

SUBMUCOSAL ANAL BULKING WITH POLYACRYLAMIDE HYDROGEL (RECTAMID™): A PROMISING OUTPATIENT PROCEDURE IN PATIENTS WITH ANAL INCONTINENCE

Hypothesis / aims of study

To test the effect of a new method of anal bulking with Polyacrylamide Hydrogel (Rectamid™) in patients with minor anal incontinence

Study design, materials and methods

Study design

This is an open, non-comparative pilot trial to determine the effectiveness and safety of polyacrylamide hydrogel (Rectamid™) injected into the submucosa of the anal canal in patients with anal incontinence.

Materials

28 patients, 26 females and 2 men, mean age 54,8 years (range 29-83 years), with a history of incontinence to gas or faecal soiling for more than 12 months were included, mean duration of anal incontinence was 9,2 years (range 1-30 years). 12 patients were included from the outpatient clinic and 16 patients were recruited from a newspaper advertise. In all patients, best conservative care was unsuccessful. Patients were included in the period 1.9.2007 – 5.9.2008. 11 patients had previous anal sphincter rupture, 4 patients previous anal surgery and 13 patients had idiopathic anal incontinence.

Patients with diabetes, inflammatory bowel disease, pregnancy or cancer/previous cancer were excluded.

2 patients were lost to follow-up. One patient died of disseminated oesophageal cancer undetected at the time of inclusion and one patient was unable to attend in the outpatient clinic at the 6 month follow-up.

Methods

After local analgesia was applied, Rectamid™ was injected submucosally in up to 3 positions at 2, 6 and 10 o'clock 10 mm above the dentate line using a special designed anoscope with grooves and needle guide. One ml was placed in each position. At 6 weeks a new injection of Rectamid™ was offered in case of insufficient effect. Up to 3 ml, one ml in each new position, at 4, 8 and 12 o'clock was injected. Before injection, intravenous gentamicine and metronidazole was administered. The positions of deposits were inspected with an anoscope and with 3-D endosonography.

At screening, anal incontinence score and anorectal physiology testing with anal manometry, maximum tolerable rectal volume (MTV), anal sensitivity and pudendal nerve terminal stimulation was performed. At 6 months this was repeated. Primary endpoint was changes to the St Marks Incontinence score at 6 months after the first treatment compared to screening. Secondary endpoints were changes in anorectal physiology testing and responder rate based on the patients perception of results at 6 months compared to screening.

Results

Primary endpoint

The St Marks Incontinence score decreased from mean 11.2 (SD 4.84) to 8.0 (SD 4.31), $p < 0.02$, two-sided t-test.

Secondary endpoints

Anorectal physiology testing showed no difference in anal resting pressure or squeeze pressure. No changes were found in rectal volume tolerability, anal sensitivity or pudendal nerve terminal motor latency (PNTML). Anorectal physiology testing is summarized in table 1.

Table 1

	Anal manometry (mmHg)				MTV (ml)		Anal sensibility (mA)		PNTML (msec.)	
	Resting pressure		Squeeze pressure							
	Screening	6 months	Screening	6 months	Screening	6 months	Screening	6 months	Screening	6 months
N	26	26	26	26	26	26	26	18	26	17
Mean	76.6	81.6	123	121	127	131	4.10	3.11	2.11	2.14
Min	25	40	42	44	60	60	1,80	0,8	1,5	1,7
Max	170	147	300	228	270	300	8,2	7,2	2,9	2,7
SD	33.9	28.1	66.3	53.6	48.9	58.4	1.47	1.88	0.38	0.30

Overall patient perception of effect at 6 months showed that no patients were cured, 8 patients were much improved, 9 patients improved and 9 patients were unchanged. No patients had worse result. Overall 61% of patients had improvement (intention to treat).

In 10 patients with incontinence to flatus 2 were much improved, 3 were improved and 5 were unchanged. In 3 patients with anal soiling alone 2 patients were improved and 1 was unchanged. In 13 patients with both incontinence to gas and anal soiling, 6 patients had much improvement, 5 patients were improved and 2 patients were unchanged.

No infections were recorded during follow-up. 4 patients had retrograde filling of Rectamid™ to the perianal skin, which needed surgical excision in local anaesthesia.

Interpretation of results

Anal bulking with Rectamid™ injected submucosally improves anal continence. 61% of the patients perceived improvement or much improvement, which is reflected in a decrease in St Marks Incontinence score from 11.2 to 8.0. Injection of Rectamid™ had no impact on anorectal physiology testing. Rectamid™ is a non-biodegradable and migration resistant anal bulking agent. It is probably improving anal sphincter closing function, especially in patients with soiling.

Concluding message

Anal bulking with Rectamid™ improves anal continence and is a simple outpatient clinic procedure without any safety concern to the patient.

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Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	De Videnskabsetiske Komiteer for Region Hovedstaden (The ethical committees of the Copenhagen Region of Denmark)
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes