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Quality of life and 3D-EUS assessment for anal incontinence after childbirth

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AUTHOR'S CONTRIBUTION

Patricia Tejedor and Carlos Pastor contributed equally in the analysis of the data and writing of the manuscript. The rest of the authors critically revised the paper for important intellectual content. All authors have contributed to the work and agreed on the final version. This manuscript is not being considered by any other journal.

- PT: project development, data collection, analysis and interpretation of data, manuscript writing, manuscript editing. Supervision.
- IB: manuscript editing.
- JP: data analysis and manuscript editing.
- MO: supervision and manuscript editing.
- CG: analysis and interpretation of data.
- DG: supervision and manuscript editing.

– CP: protocol/project development, data analysis and interpretation of data, manuscript writing.

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COMPLIANCE WITH ETHICAL STANDARDS

– Data availability: the datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

– The authors declare that they have no conflicts of interest.

– Ethical approval: all procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the Declaration of Helsinki of 1964 and its subsequent amendments or comparable ethical standards.

– Informed consent: informed consent was obtained from all individuals that participated in the study.

ABSTRACT

Background: the incidence of obstetric sphincter tears has risen to 15-30% and the prevalence of anal incontinence (AI) symptoms after childbirth may be as high as 40%. The present study evaluates the correlation between obstetric injuries detected by endoanal ultrasound (3D-EUS) and AI symptoms, as well as their impact on the quality of life (QOL) of women after childbirth.

Methods: a prospective observational study was performed of pregnant women evaluated before (baseline) and three months after childbirth to ensure the integrity of the anal sphincters and to evaluate possible injuries. The Fecal Incontinence Quality of Life (FIQL) questionnaire and the Cleveland Clinic Score of Incontinence (Wexner) were completed before and after childbirth. The questionnaire results were correlated with an assessment of sphincter defects performed by 3D-EUS.

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Results: a total of 56 females were included in the study. Overall, 48% developed symptoms of AI after childbirth, with a significant decrease in their FIQL compared to the initial evaluation, 3.9 (0.05) *vs* 3.4 (0.8), respectively (p = 0.000). In addition, 42% of the cohort presented with some kind of obstetric sphincter defect on the 3D-EUS. Instrumental assisted delivery and the sphincter defects were the only two significant factors identified via multivariate analysis that were associated with a decrease in QOL (0.4, 95% CI, 0.07-0.8).

Conclusions: AI after childbirth was associated with a huge impact on QOL, especially in patients with sphincter injuries. A complete clinical evaluation, including 3D-EUS, is recommended to prevent, manage or treat AI in primiparous females.

Key words: Quality of life. Fecal incontinence. Primiparous women. Obstetric sphincter injuries. MCID. Minimum important difference.

INTRODUCTION

The incidence of obstetric sphincter tears in females has increased in recent years, with current rates between 15 and 30% after vaginal deliveries (1-3). As a consequence, the rate of patients with symptoms of anal incontinence (AI) in the general population has risen to about 10-20% (4-6). Clinicians have several tools to define the severity and impact of AI symptoms. The Cleveland Clinic Score of Incontinence (Wexner) (7) is currently the most widely used evaluation tool, which is based on a questionnaire regarding the frequency and type of incontinence. More recently, other questionnaires have been developed that provide a better assessment of AI, such as the Fecal Incontinence Quality of Life (FIQL) (8). The endoanal ultrasound (EUS) is the gold standard for the study of sphincter defects (9). This test has improved over time and the three-dimensional volume set can be manipulated during or after an endoanal ultrasound examination (3D-EUS). The 3D-EUS makes it possible to detect small sphincter injuries that were otherwise unobserved (10-12). Thus, it is possible to detect as many as 35% of asymptomatic patients with undiagnosed sphincter injuries after vaginal deliveries (13). All females diagnosed with an obstetric injury have an important risk of developing AI in the

future (14). Therefore, early detection and treatment of these defects is important and can be achieved via the introduction of the routine use of the 3D-EUS evaluation after childbirth. As a consequence, the presence of AI symptoms will have a direct influence on quality of life (QOL) (15). There is a current lack of evidence about the exact relationship between the 3D-EUS findings, the presence of AI and their impact on QOL after childbirth. Therefore, the present study aimed to evaluate the impact of obstetric injuries and AI symptoms on the QOL of primiparous females.

