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Original Article

The effect of artificial anal band on quality of life of patients with fecal incontinence

Ebru Asmaz[1], Asim Cingi[2]

[1]Nisantasi University, Department of First Aid and Emergency, Istanbul, Turkey
[2]Marmara University Faculty of Medicine, Department of General Surgery, Istanbul, Turkey

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Abstract

Aim: The aim of this study was to evaluate incontinence levels before and after implantation of an artificial anal band (AAB), and to evaluate the change in quality of life of patients with fecal incontinence.

Material and Methods: Patients with fecal incontinence who underwent AAB implantation were included in the study. The Cleaveland Clinic/Wexner Incontinence Score (CCIS) and Fecal Incontinence Quality of Life (FIQoL) scales were evaluated before, 2 weeks and 5 years post-implantation.

Results: Eight patients underwent AAB implantation. The mean±SD pre-operative CCIS decreased significantly ($p<0.001$) from 19.4±0.5 to 3.1±0.6 two weeks after AAB activation. Similarly, a significant improvement was observed between mean pre- and post-operative FIQoL scores (49.4 vs. 102.0; $p=0.012$). Most (62.5%) of the patients could actively use the implant. Surgical revision was performed in the post-operative period in 50% of the patients (n=4, 3 women). In 2 (25%) patients, AAB was explanted either due to a secondary surgical site infection (n=1, man) or due to a perianal skin maceration (n=1, man).

Conclusion: AAB implantation is an effective treatment option for improving quality of life in patients with fecal incontinence. Appropriate patient selection criteria may improve explantation and surgical revision rates and increase the rate of effective use of AAB.

Keywords: Fecal; incontinence; artificial anal band; efficacy; quality of life.

INTRODUCTION

Fecal incontinence is involuntary loss of anal sphincter control, which causes feces to leak unexpectedly from the rectum. Depending on the incontinence level, it may have a devastating impact on the patient's psychology, social life, daily activities, and quality of life. The prevalence of fecal incontinence varies between 1% and 21% (1-4); it increases by age and is reported to be between 0.5-1% in the population aged under 65 years, and varies between 3-8% in adults aged over 65 years (1,5,6).

Although fecal incontinence is not a life-threatening dysfunction, the social, emotional, and physical life of the individual is negatively affected. Fecal incontinence significantly affects the quality of life by causing embarrassment, social stigma, depression, and anxiety (7). If not treated, the embarrassment and stress caused by fecal incontinence may lead to social isolation (8).

Even though the prevalence of fecal incontinence is high, and quality of life is negatively affected, only 10-30% of the patients with fecal incontinence share their problem with their physicians (9). In addition to social problems, fecal incontinence is also a significant financial problem. Dunivan et al. enrolled patients with chronic constipation and demonstrated that the mean annual health cost per person diagnosed with fecal incontinence was 2897$ higher than the annual health cost of patients without fecal incontinence in the United States (10). Although the prevalence of fecal incontinence is high and it is associated with significant personal and economic problems, there are few studies on this topic. Improvements in the treatment of fecal incontinence may have positive personal, social, and economic effects.

Various methods have been used in the treatment of fecal incontinence. After consideration of conservative treatment and other surgical methods such as sphincteroplasty, artificial anal band (AAB) implantation may be offered to compliant patients. To our knowledge,

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Corresponding Author: Ebru Asmaz, Nisantasi University, Department of First Aid and Emergency, Istanbul, Turkey
E-mail: drebru@gmail.com

currently there are 2 AAB device implants on the market: 1) A.M.I.® Soft Anal Band System, produced by Agency for Medical Innovations (A.M.I., Austria), and 2) Acticon Neosphincter® (Artificial Bowel Sphincter [ABS]) produced by American Medical Instruments (A.M.S., USA). The aim of the present study was to evaluate and compare incontinence levels before and after implantation of the A.M.I.® Soft Anal Band System in patients who presented with fecal incontinence symptoms, and to investigate the quality of life of these patients.

MATERIAL and METHODS

Artificial Anal Band (AAB)

The A.M.I.® Soft Anal Band System, an artificial sphincter that gives patients control of their sphincter function, was used as an AAB in this study. The complete AAB system is subcutaneously implanted and there is no need for opening a body cavity. Along with this advantage in facilitating implantation, the AAB is a dynamic system that enables patients to have control over defecation (Figure 1).

