

Anterior rectocele due to obstructed defecation relieved by botulinum toxin

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Background. Surgical repair of rectocele does not always alleviate symptoms related to difficulty in defecation, and some patients have impaired fecal continence after surgical treatment. To avoid complications of surgical repair, we investigated the efficacy of botulinum toxin in treating patients with symptomatic rectocele.

Methods. Fourteen female patients with anterior rectocele were included in the study. The patients were studied by using anorectal manometry and defecography, and then treated with a total of 30 units of type A botulinum toxin, injected into 3 sites, 2 on either side of the puborectalis muscle and the third anteriorly in the external anal sphincter, under ultrasonographic guidance.

Results. After 2 months, symptomatic improvement was noted in 9 patients ($P = .0003$). At the same time, rectocele depth (mean $\pm$ SD) was reduced from 4.3 ± 0.6 cm to 1.8 ± 0.5 cm ($P = .0000001$) and rectocele area from 9.2 ± 1.3 cm² to 2.8 ± 1.6 cm² ($P = .0000001$). Anorectal manometry demonstrated decreased tone during straining from 70 ± 28 mm Hg at baseline to 41 ± 19 mm Hg at 1 month ($P = .003$) and to 41 ± 22 mm Hg at 2 months ($P = .005$). No permanent complications were observed in any patient for a mean follow-up period of 18 ± 4 months. At 1 year evaluation, incomplete or digitally assisted rectal voiding was not reported by any patient, and a rectocele was not found at physical examination. Four recurrent, asymptomatic rectoceles were noted at defecography.

Conclusions. Botulinum toxin injections should be considered as a simple therapeutic approach in patients with anterior rectocele. The treatment is safe and less expensive than surgical repair. A more precise method of toxin injections under transrectal ultrasonography accounts for the high success rate. Repeated injections may be necessary to maintain the clinical improvement. (Surgery 2001;129:524-9.)

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RECTOCELE, A HERNIATION of the anterior rectal wall into the lumen of the vagina, is a frequent finding in female patients and its clinical relevance is questionable: from 20% to 81% of both asymptomatic women and patients with constipation may present with rectoceles.^{1,2} If less than 2 cm in diameter, rectoceles are usually accepted as a normal finding, both in constipated patients and in healthy subjects, whereas those with a diameter of more

than 2 cm can cause outlet obstruction and rectal emptying difficulties.¹⁻⁶

Although it has been suggested that some rectoceles may be caused by failure of relaxation or paradoxical contraction of the puborectalis muscle occurring during attempted evacuation,⁷⁻⁹ the reason for its formation is not clear. However, it is important to identify a rectocele when it is the primary cause of intractable obstructed evacuation.

Rectoceles may cause mild to severe anorectal symptoms that are usually associated with chronic constipation. It is probable that straining aggravates the rectocele, enlarges it, and makes evacuation even more difficult.² In patients with rectocele and paradoxical sphincter reaction, defecation has to occur through the unrelaxed pelvic floor.^{2,3,7}

Accepted for publication October 21, 2000.

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0039-6060/2001/\$35.00 + 0 11/56/112737

doi:10.1067/msy.2001.112737

Although simple to diagnose, rectocele has proved to be difficult to treat. The initial phase of management usually involves a high-residue diet to try to elicit rectal voiding. The next step is to use increasing doses of laxatives and enemas. Neither procedure is effective in solving the problem.

A wide variety of surgical approaches have been proposed with the aim of assuring rectal emptying by reducing the dimension of the rectocele. However, the results of operation are often disappointing with regard to emptying difficulties. Surgical repair—either vaginal, transperineal, or transanal—does not always alleviate symptoms and in some patients causes impaired fecal continence.^{2,10-12} Transanal repair, furthermore, may compromise anal sphincter pressures.⁴ An alternative approach should be considered when the anal sphincter is lax.

With the aim of avoiding permanent complications, we have evaluated in this study the efficacy of injections of type A botulinum toxin in improving rectal emptying in patients with symptomatic rectocele.

