Original article

PTQ™ bulking agent injection for the treatment of fecal incontinence: QoL and manometric evaluation

FRANCESCO GUERRA, FRANCESCO VELLUTI, DANIELE CROCETTI AND FILIPPO LA TORRE

U.O. Chirurgia d'Urgenza Retto e Pavimento Pelvico Dip. Emergenza Urgenza "SAPIENZA" Università di Roma

Summary: Fecal incontinence is a debilitating symptom that limits the social and working activities of the patient. Prevalence is probably underestimated, and it is higher in geriatric population and in elderly people with psychiatric disorders. First-line treatment consists of medical and rehabilitative therapy. Use of bulking agents has been proposed in the last years for the treatment of anal incontinence after failure of conservative therapy.

Sixteen patients suffering from mild to moderate fecal incontinence were treated with PTQ™ bulking agent endoanal injection from April 2004 to June 2007. Clinical and manometric evaluations were performed. Quality o Life questionnaires were administered. Good results were reported in almost all cases. CCF-FI score improved from a median of 10,4 before to 5,6 2 years after procedure. Manometry showed a marked increase in median resting and squeeze anal pressures. A limited improvement was observed in Quality of Life scores. No adverse events were registered.

Anal bulking agents should be considered for all patients suffering from fecal incontinence after failure of the conservative therapy being the procedure minimally invasive, repeatable, effective and safe.

Key words: Fecal incontinence; Bulking agents; Anorectal manometry.

INTRODUCTION

Fecal incontinence (FI) is a distressing and socially debilitating symptom which causes the patient to gradually abandon all forms of social, family and working relationships.[1] FI exists along a wide spectrum of variable complaints going from soiling of underclothes or flatus incontinence to complete loss of control of bowel emptying. In many cases, patients feel so inhibited and are so afflicted by this condition that they are reluctant to discuss the problem with a physician and FI is probably therefore an underestimated disease. The calculated prevalence of FI is between 0.5% and 18.4% in non-institutionalized adults, 32% in the geriatric population and 56% in elderly people with psychiatric disorders. [2,3,4,5] Medical treatment should be offered in all cases. Conservative treatment, such as dietary changes and pelvic rehabilitation is reported to be effective in 65-70% of cases.[6] In those patients who do not benefit from conservative treatment, a surgical approach must be proposed. Injection of bulking agents, already used in the treatment of urinary incontinence, [7] has been proposed recently as a substitute for surgical treatment of anal incontinence. [8]

