



# Prolonged avoidance of repeat surgery with endoscopic balloon dilatation of anastomotic strictures in Crohn's disease<sup>☆</sup>

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## KEYWORDS

Balloon dilatation;  
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## Abstract

### Background and aims

There is a high rate of stricturing post-operative recurrence in Crohn's disease (CD) particularly at sites of surgical anastomosis, and over 50% of these patients will require a repeat resection. Endoscopic dilatation of anastomotic strictures is an alternative to surgical resection in selected patients. We aimed to evaluate the safety and long term efficacy of endoscopic balloon dilatation of symptomatic anastomotic strictures in CD.

**Methods:** Retrospective analysis of a prospectively maintained inflammatory bowel disease database of patients attending a single academic centre (n=1244 patients with CD) who underwent dilatation.

**Results:** Fifty-five dilatations were performed in 31 patients (mean age 43±SD 12, 47% female). Median follow-up period was 46 months (IQR 14–62). Ninety percent of patients had successful initial dilatation and no complications occurred. Six (21%) avoided further dilatations or surgery in the follow-up period. Stricture recurrence was detected in 22 patients; 15 (54%) patients had repeat dilatations and seven (25%) went straight to surgery. Eight (28%) patients were managed with repeat dilatations of the stricture (median dilatations=2 range 2–6) and seven (25%) required surgery despite repeat dilatations. Median time from first dilatation to repeat surgery was 14.5 months (IQR 3–28) and to repeat dilatation was 13.8 months (IQR 4–28). There was no difference in immunomodulator use, biologic use and smoking status between the groups requiring surgery versus dilatation only.

**Conclusion:** Endoscopic balloon dilatation of anastomotic strictures is safe and effective in providing symptomatic relief in CD patients. Forty-five percent of patients had a sustained response

**Abbreviations:** CD, Crohn's disease; CI, Confidence interval; EBD, Endoscopic balloon dilatation; IBD, Inflammatory bowel disease; IFX, Infliximab; IMD, Immunomodulator; TNF, Tumor necrosis factor; SD, Standard deviation.

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to single/serial balloon dilatation with avoidance of further surgical resection for a median interval of 46 months. Post-operative medical therapy and smoking status did not predict requirement for recurrent dilatation or surgery.

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## 1. Introduction

Crohn's disease (CD) is a chronic inflammatory disorder of the gastrointestinal tract that is characterised by a progressive course leading to complications such as strictures, fistulas and abscesses.<sup>1</sup> Intestinal strictures may lead to symptoms of bowel obstruction, perforation and localised abscess formation which eventually lead to surgical resection. Despite advances in medical therapy, surgery for stricturing CD remains common.<sup>2</sup> Up to 80% of CD patients will eventually require at least one resection within 10 years of being diagnosed.<sup>3,4</sup> Improvement in surgical techniques such as laparoscopic bowel resection with its relatively low complication rates of around 5% has been advocated as a superior method of treating CD related strictures in the short to medium term.<sup>5,6</sup> However, surgery is not curative and 70% of patients will develop endoscopic recurrence of disease adjacent to the anastomotic site within a year post surgery and 40% will be symptomatic within four years.<sup>7,8</sup> More than half will have recurrent stricturing disease within 10–15 years of surgery necessitating repeat resection.<sup>5,6,8</sup> Multiple surgical resections predispose to problems such as adhesions (therefore making subsequent surgeries difficult) and may lead to problems like short bowel syndrome and malabsorption.

There has been an increasing interest in bowel conserving strategies such as stricturoplasty and endoscopic balloon dilatation (EBD). Endoscopic dilatation of CD related anastomotic strictures is an alternative to surgical resection in selected patients. With EBD, technical success rates of 71–100% and overall complication rates ranging from 0 to 17% have been reported in the literature.<sup>9–14</sup> A meta-analysis of studies investigating outcomes of EBD in CD showed a short term success rate of 78% and long term success rate of 58% at a mean follow-up of 33 months.<sup>15</sup> Long-term outcome of endoscopic balloon dilatation is less clear. Most cohort studies had relatively small numbers of patients with short follow-up and contained heterogeneous stricture phenotype. Long term surgical resection rates are variable amongst the different studies. Symptom recurrence rates of 13–100% have been reported,<sup>9–11,14,16</sup> however not all patients would necessarily require surgery as the next treatment option. The aim of our study was to evaluate the safety and long term efficacy of endoscopic balloon dilatation of symptomatic anastomotic strictures in a single centre CD population.

