# Percutaneous posterior tibial-nerve stimulation, perianal application of glyceryl trinitrate ointment, or closed lateral internal sphincterotomy in treatment of chronic anal fissure

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**Background**
Chronic anal fissures are longitudinal tear in the anoderm below the dentate line, typically occurring in the midline, with visible sphincter fibers at the fissure base, anal papillae, sentinel piles, and indurated margins. The gold-standard method of treatment is lateral internal sphincterotomy, which can be done by either open or closed technique. Medical sphincterotomy refers to pharmacological manipulation of anal sphincter tone as an alternative modality to surgery.
**Objective**
To compare the efficacy of treatment among patients receiving glyceryl trinitrate (GTN) treatment for chronic anal fissure with that among patients receiving percutaneous posterior tibial-nerve stimulation and those undergoing closed lateral internal sphincterotomy.
**Patients and methods**
In total, 120 patients were randomly allocated into three groups: 40 patients treated with percutaneous posterior tibial-nerve stimulation, 40 patients treated with GTN ointment, and 40 patients treated with closed lateral internal sphincterotomy.
**Results**
This study showed that treatment with percutaneous posterior tibial-nerve stimulation had led to complete healing in 27.5% of patients in posterior tibial-nerve stimulation group, 70% of patients in the GTN group, and 95% of patients in closed lateral internal sphincterotomy group.
**Conclusion**
Closed lateral internal sphincterotomy remains the gold standard for treatment of chronic anal fissure.

**Keywords:**
chronic anal fissure, posterior tibial nerve, sphincterotomy

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## Introduction

Most anal fissures can be traced to the passage of hard stool, trauma to anus, or tearing during delivery. Characteristic symptoms include tearing pain during defecation and rectal bleeding (usually described as bright-red blood-streaking stool). On clinical examination, the fissure can often be seen in the anoderm by gently separating the buttocks [1].

Treatment focuses on breaking the cycle of pain, spasm, and ischemia thought to be responsible for development of chronic anal fissure. At first, conservative measures are tried to minimize anal trauma, including bulk laxatives, stool softeners, and warm sitz baths [2].

The gold-standard method of treatment is lateral internal sphincterotomy, which can be done by either open or closed technique. Medical sphincterotomy refers to pharmacological manipulation of anal sphincter tone as an alternative modality to surgery. A regimen using 0.2% glyceryl trinitrate (GTN) ointment applied twice daily to anal canal for 8 weeks is the most commonly prescribed form of treatment. Another novel method of treatment is percutaneous posterior tibial-nerve stimulation using surface-adhesive electrodes [3].

Neural stimulation in the form of sacral-nerve stimulation and transcutaneous posterior tibial-nerve stimulation have been used in the treatment of fecal incontinence, with good results. It was recently postulated that both of these techniques could potentially serve as effective alternatives to GTN for the treatment of chronic anal fissure, but this suggestion

was based only on case studies and one clinical trial with a small sample size [4].

The aim of the present study, therefore, was to compare the efficacy and compliance rate of GTN treatment versus percutaneous posterior tibial-nerve stimulation for the treatment of chronic anal fissure. Although earlier studies have been performed using transcutaneous posterior tibial-nerve stimulation, the percutaneous approach is reportedly more effective than the transcutaneous one [5].

## Patients and methods

This prospective comparative study included 120 patients with chronic anal fissure presented to the outpatient clinic of Colorectal Surgery Unit, Alexandria Main University Hospital. Written consent was taken in all patients with ethical approval. The patients were divided into three groups:

Group A included 40 patients treated with percutaneous posterior tibial-nerve stimulation.

Group B included 40 patients treated with topical GTN ointment.

Group C included 40 patients who underwent closed lateral internal sphincterotomy.

Exclusion criteria:

(1) Patients with associated anal pathology.
(2) Patients with congenital anorectal anomaly.
(3) Patients with inflammatory bowel diseases.
(4) Patients with immunosuppression.
(5) Patients with fissures secondary to the underlying disease (AIDS, tuberculosis, and sexually transmitted diseases).
(6) Patients with a history of heart diseases.
(7) Patients with a history of intolerance to nitrates.
(8) Pregnant or lactating patients.