METHODS

A prospective observational study was performed in pregnant females that attended the Obstetrics Clinic in a tertiary center in Madrid, Spain (Hospital Universitario Fundación Jiménez Díaz). The inclusion criteria were primiparous pregnant women over 18 years of age, who were evaluated during pregnancy and after childbirth, with a complete evaluation at both time points. Exclusion criteria included non-primiparous patients and those with a history of anal surgery. The study was started after obtaining approval by the local institutional review board committee.

Patients were initially recruited during the standard obstetric visits during the second trimester, i.e., in the 20th week of pregnancy. After obtaining informed consent, a first 3D-EUS was performed before childbirth to ensure the integrity of the sphincter rings. This technique is inexpensive, non-aggressive and well tolerated by patients. All participants were examined in the left lateral position, without mechanical bowel preparation. A dynamic 3D-EUS was performed by the same colorectal surgeon (PT) in the outpatient clinic using an ultrasound device (type AR 54 AW, frequency: 5-10 MHz, Hitachi Medical Systems®, Japan). Axial and longitudinal images were merged into a single cube image, recorded and analyzed in multiples planes (16). The probe was inserted into the anal canal and the sphincter ring was examined from the puborectalis muscle level to the anal verge. The continuity of both anal sphincters was checked and recorded in every case in order to obtain 3D reconstruction images.

All patients also completed two questionnaires, the Wexner scale (7) and the FIQL (8). The Cleveland Clinic Wexner score is based on five parameters and each is

scored on a scale from 0 to 4, where 0 indicates perfect control and 4 indicates daily incontinence. Overall scores range from 0 to 20. The FIQL is composed of 29 items, divided into four aspects of QOL: lifestyle (ten items), coping behavior (nine items), depression (seven items) and embarrassment (three items). Each block of questions is scored between 1 and 4, where 1 indicates that the subject is very affected and 4 indicates that they are not affected at all. For example, there are questions focused on activities and relationships in terms of lifestyle. A global index between 0 and 4 is finally calculated by adding the values of each block of questions.

The following data from the electronic medical records after delivery were recorded: age and body mass index (BMI) at the time of childbirth, episiotomies, the need for instrumental delivery and the presence of obstetric anal sphincter injury assessed by the attending gynecologist using the Obstetrical Anal Sphincter Injuries (OASIS) classification (17). Patients were re-examined three months after birth and possible sphincter injuries were detected and measured via an assessment of the width and depth of the defect. These were classified according the Starck's scoring classification, as shown in figure 1 (18). Tears in the external sphincter muscle were defined as an interruption of the texture (Fig. 2) and scars are usually shown as a low reflectiveness area corresponding to fibrosis (Fig. 3). Patients filled out the same questionnaires (Wexner and FIQL) and underwent a second 3D-EUS performed by the same clinician. A second blind-observer (CP) reviewed the 3D-EUS images from all cases to obtain a second evaluation.

Statistical analysis

Sample size was estimated using the GRANMO® software, v. 7.12 (IMIM, Barcelona, Spain). Twenty-six patients would be required in each group to detect statistically significant difference FIQL questionnaire results, assuming an alpha risk of 0.05, a beta risk of 0.20, a SD of 0.6 (for FIQL) and a minimum expected difference of 0.5. The expected proportion of patients lost during follow-up was 10%.

Descriptive statistics are presented with the mean and standard deviation (SD). A comparison of differences between the groups was performed using a Chi-square analysis in order to compare proportion variables. The Fisher's exact test was used

when any observed value in the contingency table was less than 5. Dichotomous outcomes were expressed as relative risk (RR) with 95% CI. The differences between the groups were assessed using the Student's t-test and the intraclass correlation coefficient (ICC) value was also calculated for inter-observer agreement of the Starck score. A value of 1 indicated a perfect agreement between ratings; 0.81-0.99, a very good agreement; 0.61-0.80, good; 0.41-0.60, moderate; 0.21-0.40, fair; and 0.20 or less indicated a poor agreement. A multiple linear regression model was performed including variables with a $p < 0.25$ in the univariate analysis.