PATIENTS AND METHODS

Study patients. All patients who had outlet obstruction with anterior rectocele were enrolled. The inclusion criteria for treatment with type A botulinum toxin were as follows: (1) rectocele larger than 3 cm in diameter as measured during defecography; (2) absent or incomplete emptying of rectocele during the evacuation phase of the defecography; (3) incomplete, prolonged, and difficult evacuation with constant use of enemas, laxatives, and rectal and/or vaginal digitation to facilitate rectal emptying; (4) rectal or vaginal symptoms present for longer than 12 months; (5) normal colonic transit time study; (6) inability to achieve complete evacuation of barium paste during defecography, despite a measurable increase in the anorectal angle between rest and attempted evacuation.

The study protocol was reviewed and approved by the Institutional Committee of the Catholic University of Rome. Each patient provided written informed consent for the study.

Study design. This was an open label study. At 1 and 3 months follow-up, 2 examiners evaluated the outcome clinically and by comparing the depth and the area of the rectocele as measured by defecography. The values of resting anal tone, maximum voluntary contraction, and pressure during straining as measured by anorectal manometry were also evaluated. The study end point was the evaluation of symptomatic improvement and the reduction of rectocele depth and area after treatment.

Baseline assessment. All the patients underwent a pretreatment evaluation, which included clinical examination, anorectal manometry, and defecography, as reported elsewhere.¹³ Anorectal manometry was performed at rest, after maximum voluntary contraction (ie, the maximal voluntary increase above the resting tone) and during straining. One and 2 months after treatment, the patients underwent the same evaluation performed at the baseline. Anal pressures were determined by a station pull-through technique with 3 catheters water-perfused at a rate of 0.5 mL/min by a pneumohydraulic pump. At defecography, resting state, voluntary and maximum contraction of the sphincter and pelvic floor muscles, and straining during defecation were recorded. Rectal emptying was also assessed. X-ray films were taken in each position and dynamic assessment of the defecation was also obtained. A rectocele was defined as any anterior bulge outside the line of the anterior rectal wall occurring during defecation or straining with a bulge extending at least 3 cm in depth beyond the expected line of the anterior wall. The size of the rectocele was assessed by measuring the maximum depth of the bulge beyond the expected line of the anterior rectal wall. Changes in rectocele depth and area were measured by defecography at baseline and 2 months after botulinum toxin injections.

Treatment. Vials containing 100 units of lyophilized type A botulinum toxin (Botox; Allergan, Inc, Irvine, Calif) were stored at a temperature of -20°C and diluted in saline to 50 U/mL before the injections. A total of 30 units of type A botulinum toxin were injected with a 23G needle evenly divided in 3 sites, 2 on either side of the puborectalis muscle and the third anteriorly in the external anal sphincter. The sites of injection were visualized by means of transrectal ultrasonography. The toxin was injected with the patient in the left lateral position. Neither sedation nor local anesthesia was used during the procedure.

Clinical care, follow-up, and outcome measures. If the symptoms and the rectocele persisted at the 2-month evaluation, the examiners could decide to re-treat a patient (rescue treatment). The re-treated patients received 100 units of botulinum toxin in the 3 sites of injections, as described above. Each patient received 2.0 mL of solution containing botulinum toxin, divided in 3 injections: 0.6 mL was injected on either side of the puborectalis muscle and 0.8 mL was injected anteriorly into the external anal sphincter. Re-treated patients were then evaluated with the same protocol 1 month and 2 months after the rescue treatment. The healed patients were followed-up clinically until December 1999.

