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DYNAMIC GRACILOPLASTY IN TREATMENT OF SEVER FECAL INCONTINENCE: A PRELIMINARY REPORT ON THE SAFETY AND EFFICACY OF THE EGYPTIAN EXPERIENCE

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Background: *In the last decade, stimulated "dynamic" graciloplasty has shown promising results in the treatment of patients with fecal incontinence. Good results with dynamic graciloplasty have been reported by individual investigators, but the applicability of these results to a broader range of surgeons yet to be shown.*

Objectives: *The aim of this report was to analyze the results of a single-stage using a single wrap dynamic graciloplasty in patients with fecal incontinence and to show problems and pitfalls that had arisen during the learning curve of the early phase procedures.*

Patients and Methods: *This study included 6 patients (4 females and 2 males) with end stage fecal incontinence. They were treated by dynamic graciloplasty. The indications were congenital anal atresia in 3 patients, sacral meningocele in one patient, ~~and~~ spina bifida in one patient, and total anorectal reconstruction (TAR) following APR in the past in one patient. Muscle transposition, implantation of stimulation electrodes and pulse generator were done as a single-stage procedure, the "neosphincter" was wrapped in a split-sling technique. Muscle transformation was performed by controlled neuromuscular stimulation during 8 weeks. Quality of life Assessment were performed using Fecal Incontinence Quality of Life Scale*

Results: *No postoperative mortality (90 days) was observed in our series. In our early experience, the device problems occurred in 3 patients as the most prominent difficulty. Evaluation of the functional outcome showed perfect results in 2 patients who achieved continence for solids and liquids or solids alone (1 or 2 according to Williams' score) and a satisfying outcome (continence for solids alone with occasional episodes for liquids) in 4 patients. The pre-operative quality of life of our patients was extensively impaired. Dynamic graciloplasty resulted in improvement in seven out of eight examined domains of quality of life.*

Conclusion: *In this preliminary study, we have been able to perform dynamic graciloplasty as a one-stage procedure using a split-sling-technique. The procedure is associated with significant morbidity that is easily treated with successful outcome. Dynamic graciloplasty results in significant better quality of life. Finally, the results of our learning period encourage further application.*

Keywords: Dynamic graciloplasty – fecal incontinence- anorectal reconstruction

INTRODUCTION

Fecal incontinence is commonly related to social problems and surprisingly widespread disorder. Most incontinent patients respond to standard conservative care, surgery, or biofeedback, but a significant number of patients do not benefit from such therapy.

In the last decade, stimulated "dynamic" graciloplasty has shown promising results in the treatment of patients with fecal incontinence [1-3]. Chronic electrical stimulation leads to the transformation of type II, fatigue-prone muscle fibers into type I, fatigue-resistant fibers, which gives the transposed gracilis the properties required to function as a sphincter. At the end of the transformation period, the

neosphincter is maintained in tonic contraction [4]. Voluntary defecation is accomplished by deactivating the pulse generator with a handheld magnet [5].

In patients with fecal incontinence the gracilis muscle is wrapped around their native external sphincter [1,5] while after abdominoperineal resection, a perineal colostomy is created and the muscle is wrapped around this neoanus (total anorectal reconstruction, TAR) [6,7].

Good results with dynamic graciloplasty have been reported by individual investigators, but the applicability of these results to a broader range of surgeons yet to be shown. The aim of this report was to analyze the results of a single-stage using a single wrap dynamic graciloplasty [8,9] in patients with fecal incontinence and to show problems and pitfalls that had arisen during the learning curve of the early phase procedures.

PATIENTS AND METHODS

Patients

This preliminary study included six patients that constitute the early learning phase of a longitudinal prospective study. The cause of incontinence was anal atresia in 3 patients their age ranged from 11 to 20 years with a mean age of 14.25± 4.27 years, spina bifida in a ten years old girl and sacral meningocele in a seven years old girl ,for her we did dynamic graciloplasty after failure of sacral nerve stimulation. The fifth patient was a lady of 50 years; for her we did secondary total anorectal reconstruction (TAR) three years after abdominoperineal resection of low rectal cancer.