## 2. Materials and methods

### 2.1. Patient selection

Patients were identified by a search of a prospectively maintained inflammatory bowel disease (IBD) database of over 2700 patients in a single academic medical centre. The

unique identifiers of endoscopic dilatation and CD were used as the search terms. Subsequently, a retrospective chart review (including reports of cross sectional imaging, magnetic resonance enterography (MRE), barium studies and endoscopy reports) was performed for case verification and to exclude dilatations unrelated to stricturing anastomotic CD.

### 2.2. Endoscopy and dilatation

Our practice has been to perform EBD for patients with obstructive symptoms including nausea, vomiting and abdominal cramps and a short fibrostenotic anastomotic stricture (less than 5 cm long), documented by a barium small bowel study or cross sectional imaging. Some had mild inflammation at the stricture site but the symptoms were felt to be attributable to the stricture. Patients with concomitant fistula or abscesses were not subjected to EBD at our institution. All dilatations were performed with a standard colonoscope (Olympus, Hamburg, Germany) with a through-the-scope controlled radial expansion (CRE) balloon (predominantly 12–18 mm diameter (Boston Scientific, Cork, Ireland)). The balloon was filled with water under visual control, and was insufflated by a multistep inflation with 2–3 min of inflation time at each of the appropriate diameter (12-13.5-15 or 15-16.5-18 mm). In general, the average attempts of EBD per session was 3 (range 3–5). Passage of the colonoscope through the stricture was attempted in all patients and was used to define therapeutic success. All of the procedures were performed under conscious sedation using midazolam and either pethidine or fentanyl. After dilatation, patients were observed for 1–4 h in the recovery room.

### 2.3. Outcomes and follow-up

Immediate clinical success was defined as improvement of obstructive symptoms and avoidance of further EBD or surgery at the anastomosis within 30 days of index EBD. Patients were followed up as outpatients with 3–6 monthly interval visits, or sooner if they developed symptoms. Long-term efficacy of EBD was defined as the avoidance of surgical resection for obstructive symptoms and disease recurrence at the anastomosis, either with single or repeated dilatations. If patients' symptoms recurred, time to repeat dilatation or surgery was recorded from the index EBD.

### 2.4. Statistical analysis

Quantitative data are expressed as median and range or frequencies. Descriptive statistics were used to analyse patient demographics. Kaplan–Meier analysis with log rank statistics was used to estimate event-free interval and Cox forward conditional proportional hazards regression analysis

to assess predictors of disease recurrence including smoking status and medication use.

## 2.5. Ethical considerations

The study was approved by the Ethics Committee at St. Vincents University Hospital, Dublin.

## 3. Results

Initial search of the prospectively maintained database revealed a total of 74 patients with CD that had any dilatation of a stricture related to CD. After excluding patients with CD who had dilatation of non-anastomotic strictures, 31 patients remained who were suitable to analyse. Clinical data and follow-up were verified by detailed review of medical records.

### 3.1. Patient characteristics

Fifty-five EBD were performed in 31 patients. Mean age ( $\pm$ SD) at time of EBD was  $44 \pm 13$  years. Patients' demographics are listed in Table 1. The median follow-up period for all patients (following initial EBD) was 46 months (IQR, 14–62). The majority of patients,  $n=23$  (74%), had dilatations performed at an ileocolonic anastomosis. Two patients had EBD to colon to colon anastomosis and six patients had EBD to an ileorectal anastomosis. Eighty-two per cent of patients were on medical therapy for CD at the time of index dilatation. Thirty per cent were on a 5-aminosalicylates (ASA), 41% were on an immunomodulator (IMD), 8% on an anti-TNF agent and 2% were on budesonide. Post initial dilatation, 45% of patients were on anti-TNF agent and 29% on IMD (see Fig. 1).

