Original Article

Comparative Study of Efficacy and Safety of Botulinum Toxin A Injections and Subcutaneous Curettage in the Treatment of Axillary Hyperhidrosis

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Abstract

Background: Primary focal axillary hyperhidrosis is a chronic distressing disorder affecting both the sexes. When the condition is refractory to conservative management, we should go for more promising therapies like intradermal botulinum toxin A (BtxA) injections in the axilla, and surgical therapies like subcutaneous curettage of sweat glands. **Aims and Objectives:** The aim of this study is to compare the efficacy, safety and duration of action of intradermal BtxA injections in one axilla and subcutaneous curettage of sweat glands in the other axilla of the same patient with axillary hyperhidrosis. **Materials and Methods:** Twenty patients (40 axillae) received intradermal BtxA injections on the right side (20 axillae) and underwent tumescent subcutaneous curettage of sweat glands on the left side (20 axillae). Sweat production rate was measured using gravimetry analyses at baseline and at 3 months after the procedure. Subjective analyses were done using hyperhidrosis disease severity scale (HDSS) score at baseline, at 3rd and 6th month after the procedure. **Results:** At 3 months post-treatment, the resting sweat rate in the toxin group improved by 80.32% versus 79.79% in the subcutaneous curettage method ($P = 0.21$). Exercise-induced sweat rate in the toxin group improved by 88.76% versus 88.8% in the subcutaneous curettage group ($P = 0.9$). There was a significant difference in the HDSS score after treatment with both the modalities. There were no adverse events with BtxA treatment compared to very minor adverse events with the surgical method. **Conclusion:** Both intradermal BtxA injections and tumescent subcutaneous curettage of sweat glands had a significant decrease in the sweat rates with no significant difference between the two modalities. Hence, in resource poor settings where affordability of BtxA injection is a constraint, subcutaneous curettage of sweat glands can be preferred which has been found equally effective with no or minimal adverse events.

Keywords: Botulinum toxin, hyperhidrosis, subcutaneous curettage

Introduction

Hyperhidrosis is a condition characterised by sweating in excess of what is required for thermoregulation.[1] Primary hyperhidrosis is a chronic distressing disorder usually affecting palms, soles, axillae and the craniofacial areas and is not caused by any other medical condition or medications. It can be very disabling physically in the form of impairment in performing daily activities, as well as psychologically resulting in patients seeking help in the dermatology or neurology department. About 3% of the Indian population is afflicted with hyperhidrosis of some form, and about half of these people have axillary hyperhidrosis. Axillary hyperhidrosis begins during the teenage years and equally affects men and women.[2] Profuse sweating can result in skin maceration and secondary microbial infections,[3] which causes considerable embarrassment and social withdrawal.

Treatments include topical use of antiperspirants or systemic anticholinergic drugs. If these measures are ineffective, invasive or surgical treatments, such as direct excision of the sweat glands, sympathectomy and the newest surgical

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technique developed from a modification of liposuction, botulinum toxin injections are current alternatives.[4]

Recently, local injections of botulinum toxin type A (BtxA) have been shown to be a safe and effective treatment for chronic hyperhidrosis.[5] Although this method is safe and effective it is very expensive and requires repeated injections. Of the surgical modalities, open or endoscopic sympathectomy bears a relatively high risk of untoward complications.[6] Local surgical technique first described by Jemec[7] in 1975 involving removal of subcutaneous tissue of the axilla by means of curettage is well accepted and promising. The procedure is made safe by the use of tumescent anaesthesia with almost no complications.

Although subcutaneous curettage and toxin injections are well-established procedures for axillary hyperhidrosis, there are a few head to head studies comparing the two methods in the same patients. Hence, in our study, we have put forth an effort to compare the efficacy, safety and duration of effects of the two procedures in parallel in each patient using an objective measure, gravimetric analysis to weigh sweat rate and a subjective measure-patient-assessed quality of life.

