EFFICACY AND SAFETY OF BOTULINUM TOXIN IN TREATMENT OF ANISMUS

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SYSTEMATIC REVIEWS

Efficacy and safety of botulinum toxin in treatment of anismus: A systematic review

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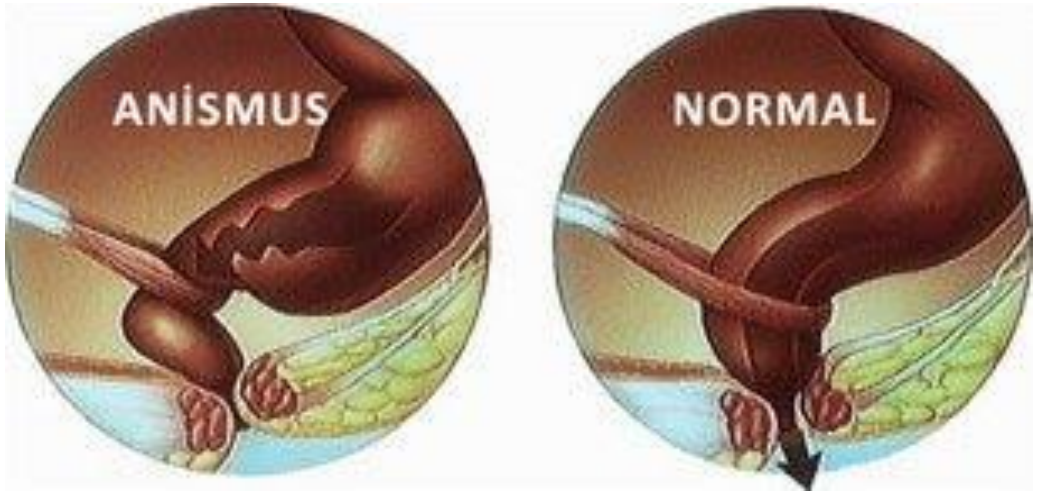
Introduction

- Anismus is a functional disorder of the defecation that entails failure of relaxation or even paradoxical contraction of the puborectalis muscle and external anal sphincter (EAS) during defecation.



Introduction

- The pathophysiology of anismus is not clearly defined.
- Yet, certain predisposing factors as physical and emotional stress, previous anorectal surgery or hysterectomy, and psychological disorders are associated with anismus.
- Sexual assault or abuse in childhood may also contribute to the development of anismus.

Introduction

- Patients with anismus typically complain of symptoms of outlet obstruction.
- Frequent attempts of evacuation, prolonged straining, anal pain, and sense of incomplete evacuation are the common presenting features of this condition.

Introduction

- On digital rectal examination (DRE), the puborectalis muscle and EAS fail to relax during straining, and sometimes a paradoxical contraction may occur.

Introduction

- Physiologic tests such as anorectal manometry, balloon expulsion test, electromyography (EMG) of the puborectalis muscle and EAS , and defecography are required to establish the diagnosis.

Introduction

- Anismus is initially managed in a conservative manner, starting with dietary modification focusing on high fiber diet, then using enemas and laxatives in increasing doses.
- However, conservative measures usually fail to solve the problem.

Introduction

- Biofeedback (BFB) retraining is an important tool in treating anismus patients with a conflicting efficacy results ranging from 31% to 89%.

Introduction

- Surgical treatment in the form of partial divison of the puborectalis muscle has been described in a few reports with long-term success reaching up to 67% of patients.

Introduction

- Hallan et al(1998) described direct injection of BTX-A into the puborectalis muscle.
- BTX-A is a potent neurotoxin that causes muscle paralysis by inhibition of release of acetylcholine at the presynaptic region.

Introduction

- Injection of BTX-A emerged as a promising option in the treatment of anismus with the advantages of being less costly and technically easier than BFB.
- BTX-A injection, unlike BFB, does not depend on patient's cooperation and compliance.

Aim of our work

- The objective of the current systmatic review was to assess the efficacy and safety of BTX-A injection in the management of anismus.

Material and methods:

- **Inclusion criteria:**

This systematic review included both comparative and non-comparative trails that evaluated BTX-A therapy for treatment of anismus with a sample size of at least 15 patients. No language restrictions were applied.

