# Outcome of endo-anal ultrasound-guided injection of botulinum toxin type-A therapy in puborectalis muscle in patients with anismus

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**Background**
Anismus is a functional disorder characterized by dyssynergia and incoordination of pelvic floor muscular contractions at defecation. Despite normal propulsive power used when attempting to defecate, a hypertonic pelvic floor dysfunction results in nonrelaxation or even paradoxical contraction of puborectalis muscle, resulting in failure to straighten the anorectal angle, hence impaired stool evacuation. This study aims at evaluating the outcome of injection of botulinum toxin type-A (BTX-A) in puborectalis muscle in patients with anismus.
**Patients and methods**
The study included 50 patients who were presented with symptoms of obstructed defecation (OD) and were diagnosed as anismus and failed conservative treatment and biofeedback training. Ultrasound-guided BTX-A injections into puborectalis muscle were done. All patients were followed up for 6 months for OD symptoms and manometric findings.
**Results**
The current study included 50 patients with a mean age of 36.6±11.9 years presented with anismus for a mean duration of 6.8±2.64 months.
There was a statistically significant improvement in the Longo score of OD at 1, 3, and 6 months when compared with the initial values ($P<0.001$), while there was no statistically significant difference noticed in the defecation frequency at 3 and 6 months when compared with the initial records.
There was a statistically significant decrease in both resting and squeeze pressures after 3 and 6 months when compared with the initial records ($P<0.001$).
The overall satisfaction significantly increased to 68 and 64% after 3 and 6 months, respectively, when compared with 0% satisfaction reported at the initial assessment.
**Conclusion**
According to the current results, injection of BTX-A therapy in puborectalis muscle in patients with anismus is assumed to be effective for short term with good overall satisfaction.

**Keywords:**
anismus, botulinum toxin type-A, obstructed defecation

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## Introduction

A combined prevalence of 14% in the community indicates that chronic constipation is a frequent condition [1,2]. Pathophysiology can be roughly categorized into cases of rectal evacuation problems, colonic dysmotility, or both [3].

Anismus is a functional defecation problem, which is a subtype of disorders of rectal evacuation without anatomical abnormalities [4]. Anismus is characterized by incorrect pelvic floor muscular contraction or nonrelaxation, despite normal propulsive power used when attempting to defecate, resulting in a blocked anal canal and impaired stool evacuation [5]. Anismus as well as other terms like 'pelvic floor dyssynergia,' 'spastic pelvic floor syndrome,' 'paradoxical puborectalis contraction,' and 'puborectalis syndrome' have mainly been replaced by the term 'dyssynergic defecation' (DD) [6].

Between 20 and 81% of patients suffering from chronic constipation who are referred for the specialized examination have anismus [5]. Biofeedback therapy

is currently the recommended course of treatment for anismus. This mode of treatment has reportedly been found to be more effective than diazepam, sham, and laxatives based on low-quality evidence, and it is preferred over surgical procedures like partial division of the puborectalis muscle, which have a high risk of incontinence in spite of its effectiveness [1,7].

Problems develop when biofeedback is unavailable, the patient is not committed, or when biofeedback is unsuccessful [6]. Botulinum toxin type-A (BTX-A) injection into the puborectalis and/or external anal sphincter muscles is a relatively new method. Before new synaptic proteins are produced, the effect on striated muscle starts to take effect after 2–5 days and lasts for 2–3 months [8]. In 1988, a small case study of seven patients [9] first revealed the use of BTX-A injection for the treatment of DD. Despite variations in delivery method, efficacy, and side effects, more trials have since been described [6,10].

The authors were inspired to undertake this study because of the debate about the effects of botulinum toxin injection.

## Patients and methods

### Study design

The current prospective study was conducted following the consideration of the ethical perspectives of Helsinki where research and ethical committees, Benha University approved the conduction of the study.

The study included 50 patients who were presented to the Colorectal Unit, Department of General Surgery, Faculty of Medicine, Benha University with anismus are unresponsive to conservative treatment and biofeedback training throughout the period from March 2021 till March 2023. Follow-up was designed for 6-month duration.

Informed written consent was obtained from all included patients.