Materials and Methods

Study design

This is an open-label non-randomised parallel assignment interventional study. The study was approved by the Institutional Ethical Review Board and was posted on clinicaltrials.gov (CTRI/2015/06/005935) before initiation of the study.

Patient selection

This study was conducted in a tertiary care hospital affiliated to a Medical College and Research Institute for the duration of 2 years from the date of approval. Written informed consent was taken from all patients.

Inclusion criteria

Patients between the age of 18 and 75 years with persistent bilateral primary axillary hyperhidrosis, with sweat measurement of more than 50 mg/min measured gravimetrically at room temperature and calm condition. We excluded patients with medical conditions that could be worsened by treatment with botulinum toxin, including myasthenia gravis, Lambert–Eaton syndrome and any other disease that could interfere with the neuromuscular function, secondary hyperhidrosis, known allergy against study medication, use of aminoglycosides, curare-like products, or other products which could interfere with the neuromuscular function, use of therapy for hyperhidrosis with aluminium chloride during the study and women of reproductive age group not on contraception.

Procedure

Patients who sought treatment for axillary hyperhidrosis in the dermatology outpatient department, who satisfied the diagnostic criteria [Table 1] for primary focal hyperhidrosis and those who were not satisfied with other modalities of treatment were considered for the study. Each patient was scheduled for five visits. On the first visit, patients were administered the Hyperhidrosis Disease Severity Scale (HDSS) [Table 2] followed by gravimetric sweat analysis. On the second visit, each patient underwent the interventional treatment of intradermal BtxA injection for one axilla and subcutaneous curettage of sweat glands on the other axilla simultaneously. For the sake of convenience, the toxin injections were done on the right axilla of all patients, and subcutaneous curettage was done on the left. On the 3rd visit, 3 months after the procedure once again HDSS was administered and gravimetric sweat analysis was performed. Six months after the procedure HDSS was administered to patients by follow-up telephone call.

Gravimetric analysis

The patient was advised to stop any antiperspirants for a week before the analysis. Resting sweat rate was first measured after which the patient was made to walk for 1 min and do knee bends twenty times, before measuring

Table 1: Diagnostic criteria for primary focal hyperhidrosis

Localised excessive sweating of at least 6 months duration with unknown cause with minimum of 2 of following traits
Bilateral and symmetric sweating
Occurs at least once/week
Impairs daily activities
Age at onset <25 years
Positive family history
Sweating ceases during sleep

Table 2: Hyperhidrosis disease severity score

How would you rate the severity of your hyperhidrosis?	Score
My underarm sweating is never noticeable and never interferes with my daily activities	1
My underarm sweating is tolerable but sometimes interferes with my daily activities	2
My underarm sweating is barely tolerable and frequently interferes with my daily activities	3
My underarm sweating is intolerable and always interferes with my daily activities	4

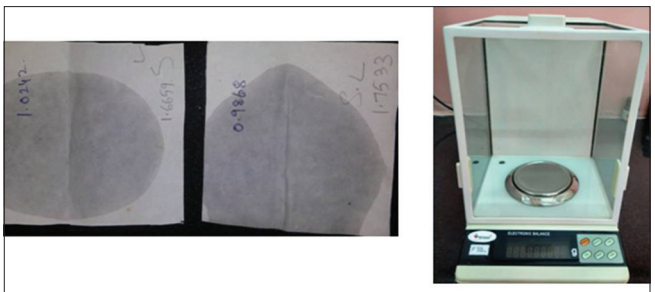

Figure 1: Gravimetry test

exercise-induced sweat rate. A 10 cm × 10 cm filter paper was weighed on high precision laboratory scales and the weight was recorded [Figure 1]. The paper was then placed under the axilla for 5 min and reweighed. The difference between the two weights was taken as sweat production in milligrams over 5 min. We chose axillary rates of sweat production greater than 50 mg/min to select patients with clinically evident axillary hyperhidrosis.

Hyperhidrosis disease severity scale [Table 2]

HDSS is a subjective assessment of the patients with respect to the sweating and its impact on daily quality of life.

Botulinum toxin A injection [Video 1]

The right axilla of each patient was chosen for this procedure after trimming the axillary hair. Field block anaesthesia was given with xylocaine 2% and adrenaline along the area which was marked 1cm peripheral to the pyriform hair-bearing region of the axilla. The marked area was divided into a grid of 1 cm^2 as shown in Figure 2. One vial of BtxA (100 units) was diluted with 5 mL of non-conserved sterile physiologic saline solution, resulting in a concentration of 2 units/0.1 mL. Using a small 26-gauge needle, 2.5 mL (=50 units) was administered by 25 intradermal injections into the centre of each grid in the area marked. The skin being rather thin in this area, care was taken to avoid injecting the material subcutaneously where it could go beyond the targeted glands. The needle bevel was kept turned up and more parallel to the skin surface, advancing 2 mm before injecting to produce a small bleb, to prevent backflow of BtxA from the injection tract, which minimises any loss of the toxin [Video 1].

Subcutaneous curettage [Video 2]

The left axilla was chosen for the surgical procedure. The patients were asked to trim their axillary hair for the convenience of surgery. Field block as mentioned above was given along the area marked 1 cm peripheral to the hair-bearing region of the skin. About 150–200 mL of tumescent solution (lidocaine 2% – 5.0 mL, adrenaline 1:1000 – 0.5 mL, $NaHCO_3$ 8.4% – 4.0 mL, normal saline 200–300 mL) was injected using 18 gauge needle into the axilla. Fifteen minutes after achieving anaesthesia a small stab incision was made with #11 blade within a natural axillary crease at the anterosuperior border of the axillary hairline or on the inferior outer border. The liposuction cannula was introduced through the stab incision [Figure 3] and through subcutaneous tunnels with the three holes turned upwards to face the subdermis and a back-and-forth movement was performed in a crisscross pattern aided by the other hand to compress the skin for effective subdermal scraping. The curettage was continued till the end point when the axillary skin became thin and pinched up easily like a piece of cloth. The intraoperative clinical clues to determine the end point of curettage is given in Table 3.[8] The incision site was left unsutured to allow easy drainage. Bulky compressive dressings were applied for 10 days [Video 2].

Outcome measures

Primary outcome measure was effectiveness based on a reduction in sweat production rate measured by gravimetry and duration of effect of both treatments. Secondary outcome measure was subject satisfaction based on a reduction in mean score on the HDSS. Adverse events were monitored and recorded.

Data analysis

As both the primary and secondary outcomes were continuous measures that were expected to be roughly normally distributed, we used paired *t*-tests to determine if there were pre-post changes within each treatment modality and changes between suction-curettage versus toxin. Because these were planned comparisons (pre-post within each treatment, and change between the treatments), adjustment was not made for multiple comparisons.

Table 3: Five intraoperative, clinical clues indicating sufficient liposuction-curettage[8]

Complete elevation of axillary skin from subcutaneous fat
Slight lividity of axillary skin
'Skin to skin' rolling shows no more fat adhering to the dermis
Palpable hair follicles during 'skin to skin' rolling
'Sipping' sounds caused by the cannula due to the axillary 'cavity' caused by complete dissection of fat and dermis

