

The Impact of Fissurectomy Combined with Botulinum Toxin Injection in the Treatment of Chronic Anal Fissure

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ABSTRACT

Objective: The aim of this prospective randomized study was to determine the outcome of fissurectomy combined with botulinum toxin type-A (BTX-A) on the healing of medically resistant fissures over that achieved with BTX-A alone.

Materials and Methods: A total of 36 consecutive patients with chronic anal fissure located on posterior midline who failed healing after topical medical therapy were enrolled. The patients were divided into 2 groups. The patients were divided into, BTX and BTX+fissurectomy (FIS) groups. They were clinically checked 1, 2, 4, and 8 weeks after the procedures. Symptomatic relief, early postoperative complications, clinical and anoscopic findings were recorded. The demographic and clinical parameters were compared using Mann-Whitney U and Chi-square tests.

Results: There were no significant difference between the two groups regarding the age and gender. The most common complaints were rectal bleeding, constipation and pain during and/or after defaecation. All of the procedures performed without any postprocedural complications. Symptoms were reduced significantly with respect to the preoperative value. Symptomatic relief was assessed in more patients in BTX+FIS group than BTX only group, but the difference was not significant. On 4th week anoscopic examination, complete healing was assessed in 14 (%77.8) and 11 (%61.1) patients in BTX+FIS and BTX groups, respectively. The median follow-up was 5 months. There was no recurrence during the follow-up. None of the patients had continence disturbance.

Conclusion: Although BTX-A injection is an effective and safe treatment option in patients with a posterior chronic anal fissure non-responsive to other medical treatments, combining it with fissurectomy does not increase the healing rate.

Key words: Anal fissure, Fissurectomy, Botulinum toxin.

ÖZET

Kronik Anal Fissür Tedavisinde Botulinum Toksini ile Birlikte Fissürektominin Etkinliği

Amaç: Bu randomize prospektif çalışmanın amacı, medikal tedaviye dirençli kronik anal fissür tedavisinde, fissürektomi ile kombine edilen botulinum toksini tip A (BTX-A) ile tek başına kullanılan BTX-A'nın etkinliklerini karşılaştırmaktır.

Gereç ve Yöntem: Arka orta hatta topikal ilaç tedavisine dirençli kronik anal fissürü bulunan, 36 ardışık hasta değerlendirildi. Hastalar, BTX ve BTX+fissürektomi (FİS) olarak iki gruba ayrıldılar. Girişimlerden 1, 2, 4 ve 8 hafta sonra klinik olarak kontrol edildiler. Semptomatik düzelme, erken ameliyat sonrası komplikasyonlar, klinik ve anoskopik bulgular kaydedildi. Demografik ve klinik parametreler Mann-Whitney U ve Ki-kare testleri kullanılarak karşılaştırıldı.

Bulgular: Gruplar arasında yaş ve cinsiyet açısından anlamlı fark yoktu. En sık karşılaşılan şikâyetler, rektal kanama, kabızlık ve dışkılama sırasında ve/veya sonrasında ağrıydı. Girişimlerin tamamı komplikasyonsuz olarak gerçekleştirildi. İşlem öncesine kıyasla semptomlar anlamlı olarak azaldı. BTX+FİS grubunda BTX grubuna göre daha fazla hastada semptomatik düzelme sağlandı ancak aradaki fark anlamlı değildi. Dördüncü haftada yapılan anoskopik muayenede, BTX+FİS ve BTX gruplarında sırasıyla 14 (%77.8) ve 11 (%61.1) hastada fissürün tamamen iyileştiği tespit edildi. Ortanca takip süresi 5 aydı. Takip sürecinde nüks görülmedi. Hastaların hiçbirinde inkontinans ortaya çıkmadı.

Sonuç: Diğer medikal tedavilere cevap vermeyen posterior kronik anal fissürde BTX-A enjeksiyonu etkili ve güvenli bir tedavi yöntemi olmakla beraber, BTX-A'ya fissürektomi eklenmesi iyileşme oranlarını artırmamaktadır.

Anahtar Kelimeler: Anal fissür, Fissürektomi, Botulinum toksini.