Inclusion criteria were patients with age between 16 and 50 years old, with a clinical history of obstructed defecation (OD) or sense of anal obstruction during attempted defecation in addition to at least three positive tests of the following:

(1) Negative balloon expulsion test for a 50-ml water-filled balloon within 1 min during attempted straining.
(2) High-resolution anal manometry: paradoxical increase or failure to decrease anal pressures during attempted straining, sphincter relaxation 20%, and defecation index 1.5.
(3) Echodefecography to assess patients with OD because of its ability to detect the same anorectal dysfunctions and anorectal angle.
(4) MRI defecography: failure of increase or even a decline in the anorectal angle with lack of pelvic floor descent during straining and defecation.

Exclusion criteria were age more than 50 or less than 16 years old, patients with sphincteric injuries, colonic inertia, positive defecography for abnormalities other than anismus, pregnancy, and known sensitivity to botulinum toxin.

### Preoperative assessment

The patients who were included in the study underwent history taking for OD symptoms, previous surgery or chronic illness. Inquiries were directed to assess the cause of OD.

Clinical examination: all patients will be assessed for obstructive defecation through Longo score for constipation.

The original Longo score (0–40) is eight points scale. Recently Longo modified this scoring system and added lifestyle change parameters. The modified Longo score is the most commonly used scoring system for treatment strategy for OD symptom patients [11] (Table 1).

All patients will be subjected to all the following:

Transanal ultrasonography using (BK Medical Flex Focus 400 with 2052 colorectal transducer) uses a three-dimensional ultrasound scanner with a 7 or 10 MHz rotating endo probe to assess the pathophysiologic status of the anal sphincter.

Endoanal ultrasound will be used to assess the anatomy of the anal canal and anal sphincter to exclude sphincteric defects or abscesses. It can be considered as one of the diagnostic tests for animus by Echodefecography. Ultrasound can guide the injection of Botox in the puborectalis muscle and follow-up patients after injection of Botox.

Anorectal manometry: physiological parameters well be evaluated by high-resolution anorectal manometry by Solar GI HRAM MMS using a 24-channel water-perfused catheter with a latex balloon. Statistical

**Table 1 Longo score for obstructed defecation**

| Defecation frequency | 1–2 defecation/ 1–2 days | 0 | 2 defecation/week or 3 defecations or attempts/day | 1 | 1 defecation/week or 4 defecation or attempts/day | 2 | <1 defecation/week or >4 defection attempts/day | 3 | |
|---|---|---|---|---|---|---|---|---|---|
| Straining | | | | | | | | | |
| Intensity | No or light short time | 0 | Moderate | 1 | Intensive prolonged | 2 | | | |
| Extension | | 1 | | | | 2 | | | |
| Sensation of incomplete evacuation | Never | 0 | <1×/\week | 1 | 2×/weeks | 2 | >2×/weeks | 3 | |
| Rectoperineal pain | Never | 0 | <1×/week | 1 | 2×/weeks | 2 | >2×/weeks | 3 | |
| Activity reduction per week | Never | 0 | <25% of activity | 1 | 25–50% of activity | 4 | >50% of activity | 6 | |
| Laxatives | Never | 0 | <25% of defecation | 1 | 25–50% of defecation | 3 | >50% of defecation | 5 | Always 7 |
| Enemas | | 0 | | 1 | | 3 | | 5 | 7 |
| Digitations | | 0 | | 1 | | 3 | | 5 | 7 |

analysis was done using IBM SPSS statistics for windows, Version 23.0. Armonk, NY: IBM Corp.

A full manometric examination will be done including resting anal pressure.

Mean squeeze pressure and assess muscle relaxation during push.

Balloon expulsion test: three attempts for expulsion of a 50-ml water-filled balloon within 1 min of straining.

#### MRI defecography

When there is a failure to rise or even a fall in the anorectal angle without pelvic floor descent after attempted straining and defecation, dynamic MRI defecography was used to demonstrate animus.

Anismus was characterized as a nonrelaxing anal sphincter during a defecation effort, a positive balloon expulsion test, and a nonrelaxing puborectalis on an MRI defecography together with a prolonged evacuation time or a failure to expel the barium paste in the presence of a normal perineal descent. Before receiving an injection of BTX-A therapy, every patient with anismus will undergo four sessions of biofeedback therapy.