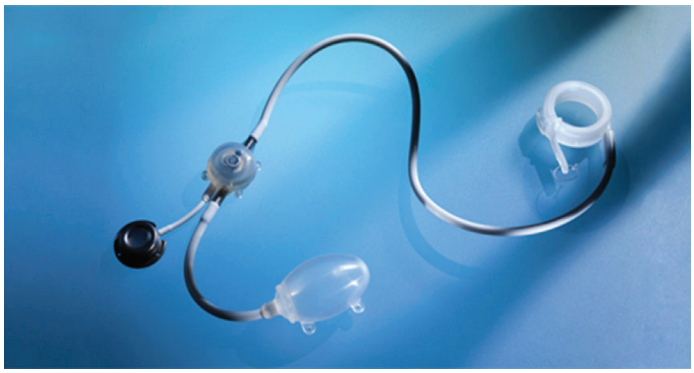

Figure 1. Artificial anal band system

The AAB system comprises a soft anal band implant (in 3 different lengths) and two extension parts (10 mm and 20 mm), a valve, activator, calibrator port (titanium), ruler, and port needles. The soft anal band implant, in an appropriate length for the patient, is inserted in a tunnel created around the anal sphincter. The valve is small, stable, and has a dome. When activated, liquid flows from the band to the activator, thus the artificial sphincter is opened. It is activated by pressing a finger on the skin over the valve. The activator is a firm silicone balloon. The liquid in the activator flows back to the band, the artificial sphincter closes, and continence is enabled when the skin over the activator is pressed. The calibration port is used to adjust the appropriate liquid volume required for the functioning of the system.

Patient Selection

The present study was planned as a single-center, prospective, clinical feasibility study. The study protocol was approved by the local ethics committee of our university hospital. The objective of the study, the treatment method, operation technique, and all other study-related procedures were explained to all patients who were considered eligible for the study. Eligible patients who presented with symptoms of fecal incontinence between June 2009 and June 2012 and accepted the study procedures were included in the study. Each patient signed an informed consent form. The inclusion criteria were as follows: age ≥18 years, patients with lifestyle alterations due to fecal incontinence, having adequate skills to use the AAB device after receiving training, and patients with Standardized Mini Mental State Examination score >24 (11). Patients with diabetes who required insulin, immunosuppressive medicine users, patients with Crohn's disease, pregnant women, patients with a history of anal intercourse, patients with severe psychiatric disease, and patients with perianal skin infection were excluded from the study.

Study Procedures

During the pre-operative evaluation, the medical history was questioned and physical examination, colonoscopy, anorectal manometry, and electromyography investigations were performed. The incontinence level of the patients was determined using the Cleaveland Clinic/Wexner Fecal Incontinence Score (CCIS) (12). Measures used for CCIS scoring are summarized in Table 1. The validated Turkish version of the Fecal Incontinence Quality of Life Scale (FIQoL) was used for the evaluation of quality of life (13,14).Post-operative pressure was measured using anal manometry when the AAB was open and closed, and compared with the pre-operative resting and squeeze pressures. The implant was activated after a post-operative 6-week recovery period. The CCIS and FIQoL Scales were applied to patients 2 weeks and 5 years after the activation of the implant and the obtained values were compared with the pre-operative values.

Table 1. Grading Scale for Cleaveland Clinic/Wexner Incontinence Score (CCIS)

Type of Incontinence	Frequency				
	Never 0 (never)	Rarely (<1/month)	Sometimes (<1/week, ≥1/month)	Usually (<1/day, ≥1/week)	Always (≥1/day)
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Score is obtained by adding points from the table. O points: Perfect continence; 20 points: Complete incontinence

Fecal Incontinence Quality of Life Scale (FIQoL)

The FIQoL self-evaluation scale, which was developed by Rockwood et al. in 2000 (13), consists of 29 items of 4 scales including lifestyle (10 items), coping/behavior (9 items), depression/self-perception (7 items), and embarrassment (3 items). In the first section of the scale, the patients evaluate their health status using the expressions "Excellent", "Very good", "Good", "Fair", and "Poor". In the second section, patients define how much of the time the items are a concern in terms of accidental bowel leakage with the options of "Most of the time", "Some of the time", "A little of the time" and "None of the time" and the extent to which they agree or disagree with items using predefined answers of "Strongly agree", "Somewhat agree", "Somewhat disagree" and "Strongly Disagree". The individual's mood is evaluated in section four in which patients express their feelings of sadness, discouragement, and hopelessness using the options of "Extremely", "Very much", "Quite a bit", "Some", "A little bit" and "Not at all". The highest scale score of 119 indicates that incontinence has no serious effect on quality of life, and the lowest possible score of 29 shows that incontinence is severely affecting the quality of life of the patient; quality of life is suggested to be negatively affected as scores decrease (13,14).

