EVIDENCE BASED REPORT

Injectable Anal Bulking Agent for the Management of Faecal Incontinence

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ABSTRACT

This study was conducted to determine the safety and efficacy of injectable bulking agents. A total of 13 procedures were performed on 11 patients with faecal incontinence during 2002 to 2007. Patients with internal anal sphincter defect and low incontinence score (Cleveland score < 10) revealed improvement. Patients with higher incontinence score and external sphincter defect secondary to obstetric damage required further intervention. At a median follow-up of 43 months, 7 (63%) patients showed improvement in incontinence score and 4 (32%) showed marked improvement in their symptoms. Fifty six percent of the patients described this as an effective procedure, though the level of effectiveness varied from person to person. Anal injectable collagen was found safe and effective in the management of faecal incontinence. Long-term follow-ups are required to re assess and consider definitive procedure in failed cases.

Key words: *Anal bulking agents. Faecal incontinence. Anal collagen plug.*

INTRODUCTION

Faecal incontinence is a physically and emotionally devastating condition resulting in poor quality of life.[1,2] The aetiology of faecal incontinence varies from traumatic and neurological to muscular conditions. The most common cause is obstetric trauma to anal sphincter during delivery. Biofeedback and/or anal sphincter exercises are considered as initial non-invasive treatment. According to the recent Cochrane review biofeedback does not enhance the outcome compared to the other conservative treatments.[3] Hence in subjects with failed biofeedback injectable bulking agents are indicated.[4] Synthetic collagen is used in sub-mucosal space to bulk the sphincter and anal canal thereby creating a better seal for continence. This study was conducted to assess the efficacy, risks involved and further management of patients undergoing anal bulking procedure.

METHODOLOGY

This was a retrospective study (case series), carried out in Castle Hill Hospital, Cottingham, UK. A total of 11 patients received anal collagen injection treatment between January 2002 and December 2007. The patients routinely underwent anorectal physiology and endoanal ultrasound assessment before the procedure. Cleveland clinic faecal incontinence score and quality of life were also assessed. Patients with history of colorectal malignancy were excluded from the study.

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Procedure was performed by a single surgeon with special interest in ano-rectal physiology. Under general anaesthesia, collagen was injected in submucosal space at sphincteric defect to create the bulk and to fill the defected area. If patient did not have a sphincter defect, collagen was injected at 4, 7 and 11 o'clock position to create the natural haemorrhoidal cushions. The morbidity of the procedure was recorded. Patients were followed in the clinic to assess the response of therapy and need for further intervention.

Quality of life was severely affected in 6 patients whereas 3 patients had moderate life style alteration. Incontinence mildly affected one patient whereas incontinence score and quality of life was not recorded in one patient. All patients had a trial of non-invasive treatment including alteration in diet, biofeedback, pelvic floor exercises and pharmaceutical treatment (Loperamide and / or Imipramine).

RESULTS

The eleven patients included 5 males and 6 females with mean age of 53 $\pm$ 15 years. Ten patients underwent endoanal ultrasound (USG) and were found to have anal sphincter deformity. Sensory function was normal in 9 patients, whilst it was not recorded in one. An isolated sphincter defect was found in 8 (72%) patients with 4 (36%) in each IAS and EAS group. Two (18%) patients had both IAS and EAS sphincter defects. The anorectal physiology record was not available for one patient. Pre-operative Mean Cleveland Incontinence score was 12 (range 9-16). Out of 11 patients, 5 (45%) found to have solid faecal incontinence, whereas 6 (55%) recorded with liquid incontinence.

The patients were initially followed at 6 weeks post-operatively. The subsequent appointments were at 3, 6,

Table I: Clinical data of 11 patients with faecal incontinence.

Gender	Age	Back ground	Incontinence	Life style alteration		Cleveland score	
			Pre-op	Pre-op	Post-op	Pre-op	Post-op
M	59	Haemorrhoids treatment (injected)	Solid	Mild	None	9	0
F	29	IBD	Liquid	Moderate	None	10	0
F	78	Obstetrical complications	Solid	Very severe	Very severe	15	15
F	65	Obstetrical complications	Liquid	Very severe	Moderate	13	10
M	41	Haemorrhoidectomy	Liquid	Severe	Mild	11	4
M	54	Haemorrhoidectomy	Liquid	Moderate	Mild	10	3
F	60	Obstetrical complications	Solid	Very severe	Very severe	16	18
M	36	Large fissure, Anal trauma (iatrogenic)	Solid	Moderate	Moderate	11	8
F	41	Obstetrical complications	Liquid	-*	None	-*	0
F	55	Obstetrical complications	Solid	Very severe	Very severe	15	16
M	71	Trauma (non-iatrogenic)	Liquid	Severe	Moderate	13	7

** Date not available.*

12 months and yearly thereafter. The median follow-up was 47 months (IQR 15-62). Six patients developed recurrent symptoms hence referred for further opinion and intervention.

