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ORIGINAL ARTICLE

Temperature-controlled radio frequency energy delivery (Secca® procedure) for the treatment of fecal incontinence: results of a prospective study

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Abstract
Purpose Fecal incontinence (FI) is a debilitating condition that can be socially and personally incapacitating. A broad range of treatment options, often stepwise, are available, depending on severity. This prospective study reports a large single-centered series of patients who have benefited of temperature-controlled radio frequency (Secca) energy delivered to the anal canal.
Material and methods This investigation was a single-center, nonrandomized, prospective, clinical study of a single patient group with each serving as the control. All patients had experienced FI for at least 3 months and had attempted, but were not satisfied, with the results of medical and/or surgical therapies. The study aims to evaluate changes in FI symptom scores and quality of life between the baseline and follow-up intervals.
Results Between March 2005 and March 2006, 15 Secca procedures were performed. All 15 patients were alive and in contact with the investigational site at time of 12 months. There were no long term complications. The mean Wexner score improved from 14.07 (±4.5) at baseline to 12.33 (±4.6) at 1 year (p=0.02). The mean fecal incontinence quality of life of life score was only improved in the depression subscore. There were no changes in endoanal ultrasound and anorectal manometry.
Conclusion This prospective trial confirmed the safety of the Secca procedure. Although we demonstrated a significant improvement in the Wexner Score, these clinical results have to be mitigated because most patients remained in the moderate incontinences category as defined by the scoring system and did not improved their quality of life excepted in the depression subscore.

Keywords Fecal incontinence · Radio frequency · Sphincter · Anal canal

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Introduction

Fecal incontinence (FI) is a debilitating condition that can be socially and personally incapacitating [1]. A broad range of treatment options, often stepwise, are available at initial diagnosis, depending on severity. Management options include modifying bowel activity with diet and medication, lifestyle changes to minimize the risk of incontinence in public, physiotherapy for pelvic floor muscles, and biofeedback techniques. If such methods are insufficient, then surgical techniques need to be considered. These include direct repair of anal sphincter disruptions, sacral nerve stimulation, and replacement of sphincter function by an artificial bowel sphincter or dynamic graciloplasty [2–6]. All of them are available and routinely performed in our department. Unfortunately, patients who fail medical and surgical options often face distressing prospect of living with their incontinence or undergoing a diverting stoma.

For that manner, new treatment are developed such as a minimally invasive endoanal procedure based on temperature-controlled radio frequency (RF; Secca procedure—Curon Medical; Fremont, CA, USA) energy delivered to

the anal canal muscle. This premise is probably based on the tissue-tightening effects with collagen contraction, focal wound healing, remodeling, and tissue compliance reduction [7]. The first studies [8;9] evaluating this procedure reported a substantial reduction in the median Cleveland Clinic Florida Fecal Incontinence and an improved Fecal incontinence quality of life.

The purpose of this study was to evaluate the 1-year effectiveness and safety of the Secca procedure on fecal incontinence symptoms.

Patients and methods

Study design and population

This investigation was designed as a single-center, non-randomized, and prospective clinical study of a single patient group with each serving as the control. All patients were thoroughly informed about the procedure, the predictable postoperative follow-up, the complications, and the outcome and gave informed consent. This study was an independent study with no financial support by Curon Medical Corporation.

All the patients enrolled had experienced FI for at least 3 months, had fecal incontinence at least once per week, and had attempted, but were not satisfied, with the results of medical therapy such as biofeedback. Patients who had not had relief or had presented complications with sphincter repair, sacral nerve stimulation, and artificial bowel sphincter implantation were eligible for this study. Patients with significant external sphincter defect suited for sphincter repair were not included. Patients were excluded if they presented any of the following disorder: collagen vascular disease, inflammatory bowel disease, fistula or abscess, active anal fissure, constipation or chronic diarrhea as major contributor to FI, pelvic irradiation, pregnancy, history of laxative abuse, or unstable psychiatric disorder.