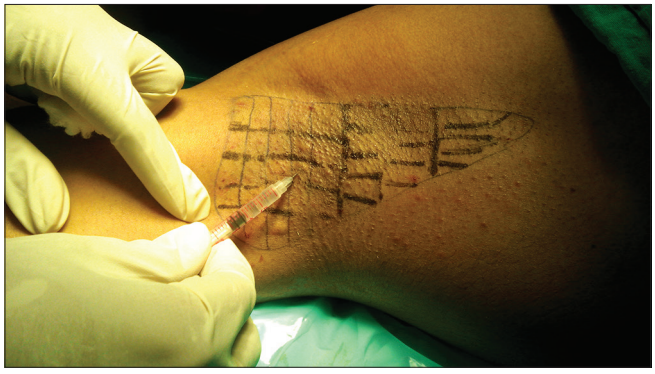

Figure 2: Intradermal injection of botulinum toxin A in the grid

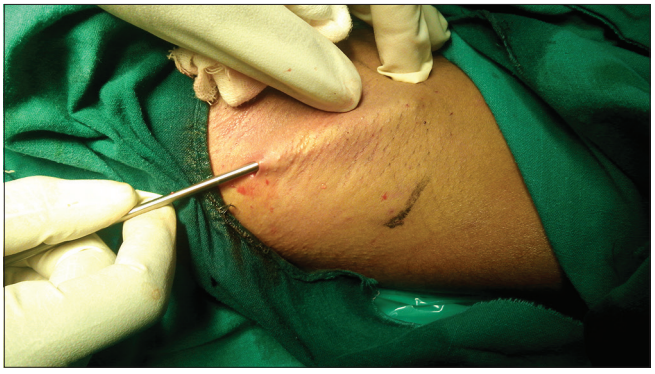

Figure 3: Subcutaneous curettage using liposuction cannula

Results

Baseline demographics

A total of twenty patients (40 axillae) were enrolled in our study based on the inclusion criteria. All the twenty patients (40 axillae) completed the study. The neurotoxin treatment group and suction-curettage treatment group each consisted of 20 axillae. The study lasted for approximately 20 months from the enrolment of the first patient to the final 6-month follow-up of the 20th patient. Patient demographics are represented in Table 4. The mean onset of the disease was 8.7 months in our study. The mean pre-treatment sweat rate of the toxin group (20 axillae) was 81.31 mg/min and that of the suction-curettage group (20 axillae) was 78.61 mg/min. The mean pre-treatment exercise-induced sweat rate of the toxin group (20 axillae) was 160.95 mg/min and that of the suction-curettage group (20 axillae) was 157.77 mg/min. The mean pre-treatment HDSS score of the toxin group was 2.95 and that of the suction-curettage group was 2.85.

Gravimetric analyses

After the toxin injections, the average resting sweat rate decreased from 81.31 to 10.14 mg/min at 3 months (P = 0.0424) and exercise-induced sweat rates reduced from 161 to 18.69 mg/min at 3 months (P = 0.0001). After the suction-curettage procedure, the mean resting sweat rate decreased from 78.61 to 10.39 mg/min (P = 0.0377) and exercise-induced sweat rate improved from 157.77 to 19 mg/min (P = 0.0004). The mean per cent reduction in the resting sweat rate 3 months after the toxin injections was 80.32% and 3 months after the suction-curettage was 79.79%. The difference between mean per cent reductions of the two modalities showed a P = 0.2072, which is insignificant. The mean reduction in the exercise-induced sweat rate 3 months after toxin injections was 88.76% and 3 months after suction curettage was 88.8%. The difference between mean reductions in exercise-induced sweat rate of the two modalities was also insignificant (P = 0.9153) [Figure 4].

Hyperhidrosis disease severity scale scores

After the toxin injections, the mean HDSS score decreased from 2.95 to 1.2 at 3 months (P < 0.0001) and 1.6 at 6 months (P < 0.0001). After the suction curettage, the mean HDSS score decreased from 2.85 to 1.15 (P < 0.0001) at 3 months and 1.65 at 6 months (P < 0.0001) [Figure 5]. There was no significant difference in the HDSS score between the two modalities of treatment.

Table 4: Patient demographics

Patient characteristics	Number
Age (years)	
18-30	14
31-40	6
Sex	
Male	17
Female	3

Only one patient had absolutely no response to both the treatment modalities. Two patients had chromhidrosis [Figure 6] and they felt there was an improvement after the procedure. One patient with bromhidrosis complained of persistent symptoms relating to odour although sweat rates decreased considerably. Two patients had hidradenitis suppurativa [Figure 7] on the