Statistical Analysis

Continuous variables were estimated as means ± standard deviations with corresponding 95% confidence intervals (CIs: lower and upper limits). The variables were investigated using analytical methods (Kolmogorov-Smirnov) to determine whether they were normally distributed. Paired t-test comparisons were performed for consecutive pairs of measurements pre- and post-operatively. A p-value of less than or equal to 0.05 was accepted as statistically significant. All statistical analyses were performed using SPSS version 20 (IBM Corp., Armonk, NY, USA).

RESULTS

A total of 8 patients were included in the study. The mean age of the patients was 53 (range, 21-72) years. Half of the patients were male (n=4). The mean body mass index (BMI) was 27 (range, 17-36) kg/m2, and the mean duration of incontinence was 54 (range, 6-240) months. Baseline patient characteristics are presented in Table 2.

Most of the patients (62.5%, n=5) were able to use the implant actively. Surgical revision was performed in the post-operative period in 50% of the patients (n=4, 3 women). AABs were explanted in a total of 2 (25%) patients, due to surgical site infection (1 male), and due to perianal skin maceration (1 male). No other major complications or mortality was observed.

Pre-operative and 2 weeks' post-operative CCIS scores were evaluated for 8 patients. The mean pre-operative CCIS score was 19.4±0.5, and 2 weeks after the AAB activation, the post-operative CCIS score significantly reduced to 3.1±0.6 (p<0.001; 95% CI: 15.7 - 16.8). Five-year follow-up data was available for 5 patients. At the 5-year post-operative evaluations, the mean CCIS score remained the same (3.2±1.6) when compared with the 2 weeks' post-operative results (p=0.799; 95% CI: -2.2 - 1.8) as shown in Figure 2.

Table 2. Patient characteristics at baseline

Patient No	Age (years)	Gender (M/F)	BMI (kg/m²)	Duration of Symptoms (months)
			Patient No	
1	21	M	17	24
2	54	M	36	6
3	65	F	18	42
4	42	M	32	24
5	58	F	26	24
6	72	F	33	48
7	55	M	27	240
8	58	F	27	24

BMI: Body mass index, M: Male, F: Female

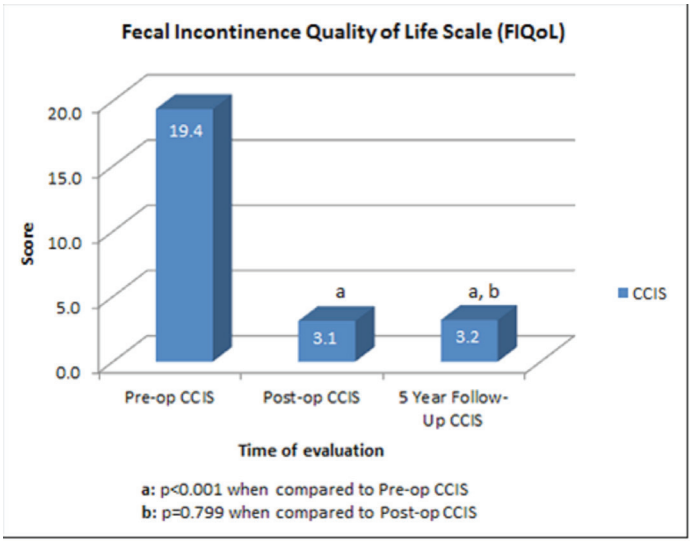

Figure 2. Mean pre-operative, post-operative (2 weeks after the artificial anal band activation) and 5 years follow-up Cleveland Clinic/Wexner Fecal Incontinence Scores (CCIS)

When the AAB was open, the mean pre- and post-operative resting pressures, as measured using anal manometry, were 26.8±13.6 mmHg and 23.5±8.7 mmHg, respectively. No statistical significance was detected between the pre- and post-operative resting pressures (p=0.680; 95% CI: -15.3 - 21.9). When the AAB was closed, the mean pre- and post-operative resting pressures were 61.6±21.0 mmHg and 65.8±15.2 mmHg, respectively; there was no significant difference between them (p=0.750; 95% CI: -33.9-25.6).

