

# Botulinum-toxin-A Injection Following Conservative Management in Patients with Dyssynergic Defaecation Only Improves Symptoms in the Short Term: A Retrospective Study

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## Abstract

**Objective** Dyssynergic defaecation (DD) is an important cause of chronic constipation. In patients where conservative treatments fail, injections of botulinum toxin A (BTX-A) into the puborectalis and anal sphincter muscles can be effective. Complications of this procedure are reported to be rare and generally mild. This study aimed to identify the complication rates and short- to medium-term success rates of BTX-A injections as a treatment for DD.

**Methods** A retrospective review was conducted on patients diagnosed with DD who had undergone BTX-A injections at a functional colorectal unit. Patient demographics, manometric assessment, conservative management, and injection technique were collected through a chart review. Subjective patient reports and comparison of pre- and postprocedure symptom scores were used to determine efficacy.

**Results** The 21 patients included (24 procedures, with 3 patients receiving BTX-A on two separate occasions) all received stool modification and dietary advice, and 20 patients underwent pelvic floor physiotherapy, averaging 8 sessions. The injections were universally applied under general anesthetic, primarily targeting the anal sphincter and/or puborectalis muscles. There were 6 reports of faecal urge/incontinence, with all but one being resolved within weeks.

The BTX-A injection was subjectively reported as beneficial in 19 cases, averaging 4.7 months (range 1–32) of improvement. Only 2 were sustained beyond 12 months. Despite overall improvements in symptom scores from pre- to postprocedure, none were statistically significant.

**Conclusion** Following a course of conservative management, the BTX-A injection appears to be a safe treatment for DD, but only has short term efficacy.

## Keywords

- ▶ constipation
- ▶ defecation
- ▶ pelvic floor disorders
- ▶ botulinum toxin-A

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## Introduction

Dyssynergic defaecation (DD), also known as anismus and pelvic floor dyssynergia, is a functional disorder characterized by either inadequate relaxation, or paradoxical contraction, of the puborectalis and anal sphincter muscles during defaecation,<sup>1,2</sup> resulting in chronic constipation. It is twice as common in women than men.<sup>3</sup> Onset is usually in childhood or after a specific event such as childbirth or trauma.<sup>3</sup> Additionally, many patients have a history of sexual abuse or excessive straining.<sup>3</sup> This is a debilitating condition, with symptoms including sensation of incomplete evacuation, excessive straining, and the requirement of digital maneuvers to defaecate.<sup>1</sup>

The clinical diagnosis of DD can be supported by anorectal physiology studies (APS) (anorectal manometry, electromyography (EMG), rectal balloon expulsion tests, and defaecography).<sup>1</sup> Two diagnostic criteria exist: the Rome IV Criteria of Functional Gastroenterological Disease and the London Classification for Disorders of Anorectal Function, both of which use anorectal physiology for diagnosis.<sup>4,5</sup> Treatment is initially conservative, including diet modification, improved toileting habits, laxatives, and pelvic floor biofeedback therapy, with success in up to 70% of patients.<sup>1</sup> If conservative treatment fails, options include botulinum toxin-A (BTX-A) injection and surgery.

The BTX-A injection causes paresis of target muscles through chemical denervation.<sup>6</sup> Injecting the puborectalis or anal sphincter with BTX-A, as first described by Hallan et al.,<sup>1</sup> results in decreased muscle tone, thus preventing disordered contraction during defaecation.<sup>2</sup> This procedure is effective after 2 to 5 days, but the treatment is temporary, lasting around 2 to 3 months.<sup>2,6</sup> The efficacy of BTX-A injection in DD is variable in the literature, with subjective symptom improvement occurring in 30 to 100% of patients.<sup>2</sup> While there is evidence of sustained improvement of symptoms beyond 12 months,<sup>7-10</sup> recurrence usually occurs within weeks to months.<sup>2</sup> Some studies also support repeating the injections to improve efficacy.<sup>7,11,12</sup>