Material and methods:

- **Exclusion criteria:**

We have excluded irrelevant articles, editorials case reports, studies that followed the patients less than six months. Articles that did not report the aim, methodology, demographic data of patients.

Material and methods:

- After reviewing the full text of 11 articles, seven of them met the eligibility criteria of the review.
- Two studies were randomized comparative trials, comparing BTX-A injection with BFB or partial division of the puborectalis muscle. The remaining five trials were observational cohort studies assessing the efficacy and complications of BTX-A injection.

Seven articles included in our review

Table 3 Characteristics of the studies included

Ref.	Country	Type	*n*	Male	Mean age (yr)	Duration of complaint (mo)	Follow up (mo)	Dose of BTX-A (IU)	Site of injection
Shafik *et al*[17]	Egypt	Prospective	15	2	41.2	105.6	14.6	25	Lateral (3, 9 o'clock)
Ron *et al*[18]	Israel	Prospective	24	9	23.7	Not reported	61.0	10-20	Lateral and posterior
Maria *et al*[19]	Italy	Prospective	24	10	56.0	28.0	39.0	60	Lateral (3, 9 o'clock)
Farid *et al*[12]	Egypt	Prospective RCT	15	15	34.7	71.1	14.7	100	Lateral (5, 7 o'clock)
Farid *et al*[20]	Egypt	Prospective RCT	24	7	34.7	Not reported	12.0	100	Lateral (5, 7 o'clock)
Hompes *et al*[21]	United Kingdom	Retrospective	56	20	47.5	Not reported	19.2	100	Lateral (3, 9 o'clock)
Zhang *et al*[22]	China	Retrospective	31	18	50.1	67.2	8.4	100	Lateral and posterior (3, 6, 9 o'clock)

Results:

- Patients were mostly middle-aged females coping with the literature.

- Most of the studies used BTX-A injection as a primary treatment except two studies that resorted to BTX-A after failure of BFB therapy.

Results⇨ guided or manual injection, does it differ ?

- Some studies used endorectal ultrasonography or EMG-guided techniques for BTX-A injection, yet none obtained superior results compared to the studies that used manual guidance, concluding no clear benefits for the guided techniques.

Results⇨ site of injection ,dose it differ ?

- Only two studies used combined lateral and posterior injections technique which was associated with higher complication rates with almost the same efficacy obtained by lateral injection alone.

Results ⇨ dose of injection ,does it differ ?

- the dose of BTX-A did not have any special significance since the studies that used the least dose reported an efficacy close to that of higher doses.