### Methods

All patients in the present study were subjected to the following:

(1) Collection of demographic information such as age, sex, and comorbidities.
(2) History taking.
    (a) Anorectal examination to assess the site of the fissure and the presence of a skin tag and other anal conditions.
(3) At presentation:
    (a) Pain score using visual analog scale (VAS).
    (b) Continence score using Wexner score.
    (c) Constipation score using Cleveland constipation scoring system (CSS).

All patients underwent regular visits at weeks 2, 4, 6, and 8. Then, they were reviewed at weeks 12, 18, and 24 by phone calls.

#### Percutaneous posterior tibial-nerve stimulation (30-min session 2 days per week for 8 weeks)

Patients underwent one 30-min session 2 days per week for 8 consecutive weeks. The patients attended the outpatient clinic to undergo the treatment [2].

Patients were placed in the supine position without anesthesia. Percutaneous posterior tibial-nerve stimulation was delivered using an electrode that was put on the skin 3–4-cm cephalad and 2 cm posterior to medial malleolus [6].

Successful placement was confirmed by the presence of an electric sensation 5 cm above and below the electrode site or digital planter flexion [6].

Percutaneous posterior tibial-nerve stimulation was delivered at the highest amplification 20 mA at a frequency of 20 Hz [6].

Perianal application of GTN ointment (twice daily for 8 weeks): Conservative treatment included topical GTN applied locally on the anal verge twice daily for 8 weeks [7].

#### Closed lateral internal sphincterotomy (with follow-up of 8 weeks)

Under anesthesia using blade 15, closed lateral subcutaneous internal anal sphincterotomy was performed with a blade scalpel after the intersphincteric groove had been located via manual palpation [8].

The full thickness of the internal sphincter was divided from the level of the dentate line distally [8].

#### Statistical analysis of the data

Data were fed to the computer and analyzed using IBM SPSS software package, version 20.0 (IBM Corp., Armonk, New York, USA). Categorical data were represented as numbers and percentages. $\chi^2$ test was applied to investigate the association between the categorical variables. While McNemar–Bowker test was used to compare between the two periods for categorical variables. For continuous data, they were tested for normality by the Kolmogorov–Smirnov test. Distributed data were expressed as mean and SD. Kruskal–Wallis test was used to compare different

groups for not normally distributed quantitative variables and followed by post-hoc test (Dunn's for multiple-comparison test) for pairwise comparison and Wilcoxon signed-rank test was assessed for comparison between two periods for not normally distributed quantitative variables. Significance of the obtained results was judged at the 5% level.

## Results

As regards the age, sex, and BMI, there were no statistically significant differences between the three groups. Out of 120 patients included in the study, 68 were males and 52 were females. There was a slight male predominance in posterior tibial-nerve stimulation group and GTN group and a slight female predominance in closed lateral internal sphincterotomy group. The median age was about 43 years in posterior tibial-nerve stimulation group, 46 years in GTN group, and 36.5 years in closed lateral internal sphincterotomy group. The median body mass index was 27 in posterior tibial-nerve stimulation group and GTN group and was 27.5 in closed lateral internal sphincterotomy group.

Posterior midline fissure was the commonest site with 30 (75%) cases in posterior tibial-nerve stimulation group, 33 (82.5%) cases in GTN group, and 31 (77.5%) cases in closed lateral internal sphincterotomy group. This was followed by anterior chronic anal fissure with seven (17.5%) cases in posterior tibial-nerve stimulation group, four (10%) cases in GTN group, and five (12.5%) cases in closed lateral internal sphincterotomy group. There were no statistically significant differences between the three groups.

The main presenting symptoms in the three groups were anal pain, constipation, anal bleeding, and anal pruritus.

Anal-pain assessment using the VAS score was done at the time of presentation, and 8 weeks.

At the time of presentation, all cases had severe pain with a mean VAS score of 8.1 in posterior tibial-nerve stimulation group, 7.95 in GTN group, and 8.2 in closed lateral internal sphincterotomy group. The pain score fell steadily over 8 weeks. After 8 weeks, VAS score reached a mean of 2.55 in posterior tibial-nerve stimulation group, 0.90 in GTN group, and 0.20 in closed lateral internal sphincterotomy group. There were statistically significant differences between the three groups. The pain improvement measured by VAS score was statistically significant in closed lateral internal sphincterotomy group more than posterior tibial-nerve stimulation group and GTN group. The pain improvement measured by VAS score was statistically significant in GTN group more than posterior tibial-nerve stimulation group (Table 1).