#### Procedure

Each patient was given a 50 mg of pethidine and 5 mg of midazolam to put them to sleep before to their injection. With the patient in the lithotomy posture, the anal canal will be cleansed with povidone–iodine before the injection process begins. Two fingers will be used to widen the anal canal before an injection is administered using a 23 G needle that was inserted directly perpendicular to the palpated anal sphincter with a l-ml insulin syringe. Endoanal ultrasound-guided injection to be exactly at the puborectalis muscle. Each side of the puborectalis muscle will receive an injection of 10 U of BTX-A (Allergan, Irvine, California, USA) or the posterior angle (puborectalis sling) will receive an injection of 20 U [12].

At each follow-up, the necessity for more injections will be evaluated. A second attempt will be provided to any patient who fails the initial injection. The identical researcher will administer each shot.

#### Outcomes

The main goal was to examine how BTX-A was administered to individuals with DD, including the route, method of administration, dosage, and frequency.

Evaluation of the treatment's rate of adverse events, short-term, and long-term efficacy, and overall effectiveness were the secondary goals.

#### Follow-up was conducted after 1, 3, and 6 months

The patient filled out a symptom questionnaire using the Longo score for constipation and potential complaint at each session. The severity of the straining, anorectal pain, the frequency of bowel movements each week, and any adverse effects will be noted. At 1, 3, and 6 months, anorectal manometry with a balloon expulsion test and echodefecography will be carried out. There will always be a clinical review. Our objectives are to achieve anal sphincter manometric relaxation and effective ejection of a 50-ml water-filled rectal balloon.

#### Statistical analysis

The sample size of $1-\beta=0.80$ (80%) for the Spearman's correlation at level $\alpha=0.05$ (5%), under these assumptions, amounts to 50 (G*power; version 3.1).

The collected data and results will be tabulated in suitable figures. Quantitative data will be summarized using mean and SD while qualitative data will be summarized using frequency and percentage. Data will be analyzed by the aid of software package of SPSS using suitable statistical tests (version 25). *P* value less than 0.05 were considered statistically significant.

## Results

The current study included 50 with the mean age of 36.6±11.9 presented with anismus for a mean duration of 6.8±2.64. Other sociodemographic data are illustrated in Table 2.

Table 2 demonstrated the clinical presentation and the OD symptoms in the studied group where the mean defecation frequency/week was 2.63±0.76 while the mean sensation of incomplete evacuation/week was 1.02±0.97. There was reduction of activity by about 27.23±6.24. Other clinical presentations are shown in Table 3.

The initial manometric assessment for the included patients showed increased mean resting pressure and squeeze pressure when compared with the normal values to be 89.2 and 211.8, respectively (Table 4). None of the included patients had positive balloon expulsion test at the initial assessment with 0% overall satisfaction.

There was a statistically significant increase in the defecation frequency at 1, 3, and 6 months when compared with the initial values ($P<0.001$) while there was no statistically significant difference was noticed in the defecation frequency at 3 and 6 months when compared with the recorded values after 1 month (Table 5). Other symptoms including straining score, sensation of incomplete evacuation/week, or rectoperineal pain or discomfort/week showed a statistically significant decrease throughout 1, 3, and 6 months follow-up compared with the initial presentation.

There was a statistically significant decrease in the resting and squeeze pressure after 3 and 6 months when compared with the initial records ($P<0.001$) with no significant change between the 3 and 6 months reports (Table 6 and Fig. 1). The balloon expulsion test was successful in 68 and 62% of patients at 3 and 6 months none of those patients showed positive balloon expulsion test at the initial assessment (Table 6). The overall satisfaction was significantly increased to be 68 and 64% after 3 and

**Table 2 Sociodemographic data**

| Variables | *N*=50 |
|---|---|
| Age (years) | |
| Mean±SD | 36.6±11.9 (16–55) |
| Disease duration (years) | |
| Mean±SD | 6.8±2.64 |
| Sex [*n* (%)] | |
| Female | 37(74) |
| Male | 13(26) |