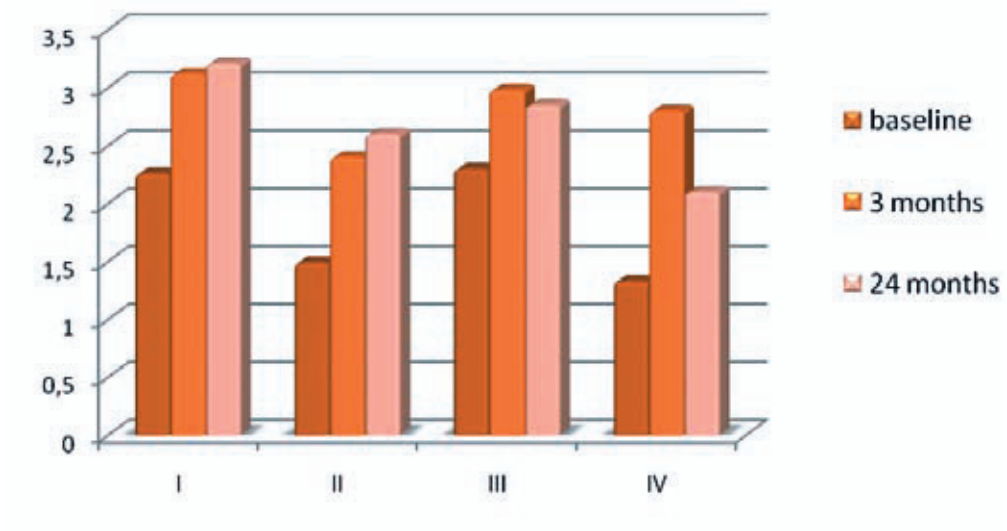
MATERIALS AND METHODS

Between April 2004 and June 2007 sixteen patients suffering from mild to moderate fecal incontinence (CCF-FI score< 15) were selected and treated with transanal injection of PTQ™ bulking agents. All patients had undergone conservative therapy, including dietary changes and pelvic rehabilitative treatment with electrostimulation and biofeedback protocols with no satisfactory improvement of symptoms. Each patient was evaluated with clinical assessment including anoscopy at baseline and at 7, 30 and 90 days and 24 months after treatment. To evaluate social and psychological impact for each patient, a Fecal Incontinence Quality of Life Scale (FIQL) was examined before and 3 and 24 months after treatment. [9] An anorectal manometric study was also performed at baseline and at 3 and 24 months after treatment. An anoscopic exam was performed to identify patients with ongoing anorectal and/or non-anorectal diseases which may modify evaluations following the procedure. Patients with rectal prolapse, fecal impaction, symptomatic haemorrhoids, perianal and anal scarring, perianal sepsis, congenital anal sphincter defect, uncontrolled diabetes, immunodeficiency, acute inflammation, infection or malignancy, pregnancy or within one year postpartum and patients who had undergone proctological surgery in the 12 months preceding enrollment were excluded. All patient completed a consent form. Subsequent clinic evaluations, including anoscopic exam, were performed 7, 30 and 90 days and 24 months after the injection to verify the correct positioning and possible dislocation of the prosthetic material. CCF-FI score calculation was needed at baseline to find the correct indication to treatment with bulking agent, which was proposed to patients with mild to moderate fecal incontinence (CCF-FI score < 15). Subsequent evaluations at 3 and 24 months after treatment were used to assess clinical trend. Anorectal manometry was performed pretreatment, and at 3 and 24 months, using a manometric system (Dyno Compact, Menfis Biomedica – Bologna, Italy) and anorectal manometry PVC catheter with balloon, 5 way,12 Fr. For each exam, maximum resting pressure and maximum squeeze pressures were registered. Each patient was treated under local anesthesia as an outpatient procedure, placed in Sims position after surgical cleaning of the area. Prophylactic broad-spectrum antibiotics were administered to each patient a few minutes before the implant. A 18-gauge rigid needle, loaded onto the PTQ™ implants syringe, was used to inject PTQ™ in the internal sphincter-submucosal interface, entering the skin about 25 mm from the anal margin. By placing a digit through anal canal, attention was paid not to damage endoanal mucosa during the procedure.[10] Three equidistant (circumferentially about 90, 210 and 330 degrees) boles of 2,5 ml of PTQ™ were injected for each patient. PTQ™ implants (PTQ™ Implants – Uroplasty BV, The Netherlands) are solid, irregularly textured, medical grade polydimethylsiloxane elastomer implants suspended in a hydrogel carrier of polyvinylpyrrolidone (PVP or povidone). PTQ™ implants are held in place at the implantation site when the hydrogel carrier is replaced by body fluids and host fibroblast subsequently deposit collagen around the implants.

RESULTS

Sixteen patients with moderate fecal incontinence (CCFIS < 15) were selected for treatment with PTQ injectable anal

Table 1. – FIQL score variations.



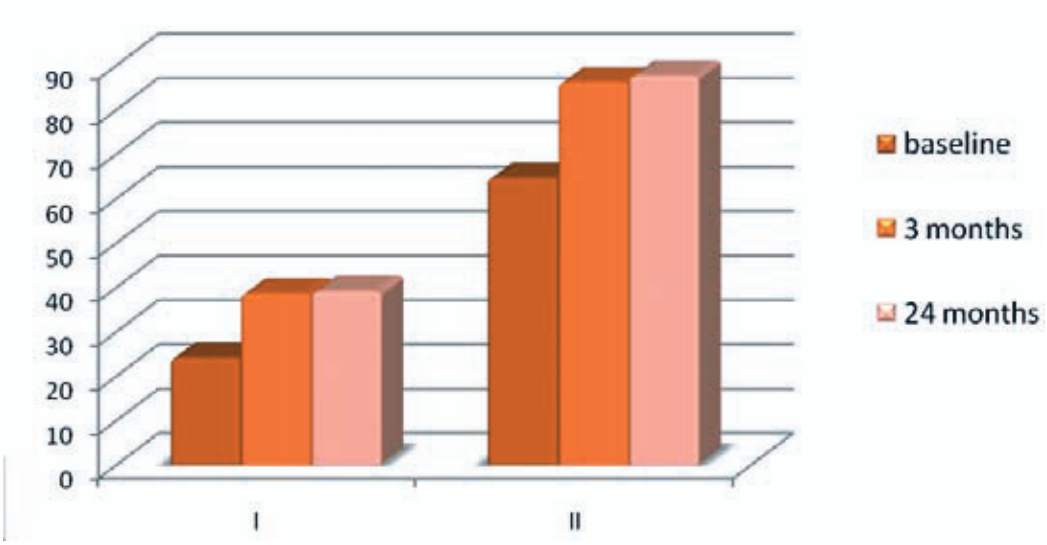
bulking agents. No serious adverse event was reported during or after the injection. No adverse events were reported such as infection or dislocation of the prosthetic material in subsequent visits. In a patient, because of the lack of improvement at 3 months control, two additional boles of PTQ were injected with the same procedure and the patient showed a modest improvement of symptoms at 2 years.