### 3.2. Efficacy and safety of endoscopic dilatation

A 100% initial technical success rate was achieved (passing of endoscope through the stricture). A high immediate success rate (defined as the improvement in patient symptom and

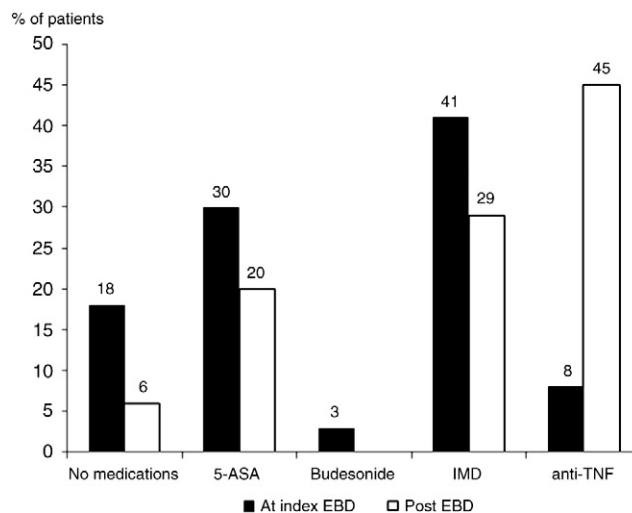


Figure 1 Medical therapy at index dilatation and post dilatation period by percentage of overall patients.

avoidance of surgery in 30 days) of 90% (28/31) was obtained for the first dilatation (see Fig. 2). Twenty one percent (6/28) of the patients who responded to EBD were asymptomatic and required no further dilatation or surgery up to the time of follow-up (46 months IQR 14–62). Seventy-nine percent (22/28) of patients had recurrence of symptoms after initial dilatation. Further dilatation was not attempted in seven of these patients (25%, 7/28) and surgery was performed as the subsequent therapeutic option. The reasons for choosing a surgical option were usually a combination of factors such as preference of the treating physician, early recurrence of symptoms post index dilatation and even patient preference to undergo surgery to remove the diseased segment over further colonoscopy and dilatation after weighing the management options. Repeat dilatation was deemed appropriate in 15/28 patients. The median number of subsequent dilatations performed was two (range 2–6). Of those 15 patients, 8 (28.5%) avoided surgery until the end of the follow-up period. Seven patients (25%, 7/28) eventually required anastomotic resection despite multiple EBD.

Median time from primary surgery to first dilatation was nine years (IQR, 2–29). Median time from first EBD to repeat surgery was 14.5 months (IQR, 3–28). Median time from index dilatation to second dilatation was 13 months (IQR, 4–60) and median time from second to third dilatation was 10 months (IQR, 2–21).

Overall, 14/31 (45%) showed sustained response to single/serial dilatations, with avoidance of further surgical resection during median follow-up time of 46 months. A Kaplan–Meier (KM) and Cox regression analysis was performed for factors associated with predicting the need for EBD versus surgical intervention. Fig. 3 shows the KM estimated surgery free interval following initial EBD; 50% of patients would require a further surgical resection by 5 years post dilatation. Smoking status (Fig. 4) and medication at the time of first dilatation (either IMD or biologic agent) did not influence time to EBD or surgery (Figs. 5a and b). Other potential predictors, such as age, gender, C-reactive protein (CRP) and disease duration, were not significantly associated with subsequent EBD or surgery (Supplementary Table 1).

Table 1 Demographic details of Crohn's disease patients with anastomotic strictures.

Number of patients	31
Total dilatations	55
Male:female ratio	17:14
Mean age $\pm$ SD	$44 \pm 13$ years
CD duration	16 years (IQR, 10–24)
Smokers	17/31 (55%)
Median follow-up	46 months (IQR, 14–62)
Median time from primary surgery to 1st dilatation	9 years (IQR, 2–29)
Median time from 1st dilatation to repeat surgery	14.5 months (IQR, 3–28)
Median time from 1st dilatation to repeat dilatation	1st–2nd: 13 months (IQR 4–60) 2nd–3rd: 10 months (IQR 2–21)

SD: standard deviation, IQR : Interquartile range.