Continence assessment was done at presentation and 8 weeks using Wexner score. A score of 0 was present in the three groups in all cases, throughout the study.

Regarding constipation, assessment was done using the Cleveland CSS at the time of presentation and 8 weeks. At the time of presentation, a mean of 14.28 was present in posterior tibial-nerve stimulation group, a mean of 13.93 in GTN group, and a mean of 13.48 in closed lateral internal sphincterotomy group. The constipation scores decreased over 8 weeks, promoting healing of the fissure. At week 8, it fell to a mean of 8.35 in posterior tibial-nerve stimulation group, a mean of 6.83 in GTN group, and a mean of 5.15 in closed lateral internal sphincterotomy group. There were statistically significant differences between the three groups. The improvement in constipation

**Table 1 Comparison between the different studied groups according to anorectal pain by visual analog scale and constipation-scoring system**

| | Group A (*N*=40) | Group B (*N*=40) | Group C (*N*=40) | *H* | *P* |
|---|---|---|---|---|---|
| Anorectal pain by visual analog scale | | | | | |
| Before treatment | 8.10±1.43 | 7.95±1.47 | 8.20±1.34 | 0.619 | 0.734 |
| After treatment | 2.55±1.81 | 0.90±1.50 | 0.20±0.88 | 40.119* | <0.001* |
| Significance between groups | | $P_2$<0.001*, $P_3$<0.001*, $P_4$=0.041* | | | |
| $P_1$ | <0.001* | <0.001* | <0.001* | | |
| Constipation-scoring system | | | | | |
| Before treatment | 14.28±1.96 | 13.93±2.07 | 13.48±2.04 | 1.572 | 0.212 |
| After treatment | 8.35±1.41 | 6.83±1.68 | 5.15±2.12 | 33.123 | <0.001* |
| Significance between groups | | $P_2$=0.001*, $P_3$<0.001*, $P_4$<0.001* | | | |
| $P_1$ | <0.001* | <0.001* | <0.001* | | |

Data were expressed using mean±SD. *H*, *H* for Kruskal–Wallis test, pairwise comparison bet. each of two groups was done using post-hoc test (Dunn's for multiple-comparison test). Group A: posterior tibial-nerve stimulation group. Group B: glyceryl trinitrate group. Group C: Closed lateral internal sphincterotomy group. *P*: *P* value for comparing between the studied groups. $P_1$: *P* value for Wilcoxon signed-rank test for comparing between before treatment and after treatment. $P_2$: *P* value for comparing between group A and group B. $P_3$: *P* value for comparing between group A and group C. $P_4$: *P* value for comparing between group B and group C. *Statistically significant at *P* value less than or equal to 0.05.

was statistically significant in closed lateral internal sphincterotomy group more than posterior tibial-nerve stimulation group and GTN group. The constipation improvement was statistically significant in GTN group more than posterior tibial-nerve stimulation group (Table 1).

Anal bleeding was present in 75% of patients in posterior tibial-nerve stimulation group, 85% of patients in GTN group, and 85% of patients in closed lateral internal sphincterotomy group. After treatment, anal bleeding was completely relieved in 56.6% of patients in posterior tibial-nerve stimulation group, 85.29% of patients in GTN group, and 100% of patients in closed lateral internal sphincterotomy group. There were statistically significant differences between the three groups. The improvement in anal bleeding was statistically significant in closed lateral internal sphincterotomy group more than posterior tibial-nerve stimulation group and GTN group. The anal-bleeding improvement was statistically significant in GTN group more than posterior tibial-nerve stimulation group (Table 2).

Anal pruritus was another symptom that was assessed at presentation and 8 weeks. At presentation, anal pruritus was present in 72.5% of patients in posterior tibial-nerve stimulation group, 77.5% of patients in GTN group, and 85% of patients in closed lateral internal sphincterotomy group. After 8 weeks, anal pruritus was completely relieved in 65% of patients in posterior tibial-nerve stimulation group, 85% of patients in GTN group, and 95% of patients in closed lateral internal sphincterotomy group. The improvement in anal pruritus was statistically significant in closed lateral internal sphincterotomy group and GTN group more than posterior tibial-nerve stimulation group. There were no statistically significant differences in the improvement of anal pruritus between GTN group and closed lateral internal sphincterotomy group (Table 2).