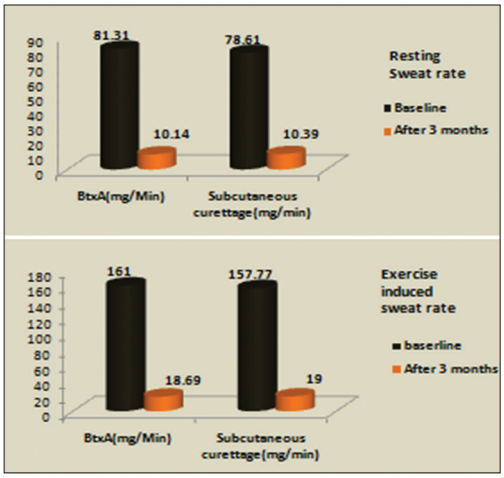

Figure 4: Graph comparing the decrease in resting and exercise-induced sweat rates with botulinum toxin A injections and subcutaneous curettage

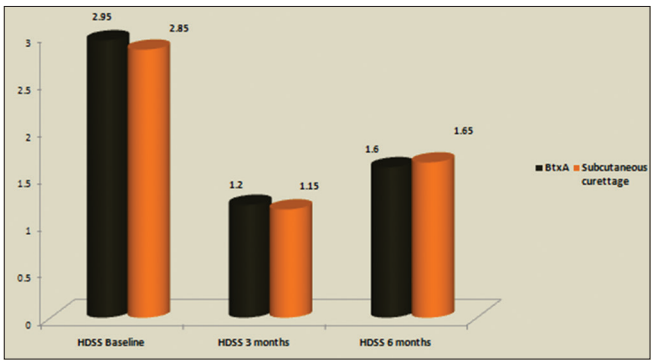

Figure 5: Hyperhidrosis Disease Severity Scale score at 3 months and 6 months after treatment with botulinum toxin A and subcutaneous curettage

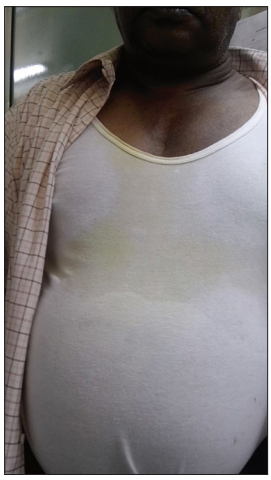

Figure 6: Chromhidrosis

left axillae for which subcutaneous curettage was done. They reported remission from the disease up to 6 months of follow-up.

Adverse events

After toxin injections, none of the twenty patients reported any discomfort or adverse reactions. After the suction-curettage procedure, two patients had bruising [Figure 8] at the site of surgery which resolved in 3 days. One patient had irritant contact dermatitis to adhesive of the plaster used for the dressing which subsided after it was removed. One patient had a painful bridle (fibrosis) formation in the surgical site which persisted for 2–3 months. The patient was counselled and treated symptomatically.

Discussion

In this study, we compared the effectiveness of subcutaneous curettage and intradermal BtxA injections in the treatment of primary axillary hyperhidrosis. We found that both the modalities were comparable in their efficacy based on the gravimetry assessment of sweat rate and HDSS score. There was a significant reduction in the sweat rates even at 6 months of follow-up with almost no adverse events in both the modalities of treatment. Axillary hyperhidrosis is a frustrating disorder because of the embarrassment it causes and failure to respond to many of the conservative treatments. Intracutaneous injections of BtxA have been used as a treatment for focal hyperhidrosis since 1996 with safety, efficacy and high levels of patient satisfaction.[9] It blocks the release of acetylcholine from the sympathetic nerve fibres that stimulates the eccrine sweat glands and causes a localised long-lasting, but a reversible decrease in sweating.[10] These patients will wish for a permanent solution for their excessive sweat production. Sympathectomy does bring a long-term resolution of the problem but is a highly invasive procedure with huge risks and potential side effects.