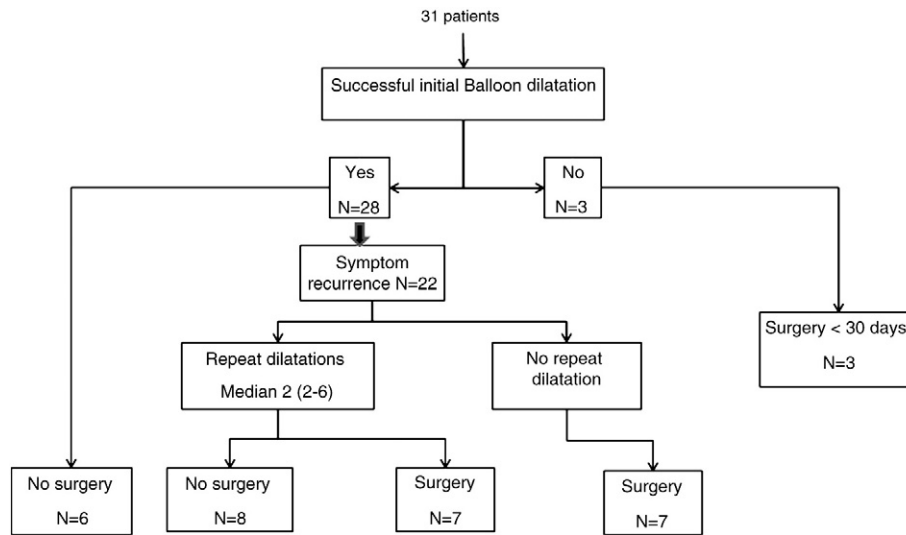


Figure 2 Outcomes of patients treated. Median follow-up period, 46 months (IQR 14–6).

### 3.3. Complications

Of the 55 dilatations performed, there were no perforations or other significant complications such as gastrointestinal bleeding or abdominal pain requiring hospitalisation. A minority of patients developed mild abdominal pain post procedure which improved and all patients were discharged home on the same day as the procedure. During follow-up, one death occurred which was not related to dilatation or subsequent surgery (road traffic accident).

### 4. Discussion

Postoperative CD recurrence at the anastomotic site is common and repeated surgical interventions may be necessary. 70%–90% of patients have endoscopic evidence of recurrent CD within a year post resection and the need for reoperation is as high as 70% after 20 years of disease.<sup>7,8,17</sup> Despite advances in therapy for CD with the use of

immunomodulators and anti- (TNF), surgery for CD has not diminished.<sup>2,18</sup> Patients with fibrotic strictures are usually refractory to medical therapy. Through the scope balloon dilatation is a well established technique with high technical success rates. Careful patient selection is important to ensure a successful procedure with minimal complications.

This study investigated the outcome of EBD in 31 patients who developed anastomotic strictures following a resection for stricturing CD disease. We identified a high initial clinical success rate of 90% in providing symptom relief following EBD. Long term relief of symptoms was achieved in 21% of patients without any further intervention for the remainder of the follow-up period. The remaining 48% required repeat EBD and this was successful in the majority. Therefore, almost half of our patients had successful management of their post-operative stricture with EBD without need for further surgery during follow-up. There were no complications in 55 dilatations performed. Neither smoking status nor medical therapy post EBD was predictive of further surgery

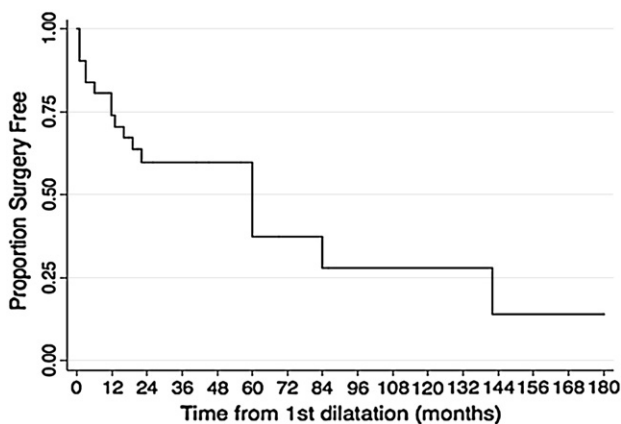


Figure 3 Overall proportion of patients remaining free of surgery over time following index endoscopic balloon dilatation.