The mean pre-operative FIQoL total score was 49.4±4.2, and 2 weeks after the AAB activation, this value incresed significantly to 102.0±5.6, p<0.012, 95% CI: -18.9 - 15.3). Similarly, a significant increase was observed in all subscales of the questionnaire (lifestyle, coping/behavior, depression/self perception, and embarrassment subscales). Detailed information including the mean scores is presented in Table 3 and Figure 3.

Table 3. Mean (±SD) Fecal Incontinence Quality of Life (FIQoL) Scale Scores

FIQoL Scale	Pre-operative Score	Post-operative Score
Total score	49.4 (±4.2)	102.0 (±5.6)
Life style	16.1 (±2.4)	36.4 (±4.0)
Coping/behavior	13.3 (±1.3)	30.4 (±2.1)
Depression/self-perception	15.6 (±2.4)	25.1 (±2.5)
Embarrassment	4.4 (±1.2)	10.1 (±2.0)

FIQoL: Fecal Incontinence Quality of Life

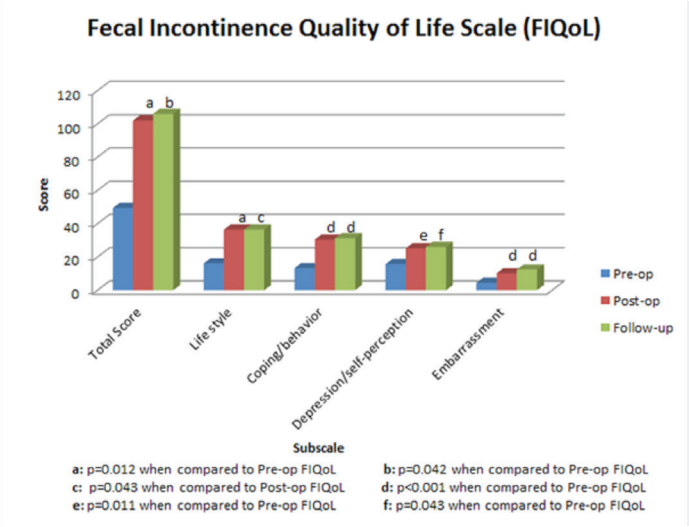

Figure 3. Mean pre-operative, post-operative (2 weeks after the artificial anal band activation) and 5 years follow-up Fecal Incontinence Quality of Life Scale (FIQoL) Scores

In the post-operative period, 25% (n=2) of the patients complained about difficulty in defecation. One (12.5%) female patient had symptoms of anal pain; however, there were no symptoms of infection in an ano-rectal examination, and pelvic magnetic resonance imaging (MRI) revealed no pathologic symptoms. Anal pain symptoms disappeared and complete recovery was observed 5 weeks after the implantation for both patients.

In another patient with a history of scleroderma, the calibration port eroded out of the skin and a revision surgery was performed under anesthesia.

Incontinence developed in 1 (12.5%) patient 5 weeks after the implantation although the AAB was detected as functional in the post-operative period. Further examination revealed that the band had spontaneously shifted to the open position due to leakage from the valve after the AAB was closed. A new valve was placed under general anesthesia.

One patient presented with incontinence symptoms approximately two weeks after the activation of AAB. Palpation in a physical examination revealed that the AAB had lost its integrity. During the surgery under general anasthesia, the anal band was detected as open from the connection point, the disconnected parts were connected, and fixation sutures were applied using nonabsorbable suturing material. The AAB was activated two weeks after revision and was detected as functional.

Post-operational wound site infection developed in one patient with a history of transverse loop colostomy, and the AAB was explanted because the infection showed no remission after antibiotic treatment.

In a patient with a BMI of 36 kg/m2, the valve could not be used due to excess subcutaneous fatty tissue and loose skin because of weight change. The valve was relocated and implanted in the suprapubic region with a revision under general anesthesia; however, the AAB was not functional and was subsequently explanted.