A recent systematic review of the use of BTX-A for management of DD in 11 studies found significant variation in the approach to the injection.<sup>2</sup> Doses ranged from 12 to 200 units (Botox-brand equivalent), with higher doses associated with increased incontinence rates.<sup>2</sup> Varying guidance modalities were used for injection including palpation,<sup>13</sup> endoanal ultrasound,<sup>8,10,11</sup> and electromyography.<sup>12,14</sup> The literature is conflicting as to whether the latter two are superior to palpation-guided injection.<sup>8,15</sup> While most studies targeted both the puborectalis and anal sphincter bilaterally, others targeted only one of these muscles.<sup>2</sup> Symptom monitoring was done using a combination of subjective reporting, validated constipation questionnaires, and anorectal physiology.<sup>2</sup>

Complications have been recorded in 0 to 70% of patients, with transient faecal and flatus incontinence occurring most commonly.<sup>2</sup> Rarer complications include anal fissure, rectal prolapse, and pain.<sup>1,2</sup> Madalinski et al. looked specifically at the side effects for BTX-A injection and found them to be

mostly transient, with no life-threatening complications across 181 patients.<sup>16</sup>

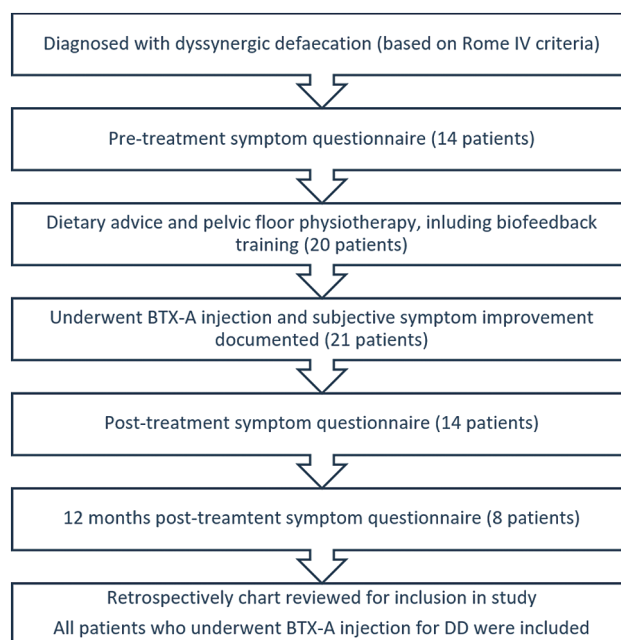
The current literature on this topic is limited and, to our knowledge, there have been no Australian studies published. This study aimed to identify the efficacy of BTX-A injection in treating DD in patients at a Functional Colorectal Unit.

## Methods

This study was performed in line with the principles of the Declaration of Helsinki and ethics approval was granted from the Metro South Health Human Research Ethics Committee, Brisbane, Australia (LNR/2020/QMS/67907). A retrospective review was undertaken of a prospectively collected database of patients attending a tertiary functional colorectal center, as outlined in ►Fig. 1. Patients diagnosed with DD who had undergone BTX-A injection between February 2014 and December 2019 were identified and included in the study. Due to the small group, all patients over 18 years of age who underwent BTX-A injection for diagnosed DD were included. No other exclusion criteria were applied. The selection process and timeline is summarized in ►Fig. 1.

The diagnosis of DD followed the current Rome IV criteria, defined as inappropriate contraction of the pelvic floor as measured with anal surface EMG or high-resolution anorectal manometry. Patients were found to have a paradoxical increase in anal tone on manometry or EMG during simulated strain. Patients also had either an abnormal balloon expulsion test or impaired evacuation on imaging.

Extensive chart reviews were conducted using a standardized collection tool. Preoperative APS data were collected as were details on the BTX-A injection technique, including anesthetic type, position, injection site, and



**Fig. 1** Flow diagram outlining timeline and methods of this study.

**Table 1** Patient demographics

Demographics and symptoms	years (range)
Age	45 (21–72)
Duration of symptoms	12.3 (1–35)
Pelvic floor history	(no. patients)
Chronic constipation	21
Anal fissures	9
Coccygeal fracture	2
Endometriosis	4
Medical history	(no. patients)
Mental Health Diagnosis	12
Sexual abuse	4

number of units injected. Intraoperative findings and postoperative complications were documented, as were details of conservative therapies utilized. Validated symptom scores were collected pre- and postoperatively, using the constipation severity score (CSS),<sup>17</sup> obstructed defaecation score (ODS),<sup>18</sup> and the patient assessment of constipation quality of life (PAC-QoL) satisfaction and dissatisfaction<sup>19</sup> questionnaires and scales. Subjective patient reports were also recorded. Finally, information was collected on patient demographics, medical history, and risk factors for DD. Details of follow-up appointments were recorded until the patient's final clinic visit or the end of the study period, whichever occurred first.

