≥ 10 [19]. Patients with both severe FI and severe constipation were considered to have a "mixed" condition. Liquid stools were defined as Bristol stool score of 5, 6 or 7 [22].

We chose to define altered quality of life on the basis of GIQLI score because the GIQLI is a validated scale for gastrointestinal complaints. A key objective of the study was to identify the factors associated with a severely altered quality of life in our population. We defined patients with scores for this scale in the lowest quartile as having a severely altered quality of life. We compared these patients with the other patients.

Statistical analysis. Quantitative data are expressed as means (interquartile ranges [IQRs: 25% and 75%]). Categorical variables are presented as totals and percentages of the cohort. Qualitative variables are expressed as positive values. The upper limit of the lowest quartile for GIQLI score was 71. Below this threshold, patients were considered to have a severely altered quality of life. We compared the patients with a severely altered quality of life (GIQLI< 71) with the other patients (GIQLI > 71), in *t*-tests for quantitative variables and Chi-squared tests for categorical variables. For each analysis, a *p*-value < 0.05 was considered to be statistically significant. Items with *p*<0.05 in the univariate analysis were integrated into a binary logistic regression model for multivariate analysis. If a univariate analysis included

several significant mutually dependent variables, only one of these variables was included in the multivariate analysis. Qualitative variables were preferred when possible. Optimal cut-off values were obtained by optimising the Youden index from an area under receiver operating characteristic (AUROC) curve analysis. The results are shown as odd ratios (ORs) with 95% CIs. Statistical analyses were performed with JMP Pro Software, version 9.0.2 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Population

From 2005 to 2016, 1870 patients with faecal incontinence (FI) and/or constipation were included in the registry and their data were recorded in a prospective database. The characteristics of the population are shown in **Table 1**. Mean GIQLI score was 86.7 (23.2). Based on the distribution of GIQLI scores in our population, 470 of 1870 (25%) patients had a severely altered quality of life (GIQLI<71). These patients were compared with the remaining 1400 patients with GIQLI >71. FI was reported by 1212 of the 1870 patients (65.1%) and was severe in 761 of the 1870 patients (40.9%). Constipation was considered significant in 1398 (74.5%) patients. Among the 658 patients with "isolated "significant constipation, 322 (48.9%) had IBS-C. Overall, 450 of the 1870 (24.1%) patients had a "mixed" condition combining both FI and constipation. Among the 470 patients with severely altered quality of life, 137 (29.1%) had constipation, 74 (15.7%) had FI and 259 (55.1%) had both. In total, 1077 patients self-reported FI: 366 (34.0%) experienced urgency, 473 (43.9%) described passive FI and 238 (22.1%) had a mixed form of FI. There was no significant difference in age or sex ratio between patients with and without severely altered quality of life. Those with a severely altered quality of life had a higher body mass index (BMI). Overall

120 of 951 patients (12.6%) were obese (BMI>30). Diabetes, neurological disease, depression and a history of colpocele surgery were more frequent in patients with a severely altered quality of life. Patients with a severely altered quality of life were more likely to have urinary incontinence.

Anorectal complaints

Patients with a severely altered quality of life had significantly higher scores for FI and constipation. The association of severe FI with severe constipation was more frequent in patients with a severely altered quality of life (182/470 (38.7%) vs 268/1400 (19.1%), p=0.0001). In terms of clinical characteristics, patients with a severely altered quality of life had stools that were more frequent and more liquid. By contrast, there was not difference between the two groups in terms of the presence of clinical dyssynergic defaecation and rectal prolapse.

Factors associated with a severely altered quality of life

According to receiver-operator characteristic (ROC) curves (data not shown), the optimal cut-off value for UDI was 8. In a multivariate analysis model including history of diabetes, neurological disease, depression, cholecystectomy, prior surgery for pelvic floor disorders, liquid stools, CCIS $\geq$ 9, KESS $\geq$ 10, and UDI score >8, the factors significantly associated with a severely altered quality of life were history of diabetes, neurological disease, depression, liquid stools, severe FI, constipation and a UDI score >8.

DISCUSSION

This study highlights the high prevalence of constipation (74.5%) and of an association of severe FI and constipation (24.1%) in our population. Patients with a severely altered quality

of life reported higher severities in assessments of both FI and constipation. These symptoms had at least as strong an impact on quality of life as neurological disease and depression.

The main strengths of this work are the large sample size, and the prospective and systematic quantification of FI, constipation and urinary disorders in a proctology unit. The data were recorded in a prospective database, according to recommended classifications and the results obtained for validated scales [13,19,22]. However, care is required in the interpretation of our results: recruitment at a tertiary centre specialising in these fields may lead to the selection of the patients with the most severe complaints. In addition, despite the adequate assessment of most patients in the registry, some data, particularly for anthropometric data or treatments were missing and not all patients had anorectal studies. Finally, specific questionnaire for the constipation as PAC-QOL [23] and for the FI as FIQL [24] were not used and that is a limitation. However, it is important to note that FIQL is validated in French [24] such as GIQLI but PAC-QOL is not.

It is not surprising to find that comorbid conditions, such as depression and neurological disorders, are associated with a decrease in QoL. Anorectal complaints may increase the impact of such conditions. It has already been suggested that HRQoL is associated with depression in patients with FI [8,14,25]. Anorectal complaints are frequently observed in patients with neurological disease are generally involve both FI and constipation [26]. These problems are known to reduce the patient's quality of life and to cause anxiety [27]. The items "depression" and "neurological disease" (e.g. diabetes) are very difficult to modify because they are chronic diseases causing permanent damage. However, physicians must take into account as the impact of the patients' backgrounds on their quality of life, in addition to their complaints.