The study aims to evaluate changes in fecal incontinence symptom scores and quality of life between the baseline and follow-up intervals. All subjects completed the fecal incontinence grading scale (Cleveland Clinic Florida Fecal Incontinence score–Wexner Score) [10], the fecal incontinence quality of life of life questionnaire (FIQL) [11] at baseline and at 3, 6, and 12 months. Both questionnaires have been validated for French language patients [12]. Anorectal manometry and ultrasound were performed, according with standard technique, at baseline and 12 months. An evaluation of anal sphincter pressure and anal compliance was performed according to the technique described by Gibbons et al., at baseline and 12 months [13] Patients were carefully monitored during the postoperative period to detect any complications.

SECCA® energy delivery technique

Patients were treated in conventional surgery unit, and the duration of hospitalization was evaluated. Patients discontinued use of plated-inhibiting medications 7 days before surgery and were not permitted to restart until 3 weeks after treatment. All patients received prophylactic antibiotics and continued for 15 days after the procedure (ciprofloxacin 500 mg twice daily and metronidazole 500 mg three times daily).Two investigators (FM, JJT) performed all the procedures. The procedure was carried out in a classical operative room under general anesthesia. Subject underwent the Secca procedure as described previously [8, 9,14].

Statistics

Data were analyzed with STATVIEW software. Continuous outcomes such as Wexner score and FIQL were evaluated by computing the difference between the baseline and 1-year value and applying the Wilcoxon rank test. The McNemar's statistical test was used to compare binary outcomes. Intention-to-treat analysis was not performed since all subjects were available for follow-up at 12 months. Statistical significance was accepted when the value of p was <0.05.

Results

Between March 2005 and March 2006, 15 Secca procedures were conducted by two senior colorectal surgeons. These patients with an average age of 53 years (range 33–72) and mostly female (n=14–93%) presented severe incontinence who had failed prior medical or surgical therapies. Long term fecal incontinence was noticed since an average number of month of 70 (range 14–228). Obstetrical and surgical histories are mentioned in Table 1,

Table 1 Obstetrical and surgical histories

Obstetrical and surgical history	Number (%)
Previous vaginal deliveries (14 females)	
0	0(0)
1	5(36)
2	3(21)
3	4(29)
4+	2(14)
Mean	2.13
Forceps delivery (n=14 females)	6(43)
Episotomy (n=14 females)	7(50)
Postpartum repair (n=14 females)	8(57)
Hemorrhoid surgery (n=15)	2(14)
Fistula Surgery (n=15)	1(7)

Table 2 Previous fecal incontinence surgeries

Previous fecal incontinence surgery	Number (%)
Overlapping sphincter repair	2(13%)
Artificial bowel sphincter repair	
Implantation	2(13%)
Explantation	2(13%)
Sacral nerve stimulation test	8(53%)

and previous FI surgeries are collected in Table 2. Comorbidities included diabetes mellitus for two patients.

Delivery of radio frequency energy was completed for all patients with a mean operating time of 32 min (range 20–40). There were no cases of bleeding during or immediately after the procedure. The mean hospital stay was 3+ or −1 days.

Patients' follow-up

All 15 patients were alive and in contact with the investigational site at time of 12 months visit, and each completed the questionnaire evaluation and examination protocol. There were no long term complications noted at 12 months.

The mean Wexner score improved significantly from 14.07 (±4.5) at baseline to 12.33 (±4.6) at 1 year (p=0.02; Table 3). This represents a score improvement for nine patients and no modification or even worsening for the six others. With a clinical response defined as >50% reduction in the Wexner score, the patient response rate was 13%. If this clinical response rate is defined as >20% reduction in the Wexner score, the patient response rate is brought to 26%. When evaluated separately, these results are comparable for the five questions of the Wexner score. Comparison of the Wexner scores at 3, 6, and 12 months showed no modification in effect over time.

On the other hand, the mean FIQL score was improved only in one of the four categories (Table 3). Indeed in the depression category, the score improved from 1.92 (0.62) at baseline to 2.33 (0.74) at 12 months (p=0.01). Comparison of each subscores at 3, 6, and 12 months showed no modification in effect over time.