The injection's efficacy was evaluated using two methods: subjective patient reports recorded at follow-up and comparison of patient symptom scores pre- and postprocedure. Symptom scores obtained pre- and post-BTX-A, and at 12 months postprocedure were compared with each other using paired *t*-tests. Additionally, a one-way analysis of means (not assuming equal variances) was conducted using all data.

## Results

The present study included 21 patients (19 females), with a mean age of 45 years (range 21–72), all of whom underwent BTX-A injection for DD management within the study period (► **Table 1**). From that total, 3 patients received two BTX-A injections on separate occasions. On average, patients had symptoms for a mean of 12.3 years prior to clinic presentation, with 3 experiencing symptoms from childhood (► **Table 1**). History was significant for obstetric trauma in 12 patients, anal fissures in 9, sexual abuse in 4, coccygeal fracture in 2, endometriosis in 4, and a mental health disorder in 12 patients (► **Table 1**). Preoperative symptom scores are outlined in ► **Table 2**.

The BTX-A injection was subjectively reported as beneficial in 19 procedures (79%), with a mean duration of 4.7 months in those who had any symptom improvement (range 1–32) (► **Table 2**). Overall, the average duration of efficacy was 3.8 months when including the remaining 5 injections,

which resulted in no subjective symptom improvement. The level of benefit varied between patients, from mild improvement to complete symptom resolution. Sustained improvement (beyond 12 months) was only seen in two patients. A second BTX-A injection was administered in 3 patients with each one reporting a longer duration of subjective efficacy after the second injection (► **Table 2**).

The scores of 15 cases were collected pre- and postoperatively, with postoperative collection occurring at different times for each patient (mean 4.8 months, range 1–16 months). Only 8 patients had scores collected at over 12 months post-BTX-A injection due to varying reasons including discharged from clinic, loss of follow-up, or scores not collected at the appointment. The mean of all four constipation scores across the cohort improved, when compared to the pre-BTX-A scores, both at the first follow-up and at 12 months (► **Table 3**). While there was a statistically significant improvement in QoL at 12 months postprocedure, when the data was adjusted for those lost to follow-up ( $n=7$ ), there was no statistical significance.

Individually, there was at least 25% improvement in CSS in 4 patients, ODS in 5 patients, PAC-QoL dissatisfaction in 4 patients, and PAC-QoL satisfaction in 7 patients at first visit (► **Table 2**).

At 12 months post-BTX-A, an improvement greater than 25% was reached in scores by 3 patients in CSS and ODS, 2 in PAC-QoL dissatisfaction, and 6 in PAC-QoL satisfaction. Of the two patients with sustained subjective improvement beyond 12 months, one (patient 16) had improved CSS, ODS, and PAC-QoL satisfaction scores. The other did not have scores collected beyond 12 months.

After the procedure, 6 of the BTX-A injections resulted in faecal incontinence or urge (► **Table 4**); 1 patient had a singular postprocedural episode of passive faecal passage; 4 had mild leakage, which resolved; and the remaining patient reported ongoing leakage 8 months post-BTX-A. There was no faecal incontinence or urge reported following a second dose of BTX-A. Two patients reported mild, temporary per rectum bleeding, and another two had initial postprocedural pain or discomfort. There were no intraoperative complications.

Pelvic floor physiotherapy, incorporating biofeedback training, was attended by 20 of the 21 patients, for a mean of 8 visits (range 2–22), with all but two beginning physiotherapy prior to BTX-A. The only patient without physiotherapy was referred but failed to attend. All patients received dietary advice and defaecatory assistance as adjuvant treatment. Compliance varied due to factors such as cost, side effects, and perception of prolonged laxative use.