All the patients were interviewed and an informed consent was obtained from each patient. The study protocol was registered and approved by the Committee of Postgraduate Studies and Medical Research, Faculty of Medicine, University of Alexandria.

Patients Evaluation

Anal Manometry

Anal manometry was performed before and after dynamic graciloplasty using a water-perfused catheter (Sandhill Vectrogram Catheter: part number AGS- 108) has 8 side holes oriented at 45° to one another and arranged in two rows. The catheter was perfused using pneumohydrolic pump (Mui Scientific Mississauga, Canada). Using station pull-out technique, the catheter was pulled out 0.5 cm each time according to the standard marks on the catheter. Pressures were recorded using Smart Lab (Sandhill Scientific, Inc., Denver, Colorado) with pressure amplifiers. The Analgraph® computer software (Sandhill Scientific, Inc., Denver, Colorado) creates a 3-D vectrogram and automatically produces numeric report of the mean resting anal pressure (MRAP) and maximal contraction pressure.

Continence Score

Patients were accepted into the study if they had grade 5 incontinence as classified on a scale of 1 to 5 according to Williams score [3] (Table 1). Moreover, the length of time during which a 200 ml saline enema could be retained was assessed before and after muscle transposition and again after eight weeks and sex months of electrical stimulation. The enema was given with the patient in the left lateral position, and the time of the first leakage was recorded.

Quality of Life Assessment

Quality of life Assessment were performed using Fecal Incontinence Quality of Life Scale (FIQL) [10], which includes the continence-related questions, global performance using Nottingham Health Profile and subjective quality of health and quality of life using Questionnaire for Attitudes Toward Quality of Health and Toward Quality of Life

The questions were grouped with Scales ranging from 0 (=worst) to 25 (=best) according to their content:

1- Specific symptoms	S-SPSY
2- Sexual function	S-SEXU
3- Mobility	S-MOBIL
4- Social Contact	S-SOCI
5- Family relation	S-FAMIL
6- Work	S-WORK
7- Spare time	S-SPT
8- Food	S-FOOD
9- Subjective Quality of health	S-QOH
10- Subjective Quality of life	S-QOL

Surgical Technique

The graciloplasty was performed according to the technique described by Rosen et al [8,9]. An incision (about 25 cm) was used to mobilize the gracilis muscle down to its insertion in the tibial tuberosity and small incision below the knee through which the tendon was cut. The neurovasular bundle was identified (by nerve locator, Neuro-Pulse, Aaron, Florida, U.S.) and left intact, and the muscle was wrapped either around the neorectum (TAR) or the insufficient external sphincter anti-clockwise. The tendon was brought through the belly of the muscle by a small incision carried out parallel to the muscle fibers (Fig.1) and anchored to the skin with non-absorbable suture (Prolene 2/0, Ethicon, Edinburgh), which remained for 4 weeks. During the same operation, intramuscular electrodes (Model 4300-50; Medtronic, Kerkrade, The Netherlands) were implanted at the site of nerve entry in

such a way that a full muscle contraction (equivalent to a squeeze pressure between 90 to 130 mmHg) was achieved with stimulation amplitude below 1.0 V at a frequency of 20 Hz and a pulse width of 210 usec by use of external stimulator. After correct electrode position was confirmed, electrodes were connected through a subcutaneous tunnel to the pulse generator (Interstim-Itrel II™ 3023; Medtronic), which was placed in a subcutaneous pocket in the abdominal wall.

All patients received a conventional bowel preparation and systemic antibiotic prophylaxis, which consisted of metronidazol 1 gm and cefotaxem 1 gm 24 hours before operation and during surgery, prophylaxis was extended to 5 days with cefotaxim 1 gm and metronidazol 500 mg three times daily. Additionally, a gentamycin-impregnated collagen sponge (Septocol; Merck, Darmstadt, Germany) was administrated with the implants in all patients.

A protective stoma was done in three patients (ileostomy following TAR and a transverse colostomy in two patients) that were closed after completion of the muscle transformation and a water-soluble contrast enema 10 weeks after operation.