Distribution-based approaches were used to determine the minimal clinically important difference (MCID) for each of the FIQL measures (0.5 x SD). The change from baseline to three months in the scale scores that corresponded to a medium effect size (0.5 baseline SD) were also calculated. All statistical analyses were performed using SPSS® version 22 software (SPSS, Inc., Chicago, IL).

RESULTS

A total of 68 primiparous females were included in the study. However, nine patients were lost during follow up and three did not complete both questionnaires. Therefore, there were 56 patients with complete evaluations. The mean age was 33.1 ± 5 years and the mean BMI was 23.7 ± 4 kg/m^2. The integrity of both sphincters before childbirth was confirmed in every patient by 3D-EUS. Baseline characteristics of the study population are shown in table 1. A severe obstetric anal sphincter injury (OASIS) > III was diagnosed in seven cases (14.9%). The presence of sphincter defects was found via 3D-EUS after childbirth in 25 patients (44.6%), while the remaining patients (n = 31) had normal sphincters. Of these, 64% were symptomatic at the time of the evaluation. The ICC value for agreement between observations at the time of assessing the Starck's Score was 0.94 (95% CI, 0.91-0.97). The majority of defects affected the EAS and defects were observed with a total depth of more than a half of the length of the sphincter (Starck's score > 4). In addition, an isolated defect of the IAS was identified in three cases and other three cases were classified as Starck's score ≥ 8, which means that both sphincters were affected.

Multivariate analysis took into account age and BMI, the type of delivery (vaginal/caesarean section/instrument assisted delivery), the presence of episiotomy, the Wexner's scores, the presence/absence of symptoms and the presence of sphincter defects detected by 3D-EUS. An instrument delivery and the presence of sphincter lesions were the only independent variables that demonstrated a negative influence on QOL, which decreased the overall score by 0.4 (95% CI, 0.07-0.8, p = 0.04). These results are shown in table 1. The ultrasound findings were correlated with all the items of the FIQL and the presence of sphincter defect had a significant negative impact on QOL.

Continence test and QOL questionnaires showed an overall rate of 48% in symptomatic patients. There was a direct correlation between sphincter injuries (detected by 3D-EUS) and AI symptoms (OR 3.2 [1.1-9.7]) (p = 0.036). Changes in scale scores and MCIDs values for each item from baseline to three months after childbirth are presented in table 2. A significantly lower score was reported in symptomatic patients compared to the non-symptomatic (3.4 [0.8] *vs* 3.9 [0.1] respectively, p = 0.000), according to the univariate analysis. The MCIDs calculations suggested that there were important clinical differences in every FIQL item between patients stratified by the presence/absence of AI symptoms and sphincter defects. However, there was no statistically significant reduction in the scale scores. The comparison of each specific item before and after childbirth is presented in table 3. All items evaluated in the questionnaire improved after delivery in asymptomatic patients and also in patients with sphincter integrity. In contrast, QOL decreased significantly three months after delivery in symptomatic patients or those with a sphincter lesion. Most women experienced more than one type of sphincter loss; soiling or gas incontinence were the most frequently reported symptoms (more than 80%). However, the impact on the decline in QOL was not significant. On the other hand, the loss of solids had major significant influence on QOL, followed by the loss of liquids. Coping behavior was the most affected social aspect in the patients' lives due to these problems, followed by depression.

The Wexner's score results are presented in figure 2. Of note, 10 to 20% of women reported daily episodes. The frequency of episodes of incontinence (daily as opposed

to weekly/monthly) had a significant negative impact on QOL (3.57 [0.6] *vs* 2.28 [1.4], p = 0.01).

DISCUSSION

In our study, 48% of the primiparous females had AI symptoms after childbirth and half of the cohort had sphincter injuries on ultrasound endoscopy. Anal incontinence after childbirth and the presence of sphincter injury had a significant association with QOL for primiparous females after birth, as measured by the FIQL and Wexner scores.