All 24 BTX-A (Botox, Allergan Inc., Dublin, Ireland) injections were performed in lithotomy position under general anesthetic. 21 used 100 units of BTX-A split bilaterally into two doses of 50 units (► **Table 4**). One injection used 50 and another used 60 units, both split evenly bilaterally; one injection administered 120 units split evenly across four quadrants. The BTX-A was injected to various sites: 9 into the inter-sphincteric space, 9 into puborectalis, 2 into levator ani, 2 into the internal anal sphincter (IAS), and 2 into the

**Table 2** Subjective efficacy (months) and objective patient constipation scores pre, post and >12 months post BTX-A

Pt no.	Subjective efficacy (months)	CSS			ODS			PAC-QoL Dissatisfaction			PAC-QoL Satisfaction		
		Pre	Post	>12 months	Pre	Post	>12 months	Pre	Post	>12 months	Pre	Post	>12 months
1	3	-	-	-	-	-	-	-	-	-	-	-	-
2	none	22	20	-	21	15	-	79	45	-	0	4	-
3	3	25	18	16	23	17	17	99	79	76	0	0	6
4	14	5	10	-	13	20	-	79	43	-	8	12	-
5	2	-	-	-	-	-	-	-	-	-	-	-	-
6	none	11	15	11	11	12	18	88	100	56	3	0	6
7	2	16	14	16	17	14	18	83	70	89	3	1	8
8	4	-	-	-	-	-	-	-	-	-	-	-	-
9 <sup>a</sup>	2	20	17	-	12	11	-	66	106	-	3	12	-
9 <sup>a</sup>	7	-	-	-	-	-	-	-	-	-	-	-	-
10	none	-	-	-	-	-	-	-	-	-	-	-	-
11	1	22	14	26	22	13	17	108	95	114	0	10	4
12	2	27	28	28	15	15	15	93	90	90	0	4	4
13 <sup>a</sup>	1	-	-	-	-	-	-	-	-	-	-	-	-
13 <sup>a</sup>	2	-	-	-	-	-	-	-	-	-	-	-	-
14	3	17	18	18	15	20	20	63	76	76	8	8	8
15	1	14	17	-	21	20	-	93	102	-	10	13	-
16	32	12	1	5	13	3	3	45	0	28	3	20	16
17	none	20	16	13	22	17	7	115	103	48	9	3	8
18 <sup>a</sup>	3	14	16	-	14	15	-	41	43	-	5	5	-
18 <sup>a</sup>	4	16	10	-	15	9	-	43	23	-	5	4	-
19	2	7	6	-	12	12	-	27	86	-	11	6	-
20	2	-	-	-	-	-	-	-	-	-	-	-	-
21	none	-	-	-	-	-	-	-	-	-	-	-	-
Average	4.7 <sup>b</sup>	16.5	14.7	16.6	16.4	14.2	14.4	74.8	70.7	72.1	4.5	6.8	7.5

**Abbreviations:** BTX-A, botulinum toxin-A, CSS, constipation severity score; ODS, obstructed defaecation score; PAC QoL, patient assessment of constipation quality of life. **Notes:** <sup>a</sup> had repeat BTX-A injections. <sup>b</sup> average of those who had efficacy. - not completed. Bold denotes >25% improvement in score compared to pre-BTX-A.

**Table 3** Average objective constipation scores and improvement in scores at first visit and at 12 months post-BTX-A injection

	First visit post-BTX-A (15 procedures)			> 12 months post-BTX-A (8 procedures)			p-value	
	Pre-BTX-A mean (SD)	First visit post-BTX-A mean (SD)	Change (%)	p-value	Pre-BTX-A mean (SD)	>12 months post-BTX-A (8 procedures) mean (SD)		Change (%)
CSS	16.5 (6.3)	14.7 (6.2)	10.9 (imp)	0.15	18.8 (5.8)	16.6 (7.6)	11.3 (imp)	0.3
ODS	16.4 (4.2)	14.2 (4.6)	13.4 (imp)	0.10	17.3 (4.6)	14.4 (6.0)	16.7 (imp)	0.3
PAC-QoL (Dis.)	74.8 (26.4)	70.7 (32.6)	5.4 (imp)	0.6	86.8 (23.2)	72.1 (27.3)	16.9 (imp)	0.2
PAC-QoL (Sat.)	4.5 (3.9)	6.8 (5.6)	50.0 (imp)	0.2	3.3 (3.5)	7.5 (3.8)	130.8 (imp)	<0.05 <sup>a</sup>

**Abbreviations:** BTX-A, botulinum toxin-A; CSS, constipation severity score; Dis., dissatisfaction; Imp, improvement; ODS, obstructed defaecation score; PAC-QoL, patient assessment of constipation quality of life; Sat., satisfaction; SD, standard deviation. **Notes:** <sup>a</sup>Not significant when missing data taken into account.

puborectalis and IAS combined. For 13 patients, pudendal nerve block was used to prophylactically manage pain. All cases were palpation-guided, except for one endoanal ultrasound-guided injection. Examination under anesthetic (EUA) was concurrently performed in all procedures, with internal rectal prolapse diagnosed in 13 patients, 8 of which were high-grade (grade 3 or 4).