Complete healing of fissure is defined by absence of symptoms (acute anorectal pain, constipation, anal pruritus and anal bleeding) and complete re-epithelialization of the fissure as determined by physical examination. Complete re-epithelialization and complete healing occurred in 27.5% of patients in posterior tibial-nerve stimulation group, 70% of patients in GTN group, and 95% of patients in closed lateral internal sphincterotomy group. There were statistically significant differences between the three groups (Table 3).

The complete healing of the fissure was statistically significant in closed lateral internal sphincterotomy group more than posterior tibial-nerve stimulation group and GTN group. The complete healing of the

**Table 2 Comparison between the different studied groups according to anal bleeding and pruritus**

| | Group A (*N*=40) [*n* (%)] | Group B (*N*=40) [*n* (%)] | Group C (*N*=40) [*n* (%)] | $\chi^2$ | *P* |
|---|---|---|---|---|---|
| Anal bleeding | | | | | |
| Before treatment | 30 (75.0) | 34 (85.0) | 34 (85.0) | 1.781 | 0.410 |
| After treatment | 13[a] (32.5) | 5[b] (12.5) | 0[c] | 16.863* | <0.001* |
| $P_1$ | <0.001* | <0.001* | <0.001* | | |
| Anal pruritus | | | | | |
| Before treatment | 29 (72.5) | 31 (77.5) | 34 (85.0) | 1.866 | 0.393 |
| After treatment | 14[a] (35.0) | 6[b] (15.0) | 2[b] (5.0) | 12.468* | 0.002* |
| $P_1$ | 0.001* | <0.001* | <0.001* | | |

$\chi^2$, $\chi^2$ test. Common letters are not significant (i.e. different letters are significant). Group A: posterior tibia- nerve stimulation group. Group B: glyceryl trinitrate group. Group C: Closed lateral internal sphincterotomy group. *P*: *P* value for comparing between the three groups. $P_1$: *P* value for McNemar test for comparing between before and after in each group. *statistically significant at *P* value less than or equal to 0.05.

**Table 3 Comparison between the different studied groups according to complete re-epithelialization of the fissure and complete healing after treatment and recurrence of anal fissure**

| | Group A (*N*=40) [*n* (%)] | Group B (*N*=40) [*n* (%)] | Group C (*N*=40) [*n* (%)] | $\chi^2$ | *P* |
|---|---|---|---|---|---|
| Complete re-epithelialization of the fissure | 11[a] (27.5) | 28[b] (70.0) | 38[c] (95.0) | 40.519* | <0.001* |
| Complete healing after treatment | 11[a] (27.5) | 28[b] (70.0) | 38[c] (95.0) | 40.519 | <0.001* |
| Recurrence of fissure | | | | | |
| After 12 weeks of treatment | 0 | 0 | 0 | – | – |
| After 18 of weeks treatment | 1 (2.5) | 1 (2.5) | 1 (2.5) | 0.431 | 1.000 |
| After 24 of weeks treatment | 2 (5.0) | 2 (5.0) | 1 (2.5) | 0.603 | 1.000 |

$\chi^2$, $\chi^2$ test. Common letters are not significant (i.e., different letters are significant). Group A: posterior tibial-nerve stimulation group. Group B: glyceryl trinitrate group. Group C: closed lateral internal sphincterotomy group. *P*: *P* value for comparing between the three groups. *Statistically significant at *P* value less than or equal to 0.05.

**Figure 1**


Neuro track TENS unit.

fissure was statistically significant in GTN group more than posterior tibial-nerve stimulation group (Table 3).

Patients who showed no healing (29 in posterior tibial-nerve stimulation group, 12 in GTN group, and two in closed lateral internal sphincterotomy group) were observed again at 10 weeks, to give a chance for the treatment course to be completed. Only the two nonhealed patients of closed lateral internal sphincterotomy group showed complete healing. Other nonhealed patients who had persistent symptoms and a high pain score (failure of treatment) were candidates for lateral internal sphincterotomy.