According to the literature, the incidence of AI in the general population has risen to around 10-20% (4-6) and the rate of sphincter trauma after vaginal delivery has increased over the last decade to nearly 30% (12,13,19). In addition, the rate of patients with any kind of continence disorder after childbirth is close to 50-60%. Due to the presence of a compensatory mechanism in younger patients with AI, the symptoms will normalize between three to six months after childbirth (20-23). However, it is reported that AI symptoms return in middle-aged women that are associated with other pelvic floor diseases (14,21,24).

According to our data, 48% of patients presented with any type of AI symptoms after childbirth; the majority (80%) suffered from soiling and/or gas incontinence measured by the FIQL test and Wexner score. The type and frequency of soiling can affect QOL differently. According to previously published studies, the FIQL score in females with solid or liquid stool discharge were more severely affected compared to patients with only gas incontinence (25). Moreover, the frequency of AI episodes had more of an impact on QOL than the type of soiling itself; FIQL score 2.28 (1.4) *vs* 3.57 (0.6) (p = 0.01) (26). Some authors suggest that women could view gas incontinence as a normal physiologic activity (27) and the FIQL questionnaire does not discriminate between gas incontinence and solid loss. The prevalence found in our study was slightly higher than that expressed in other previously published studies (20). This may be due to the fact that women are more likely to reveal AI symptoms via questionnaires and when asked specifically about flatus incontinence.

Many risk factors have been investigated and have been shown to have a negative impact on QOL after childbirth (1,28-30). These include the presence of an episiotomy, prolonged or instrumental deliveries, the occurrence of OASIS and sphincter defects, newborn weight or age of the mother. In our study, an instrumental assisted delivery and the presence of a sphincter defect diagnosed by 3D-EUS were the only two significant factors that decreased QOL, according to the multivariate analysis, whereas the presence of any other factor showed a trend towards a worse QOL with every item.

Based on our data, there is a correlation between AI symptoms and sphincter defect, (OR 3.2; 1.1-9.7; p = 0.036). However, 31% of females with obstetric injuries were asymptomatic. Even though some asymptomatic patients did not experience a decrease in QOL, it is important to highlight that AI symptoms may appear up to ten years after childbirth (14,20-24). Consequently, the effect on QOL may also appear during the following years. Therefore, it is crucial to take this into account and not delay treatment for this condition, as it will result in a lower QOL over time (31). Therefore, we believe that patients with occult obstetric injuries, even when asymptomatic, should be referred for biofeedback. This is due to the fact that pelvic floor exercises have been shown to reduce AI symptoms (32) and also have potential benefits for QOL (33,34). This area needs further investigation, as changes in obstetric practice may be required from the beginning and strategies planned during and immediately after childbirth in order to prevent AI (30).

The MCID is the smallest change detected by an instrument that is associated with a clinically meaningful change (35), this has been used to identify clinically relevant changes in different conditions related to AI. However, to the best of our knowledge, MCIDs for all the items of the FIQL questionnaire have never been calculated before. These calculations are presented in table 2 and range between 0.21 and 0.31. As shown in table 3, the difference between the baseline and three month evaluation of all the FIQL values were similar to the MCIDs thresholds. Although they were not statistically significant and they should be considered as clinically relevant.

This study has some limitations that should be mentioned. This was an observational study with a small sample size. However, statistically significant differences were

identified despite the small sample size. We also believe that patients had a complete evaluation before and after childbirth by questionnaires as well as an assessment by endoanal ultrasound. Our data demonstrate the great impact of AI and sphincter defects on QOL and the importance of further investigation and treatment options in this area.

CONCLUSION

AI after childbirth is associated with a great impact on QOL, especially in females with sphincter injuries. Clinicians should perform a postpartum screening for AI and offer treatment to symptomatic patients or those with a sphincter defect detected by 3D-EUS. Even if they are asymptomatic.