Muscle Transformation

Muscle transformation was initiated 14 days following graciloplasty in 4 patients and after 35 days in one patient. The muscle was stimulated by telemetry (Programmer Console model 7432, Medtronic) according to the protocol depicted in (Table 2) at increasing short periods over 8 weeks to achieve tetanic contraction [9]. During every follow-up, the stimulation amplitude, necessary to keep the contraction sufficient for continence, was checked and recorded.

Data analysis and statistical methods:

Analysis of variance (one-way ANOVA) was used to compare data before, eight weeks and six months following surgery.

RESULTS

Morbidity and mortality

No operative or post-operative mortality was observed in the studied group of patients. Intra-operative morbidity was observed in two cases where a small bowel was injured during construction of colostomy, which was identified and repaired on the spot in one patient and the rectum was injured during formation of the muscle wrap that was identified and repaired with covering colostomy in another patient. Post-operative morbidity in such a learning period included a total of 12 complications over the entire follow-up period (Table 3). The most common problems are difficulties related to the hardware, four patients (No.2,3,4,6) reported significant difficulties knowing when the stimulator is on or off, inability to use the magnet correctly and continuous on/off switching. Difficulties with the hardware were overcome by repeated educational sessions. The first patient was a university student, who had no difficulty with the hardware and the fifth patient preferred to use a remote control to switch the pulse generator. Two patients complained of pain in the leg that responded to diclofenac sodium. One patient observed minor wound complications. After initiation of the continuous contraction two patients with anal atresia experienced fecal impaction, which resolved on enema evacuation while the patient with TAR had evacuation difficulties that needed irrigation of her rectum with a Foly's catheter and 100 to 300 ml water in order to empty her rectum voluntarily.

The most serious morbidity was major wound complications. One patient experienced erosion of the skin over the device site requiring temporary explant of the device, the same patient experienced lat erosion of the skin over the electrodes that required debridment and closure.

Functional Results

Continence score at follow-up is shown in (Table 1). Two patients obtained satisfactory continence (score 2) and four patients had improved continence with a change from score 5 to 3. None of our patients considered complete failure. Results of anal manometry (Table 4) could demonstrate a significant increase of the resting pressure from 15.6+11.23 cmH_2O to 36.17+23.54 cmH_2O after 8 weeks and 44.16+12.98 cmH_2O after 6 months. When the stimulator switched on, the pressure increased significantly to 69.44+12.66 cmH_2O at 8 weeks with further increase to 72.88+9.05 cmH_2O after 6 months. To maintain sufficient contraction the voltage of the stimulator had to be increased during the follow-up period in 4 patients to a mean of 2.8 V (range=2.4 to 3.2 V) (Table 5).

The mean frequency of defecation decreased from 5.6±1.3 per 24 hours to 3 per 24 hours after 8 weeks and then to 1-2 per 24 hours at the end of 6 months follow-up. The time defecation can be postponed increased from few seconds before operation to reach 10-15 minutes at 8 weeks and to 20 minutes at 26 weeks (Table 4). The time, of the 200 ml saline enema, could be retained was 0 before transposition, 60 seconds at 8 weeks and180 seconds at 26 weeks (Table 4).

Quality of Life Assessment

The results of Quality of Life Assessment are shown in (Table 6). Sexual function and quality of work could not be assessed in our patients. There was significant improvement in the "specific symptoms" (from 0 to 19),

mobility (from 3 to 15), social contact (from 6 to 12) and subjective quality of life (from 7 to 16). All other domains of quality of life did not change significantly after 6 months follow-up period.