Table 3 Specific fecal incontinence scores: results from baseline and 12 months

Score	Mean at baseline	Mean at 12 months	*P* value
Wexner[a]	14.07±4.5	12.33±4.57	0.02
FIQL[b], lifestyle	2.3±1	2.05±0.86	0.48
FIQL[b], coping	1.77±0.68	1.82±0.77	0.92
FIQL[b], depression	1.92±0.62	2.33±0.74	0.01
FIQL[b], embarrassment	2.49±1.43	1.62±0.80	0.09

[a] Cleveland Clinic Florida Fecal Incontinence score–Wexner Score) [10]

[b] Fecal incontinence quality of life of life questionnaire (FIQL) [11]

Table 4 Physiological testing results: results from baseline and 12 months

Paramaters	Mean at baseline	Mean at 12 months	*P* value
Anorectal manometry (mean)			
Resting pressure (cm H_2O)	52.9±19.7	42.5±20.4	0.07
Voluntary squeeze pressure (cm H_2O)	92.1±40.7	85.5±17.5	0.44
Maximum rectal distension volume (ml)	179.6±38.5	177.7±41.6	0.59

Normal values: resting pressure 60–120 cm H_2O; Voluntary squeeze pressure: >60 cm H_2O; maximum rectal distension volume: 100–400 cm

There were no changes in anorectal manometry parameters from baseline to the 12-month evaluation (Table 4). Anorectal ultrasound showed isolated internal sphincter defect in 33%, isolated nonsignificant external sphincter defect in 13%, and combined internal and nonsignificant external defect in 13%. There were no additional defects or scar at 12 months. For four patients, the 12 months anorectal ultrasound control showed small areas of fibrosis within the internal anal sphincter and thickening of the anoderm. Finally, there was no difference in the pudendal nerve motor latency and anal compliance recordings during the study period.

The individual Wexner score, FIQL score, and anal resting pressure at baseline and 12 months are detailed in Table 5.

It has to be noticed that after the initial 1-year follow-up, two patients were elected to have a colostomy constructed to control fecal incontinence symptoms. Two other patients were elected to have artificial sphincter implantation for the same reasons.

Discussion

Fecal incontinence is a chronic, even lifelong, disorder for which there are limited therapeutic options that are safe, effective, and acceptable for patients. This prospective study reports a large single-centered series of patients who have benefited of temperature-controlled radio frequency (Secca procedure) energy delivered to the anal canal muscle.

This study confirmed, on a moderate size series, the safety of the procedure since we did not observe any adverse events, no significant pain, and the recovery

Table 5 Individual parameters

Patients	Continence		Quality of life								Anorectal manometry	
	Wexner score		FIQL: lifestyle		FIQL: coping		FIQL: depression		FIQL: embarrassment		Resting pressure	
	B	12	B	12	B	12	B	12	B	12	B	12
1	18	16	3	1.3	1.15	1.3	1.21	1.7	1	1	34	44
2	7	8	1.3	1.8	1.11	1.44	3	3.5	1.67	2	47	21
3	20	20	1	1.1	1.23	1	1.12	1.2	1	1	9	8
4	16	16	3	1.3	1.1	1.2	1.36	1.8	3	1.3	72	80
5	13	11	2	3.8	3	3	2.79	3	5	1.3	45	41
6	19	17	3	1.7	1.54	2.44	1.93	2.83	4	1.67	62	23
7	8	3	2	3.8	2.54	3.56	2.25	3.17	1	4	55	47
8	10	7	5	2.3	2.77	2.3	2.07	2.7	1	2.7	90	53
9	19	18	2	1.3	1.15	1.22	1.5	1.33	4	1	48	66
10	13	13	2	1.3	2.23	1.1	1.79	1.7	3	1	55	50
11	11	12	1	2.5	2.46	1.89	1.93	1.6	1	1.67	62	16
12	20	10	3	2.63	1.39	2.33	1.29	3	2	1.33	80	68
13	11	9	1.9	2.22	1.2	1.56	2.7	2.67	1.7	1.33	33	32
14	10	12	2	2.2	2.15	1.8	2.5	2.7	4	1.7	51	53
15	16	13	3	1.5	1.54	1.11	1.29	2	4	1.33	50	35