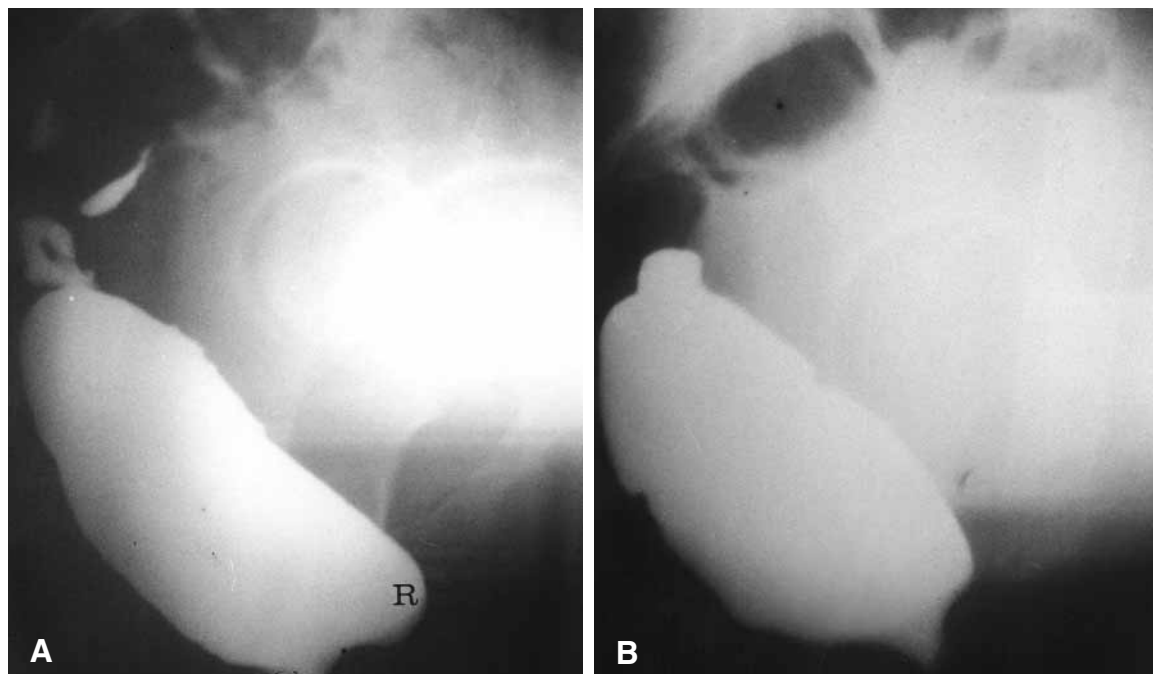


Figure. Defecography during straining before (A) and after (B) treatment. A large rectocele (R) was shown at defecography (A) and it disappeared 2 months after the treatment with botulinum toxin (B).

Statistical analysis. All statistical elaborations were obtained by using Statistics for Windows (Statsoft; Tulsa, Okla). The results were expressed as mean $\pm$ SD; differences between mean $\pm$ SD data were compared by the Student *t* test, while differences between percentages were analyzed by Fisher's exact test. All *P* values were 2-tailed. *P* values of less than .05 were considered statistically significant.

RESULTS

Baseline assessment. From January to December 1998, fourteen female patients, with a mean age of 55 ± 11 years, were included in the study. Twelve patients had experienced at least 1 vaginal delivery; only 2 of these patients related the onset of symptoms to childbirth. Six patients had undergone a hysterectomy. All patients reported a history of incomplete, prolonged, and difficult evacuation that had been present for a mean period of 28 ± 11 months. All patients experienced a feeling of incomplete rectal emptying, sense of fullness, and constipation. Twelve patients digitally assisted defecation through the vagina and 11 through the rectum. Excessive straining during defecation was reported by 12 patients; 9 of these patients had anorectal pain.

At physical examination, a rectocele was found in all of the patients. Resting anal pressure was 62 ± 16 mm Hg and maximum voluntary contraction was 45 ± 23 mm Hg. Pressure during straining was 70 ± 28

mm Hg. At defecography, rectocele depth was 4.3 ± 0.6 cm and rectocele area was 9.2 ± 1.3 cm².

The botulinum toxin injections were easily performed in all of the patients; there were no complications observed in any of the patients during the procedure.

One-month evaluation. Inspection revealed a symptomatic improvement in 7 patients ($P = .005$ versus baseline assessment). Compared with pre-treatment records, incomplete evacuation had disappeared in 7 patients ($P = .005$) and was reduced in 2 patients. The sense of fullness had disappeared in 6 patients ($P = .01$) and constipation in 5 patients ($P = .02$). Six patients digitally assisted defecation through the vagina ($P = .01$) and 5 through the rectum ($P = .03$). Blood or mucus discharge, or both, had disappeared in all 7 patients who had previously reported it ($P = .005$).

As compared with baseline values, resting pressure (54 ± 19 mm Hg, $P = .2$) and maximum voluntary contraction (39 ± 22 mm Hg, $P = .5$) were unchanged. The pressure during straining (41 ± 19 mm Hg) was reduced by 41.4% ($P = .003$) as compared with the baseline value and was significantly lower ($P = .04$) than the resting pressure value at the same time.