Improvement in CCFIS was from a median of 10,4 (range 6-14) at baseline to 5,5 at 3 months and to 5,6 at 24 months after treatment. An improvement in patients quality of life was demonstrated by FIQL median score variation from baseline to 3 and 24 months follow-up with encouraging results as shown in table n.1. Median scores are calculated for each FIQL's domain: lifestyle (I), coping/behavior (II), depression/self perception (III), embarrassment (IV). Global improvement was also reported by manometric findings. As shown in table n.2 median anal resting pressure (I) was of 24 mmHg at baseline (range 10 – 35) and improved to 38,5 (range 20 – 50) at 3 months and to 39 (range 25 – 50) at 24 months control. Similar results were given by maximal squeeze pressure (II) that increased from a median of 64,5 mmHg at baseline (range 25 – 140) to 86 (range 65 – 145) at 3 months and to 87,5 (65 – 135) at 24 months after the procedure.

DISCUSSION

Use of bulking agents already registered good results for the treatment of urinary incontinence. Endoanal injection of prosthetic bulking agents for the treatment of anal incontinence is reported to be safe and effective in a high number of short- and medium-term studies.[11,12] In our experience PTQ™ implants have shown no complications with good results on clinical and manometric evaluation with an encouraging keeping of improvement at 2-years follow up.[13] The procedure has proved to be safe and easy to perform by expert operators and well-tolerated by the patient.[14] According to literature bulking agents should always be taken into consideration in cases in which conservative medical therapy has not proved effective.[15] To date, the large number of conservative therapeutic solutions in the treatment of fecal incontinence should be considered for all degrees of incontinence.[16] It is demonstrated that mild to moderate anal incontinence is healed in a good percentage of patients and improved in almost all cases.[17] However, non-surgical treatment of severe fecal incontinence can be taken into consideration with non-curative purposes, but in preparation for a possible restorative or substitutive intervention with improved outcomes.[18]

Table 2. – Median manometric findings variations.



Encouraging results obtained, in agreement with most recent literature, show that endoanal injection of bulking agents is effective in treating mild to moderate fecal incontinence. This procedure is minimally invasive, repeatable, not associated with major complications and is feasible in an outpatient regime. Moreover the good patient compliance associated with favorable cost-benefit analysis requires further studies with a longer term follow-up to assess bulking agents as the first line treatment for mild to moderate fecal incontinence non-responsive to medical therapy.

REFERENCES

1. Appell RA,Bourcier AP, La Torre F. Pelvic floor dysfunction. Investigations and conservative treatment. Casa Editrice Scientifica Internazionale 1999.
2. Corman ML. Anal Incontinence. In "Colon and Rectal Surgery" 3rd ed. Philadelphia: J B Lippincott Company 1993; 188 – 261.
3. Shamliyan Ta, Bliss Dz, Du J, Ping R, Wilt TJ, Kane RL. Prevalence and risk factors of fecal incontinence in community-dwelling men. Rev Gastroenterol Disord. 2009 Fall;9(4):E97-E110.
4. Whitehead WE, Borrud L, Goode PS, Meikle S, Mueller Er, Tuteja A, Weidner A, Weinstein M, YE W. Fecal incontinence in US adults: epidemiology and risk factors. Gastroenterology. 2009;137(2):512-7.
5. Pretlove SJ, Radley S, Toozs-hobson PM, Thompson PJ, Coomarasamy A, Khan KS. Prevalence of anal incontinence according to age and gender: a systematic review and meta-regression analysis. Int Urogynecol J Pelvic Floor Dysfunct. 2006;17(4):407-17.
6. Ozturk R., Niazi S, Stessman M, Rao SS. Long term outcome and objective changes of anorectal function after biofeedback therapy for faecal incontinence. Aliment Pharmacol Ther. 2004; 15:20(6):667-74.
7. Harriss DR, Iacovou JW, Lemberger RJ. Peri-urethral silicone microimplants (Macroplastique) for the treatment of genuine stress incontinence. Br J Urology 1996;78:722-728.
8. Tjandra JJ, Lim JF, Hiscock R, Rajendra P. Injectable silicone biomaterial for faecal incontinence caused by internal anal sphincter dysfunction is effective. Dis Col Rectum. 2004;47(12):2138-46.
9. Yusuf SA, Jorge JM, Habr-Gama A, Kiss DR,, Gama Rodrigues J. Evaluation of quality of life in anal incontinence: Validation of the questionnaire FIQL (Faecal Incontinence Quality of Life) Arq Gastroenterol. 2004;41(3):202-8
10. Tjandra JJ, F.R.A.C.S., Lim J.F. et al. Injectable silicone biomaterial for fecal incontinence caused by internal anal sphincter dysfunction is effective. Dis Col Rectum 2004:47:2138-2146.
11. De la Portilla F, Fernandez A, Leon E et al. Evaluation of the use of PTQ implants for the treatment of incontinent patients due to internal anal sphincter dysfunction. Colorectal Dis. 2008;10(1):89-94. Epub 2007 Jun 30.
12. Altomare DF, La Torre F, Rinaldi M, binda GA, Pescatori M. Carbon-coated microbeads anal injection in outpatient treatment of minor fecal incontinence. Dis Colon rectum. 2008;51(4):432-5.
13. Bartlett L, Ho YH. PTQ anal implants for the treatment of faecal incontinence. Br J Surg. 2009;96(12):1468-75.
14. Luo C, Samaranayake CB, Plank LD, Bissett IP. Systematic review on the efficacy and safety of injectable bulking agents for passive fecal incontinence. Colorectal Dis. 2009 Mar 6 Epub.
15. Khaikin M, Wexner SD. Treatment strategies in obstructed defecation and fecal incontinence. World J Gastroenterol 2006;12:3168-3173.
16. Whitehead We, Wald A, Norton NJ. Treatment options for fecal incontinence. Dis Colon Rectum 2001;44(1):131-42.
17. Aigner F, Conrad F, Margreiter R, Oberwalder M; Anal submucosal carbon bead injection for treatment of idiopathic fecal incontinence: a preliminary report. Dis Colon Rectum 2009;52(2):293-8.
18. Tan JJ, Chan M, Tjandra JJ. Evolving therapy for fecal incontinence. Dis Colon Rectum 2007;50(11):1950-67.