**Table 3 Initial obstructed defecation symptoms**

| Variables | *N*=50 |
|---|---|
| Defecation frequency/week | |
| Mean±SD | 2.63±0.76 |
| Straining score | |
| Mean±SD | 0.87±0.21 |
| Sensation of incomplete evacuation/week | |
| Mean±SD | 1.02±0.97 |
| Rectoperineal pain or discomfort/week | |
| Mean±SD | 1.24±0.82 |
| % of activity reduction per week | |
| Mean±SD | 27.23±6.24 |
| Laxatives use score | |
| Mean±SD | 2.89±0.68 |
| Enemas use score | |
| Mean±SD | 2.66±1.02 |
| Digitations use score | |
| Mean±SD | 1.22±0.29 |
| Time: minutes in lavatory per attempt | |
| Mean±SD | 38.23±11.23 |
| Failure: unsuccessful attempts for evacuation/24 h | |
| Mean±SD | 1.03±0.84 |

**Table 4 Initial manometric assessment, defecography, Longo score, and overall satisfaction**

| | *N*=50 |
|---|---|
| Variables | |
| Resting pressure (normal mean resting pressure is 69±14 mmHg) [13,14] | 89.2±12.5 |
| Squeeze pressure (normal mean squeeze pressure is 191±64 mmHg) [13,14] | 224.8±65.3 |
| Functional length of anal sphincter (cm) | 4.76±0.72 |
| Balloon expulsion test success rate | 0% |
| Constipation score | 13.64±2.37 |
| Positive defecography | 78% |
| Overall satisfaction | 0% |

**Table 5 Comparison between the initial obstructed defecation symptoms and 1, 3, and 6, months after Botox injection**

| | | | | | *P* value | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Initial | Post 1 month | Post 3 months | Post 6 months | Initial vs. post 1 month | Initial vs. post 3 months | Initial vs. post 6 months | Post 1 month vs. post 3 months | Post 1 month vs. post 6 months | Post 3 months vs. post 6 months |
| Defecation frequency/week | 2.63±0.76 | 5.22±1.05 | 5.02±0.86 | 4.67±0.54 | <0.001 | <0.001 | <0.001 | 0.45 | 0.49 | 0.78 |
| Straining score | 0.87±0.21 | 0.38±0.19 | 0.41±0.26 | 0.51±0.27 | <0.001 | <0.001 | <0.001 | 0.62 | 0.67 | 0.72 |
| Sensation of incomplete evacuation/ week | 1.02±0.97 | 0.65±0.32 | 0.63±0.26 | 0.74±0.25 | <0.001 | <0.001 | <0.001 | 0.37 | 0.29 | 0.93 |
| Rectoperineal pain or discomfort/week | 1.24±0.82 | 0.89±0.32 | 0.83±0.41 | 0.95±0.34 | <0.001 | <0.001 | <0.001 | 0.06 | 0.16 | 0.88 |
| % of activity reduction per week | 27.23 ±6.24 | 17.45±3.87 | 17.65±4.01 | 18.94±3.21 | <0.001 | <0.001 | <0.001 | 0.19 | 0.34 | 0.12 |
| Laxatives use score | 2.89±0.68 | 1.75±0.42 | 1.76±0.47 | 1.91±3.65 | <0.001 | <0.001 | <0.001 | 0.54 | 0.29 | 0.66 |
| Enemas use score | 2.66±1.02 | 1.68±0.76 | 1.71±0.68 | 1.82±0.78 | <0.001 | <0.001 | <0.001 | 0.07 | 0.09 | 0.27 |
| Digitations use score | 1.22±0.29 | 0.85±0.12 | 0.87±0.19 | 0.92±0.16 | <0.001 | <0.001 | <0.001 | 0.82 | 0.92 | 0.28 |
| Time: minutes in lavatory per attempt | 11.23 ±6.23 | 4.98±2.24 | 4.86±2.66 | 5.02±2.56 | <0.001 | <0.001 | <0.001 | 0.18 | 0.22 | 0.59 |
| Failure: unsuccessful attempts for evacuation/24 h | 1.03±0.84 | 0.67±0.49 | 0.65±0.51 | 0.72±0.53 | <0.001 | <0.001 | <0.001 | 0.75 | 0.23 | 0.81 |

**Table 6 Comparison between the initial manometric assessment, defecography, Longo score, and overall satisfaction and 3 and 6 months post Botox injection**