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Table 1. Patient baseline characteristics and outcomes of FIQL after childbirth according to pre and post-delivery characteristics. Results of the univariate and the multivariate analysis

Variable		*n = 56*	*FIQL scale** after childbirth (mean [SD])	*p value (univariate analysis)*	*p value (multivariate analysis)*
Age (mean ± SD)		33.1 ± 5 years			
BMI (mean ± SD)		23.7 ± 4 kg/m^2			
Overall FIQL (mean ± SD)		3.8 (0.3)[†]	3.7 (0.4)	*NS*	
Type of delivery	Caesarean section	9/56 (16.1%)	3.9 (0.2)	0.18	0.988
	Vaginal delivery	47/56 (83.9%)	3.7 (0.7)		
Mediolateral episiotomy	No	19/47 (40.4%)	3.9 (0.1)	0.025	0.804
	Yes	28/47 (59.6%)	3.5 (0.8)		
Instrumented deliveries	No	26/47 (55.3%)	3.9 (0.1)	0.134	*0.017*
	Yes	21/47 (44.7%)	3.4 (0.9)		
OASIS	Grades 0-II (%)	40/47 (85.1%)	3.7 (0.6)	*0.014*	0.541
	Grade III (%)	7/47 (14.9%)	3.6 (0.2)		
Wexner (3 months after childbirth)	= 0 (asymptomatic)	29/56 (51.8%)	3.9 (0.1)	*0.001*	0.115
	≥ 1 (symptomatic)	27/56 (48.2%)	3.4 (0.8)		

Starck (3 months after childbirth)	= 0 (no sphincter defect) ≥ 1 (sphincter defect)	31/56 (55.4%) 25/56 (44.6%)	3.9 (0.3) 3.4 (0.9)	*0.04*	*0.045*

*Scales range from 1 to 4; 1 represents a poorer QOL. †Before childbirth.

Table 2. Changes in scores and distribution-based MCIDs for FIQL (n = 56)

*FIQL scale**	*Baseline mean (SD)*	*3 months mean (SD)*	*3 months-baseline (SD)*	*p value*	*MCID (95% CI)*	*Effect size†*
Overall FIQL	3.8 (0.3)	3.7 (0.4)	-0.03 (0.8)	NS	0.15 (0.06, 0.34)	-0.08
Lifestyle	3.8 (0.4)	3.7 (0.6)	-0.06 (0.7)		0.20 (0.09, 0.29)	-0.18
Coping behavior	3.7 (0.6)	3.7 (0.6)	0.05 (0.9)		0.30 (0.11, 0.46)	0.07
Depression	3.8 (0.5)	3.6 (0.6)	-0.09 (0.9)		0.25 (0.09, 0.40)	-0.15
Embarrassment	3.9 (0.4)	3.8 (0.6)	-0.04 (0.8)		0.20 (0.04, 0.40)	-0.08

FIQL: Fecal Incontinence Quality of Life; MCID: minimal clinically important difference (0.5 * SD). *Scales range from 1 to 4; 1 represents a poorer QOL. †Effect size = (3 months mean-baseline mean)/baseline SD.

Table 3. Outcome summaries of FIQL scores before and after childbirth by the presence/absence of AI symptoms and sphincter defects (p values were calculated using the Wilcoxon test)

FIQL scale* mean (SD)	Wexner = 0 (asymptomatic)		p value	Wexner ≥ 1 (symptomatic)		p value	Starck = 0 (no sphincter defect)		p value	Starck ≥ 1 (Sphincter defect)		p value
	Baseline	3 months		Baseline	3 months		Baseline	3 months		Baseline	3 months	
Overall FIQL	3.7 (0.5)	3.9 (0.05)		3.8 (0.2)	3.4 (0.8)		3.7 (0.5)	3.9 (0.2)		3.9 (0.2)	3.4 (0.8)	
Lifestyle	3.7 (0.4)	3.9 (0.2)		3.8 (0.2)	3.4 (0.8)		3.7 (0.4)	3.8 (0.3)		3.9 (0.2)	3.5 (0.8)	
Coping behavior	3.6 (0.7)	3.9 (0.1)	NS	3.8 (0.3)	3.4 (0.8)	NS	3.7 (0.7)	3.9 (0.2)	NS	3.8 (0.3)	3.5 (0.8)	$p < 0.05$
Depression	3.7 (0.6)	3.9 (0.1)		3.7 (0.5)	3.3 (0.9)		3.7 (0.5)	3.9 (0.2)		3.8 (0.4)	3.3 (0.9)	
Embarrassment	3.8 (0.5)	4 (0.01)		3.8 (0.3)	3.5 (0.8)		3.8 (0.5)	3.9 (0.1)		3.9 (0.1)	3.5 (0.9)	

FIQL: Fecal Incontinence Quality of Life. *Scales range from 1 to 4; 1 represents a poorer QOL.