DISCUSSION

There are various causes of fecal incontinence, which is a significant problem for individuals and for society. Different treatment methods from behavioral changes to surgical methods such as sphincteroplasty, graciloplasty, and permanent ostomy have been described. In the present study, patients with fecal incontinence were given an alternative surgical treatment, AAB implantation, and its effect on quality of life was investigated.

Although it is difficult to evaluate the success of treatment methods in a functional problem such as fecal incontinence, this effect may be demonstrated using treatment efficacy, continence, and quality of life scoring systems., Altamore (15), Lehur (16) and Vaizey (17) demonstrated a significant improvement in the incontinence scores and quality of life scales in their studies where they used an artificial anal sphincter model of Acticon® Neospinchter, similar to the AAB. In another study, Wong (18) demonstrated significant change in the incontinence scores and quality of life scales where a similar surgical implant with a magnetic anal sphincter was used. We performed our evaluations during the pre-operative period, and 2 weeks and 5 years after the activation of the AAB in the post-operative period. Our results indicated significant improvements both in CCIS and FIQoL scores. In compliance with the literature, the results showed that an efficiently functioning AAB system provides a successful treatment.

A significant increase was reported in resting pressures obtained with anal manometry in studies conducted with an artificial anal sphincter (AAS) (19,20). Squeeze pressures were reported in 2 studies and no statistically significant difference was detected between the pre-operative and post-operative squeeze pressures where

an AAS was used (15,20). However, Devesa (21) showed a significant difference between the two measurements in his study. In our study, we observed no significant difference between pre- and post-operative resting or between pre- and post-operative squeeze pressure measurements. However, in the present study, a comparison of the mean pre-operative resting pressure and the mean post-operative squeeze pressure showed a significant difference. Similarly, Michot et al. (22) detected a significant difference between the mean pre-operative resting pressure and the mean post-operative squeeze pressure in their study using an artificial anal sphincter. In patients using AABs, the pressure measured after system activation should be compared with the resting pressure because this value is equal to the involuntary pressure measurement of the patient during the day.

The most significant problem in the implantation of artificial anal sphincters is the high rates of revision and explantation. In the published literature, revision rates vary between 12.5 and 50.0% (18,23). In the present study, half of the patients required post-operative surgical revision (n=4, 3 women, 1 man), which is in line with the published reports. Baumgartner (24) reported the rate of explantation due to infection and anal penetration as 60% in patients who used Acticon® Neosphincters. The most significant problem in the same study in patients who used AABs was non-functioning valves, which required replacement with a new valve. In another study, Wong (25) reported that the majority (42.9%) of explantations were due to localized infection around the device components. In the present study, explantation was required in 1 (12.5%) patient due to infection, and a new valve was implanted in 1 (12.5%) patient due to a non-functioning valve. Explantation was performed due to infection irresponsive to antibiotic treatment that emerged near the valve, and progressed to the anal implant in 1 patient out of 2 in the present study. We suggest that post-operative infection rates should be minimized, and thus AAB explantations may be reduced with the use of attentive surgical technique and through strict pre-operative asepsis protocols.

Infection-associated AAB system explantations or revision operations were performed without damaging the neighboring tissues due to the development of fibrous pseudocapsules surrounding the AAB components. We observed that the tissues adjacent to the implant were not fragile even in the infected patient; the tissues were easily dissected, and wound sites demonstrated complication-free recovery after explantation. The patient who had a transverse loop colostomy prior to the implantation developed an infection around the AAB system. Patients with ostomy were reported to be more prone to infection by Wexner et al. (26); however, the association between the ostomy and the development of infection has not yet been clarified completely. The ostomy may have negative effects on the surgical region preparation and surgical drapes; therefore, it is not routinely opened before AAB implantation in our clinic.

The small sample size is a major limitation for this study. After initiation of the study, due to an increase in the cost of the device and changes in the reimbursement system of the government, use of this device was negatively affected in our clinic. Therefore, patient enrollment was stopped after 3 years.

CONCLUSION

In conclusion, the AAB system is an efficient method, which positively decreased the incontinence scores and increased the quality of life of the patients in our study. With appropriate patient selection and surgical techniques, explantation and surgical revision rates may be minimized. Further large scale studies are recommended to evaluate the impact of AAB implantation on the quality of life of patients with fecal incontinence.

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Ebru Asmaz ORCID: 0000-0001-8938-1345
Asim Cingi ORCID: 0000-0002-9081-8919

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