Correspondence to:
Prof. Filippo La Torre
Via Trionfale 6551
00135 Roma – Italy
filippo.latorre@uniroma1.it

Pelvic Floor Digest

continued from page 19

Anterior sphincteroplasty for fecal incontinence: a single center experience in the era of sacral neuromodulation. *Oom DM, Gosselink MP, Schouten WR. Diseases of the Colon & Rectum. EPUBDATE: 2009-12-08.* It has been reported that patients with external anal sphincter defect may also benefit from sacral neuromodulation. The success of this technique raises the question whether anterior overlapping sphincteroplasty still deserves a place in the surgical treatment of fecal incontinence. This study investigated the outcome of anterior sphincteroplasty in a series of 172 patients after a median follow-up of 111 months. Results were acceptable to excellent in 60% of patients, especially in those under the age of 50 years at surgery.

Myoblasts differentiated from adipose-derived stem cells to treat stress urinary incontinence. *Fu Q, Song XF, Liao GL, Deng CL, Cui L. Urology. EPUBDATE: 2009-12-09.* Adipose-derived stem cells have the ability of differentiating into multiple lineages, including myoblasts. This ability to induce myoblasts can be used to treat stress incontinence, with the advantages of minimal invasion and faster recovery as proved in 20 female incontinent rats.

7 PAIN

Efficacy of montelukast, a leukotriene receptor antagonist, for the treatment of dysmenorrhea: A prospective, double-blind, randomized, placebo-controlled study. *Fujiwara H, Konno R, Netsu S et al. European Journal of Obstetrics & Gynecology and Reproductive Biology. EPUBDATE: 2009-12-01.* Montelukast is a clinically reasonable management option to consider before prescribing an hormonal agent, it may be effective in alleviating pain associated with dysmenorrhea in some women. It is safe and does not influence hormonal levels.

Increased cold-pain thresholds in major depression. *Schwier C, Kliem A, Boettger MK, Bär KJ. Journal of Pain. EPUBDATE: 2009-12-01.* Patients suffering from major depressive disorder show a decreased sensitivity for external or skin surface pain, eg, for heat or electrical stimuli, as compared to healthy controls.

Effect of meal ingestion on ileocolonic and colonic transit in health and irritable bowel syndrome. *Deiteren A, Camilleri M, Burton D et al Digestive Diseases and Sciences. EPUBDATE: 2009-12-02.* Postprandial symptoms in irritable bowel syndrome (IBS) have been associated with increased bowel contractility. This study shows that ileocolonic transit immediately after eating is higher in IBS diarrhea predominant (IBS-D) patients than in the healthy controls, whereas colonic transit is blunted in IBS-C (constipation predominant).

The PFD continues on page 32