Defect characteristics	*Score*			
	0	*1*	*2*	*3*
External sphincter				
Length of defect	None	Half or less	More than a half	Whole
Depth of defect	None	Partial	Total	-
Size of defect	None	< 90º	91-180º	> 180º
Internal sphincter				
Length of defect	None	Half or less	More than a half	Whole
Depth of defect	None	Partial	Total	-
Size of defect	None	< 90º	91-180º	> 180º

Fig. 1. Starck's score.

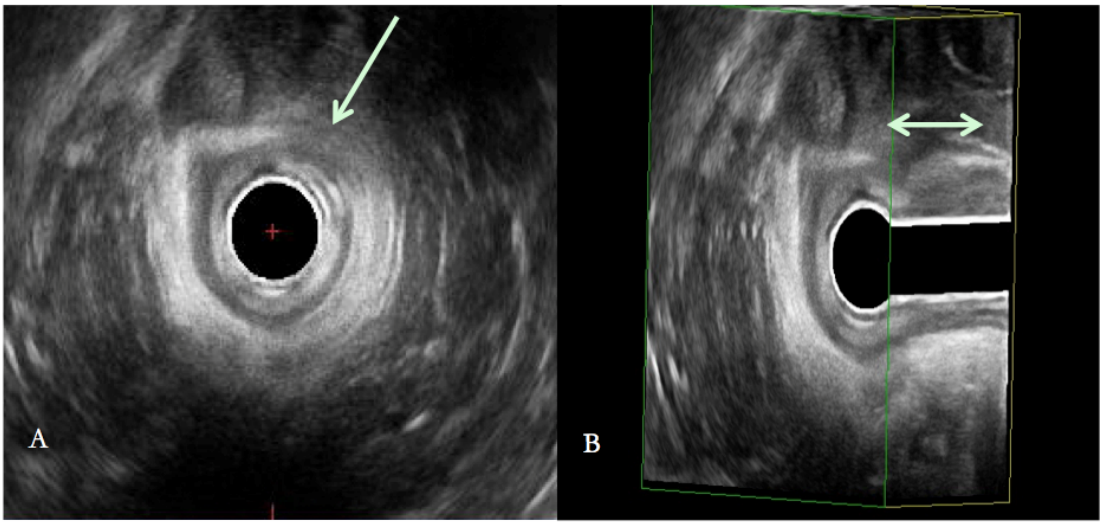

Fig 2. Anterior sphincter defect. EAS visualized in a 3 dimensional image. A. Sagittal plane. B. Longitudinal plane.

Fig. 3. Anterior scar visualized via an endoanal ultrasound.