Patients who showed complete healing in the three groups were observed for recurrence at 12, 18, and 24 weeks. At 12 weeks, no cases had recurrence in three groups. At 18 weeks, recurrence rates were similar with one (2.5%) case in each group. At 24 weeks, one (5%) recurrent case increased in each of GTN group and percutaneous posterior tibial-nerve stimulation group, but the incidence of recurrence remained 2.5% in closed lateral internal sphincterotomy group. There was no significant difference between the three groups (Table 3 and Fig. 1).

## Discussion

In the current study, the effect of percutaneous posterior tibial-nerve stimulation, GTN, and closed lateral internal sphincterotomy on patients with chronic anal fissure was compared regarding anal pain, constipation, anal bleeding, anal pruritus, and complete healing.

Regarding the effect on pain relief, all patients complained of severe pain at presentation. After 8 weeks of treatment, pain VAS score dropped to a mean of $2.55 \pm 1.81$ in posterior tibial-nerve stimulation group, $0.90 \pm 1.50$ in GTN group, and $0.20 \pm 0.88$ in closed lateral internal sphincterotomy group. There were statistically significant differences between the three groups. The pain improvement measured by VAS score was statistically significant in closed lateral internal sphincterotomy group more than posterior tibial-nerve stimulation group and GTN group. The pain improvement measured by VAS score was statistically significant in GTN group more than posterior tibial-nerve stimulation group.

This dramatic reduction in mean pain scores is consistent with the study of Khanzada and Samad [9], who reported 96% pain relief with GTN. Bailey *et al.* [10] and Kennedy *et al.* [11] also noted the significant effect that 0.2% GTN had on reducing pain. Utzig *et al.* [12] and Nothmann and Schuster [13] noted reduction in pain after lateral internal sphincterotomy in 95% of patients. This is comparable to Hancock [14], Moya *et al.* [15], and Youssef *et al.* [4] who noted reduction in pain in 87.5, 85, and 75%, respectively, of patients after posterior tibial-nerve stimulation.

In the current study, continence assessment was done at presentation and 8 weeks using Wexner score. A score of 0 was present in the three groups in all cases, throughout the study.

In the current study, constipation assessment was done using the Cleveland CSS. After 8 weeks, scores dropped from a mean of 14.28–8.35 in percutaneous posterior tibial-nerve stimulation group, from a mean of 13.93 to a mean of 6.83 in GTN group, and from a mean of 13.48 to a mean of 5.15 in closed lateral internal sphincterotomy group. There were statistically significant differences between the three groups. The improvement in constipation was statistically significant in closed lateral internal sphincterotomy group more than posterior tibial-nerve stimulation group and GTN group. The constipation improvement was statistically significant in GTN group more than posterior tibial-nerve stimulation group. The decrease in constipation was associated with healing of anal fissure. No previous studies using percutaneous posterior tibial-nerve stimulation, GTN ointment, or closed lateral internal sphincterotomy to treat chronic anal fissure, have assessed constipation throughout the treatment.

Anal bleeding, although not uncommon, is usually limited to minimal bright-red blood seen on the toilet. After treatment, anal bleeding was completely relieved in 56.6% of patients in posterior tibial-nerve stimulation group, 85.29% of patients in GTN group, and 100% of

patients in closed lateral internal sphincterotomy group. There were statistically significant differences between the three groups. The improvement in anal bleeding was statistically significant in closed lateral internal sphincterotomy group more than posterior tibial-nerve stimulation group and GTN group. The anal-bleeding improvement was statistically significant in GTN group more than posterior tibial-nerve stimulation group.

Another encountered symptom in our study was perianal itching, which also occurred in 72.5% of patients in posterior tibial-nerve stimulation group, 77.5% of patients in GTN group, and 85% of patients in closed lateral internal sphincterotomy group. After 8 weeks, anal pruritus subsided in most patients and was completely relieved in 65% of patients in posterior tibial-nerve stimulation group, 85% of patients in GTN group, and 95% of patients in closed lateral internal sphincterotomy group. The improvement in anal pruritus was statistically significant in closed lateral internal sphincterotomy group and GTN group more than posterior tibial-nerve stimulation group. There were no statistically significant differences in the improvement of anal pruritus between GTN group and closed lateral internal sphincterotomy group. In other studies, itching was seen in 10% of patients [16].