B Results at baseline, *12* results at 12 months

process was uneventful. Indeed we did not reported complications such as the three significant procedural complications and 26 adverse events reported by Effron et al. [9]. In comparison of artificial anal sphincter, because this procedure does not involve the implantation of a foreign body, there were no infections. Since prior study [8] graded discomfort associated with RF delivery and hand piece insertion for 50% of their patients, the procedure was carried out in a classical operative room under general anesthesia.

The efficacy of the treatment has been outlined in the pilot study conducted by Takahashi et al. [8]. They reported on ten patients a substantial reduction in the median Cleveland Clinic Florida Fecal Incontinence score from 13.5 at baseline to 5 at 12 months (p=0.0009), reflecting an 80% response rate. Follow-up of these patients at 2 years demonstrated a persistent improvement in fecal incontinence symptoms [15]. Effron et al. [9] confirmed this efficiency in a multicenter study. With so promising initial results, it is quite surprising that these both teams have not published, since 2003, larger series. It is interesting to note that our study did not report the same level of improvements as reported in the studies by Takahashi et al [8, 15, 16] and by Efron [9]. If the overall reduction in Cleveland Clinic Florida Fecal Incontinence scores was 6.1 points in the study by Takahashi [16] and 3.5 points in the study by Efron [9], our was only 1.74. Furthermore, the overall response rate was 84% in the study by Takahashi et al., 60% in the study by Efron et al., and ours of 13%.

Felt Bersma et al. reported the moderate improvement observed with the Secca procedure on 11 patients with long-standing fecal incontinence during a follow-up of a year [17]. The Vaizey incontinence score improved from 18.8 to 15 (p=0.03), and five patients (45%) stated that they had experience a notable improvement of their FI.

Although we demonstrated a significant improvement in the Cleveland Clinic Florida Fecal Incontinence Score (p= 0.02), in reality, it seems that there was no true clinical improvement because most patients remained in the moderate incontinences category as defined by the scoring system. With a clinical response defined as >50% reduction in the Wexner score, the patient response rate was only of 13% and 26% when considering the clinical response rate as 20% reduction of the Wexner score. The moderate efficacy of the procedure is confirmed by the fact that we did not report improvement in Fecal Incontinence Quality of Life Score except in the depression subscore. The evaluation of the quality of life is a major parameter for FI treatment evaluation. The population included in this study is quite heterogeneous since many patients had beneficiated of previous surgical procedures for their FI which might mitigate the efficacy results.

We were unable to determine the precise mechanism of action for the Secca procedure since we did not record any changes in anorectal manometry, anorectal ultrasound, and pudendal nerve motor latency recordings parameters. The hypothesis that radio frequency would augment resting and squeeze anal pressure was not outlined in our study. If Takahashi et al. [15] reported that maximum tolerable volumes were significantly reduced at 12 months, we were not able to confirm this fact.

Since the conduction of our trial, Curon Corporation has experienced financial difficulties and to date, the Secca device is no longer commercially available. However, since the procedure has been conducted in many surgical departments across the world, we do feel that our evaluation adds to the overall experience.

All these points might confirm the hypothesis given by Nunoo-Mensah [18] that the Secca procedure probably induces a placebo effect or a certain degree of scarring within the anal canal, which may improve continence. Because of the concern of the possible placebo effect of the Secca® procedure in our trial, a single-blinded placebo control group should be necessary like the one developed in the evaluation of other surgical procedures such as sacral nerve stimulation [19].

Due to the limited number of clinical trials that have been conducted and the limitations of those trials, the efficacy of radio frequency therapy for fecal incontinence is not supported in the evidence-based literature. Further research is needed before radio frequency therapy can be recommended for use outside of clinical research protocols.

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