Patients were followed up for an average of three visits (range 1–6), with initial follow-up occurring on average 2.7 months (range 1–5) after the procedure. At the end of the study period, 3 patients were discharged, 5 were continuing follow-up, 5 required further management, and 8 were lost to follow-up.

### Discussion

Across 24 injections in 21 patients, we have found that BTX-A injection for DD subjectively improves symptoms in the majority of cases, with the improvement lasting 4.7 months on average (mean). All objective scores showed some improvement on average across the cohort (at initial collection and at 12 months), though this improvement was only statistically significant at the *p*-value of 0.05 for PAC-QoL Satisfaction. This difference disappears when all data, including missing data, is considered. There is also potential positive bias, if loss to follow-up wasn't random. All patients but one underwent physiotherapy, while adjuvant treatments, offered to all patients, had variable compliance. There were 3 cases who had repeat BTX-A injections, with all of them subjectively reporting improved efficacy and no side effects afterwards.

There were 6 patients with reports of faecal incontinence or urge, with all but one resolving in the weeks postprocedure. There was no association between dosage and complications, with persistent faecal urge/incontinence occurring in the patient who received only 60 units of BTX-A. Given that faecal urge/incontinence is also part of the symptom complex which can be seen in DD, it is possible that this development was not BTX-A associated.

This paper's main weakness is the small sample size of 21 patients. This is exacerbated by the heterogenous nature of DD, as there is significant variation in disease etiology, duration, and severity between patients. Additionally, disease management was inconsistent due to different operators, with different doses and sites of injection used, which would contribute to variation in response. Furthermore, while every patient was offered physiotherapy and adjuvant treatments, the timing, compliance, and success of these treatments differed for each patient, influencing the effect, or perceived effect, of BTX-A treatment. It is important to point out, however, that all these variations reflect real-life practice.

Another limitation of this study is the measurement of efficacy. Lack of uniform follow-up meant efficacy measurements were collected at varying time points post-BTX-A, which precludes comparison between patients. The symptom scores also do not necessarily reflect peak efficacy in patients whose treatment efficacy waned prior to initial score collection. This may partially account for the

**Table 4** Procedural technique and complications of botulinum toxin-A injection and findings on examination under anesthetic

Pt no.	Injection Site	Dose (units)	Complications	Rectal Prolapse
1	PR	100	FI/FU	Grade 3
2	PR	100	–	Grade 3
3	PR	60	FI/FU	–
4	ISS	100	–	–
5	PR + sphincter complex	100	–	Grade 3/4
6	Levator ani	100	FI/FU	Grade 3
7	IAS	100	–	Grade 3
8	ISS	120 <sup>b</sup>	Bleed	–
9 <sup>a</sup>	ISS	100	–	–
9 <sup>a</sup>	IAS	100	–	–
10	PR	100	–	–
11	ISS	100	–	–
12	PR	100	–	–
13 <sup>a</sup>	ISS	100	FI/FU	–
13 <sup>a</sup>	PR + IAS	100	Bleed	Grade 3
14	ISS	100	FI/FU	Grade 4
15	PR	100	FI/FU	–
16	ISS	100	–	–
17	PR	100	Pain	–
18 <sup>a</sup>	PR (ultrasound-guided)	100	–	–
18 <sup>a</sup>	PR	100	–	–
19	ISS	50	–	Grade 4
20	ISS	100	Pain	–
21	Levator ani	100	–	–

**Abbreviations:** BTX-A, botulinum toxin-A; FI/FU, faecal incontinence/faecal urge; IAS, internal anal sphincter; ISS, intersphincteric space; Pt., patient; PR, puborectalis. **Notes:** <sup>a</sup>Had repeat BTX-A injections. <sup>b</sup>Split across four quadrants (all other doses were split equally left and right).

discrepancy between subjective and objective measurements of efficacy. Furthermore, the extent of subjective symptom improvement was not considered, as it was treated as binary.