Figure representing improvement and complications after BTX-A injection

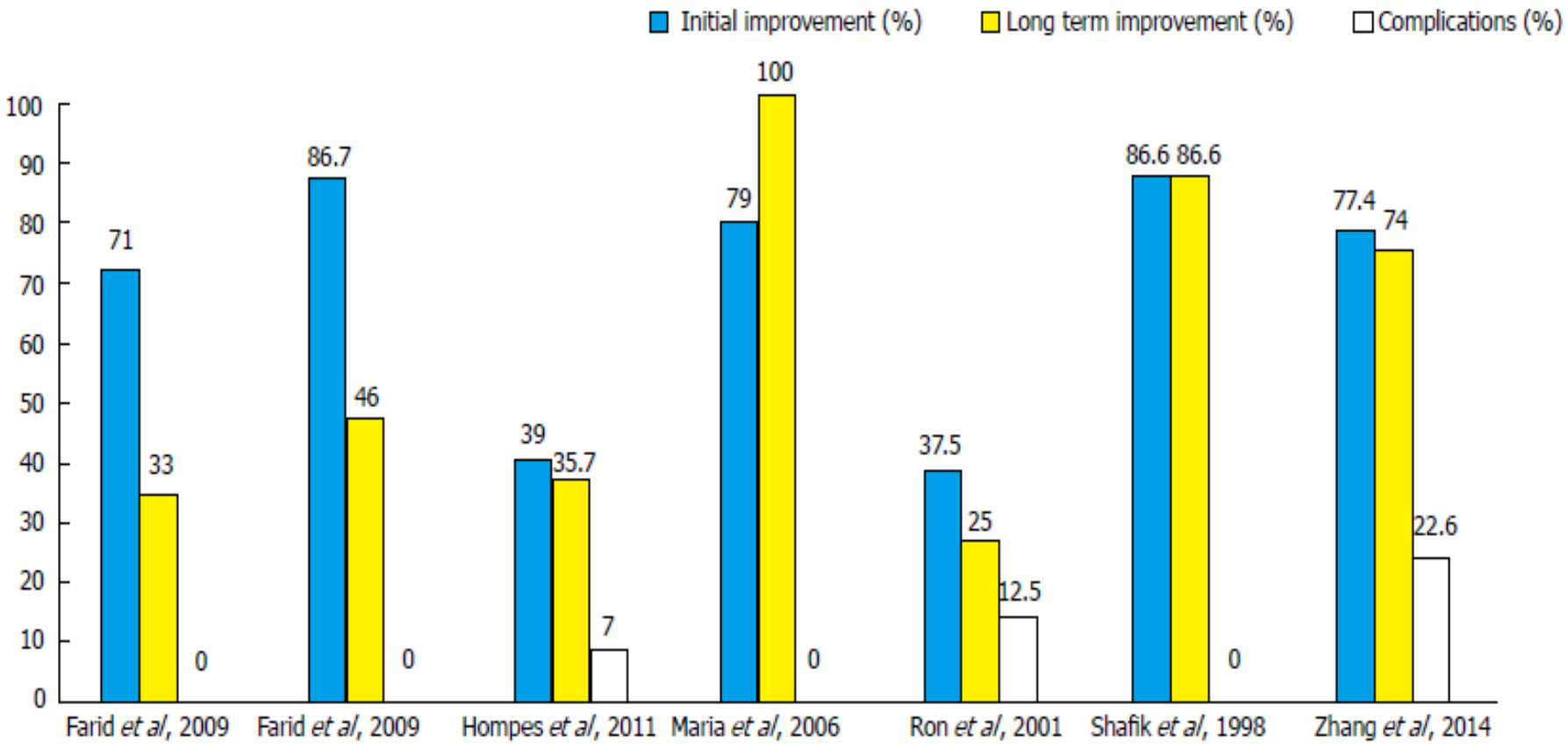


Figure 3 Improvement of symptoms and complications after injection of botulinum toxin type A.

Results⇨ improvement

- The median rate of initial improvement of symptoms after injection was 77.4% .
- Unfortunately, these initial good results did not last longer as they dropped to a median of 46% after three months necessitating repeated injections of BTX-A in three studies.

Results⇨ improvement

- The studies that reported satisfactory long term results had to repeat the injection twice or more.

- The reason of why repeated injections attained better long-term results can be attributed to the cumulative effect of BTX-A on the puborectalis muscle.

Results⇨ improvement

- Interestingly, we found that the repeated injections do not necessarily induce higher complication rates

Results of physiological tests after BTX-A

- Anorectal manometry reported a decrease in anal pressures in two studies only.
- Conversely, the remaining studies showed no significant change in the anal pressures, although clinical improvement was evident.

Results of physiological tests after BTX-A

- balloon expulsion test, EMG, and defecography show significant changes after BTX-A.

Results of physiological tests after BTX-A

- Interestingly, the highest rates of improvement according to clinical examination, EMG, and defecography were the same (86%) implying the harmony of these tests with the clinical examination.

Results⇨ Complications

- Complications after BTX-A injection were detected in 7.4% of patients.

- The most common complication was FI which was only transient, for two weeks, and of a minor grade. FI was reported in two studies, both applied combined lateral and posterior injections.

Results:

- Other morbidities as posterior anal fissure and complete rectal prolapse were observed only by one study that also used posterior injection in addition to lateral injection.

Conclusion:

- The injection of BTX-A is a simple, technically feasible outpatient procedure. The initial satisfactory improvement of symptoms after BTX-A injection remarkably deteriorated after three months of the procedure.

- However, repeated injections may provide better sustained results with no additional morbidities.

Conclusion:

- The endorectal ultrasonography and EMG-guided injection did not add significant value regarding both initial and long-term improvement.

- Combined lateral and posterior injections technique did not achieve better results than lateral injection alone, on the contrary the studies that employed the combined injections technique reported higher complication rates.

Conclusion:

- Overall, further analysis of more patients is necessary to conclude the safety of BTX-A in the treatment of anismus.

THANK YOU