Chronic anal fissure is a common problem in routine anorectal practice and needs careful evaluation to choose the optimum treatment modality (1-3). Despite the advent of new modalities in the medical treatment of chronic fissures, they frequently need surgical treatment (4). Lateral internal sphincterotomy (LIS) heals chronic fissure in ano in over 90% of cases, but it is associated with potential long-term complications (3-6). BTX-A injection is one of the most popular non-

surgical treatment option with lower complication rates compared to LIS. Chemical sphincterotomy using BTX-A treats internal sphincter spasm alone but not chronic fibrosis (7-9). Fissurectomy is a surgical treatment option that preserves anal sphincters and healing rates may be improved with lower postoperative complications if combined with BTX-A injection. The aim of this prospective randomized study was to determine the outcome of fissurectomy

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combined with botulinum toxin type-A (BTX-A) on the healing of medically resistant fissures over that achieved with BTX-A alone.

MATERIALS AND METHODS

A total of 36 consecutive patients with chronic anal fissure located on posterior midline who failed healing after topical medical therapy were enrolled for this randomized prospective study. Anal manometry was not used in any of the patients. All gave written informed consent and the local ethical committee approved the study. The patients with other anorectal disorders and multiple fissures were excluded. Medically resistant fissure was defined as failure of healing after topical isosorbide dinitrate 1% ointment, applied 6 times a day for at least 8 weeks and high fibre diet. The patients were divided into 2 groups, 18 patients in each group. The choice of treatment option was based on the patient's preference. The patients in group BTX were only treated by BTX-A injection. The patients in BTX+FIS group underwent fissurectomy combined with intrasphincteric BTX-A injection. Purified BTX-A (Botox[®], Botulinum Toksin Type-A, Abdi İbrahim, İstanbul, Türkiye) was diluted by using 2.5 ml 0.9% NaCl and 0.5 ml (20 U) of BTX-A were injected into the internal anal sphincter at the opposite side of the fissure after digital rectal examination in both groups. Fissurectomy procedures were performed in the lithotomy position under local anaesthesia in day care. Lidocain hydrochloride was used for local anaesthesia. The fibrotic fissure edges were excised, fissure bases were curetted. Any skin tag or sentinel pile was excised. The healthy edges of the fissure tract were sutured using 3/0 absorbable sutures. No anal tampons were used. The patients in both groups were discharged several hours after the procedures with warm sitz bath and fibery diet for at least 2–3 weeks. An analgesic was prescribed as needed. The first visit was scheduled within 1 week and they were clinically checked 2, 4, and 8 weeks after the procedures. Patients were asked if symptoms had changed and if they had experienced any changes in continence. A physical examination was performed to evaluate healing of the fissure. On postoperative 4th week visit they were also checked by using anoscope. Improvement in symptoms was graded as follows: symptoms completely resolved (0), symptoms improved (not requiring additional surgery) (1),

symptoms persisting (2). Fissure healing by anoscopic examination was defined as follows: complete epithelization of the fissure base (0), partial epithelization of the fissure base (1), no healing with typical appearance of a chronic anal fissure (2). Symptomatic relief, early postoperative complications clinical and anoscopic findings were recorded. The median follow-up was 5 months (ranging from 3 to 12 months). All data were expressed as mean and standart deviation (SD). The demographic and clinical parameters were compared using Mann-Whitney U and Chi-square tests. The level of statistical significance was set at $p < 0.05$.

RESULTS

There were a total of 25 (69%) female and 11 (31%) male, with a median age of 37 (ranging from 19 to 48). Table 1 summarizes the demographics of the groups. There were no significant difference between the two groups regarding the age and gender. Thirty-five patients (97.2%) presented with rectal bleeding and constipation. Thirty-two of them (88.9%) complained of pain during and after defaecation. Sixteen (44.4%) patients complained of perianal swelling while 14 (38.9%) patients complained of perianal pruritus. All of the procedures performed without any postoperative complications. Symptoms were reduced significantly with respect to the preoperative value ($p < 0.0001$). The patients in BTX+FIS group complained pain but none of them required narcotic analgesics. The symptomatic and anoscopic evaluation grades were given in Table 2. Symtomatic relief was assesed in more patients in BTX+FIS group than BTX only group, but the difference was not significant ($p > 0.05$). On 4th week anoscopic examination, complete healing was assesed in 14 (%77.8) and 11 (%61.1) patients in BTX+FIS and BTX groups, respectively. There was no recurrence during the follow-up. None of the patients had continence disturbance.