Interestingly, Qol was more strongly linked to constipation than to FI. Very few studies of quality of life in patients with anorectal disorders have included evaluations of constipation [2,6,10,14]. However, in one cohort of patients with various anorectal disorders, the authors [2] suggested that patients with severe constipation or with both severe constipation and FI had a poor quality of life. These findings are consistent with our data for a population of patients with anorectal disorders. Two paediatric studies [10,11] have shown that children with functional constipation and FI are at particular risk of developing specific HRQoL problems, such as illness-related activity limitations, psychosocial issues, disease burden and worry, and family conflict. These results suggest that the management of patients with poor HRQoL and anorectal disorders should involve the detection and treatment of constipation. It would be interesting to follow our population to assess the efficacy of the treatments.

Finally, both stool consistency and stool frequency were major factors associated with HRQoL in our study. However, conflicting results have been obtained for these factors in previous studies. Some studies have reported that hard stools have a stronger negative impact on HRQoL than liquid stools [3], but stool consistency was not evaluated with the validated Bristol Stool Form Scale [22]. Other studies focusing on FI have reported that liquid stools have a more negative impact on general QoL than solid stools [28]. In our study, liquid stools were associated with a poor HRQol, as were constipation and severe FI. A liquid consistency of the stools may be linked to severe constipation (stercoral diarrhoea) and severe FI. Taken together, these results highlight the need for better therapeutic control of stool consistency.

In conclusion, this study quantified the link between poor QoL and constipation and/or FI. By contrast to constitutive comorbid conditions (diabetes, neurological disorders, depression),

it may be possible to use simple therapeutic approaches to improve some components (stool consistency, straining at stool, restraining) in patients with a combination of constipation and faecal incontinence (a quarter of the study population). A prospective longitudinal study would be useful, for analysis of a step-by-step therapeutic approach to Qol. This comprehensive approach would make it easier to determine the strategies to be given priority in multimodal treatments.

Author contributions:
Conception and design of the study: CB, LS
Acquisition of data: CB, MC, AML, AR, TW, LS
Analysis and interpretation of data: CB, LS
Statistical analysis: CB, LS
Drafting of the article: CB and LS
Critical revision for intellectual content: AR, GB
All authors reviewed the paper and approved the final submitted version.

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Variable	All (N=1870) N(%) or mean (SD)	GIQLI <71 (n=470) N(%)or mean (SD)	GIQLI>=71 (n=1400) N (%) or mean (SD)	Univariate analysis p-value	Multivariate analysis OR [95% IC] p-value
Age (years)	58.7 (14.6)	59.0 (14.7)	58.6 (14.6)	0.5408	
Female sex (ratio F/M)	1662/208 (88.9/11.1)	421/49 (89.6/10.4)	1241/159 (88.6/11.4)	0.5878	
BMI (kg/m^2)	24.6 (5.1)	25.2 (5.9)	24.3 (4.8)	0.0173	
Diabetes	59 (31.6)	23 (4.9)	36 (2.6)	0.0124	2.18 [1.12 – 4.25], 0.0224
Neurological disease	113 (6.4)	50 (10.6)	63 (4.5)	0.0001	1.91 [1.14 – 3.21], 0.0138
Depression	350 (18.7)	144 (30.6)	206 (14.7)	0.0001	2.38 [1.73 – 3.27], 0.0001
Past treatments					
Hemorroidectomy	217 (11.6)	63 (13.4)	154 (11.0)	0.1591	
Cholecystectomy	162 (8.7)	53 (11.3)	109 (7.8)	0.0199	1. 39 [0.89 – 2.18], 0.1472
Surgery of anterior colopocele	195 (10.4)	63 (13.4)	132 (9.4)	0.0147	1.55 [0.98 – 2.44], 0.0589
Surgery of posterior colopocele	81 (4.3)	27 (5.7)	54 (3.9)	0.0820	
Clinical caracteristics					
Duration of symptoms (months)	60.5 (94.4)	63.3 (124.1)	59.6 (82.4)	0.4939	
Urinary incontinence	654 (35.0)	181 (38.5)	473 (33.8)	0.0631	
Liquid stool (Bristol stool (5-6-7))	421 (30.7)	125 (35.5)	296 (28.3)	0.0005	1.77 [1.31 – 2.38], 0.0002
Number stools/week	11.0 (11.0)	13.6 (15.5)	10.6 (9.3)	0.0001	
Clinical dyssynergic defecation	207 (11.1)	46 (9.8)	161 (11.5)	0.3058	
Rectal prolapse	160 (9.9)	41 (10.4)	119 (9.7)	0.6964	
Scores					
CCIS score	7.9 (5.7)	9.5 (6.0)	7.3 (5.5)	0.0001	
CCIS score>=5	1212 (65.1)	333 (71.3)	879 (63.0)	0.0011	
CCIS score>=9	761 (40.9)	245 (52.5)	516 (37.0)	0.0001	2.13 [1.59 – 2.85], 0.0001
KESS	15.4 (8.8)	19.0 (9.4)	14.3 (8.3)	0.0001	
KESS >=10	1398 (74.5)	396 (84.3)	1002 (71.6)	0.0001	3.44 [2.34 – 5.07], 0.0001
UDI score	6.2 (4.8)	8.4 (5.0)	5.5 (4.5)	0.0001	
UDI score >8	577 (31.7)	223 (49.2)	354 (25.9)	0.0001	2.58 [1.95 – 3.42], 0.0001

Abbreviations : BMI= Body Mass Index; CCIS= Cleveland Clinic Incontinence Score; KESS= Knowles-Eccersley-Scott Symptom Constipation Score; GIQLI= Gastrointestinal Quality of Life Index; UDI= Urinary Distress Inventory scale; I