Variable symptom improvement was noticed in 7 patients (63%) out of the total study group. Four patients (36%) had significant improvement whilst 3 remained symptom free with Cleveland score 0 at 47 months follow-up. All three of them had isolated internal anal sphincter defect. In the fourth patient, with marked improvement, the sphincter defect was not classified (Table I).

Mild improvements were recorded in 2 (18%) patients including 1 IAS, 1 EAS group. Out of 2 patients with both sphincter defects, one was fully continent whereas the other required a repeat injection. Life style improvement was also recorded in this group. The improvement in quality of life following the procedure has been described in Table II.

Table II: Visual analogue score for quality of life before and after the procedure.

Life style alternatoin score	Pre-op patients (n)	Percentage (%)	Post-op patients (n)	Percentage (%)
4 (every severe)	4	55	3	27.5
3 (severe)	2		0	
2 (moderate)	3	27.5	3	27.5
1 (mild)	1	8.7	2	45
0 (no alternation)	-*	8.7	3	

** Data not available.*

The patients with obstetric, iatrogenic or non-iatrogenic anal trauma had minimal or no improvement after this procedure and required further intervention, whereas all 3 patients with idiopathic aetiology and the post haemorrhoid treatment showed significant improvement (Table I).

Mean pre-operative incontinence score was 12.3 ± 2.4 which improved to 7.3 ± 6.7 at the median 47 months (IQR 15-62) follow-up. Patients with low score (3-6) had good results whereas patients with higher score had very little long-term benefit.

One patient with anal fissure, treated for incontinence, required repeated examination for perianal sepsis. Six patients were referred for further interventions, whereas 4 were satisfied with the results and did not want further follow-ups. One patient died of a cause not related to the incontinence or related intervention.

DISCUSSION

Faecal incontinence is a common problem especially in elderly population and this may lead to significant impairment in their daily activities.[3] In majority of the patients it results from structural, physiological and psychological factors. With the help of anorectal physiology and endoanal ultrasound, the correct characterization of the underlying cause can be performed. Treatment of incontinence is not easy as the recent Cochrane review suggests that there is no evidence of biofeedback enhancing the outcome of treatment compared to other conservative methods.[3] Therefore, an alternative approach by enhancing the resting anal pressure for better seal for continence using anal bulking agents is used.

Different injectable bulking agents like autologous fat, collagen, silicon and carbon beads have been used to treat faecal incontinence.[4-9] Current evidence comprising of small case series and one RCT showed short-term benefit in a maximum of 65% patients.[4-8,10,11] Another study reported an improvement of Cleveland score from 12 to 8.07 at 12 months follow- up.[10] None of the studies illustrated enough data and long-term follow-up to be certain about the efficacy of this procedure.[2] Stojkovic *et al.* in their study of 73 patients noticed 63% improvement in incontinence score.[6] Whereas in a recent case series of 33 patients improved incontinence was noticed in only 11 (33%) patients.[4] Hence the overall outcome of this procedure is yet to be established.

In this study, the results were similar to the published literature and procedure was initially effective in 63% patients and sustained in 36% patients at the last follow-up. Long-term quality of life and patients' satisfaction is not yet established. We noticed improvement in quality of life as less patients i.e. 27.3% experienced severe

symptoms compared to the pre-operative 54.5% and mild or no life style alteration were recorded in 45.5%. There was an improvement in faecal incontinence score and the procedure was effective in 56% patients.

It is important, however, to appreciate the limitation of this study in terms of small number, single centre, and case series with no control and / or other intervention group. Moreover, the long-term quality of life and patient satisfaction could not be established. Therefore, we propose a well designed randomised trial with adequate sample size to assess the outcomes of different treatments for faecal incontinence.

CONCLUSION

The procedure appears to be safe and quick to treat idiopathic incontinence. It does not require a hospital stay and feasible to perform as a day case surgery. The complication rate is very low and in failed or recurrent cases re-injection can be used. It should be carried out under strict clinical governance and audit guidelines as there is lack of sufficient data to conclude or exclude the procedure for routine patients care.

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