Table 1. Demographic parameters of the patients in the treatment groups

	BTX(n=18)	BTX+FIS(n=18)	p
Age			
(year)(mean±SD)	38±12	35±9	0.6
Gender			
Female	12	13	
Male	6	5	0.7

Table 2. Grading according to symptomatic response and anoscopic examination after each treatment

Symptom grade		0	1	2	p
2nd week	BTX	5 (%27.8)	8 (%44.4)	5 (%27.8)	ns
	BTX+FIS	11 (%61.1)	5 (%27.8)	2 (%11.1)	
4th week	BTX	11 (%61.1)	2 (%11.1)	5 (%27.8)	ns
	BTX+FIS	14 (%77.8)	2 (%11.1)	2 (%11.1)	
8th week	BTX	11 (%61.1)	2 (%11.1)	5 (%27.8)	ns
	BTX+FIS	14 (%77.8)	2 (%11.1)	2 (%11.1)	
Anoscopic examination grade		0	1	2	p
4th week	BTX	11 (%61.1)	2 (%11.1)	5 (%27.8)	ns
	BTX+FIS	14 (%77.8)	2 (%11.1)	2 (%11.1)	

*ns: non-significant ($p > 0.05$)

DISCUSSION

A chronic anal fissure is a non-healing linear tear in the distal anal mucosa below the dentate line. Where acute fissures usually heal spontaneously, chronic fissures are unlikely to heal with conservative therapy. A chronic fissure can be morphologically identified by the presence of indurated edges, hypertrophy of the anal papilla, a sentinel skin tag, exposed internal sphincter muscle at the base of the fissure (6, 9). Patients present with anal pain commonly during defaecation and/or rectal bleeding. The most common symptoms in our series were rectal bleeding, constipation and pain during or after defaecation. Most fissures occur in the posterior midline; this may be anatomically related as there is a lack of tissue support posteriorly within the anal canal (10). In our series all of the selected patients had posterior midline fissures. It has been estimated that chronic anal fissure afflicts about 10% of the patients who come to colorectal clinics, with both sexes affected equally (2). In our series the number of females were more than males in both groups. There was no significant difference between the groups regarding the age.

LIS is an effective treatment option but it carries potential complications including anal incontinence (3, 5, 6). LIS is considered the surgical treatment of choice for only the patients unresponsive to medical management (2, 6, 11, 12). Developments in the understanding of the physiology of internal anal sphincter have resulted in more conservative treatment options instead of surgery (1, 3). Glyceryltrinitrate, diltiazem and Botulinum Toxin A (BTX-A) are the most common pharmacological treatment options (1, 3). Chemical sphincterotomy, using BTX-A has become one of the most popular first-line medical treatment option. It offers reducing internal anal sphincter pressure without the risk of incontinence (13). BTX-A is produced by *Clostridium botulinum* and is a potent neurotoxin. It blocks synaptic release of acetylcholine and causes a severe paralysis muscles. Jost and Schimrigk reported for the first time the treatment of anal fissures with BTX-A (14). There

is no consensus on dosage, precise site of administration, and number of injections (6, 9, 12, 15-18). In this study we achieved 61.1% healing rate after injection of 20 U BTX-A to internal anal sphincter at the anterior side of the anal canal. BTX-A injection has risk of complications like transient anal incontinence, epidididimitis, hematoma, prolapsus of hemorrhoids. Fissure recurrence is a serious problem and repeated BTX-A injections can be performed (5, 10, 12). In this study we did not have any complications related to BTX-A injection. It may be due to relatively low dose usage of BTX-A, compared with the other studies in the literature.

Botulinum toxin heals only approximately 50-65% of glyceryl trinitrate-resistant chronic anal fissures, perhaps because chemical sphincterotomy alone treats internal sphincter spasm but not chronic fissure fibrosis (7, 8, 10). Healing rates for BTX-A injection for anal fissure may be improved if combined with fissurectomy. It has been reported that, fissurectomy with or without advancement flaps are also effective options for chronic anal fissure with low incidence of complications related to LIS (1, 6, 19). There are reports about different combinations of both surgical and medical treatment modalities including the combination of BTX-A injection with fissurectomy (5, 12, 13, 15, 20-23). In this study with combination of BTX-A with fissurectomy we achieved 77.8% healing rate. Significant symptomatic improvement was seen in both groups on 2nd and 4th weeks compared to pretreatment period, but the difference between the two treatment groups was not significant. The only postprocedural problem was pain after fissurectomy procedures. There were no complications related to fissurectomy.

In conclusion, although BTX A injection is an effective and safe treatment option in patients with a posterior chronic anal fissure non-responsive to other medical treatments, combining it with fissurectomy does not increase the healing rate.

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Gönderilme Tarihi: 17.04.2012