Complete healing of fissure is defined by absence of symptoms (acute anorectal pain, constipation, anal pruritus, and anal bleeding) and complete re-epithelialization of the fissure as determined by physical examination. Complete re-epithelialization and complete healing occurred in 27.5% of patients in posterior tibial-nerve stimulation group, 70% of patients in GTN group, and 95% of patients in closed lateral internal sphincterotomy group. There were statistically significant differences between the three groups. The complete healing of the fissure was statistically significant in closed lateral internal sphincterotomy group more than posterior tibial-nerve stimulation group and GTN group. The complete healing of the fissure was statistically significant in GTN group more than posterior tibial-nerve stimulation group. Tauro *et al.* [17] demonstrated that adequate healing of fissure requires treatment for more than 6 weeks and in some cases up to 12 weeks.

This is comparable to Hancock [14] Moya *et al.* [15], and Youssef *et al.* [4] who noted complete healing in 87.5, 85, and 75%, respectively, of patients after posterior tibial-nerve stimulation. Similar healing rates with GTN application were observed by Carapeti *et al.* [18] at 67%, Jonas *et al.* [19] at 60%, Bacher *et al.* [20] at 63%, and Suvarna *et al.* [21] at 68%. More studies conducted by Hashmat and Ishfaq [22], Mustafa *et al.* [23], and Jawaid *et al.* [24] showed healing rates at 64, 70, and 82.5%, respectively. Lower healing rates after GTN application, were reported by Pitt *et al.* [25] and Hasegawa *et al.* [26] at 41 and 33%, respectively. This is in agreement with Utzig *et al.* [12] and Nothmann and Schuster [13] who also showed complete healing of 95% of patients after lateral internal sphincterotomy. Christie and Guest [27] found that the initial use of GTN compared with lateral internal sphincterotomy offered potential cost reduction without any loss in effectiveness. Hence, GTN is potentially a cost-effective first-line treatment strategy for the management of a chronic anal fissure.

Libertiny *et al.* [28] concluded that lateral sphincterotomy remains effective but should be reserved for patients who fail to respond to initial chemical sphincterotomy.

Mishra *et al.* [29] concluded that topical GTN should be the initial treatment in chronic anal fissure and lateral sphincterotomy should be reserved for patients with severe disabling pain and those not responding to at least 4 weeks of GTN therapy.

Thus, chemical sphincterotomy is a noninvasive, cost-effective, easier to apply, well-tolerated, and effective therapy for anal fissure and is a first-line treatment, especially in patients who are unwilling or unfit for surgery. For recurrent or persistent chronic fissure, the lateral internal sphincterotomy was superior, curative, easy, and safe in the hands of an expert and skilled surgeon with less complications and recurrence [30].

Moreover, in our socioeconomic conditions where there are financial constraints and patients, especially females, are reluctant to undergo surgery by male surgeons and patients having contraindications for surgery, GTN is an effective alternative treatment for such patients [31].

At the end of the study, patients who showed no healing (29 in posterior tibial-nerve stimulation group, 12 in GTN group, and two in closed lateral internal sphincterotomy group) were observed again at 10 weeks, to give a chance for the treatment course to be completed. Only the two nonhealed patients of closed lateral internal sphincterotomy group showed complete healing. Other nonhealed patients who had persistent symptoms and a high pain score (failure of treatment) were candidates for lateral internal sphincterotomy.

## Conclusion

From the current study, various points were concluded:

(1) Closed lateral internal sphincterotomy remains the gold standard for treatment of chronic anal fissure.
(2) GTN ointment offers an affordable noninvasive treatment option with acceptable success rate.
(3) Percutaneous posterior tibial-nerve stimulation is a novel noninvasive method with early low encouraging results that can change in the future with further experience and improvement of the technique.

### Recommendations

(1) Lateral internal sphincterotomy remains the gold-standard treatment for chronic anal fissure, and can be applied without medical-treatment failure.
(2) GTN should be the first line of treatment of acute anal fissure.
(3) Percutaneous posterior tibial-nerve stimulation is a novel method that needs further practice and improvement of the technique to increase its success in treatment.
(4) Further studies should be done on the effect of combined therapy with GTN and percutaneous posterior tibial-nerve stimulation on treatment of chronic anal fissure.

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### Conflicts of interest
Nothing to declare.

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