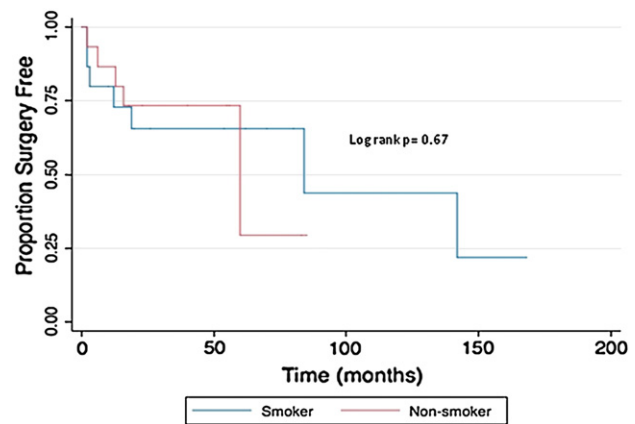
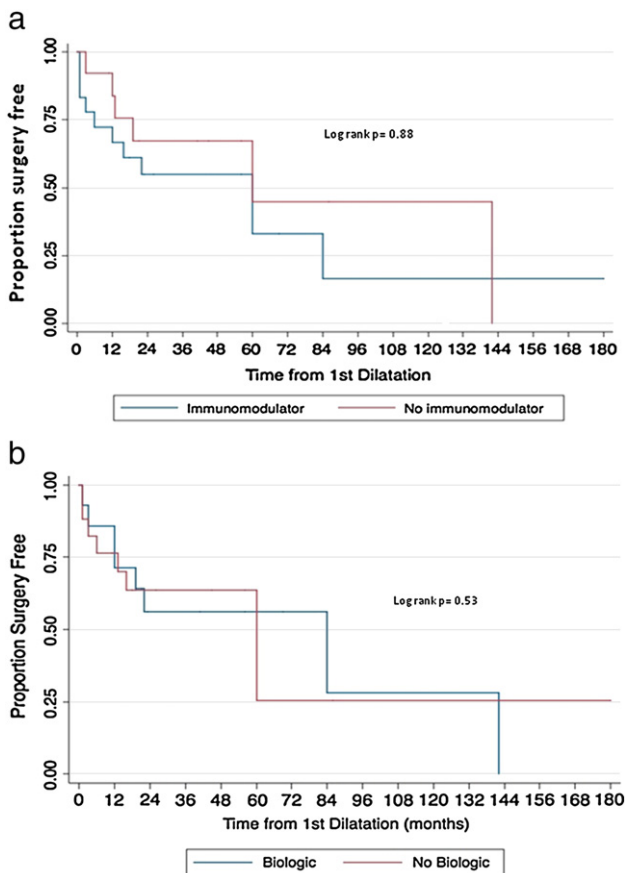


Figure 4 Impact of smoking activity on the redilatation or repeat surgery rate over time.



**Figure 5** a. Impact of immunomodulator use on the dilatation/surgery free survival rate. b. Impact on biologic agent use on the dilatation/surgery free survival rate.

versus EBD. The favourable median length of time from first EBD to repeat surgery (14.5 months) proves that EBD is an advantage to patients in terms of avoiding or delaying repeat surgery. Subsequent dilatations appear to give shorter duration of benefit, but still considerable (median 10–13 months), with no increase in complications.

Our findings are broadly comparable to other published reports in the literature but with a longer duration of follow-up than most prior studies. A meta-analysis conducted by Hasan et al. showed immediate success rates of 71–100% (overall 86%), recurrence of symptom following EBD between 13 and 100% with complications (mostly perforations) of 0–11%.<sup>15</sup> The long term efficacy was 58%. Most of the strictures were short and of anastomotic origin. Data on long term success rates were scant due to the small numbers ( $n=17-59$ ) and short follow-up periods (mean 33 months) of the earlier studies. In one of the largest reported series with the longest follow-up, 138 patients underwent 237 dilatations with mean follow-up of 5.8 years.<sup>13</sup> 54% had long term relief of symptoms, without the need for repeat dilatation or surgery in 76% of patients after the first dilatation. 46% required further dilatation and 24% required surgery. However, the rate of serious complications was 9% which is greater than that observed in our series. The success of this technique was not affected by disease activity at the stricture or medical therapies used. In our study, the lack of both mild and severe complications could be explained by the

use of a maximum balloon size of 18 mm, compared to other series with more complications using a larger diameter balloon up to 25 mm.