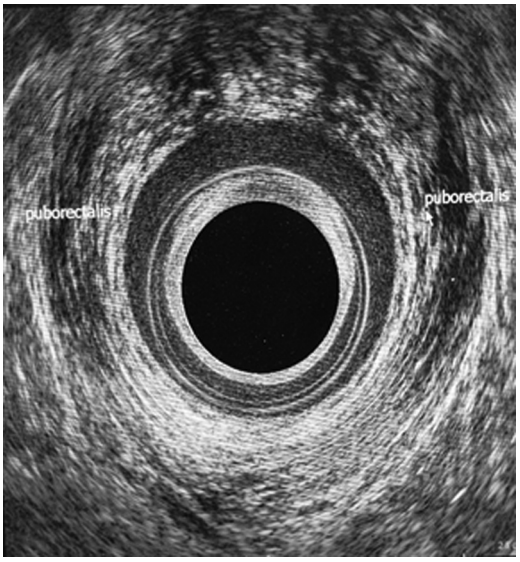
| | | | | *P* value | | |
|---|---|---|---|---|---|---|
| Variables | Initial | Post 3 months | Post 6 months | Initial vs. post 3 months | Initial vs. post 6 months | Post 3 months vs. post 6 months |
| Resting pressure | 96.2±12.5 | 63.26±11.53 | 69.21±12.23 | <0.001 | <0.001 | 0.092 |
| Squeeze pressure | 224.8±65.3 | 192.2±54.6 | 196.7±57.6 | <0.001 | <0.001 | 0.16 |
| Functional length of anal sphincter (cm) | 4.76±0.72 | 3.56±0.46 | 3.64±0.49 | <0.001 | <0.001 | 0.056 |
| Balloon expulsion test success rate | 0% | 68% | 62% | <0.001 | <0.001 | 0.082 |
| Constipation score | 13.64±2.37 | 7.98±2.61 | 8.22±2.54 | <0.001 | <0.001 | 0.32 |
| Positive defecography | 78% | 58% | 60% | <0.001 | <0.001 | 0.89 |
| Overall satisfaction | 0% | 68% | 64% | <0.001 | <0.001 | 0.72 |

6 months, respectively, when compared with 0% satisfaction reported at the initial assessment (Table 6 and Fig. 2).

## Discussion

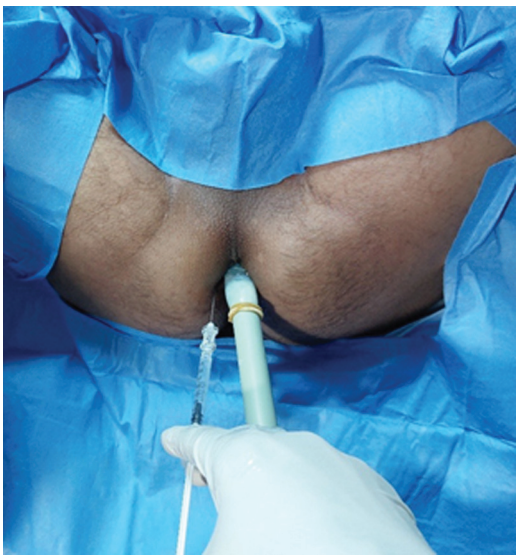
The vast majority of patients who experienced constipation had issues with outlet obstruction. Although the cause and frequency of anismus is unknown, it is assumed to be the most likely common cause of OD. Biofeedback treatment generally resulted in higher patient satisfaction among anismus patients [15] (Figs 3 and 4).

**Figure 1**




Identification of puporectalis.

**Figure 2**



Ultrasound-guided injection of BTX-A. BTX-A, botulinum toxin type-A.

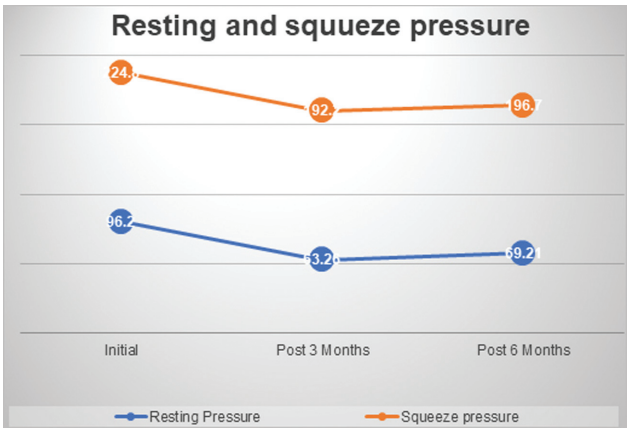
Few anismus patients respond to a regular course of biofeedback training because the pelvic floor muscles cannot be relaxed, a necessary condition for optimal function. Numerous surgical and pharmacological procedures have been used to treat the pressure caused by the spastic puborectalis and anal sphincter [16,17].