Table (1): ***Continence score before and after dynamic graciloplasty.***

Continence Score	*Symptoms*	*Before(n)*	*After surgery (n)*	
			8 weeks	*26 weeks*
Score 1	Continence to solids, liquids and flatus	0	0	0
Score 2	Continence to solids, liquids but not to flatus	0	1	2
Score 3	Continence to solids but occasional incontinence to liquids	0	2	4
Score 4	Occasional episodes of incontinence of solids	0	2	0
Score 5	Frequent episodes of incontinence of solids and liquids	6	1	0

Table (2): ***Stimulation Protocol.***

Parameter	*0-2 Weeks*	*2-4 Weeks*	*4-6 Weeks*	*6-8 Weeks*	*8 Weeks*
On time (Sec)	0.1	0.2	0.4	1.0	Tetanic
Off Time (Sec)	1.0	1.0	0.7	0.5	-
Duty Cycle %	11	12.5	36	66	100
Frequency (Hz)	21	21	21	21	15-21

Table (3): ***Early and late complications over the entire follow-up period.***

Complication	*No.*	*%*	*Management*	*Outcome*
-Erosion of IPG Pocket	1	8.33	Explant and reimplant	Resolution
-Skin erosion along leads tunnel	1	8.33	Debridement and reimplant	Resolution
-Leg pain	2	16.66	NSAID	Resolution
-Device/ stimulation problems	4	33.33	Education	Resolution
-Small bowel injury during stoma formation	1	8.33	Repair	Resolution
-Rectal Injury	1	8.33	Repair + Colostomy	Resolution
-Fecal impaction	2	16.66	Enema	Resolution
Total	12	100		Resolution

Table (4): ***Physiological parameters before and after dynamic graciloplasty.***

Variable	*Before*	*After Surgery*	
		8 weeks	*26 weeks*
Pressure at rest (cmH_2O)	15.6+11.23	36.17+23.54	44.16+12.98*
On Stimulation (cmH_2O)	-	69.44+12.66	72.88+9.05*
Voltage (V)	-	2.2	3.1
Defecation Frequency (Times/Day)	5.6+1.3	3	1-2
Ability to postpone defecation (min)	-	10-15	20-25
Enema retention (Sec)	-	60	180

* Significant $p<0.05$

Table (5): ***Stimulation Voltage.***

Time (Weeks)	*Voltage (V)*	*Patients (n)*
Intra-operative	0.1-0.2	6
0	1.2-1.5	6
8	2.2 (2.0- 2.6)	6
16	2.7 (2.4-3.2)	4
26	2.8 (2.4-3.2)	4

Table (6): ***Quality of life assessment in patients after dynamic graciloplasty.***

	Before	*After surgery*	
		8 weeks	*26 weeks*
S-SPSY	0	8	19 *
S-SEXU	NA	NA	NA
S-MOBIL	3	6	15 *
S-SOCI	6	12	12 *
S-FAMIL	7	6	7
S-WORK	NA	NA	NA
S-SPT	5	5	7.5
S-FOOD	8	7	9.5
S-QOH	10	11	14
S-QOL	7	10	16 *

* significant $p<0.05$, NA- not assessed.

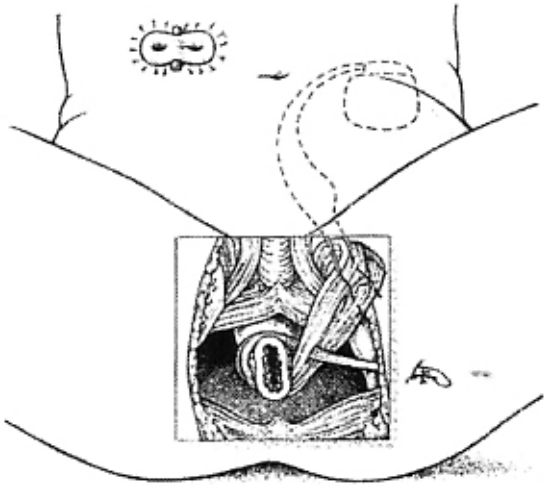

Fig (1): Total anorectal reconstruction (TAR) using graciloplasty of the split-sling technique. Rosen HR etal. AmJ Surg 1998.