In our study, smoking status did not seem to predict the likelihood of surgery versus successful EBD. Others have shown mixed results. Hoffman et al. studied 32 patients (27/32 anastomotic) and showed that smoking is a significant risk for recurrent disease.<sup>19</sup> Sabate et al. showed that in their 38 patients (28 anastomotic) smoking was associated with an increased need for surgery with a hazard ratio of 4.13 (1.04–17.7).<sup>20</sup>

Following initial EBD, most patients were on immunosuppressive therapy. When the endoscope was passed through the stricture, on some patients, it would become evident of the presence of ulceration or active inflammation in the non stenotic segment. Using the Rutgeert's scoring grade, patients with significant ulcerations or inflammation in these segments were managed with escalation of medical therapy due to the risk of progression of disease. However, medical therapy did not predict the likelihood of undergoing surgery or EBD in the follow-up period. Similar observations have been reported by others.<sup>13,20</sup> Our results do highlight an interesting difference in medical management before and after EBD, namely that a significant proportion of patients had anti-TNF therapy initiated subsequent to the procedure. This reflects the fact that balloon dilatation would have allowed the anastomosis to be passed with a scope allowing endoscopic evaluation of the pre-anastomotic ileum or colon. At least part of the utility of EBD may also be in facilitating better assessment of disease activity with subsequent optimisation of anti-inflammatory therapy. This aspect of EBD, has not previously been so clearly shown, but may explain the durable symptoms relief observed following single EBD in many patients.

Successful treatment of the inflammatory component of small bowel strictures has previously been demonstrated. In a retrospective study of 18 patients with symptomatic small bowel strictures that failed conventional treatment with azathioprine and steroids, infliximab caused a partial/complete response in 17/18 at week 8 and 7/17 remained asymptomatic after a median 18 months.<sup>21</sup> There has been concern, nonetheless, that anti-TNF agents such as infliximab may be associated with accelerated healing and cause early development of fibrosis and actually worsen obstruction.<sup>22,23</sup> While Van Assche et al. showed that per patient year follow-up, the proportions of patients needing redilatation and/or surgery were highest in the anti-TNF treatment group at 13.8%,<sup>13</sup> we did not observe an association between use of anti-TNF post EBD and need for repeat EBD or surgery.

In conjunction with medical therapy there has been an attempt to reduce post dilatation recurrence with several forms of auxiliary techniques. These include local intramural injection of steroid after EBD which has shown mixed results.<sup>12,24-26</sup> Another suggested technique involves local injection of infliximab, in patients refractory to all medical therapy,<sup>27</sup> and in patients with endoscopic evidence of recurrence at the ileocaecal anastomosis.<sup>28</sup> Early results are encouraging but require confirmation in larger controlled studies. More aggressive use of novel endoscopic techniques such as EBD followed by cutting the stricture with a sphinctertome has been described.<sup>29</sup> In addition, temporary endoscopic stenting of strictures has been reported with beneficial early outcomes in a small number of patients but

had significant stent migration rates.<sup>30,31</sup> Prospective controlled trials are also needed to further evaluate these techniques and aid in patient selection.

The retrospective nature of this study with a relatively select small group of patients lacks the statistical power to detect significant differences between the groups. However, we believe the data are reflective of real-life clinical practise and are a useful addition to the accumulated experience of outcomes for EBD of anastomotic strictures in CD.

In conclusion, our study shows that endoscopic dilatation to treat CD anastomotic strictures is a safe and effective procedure. Single or repeated EBD can facilitate a prolonged avoidance of further surgical resection in almost half of all patients. Our study adds to the current evidence which shows that in experienced hands with proper patient selection, EBD is safe and has excellent immediate and long term success rates.

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.crohns.2012.07.019>.

## Conflicts of interest

Kavinderjit Nanda has received an unrestricted educational grant from Merck, Sharp & Dohme (MSD).

## Statement of authorship

KN and WC carried out the study and data analyses and drafted the manuscript.

DK, BN and KB carried out the chart reviews and also conducted data analyses.

HM performed the statistical analysis.

DOD and GD conceived the study, and participated in its design and coordination and helped to draft the manuscript.

All authors read and approved the final manuscript.

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