According to experts, there is currently no therapy method that has been shown effective for treating anismus. Although surgical attempts to weaken or expand the puborectalis muscle typically fail [18], direct injections of botulinum toxin into the puborectalis muscle have shown encouraging results [12]. Biofeedback training has been found to be an effective treatment for persons with anismus, with efficacy rates varied from 9 to 100% [19].

Direct injection of BTX-A into the puborectalis muscle was documented by Hallan *et al.* [9]. By inhibiting the release of acetylcholine at the presynaptic area, the neurotoxic BTX-A paralyses muscles [8,10]. The use of injections of BTX-A, which are less expensive and technically simpler than BFB retraining, has shown promise in the treatment of anismus [20]. Contrary to BFB, BTX-A injection is not dependent on the patient's participation or compliance, which are essentially subjective. The BTX-A injectable therapy was deemed successful in terms of short-term symptomatic relief of anismus because the effect of BTX-A is transient and lasts for around 3 months after delivery. Repeated injections are required for longer-term improvement in order to maintain the achieved clinical improvement [21].

The identification of the injection site and dosage distribution to the proper muscle were made easier by ultrasonography guidance during the injection. By inhibiting presynaptic acetylcholine release and lowering resistance during evacuation, BTX-A

**Figure 3**




Manometric findings after 3 and 6 months.

**Figure 4**


Overall patients satisfaction.

instantaneously paralyzed muscles. However, patients with anismus also have a lack of concordance during defecation in addition to puborectalis and external sphincter spasm. Following biofeedback training aims to enhance the puborectalis and external sphincter's motor coordination, which has a long-lasting effect. Several authors have stated that botulinum toxin appears to be a promising treatment for anismus patients [20,21].

In the current study, there was a statistically significant improvement of the clinical symptoms including defecation frequency/week, straining score, sensation of incomplete evacuation/week, and rectoperineal pain or discomfort/week and the maximum improvement was obtained after 1 month this improvement was slightly decreased after 3 and 6 months, respectively, but it was not significant and this matched the results of Emile *et al.* [10] who reported a median % of patients who reported initial improvement of symptoms was 77.4% and this declined to a median of 46% at 4 months after injection of BTX-A and this is assumed to the decrease of spasticity of the puborectalis that was clearly detected by the decrease of both resting and squeeze pressure similar to what was reported by Faried *et al.* [17] who reported manometric relaxation in 70.83% of patients following botulinum toxin injection, on the contrary, Ron *et al.* [21] reported only 28.5% manometric relaxation two studies [12,20] reported a significant decrease in the mean resting and squeeze anal pressures 3 months after injection.

Positive balloon expulsion was reported in many studies [12,17,21,22], with a median rate of 74.6% ranging from 37.5 to 80% matching the results of the current study where 68% of patients showed successful balloon expulsion test and this is assumed to be due to relaxation of puborectalis following injection of BTX-A.

In the current study a statistically significant improvement signs of anismus in the postinjection defecogram matching the results of several studies [17,18,22,23] that reported improvement of 25–86.6% of patients.

The primary criterion for determining whether a treatment plan was successful is patient satisfaction. Due to its brief medical efficacy, BTX-A was viewed as a temporary therapy for anismus. According to our research, BTX-A injection and pelvic floor biofeedback training are more effective ways to cure anismus because of its long-lasting effects. Compared to BTX-A or biofeedback training alone, it is a safer and more efficient treatment technique for intractable anismus and this is similar to what was reported by Zhang *et al.* [12] and this can be simply explained by the significant improvement of the symptoms of anismus.

## Conclusion

According to the current results, injection of BTX-A therapy in puborectalis muscle in patients with anismus is assumed to be effective for short term with good overall satisfaction.

### Recommendations

Further studies should be conducted to determine the long-term effect of BTX-A therapy.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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