Two-month evaluation. A symptomatic improvement was found in 9 patients ($P = .0003$). Anorectal pain had disappeared in all patients who had previously reported it ($P = .0003$). Incomplete evacua-

tion had been reported by 5 patients ($P = .0003$) and a sense of fullness by 3 patients ($P = .00001$). Four patients digitally assisted defecation through the vagina ($P = .003$) and 3 through the rectum ($P = .007$). Straining during defecation was reported by 5 patients ($P = .009$).

The resting anal pressure (57 ± 22 mm Hg, $P = .5$) and the maximum voluntary pressure (50 ± 28 mm Hg, $P = .5$) were not changed as compared with baseline values. The pressure during straining (41 ± 22 mm Hg) was reduced, as compared with baseline value, by 41.3% ($P = .005$) and was lower than resting anal pressure ($P = .03$).

At defecography (Figure), rectocele depth was reduced from 4.3 ± 0.6 cm to 1.8 ± 0.5 cm ($P = .0000001$) and rectocele area was reduced from 9.2 ± 1.3 cm² to 2.8 ± 1.6 cm² ($P = .0000001$). Anorectal angle measured during straining increased from a mean of $98^\circ \pm 15^\circ$ before treatment to a mean of $121^\circ \pm 19^\circ$ ($P = .001$).

Follow-up and long-term outcomes. A rescue treatment with 100 units of type A botulinum toxin was proposed to the 5 symptomatic patients. Two months after the rescue treatment, symptomatic improvement was observed in all these patients. At the same time, rectocele depth and rectocele area were reduced in these patients from 5 ± 1.1 cm to 1.7 ± 0.7 cm ($P = 0.02$) and from 8.5 ± 1.9 cm² to 2.3 ± 1.1 cm² ($P = .01$), respectively.

In the same patients, resting anal pressure (from 62 ± 17 mm Hg to 73 ± 19 mm Hg and to 68 ± 15 mm Hg at 1 month and 2 months after the rescue treatment, respectively) and maximum voluntary pressure (from 48 ± 31 mm Hg to 40 ± 16 mm Hg and to 52 ± 22 mm Hg at 1 month and 2 months after the rescue treatment, respectively) were unchanged. The pressure during straining was reduced from 70 ± 7 mm Hg to 39 ± 10 mm Hg ($P = .0007$) at the 1-month evaluation and to 33 ± 10 mm Hg ($P = .0002$) at the 2-month evaluation. At the 1- and 2-month evaluations, the values of the pressure during straining were significantly lower ($P = .02$) with respect to the values of the resting anal pressure.

All the patients were followed up for an average 18 ± 4 months. During this time, there was no relapse of symptoms in any of them. No complications or side effects were reported during follow-up, with the exception of 1 patient who had mild flatus incontinence 15 days after treatment with the rescue dose of 100 units of type botulinum toxin: incontinence lasted a week and spontaneously disappeared.

At the 1-year evaluation, incomplete or digitally assisted rectal voiding had not been reported by

any patient. Rectocele was not found at physical examination. The resting anal pressure (60 ± 19 mm Hg, $P = .7$) and the maximum voluntary pressure (45 ± 22 mm Hg, $P = .9$) were not changed as compared with baseline values. The pressure during straining (49 ± 12 mm Hg) was reduced as compared with baseline values ($P = .01$), and was not significantly lower than resting pressure ($P = .08$). Defecography showed 4 recurrent rectoceles, all asymptomatic. Rectocele depth was 1.9 ± 1 cm ($P = .00001$ versus baseline value) and rectocele area 3.1 ± 0.9 cm² ($P = .00001$ versus baseline value). Anorectal angle was $119^\circ \pm 26^\circ$ ($P = .01$ versus baseline value).