Several papers have shown BTX-A injections to be effective in DD treatment.<sup>7–12,14,20–22</sup> The extent and duration of symptom improvement varies greatly across the literature, as does the measurement of efficacy, which includes subjective patient reports, repeat APS, and objective scoring systems. Subjective symptom improvement at the initial follow-up has been reported at rates from 29 to 100%,<sup>2</sup> within which our rate of 79% falls. Recurrence of symptoms occurred on average at 4.7 months in this study, while previous research described recurrence from 5 weeks to 4 months.<sup>2</sup> Several studies have shown sustained symptom improvement at 12 months, as seen in two patients in our study.<sup>2</sup> In all three published studies which monitored BTX-A efficacy according to the CSS results,<sup>10,13,22</sup> a statistically significant difference between pre- and postprocedure scores was found. The present study did not find a statistically significant difference in CSS, though there is a reasonable

chance that a moderate effect may have been missed due to our small sample size.

Hompes et al. found that 94% of nonresponders to BTX-A injections had a high-grade rectal prolapse, which they suggested could be the cause of their symptoms, thus rendering BTX-A ineffective.<sup>7</sup> In this study, of the 8 patients diagnosed with high-grade rectal prolapse, only two were nonresponders to the injections. When eliminating patients with advanced prolapse, Hompes et al.'s success rate improved, while ours was consistent at 81% (13/16 procedures).

Our rate of faecal urge/incontinence (25%) was higher than the aggregated literature rate of 4.1% for flatus incontinence and 6.9% for faecal incontinence.<sup>2</sup> This could be due to higher doses of BTX-A used in this study, while the studies that reported no faecal or flatus incontinence used doses of 12 to 40 Botox-equivalent units.<sup>11–14,22</sup> Although, a study assessing side effects of the injections at doses equivalent to the present study (albeit in patients with anal fissures, rather than DD) found no increased rate of faecal incontinence at higher doses.<sup>16</sup> Regardless, for the majority of patients, this complication was transient and acceptable, with one patient

receiving a second BTX-A injection despite temporary faecal incontinence after the first. No other known side effects due to local or systemic spread of the injection were observed in this study, such as intertrigo and influenza-like syndromes.<sup>16</sup>

There is good evidence for biofeedback as a treatment for DD, with some studies showing long-term efficacy.<sup>23,24</sup> However, other studies preference BTX-A injection as a cheaper, faster,<sup>11</sup> and more successful treatment<sup>13</sup> (albeit of shorter duration). Several papers have used this procedure as a second line therapy to biofeedback. Only Zhang et al. had a similar approach to this paper, utilizing both biofeedback and BTX-A in conjunction, finding an overall improvement in the CSS.<sup>10</sup>

In the present study, as is commonplace in pelvic BTX-A injections for other indications, general anesthetic was used to facilitate the procedure, which is in contrast to much of the literature on BTX-A injections in DD.<sup>2</sup> In addition to general anesthetic, over half the cases in this study received a pudendal nerve block for pain management. Despite the difference in anesthetic technique between this study and the literature, the rate of pain as a side effect appears to be similar.<sup>2</sup>

The only literature on endoanal ultrasound-guided BTX-A for DD comes from two papers by Maria et al.<sup>8,11</sup> They suggested that failure of efficacy or early relapse could be due to partial or complete inaccuracy in injecting the target muscles.<sup>8</sup> However, this study achieved similar rates of efficacy to Maria et al.'s study despite only using ultrasound-guidance in one patient. Furthermore, the patient in question only had a short duration of subjective symptom improvement, at two months.

## Conclusion

In conclusion, it is the authors' opinion that BTX-A appears to be safe and can be effective as a short-term treatment for any patient with DD, following a full course of conservative management. As expected, its efficacy is only temporary, with some short-lived subjective improvement in constipation symptoms. The main side effect of faecal leakage, which was observed in one quarter of the study's patients, is worthy of consideration when deciding whether to treat DD with BTX-A injection, though it does appear to be mild and self-limiting.

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### Conflict of Interests

The authors have no conflict of interests to declare.

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