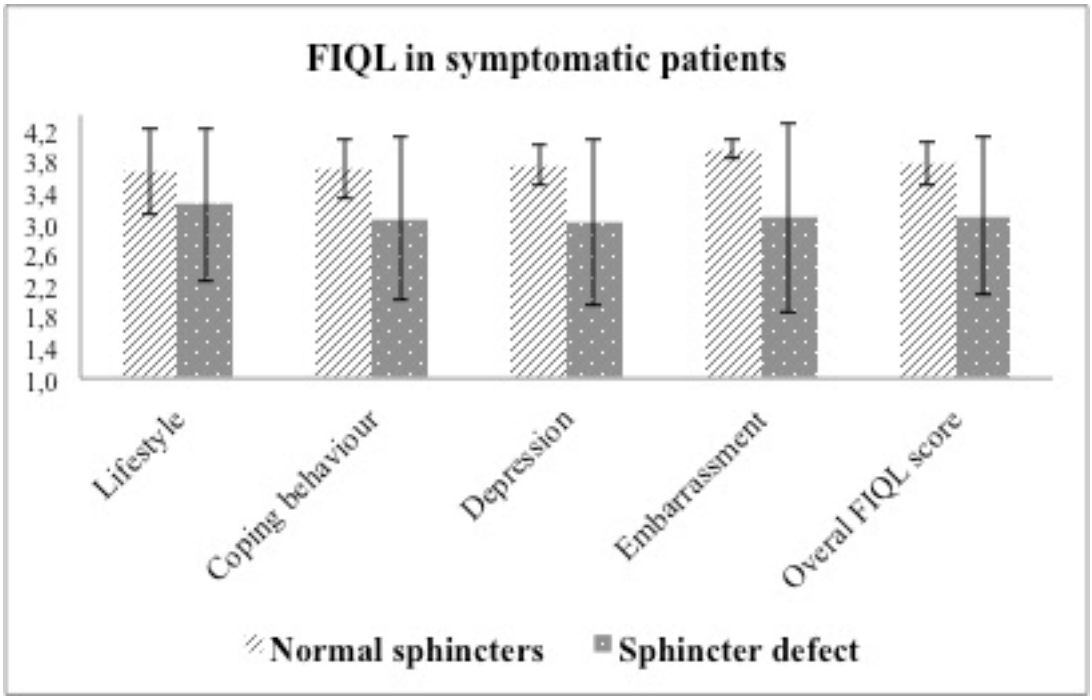

Fig. 4. Association of FIQL scales with sphincter defects in symptomatic females ($p < 0.05$ according to the multivariate analysis).

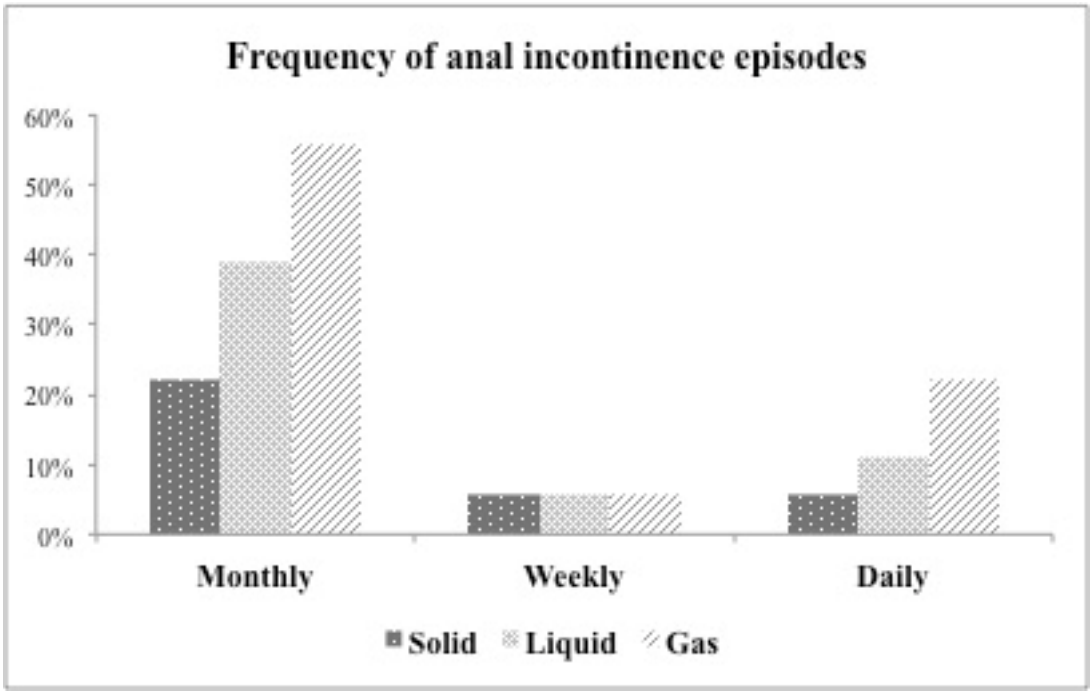

Fig. 5. Frequency of solid, liquid and gas loss in females that reported AI episodes. These figures are based on data collected from the Wexner questionnaires.