DISCUSSION

In recent years, dynamic graciloplasty has significantly progressed as a restorative technique for insufficient or excised anal sphincter. Reported success rates ranged from 53% to 80% with better success reported for acquired fecal incontinence [1-3] than congenital fecal incontinence or after APR for anorectal malignancy [11]. The results achieved in this preliminary trial are in correspondence with those reported elsewhere. Increasing experience is a critical factor in avoiding complications and obtaining successful outcomes. In our study, major wound complication rate after 6-month follow-up was 16.66%, compared with 17% at two most experienced centers and with 33% at centers new to the technique [11]. The overall success rate in our early cases was extremely high (total success = 100%, 40% perfect and 60% good) if compared to 80% at the most experienced centers and with 47% at new centers [11]. This might be related to exchange of multiple visits between our unit and two highly experienced centers in Netherlands and Austria. In spite of these successful preliminary results, no conclusions can be drawn because of the small number of patients. Given the relatively small number of patients who require dynamic graciloplasty, we agree with Madoff et al that this procedure should be reserved for specialized centers where an adequate experience can be easily obtained and clinical expertise is maintained [11].

In our limited series, the device problems were common among our patients. Three patients reported significant difficulties knowing when the stimulator is on or off, inability to use the magnet correctly and continuous on/off switching. Difficulties with the hardware required extensive explanation over several educational sessions. The first patient, who had no difficulties with the hardware, is continuously worry about premature battery depletion and the fifth patient, who uses a remote control; consider it not a friendly user. Such device problems have been reported worldwide [1,5,11] and are not peculiar to our patients. However, we want to point out that patients must be informed extensively before surgery about potential problems in order to achieve satisfactory results.

Infection was only a minor problem in this preliminary report as there was only one case of infection around the leads and related to the stimulator, whereas in the series of Baeten et al [1] seven out of 52 had infection around the stimulator, while Christiansen et al [12] had one out of 13 infection around the device. Because the procedure involves both clean (thigh, abdominal wall) and contaminated (perineal) areas as well as implantation of foreign material, meticulous attention must be paid to skin preparation, preoperative antibiotic, and surgical technique. The use gentamycin-impregnated collagen sponge at the stimulator site can substantially reduce the infection rates. Baeten et al [5] and Rosen et al [9] recently reported similar results [18].

In this study two patients obtained satisfactory continence (score 2) and four patients had improved continence with a change from score 5 to 3. Several authors considered that change from score 5 to 3, although not a satisfactory, represented a good improvement and not

included among failures. Consequently none of our patients considered complete failure.

One of the most important factors contributing to a reduction in patient satisfaction with the operation is impaired rectal emptying [9,12,18-20]. In this study, only one patient complained of impaired evacuation following total anorectal reconstruction.

The pressure increase obtained in this study is lower than that reported by Baeten et al [1,5], Christiansen et al [12] and Rosen et al [9]. This may be due to different patient selection as our patients are either with anal atresia or after abdominoperineal resection with no residual sphincter. Moreover, the important effect of the gracilis wrap is lengthening of the anal canal high-pressure zone [12].

The Fecal Incontinence Quality of Life Scale, as described by Rockwood et al [10], is a useful measure of quality of life for patients with fecal incontinence. The content of the four scales really tap aspects of life for patients with fecal incontinence that could pose problems and affect social functioning in addition to self-image. In agreement with other authors [1,5,13-15], we observed preoperative significant impairment of quality of life. The quality of life scale demonstrated marked limitation of mobility, social isolation, restriction in food and subjectively worse quality of life. The quality of life of our patients was extensively affected if compared to western community [10,14,15]. Dynamic graciloplasty resulted in improvement in seven out of eight examined domains of quality of life. This is in accordance with other authors that dynamic graciloplasty leads to better quality of life [1,5,10,14].

We observed in our patients a discrepancy between continence scored by Williams score [3] and the results of quality of life scale with regard to the domain of specific symptoms. This observation confirms previous reports by others [16] that the most available scoring systems for continence are far from being a perfectly reliable tool and that a parallel assessment of quality of life is advisable to get the best information about the patient's postoperative situation [17].

Our preliminary results with dynamic graciloplasty are strongly encouraging. We should direct our future efforts toward optimizing patient selection and surgical technique to minimize morbidity and maximize satisfactory functional outcomes.

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