DISCUSSION

Symptoms related to difficulty in defecation have been observed in 23% to 70% of patients with a rectocele.^{2,3,11} Its surgical repair is associated with subjective improvement in the majority of patients with rectal emptying difficulties. However, surgical repair—either vaginal, transperineal, or transanal—is not always successful. From 30% to 72% of patients still had difficulties with evacuation in the postoperative period.^{3,11} Fifty-four percent of patients still complained of constipation, in many cases severe, after the surgical procedure; 17% of them noted persistent anorectal pain; and 34% had impaired fecal continence.¹¹ Furthermore, a higher postoperative incontinence rate has been reported after a transanal approach to rectocele repair. Six months after successful transanal repair of rectoceles, Ho et al⁴ found a significant impairment in the resting and squeezing anal pressures, probably correlated to stretched anal sphincters. Moreover, it has been noted that there was an increased incidence of rectovaginal fistulae and vaginal narrowing and significant postoperative pain when the transvaginal approach was used.¹²

Puborectalis syndrome is considered by many experts to be the most important cause of disturbed defecation.^{2,3,7} It has been suggested that it causes rectoceles because constant forceful straining results in dissipation of the vector force through the rectovaginal septum. This is likely to be the weakest structure surrounding the lower rectum, and it is most likely to stretch if excessive pressure is applied to the rectum and the anal canal.²

However, poor postoperative results depend on the fact that surgical repair tends to reduce the dimensions of the rectocele, while symptoms are probably related at least in part to factors other than the size of the anterior herniation. Furthermore, both transvaginal and transrectal repairs

include puborectalis muscle plication, which may aggravate obstructed defecation.

To obtain a higher rate of symptomatic improvement, avoiding postoperative complications, alternative therapies that produce a reversible reduction of anal canal pressure during straining, inducing an inhibition of the paradoxical puborectalis contraction, may be effective.

Botulinum toxin exerts its effects on the peripheral nerve terminal at the neuromuscular junction, resulting in a flaccid paralysis¹⁴⁻¹⁷ caused by the irreversible and selective multiphasic blockade of acetylcholine release from peripheral nerve endings. Botulinum toxin has been used to selectively weaken the external anal sphincter and puborectalis muscle in constipated patients.¹⁸⁻²³ Hallan et al²¹ have demonstrated that the toxin relaxes the puborectalis muscle; as a consequence, the anorectal angle increases during straining and evacuation is possible. However, despite good results, the effect of botulinum toxin injections is fairly short-term. Joo et al²² used 6 to 15 units of type A botulinum toxin, injected under electromyography guidance into the external anal sphincter or the puborectalis muscle. Of 4 patients who had failed to respond to conventional biofeedback, all improved with this treatment. However, long-term results were only 50% successful.²² In a recent study, a symptomatic improvement was noted in 13 of 15 patients after injections of 25 units of botulinum toxin into the external anal sphincter. Improvement was maintained for a mean of 5 months, after which time reinjection was necessary.¹⁸

The current study provides further evidence of the usefulness of type A botulinum toxin in the management of anorectal tract and pelvic dysfunction. Botulinum toxin seems to be a promising treatment in patients with anterior rectocele caused by obstructed defecation. It is less expensive and easier to perform than surgical treatment. In our experience, there were no observable permanent side effects or complications; and symptomatic improvement was achieved in all patients after 1 or 2 treatments, and it was maintained for follow-up period. We have noted that pressure values declined after treatment. As expected, resting pressure and maximum voluntary contraction were unchanged, as compared with baseline values; pressure during straining was lower than the pretreatment value and the resting anal pressure at the same times in all patients. The reduction of anal canal pressure during straining, related to an inhibition of the paradoxical puborectalis contraction, is effective to induce a

reduction of depth and area of the rectocele, with complete emptying of barium paste, as showed at defecography. In each case, subjective reports were in accordance with the objective manometric and defecographic findings, and in absence of any other treatment these results could be attributed only to the effect of botulinum toxin.

In an effort to maximize the amount of botulinum toxin delivered to the puborectalis muscle and external anal sphincter, we used transrectal ultrasonography to guide injections. Because the electromyography-guided method of injecting botulinum toxin is a blind technique, it is possible that in patients who did not respond, or relapsed early after a response, the needle was not in the muscle or was only partly inserted into it, respectively. Despite a more precise method of botulinum toxin injection under ultrasonographic guidance, repeated injections were needed in 5 patients to maintain clinical improvement. Nevertheless, when botulinum toxin is used for the first time at fixed doses, variable clinical responses can be observed.

In summary, botulinum toxin appears to be a promising approach for the treatment of defecatory dysfunction associated with anterior rectocele. It relieved the contraction of the puborectalis muscle, allowing resumption of normal rectal voiding.

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