Surgical ablation of apocrine/eccrine glands seems to be a promising solution for long lasting or permanent decrease in the sweat rates. Local surgical treatment is divided into three categories: (1) excision of skin and glandular tissue, (2) curettage or liposuction procedures to remove the subcutaneous sweat glands or (3) a combination of limited skin excision with glandular tissue removal.[11] Liposuction curettage showed better results compared to the excision procedures.[12] It has been used safely, and with moderate long-term efficacy in axillary hyperhidrosis.[13]

There are many studies in the past that have shown the efficacy of BtxA in the treatment of axillary hyperhidrosis. Heckman *et al*. conducted a multicentric randomised blinded study with BtxA and placebo and showed that there was decrease in the sweat rate from 192 mg/min to 24 mg/min compared to 144 mg/min in the placebo group. This was similar to the efficacy shown in the toxin group in our study.[14] The recurrence of the symptoms varied from 4 to 17 months in various studies. The exact mechanisms of recurrent hyperhidrosis after intradermal injection of BtxA are unknown. It has been consistently shown that new nerve endings grow within 3 months after intramuscular injection of BtxA;[15] however, sympathetic nerve endings that innervate the sweat glands have not been studied. Resistance to BtxA occurs in up to 5% of patients with dystonia[16] and has been attributed to the induction of antibodies against BtxA. This has not been seen in any of the studies conducted in patients with axillary hyperhidrosis. Other prospective trials have shown similar efficacy in the treatment of axillary hyperhidrosis using variable doses of toxin.[17,18] No adverse events have been reported in the past, similar to our study.

In the last few years, tumescent suction curettage has emerged as one of the surgical treatment modalities in axillary hyperhidrosis.[19] This technique is performed under local anaesthesia, and the tumescent fluid containing saline, bicarbonate, epinephrine and lidocaine is used. Tumescent solution compresses the blood vessels in the fibrous septae and prevents bleeding. There is a reduced infection rate due to open drainage, and chances of haematoma formation are minimal not only because of pure compression but also because of the prolonged action of epinephrine.[20]

There are very few studies comparing the efficacies of surgical modalities and BtxA injections in axillary hyperhidrosis.

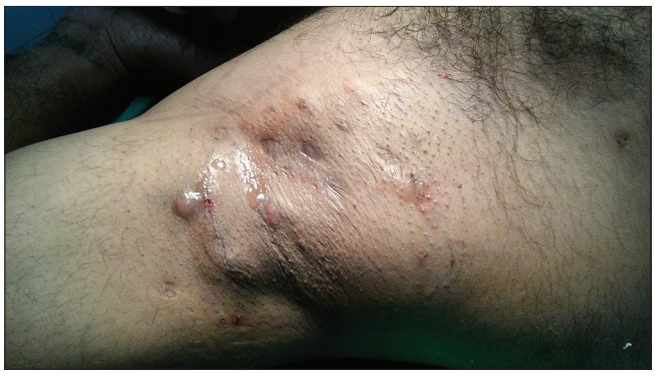

Figure 7: Hidradenitis suppurativa

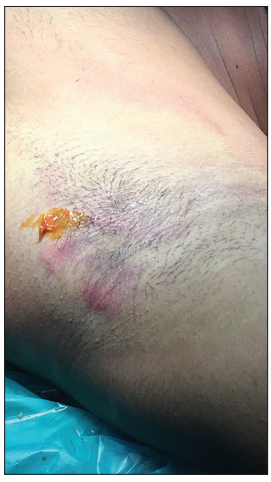

Figure 8: Post-operative bruising

Although suction curettage is a well-established procedure, there are hardly any randomised controlled studies comparing its efficacy. Only one study by Ibrahim *et al*. compared suction curettage with botulinum toxin injection, and they found by objective measures 3 months after treatment, that neurotoxin injections are nominally more effective than suction-curettage in all cases, and markedly more effective in heavy sweaters.[21] BtxA required repeated intradermal injections, which is very expensive and is not covered by public health insurance system in India. In this study, we compared subcutaneous curettage with BtxA injection in the same patient with different modalities on each axilla. The results of this study, showed that the sweat rate assessed by gravimetry decreased significantly with both the modalities of treatment and were similar in efficacy, contrary to what was found in the study by Ibrahim *et al*. A study[22] done on the efficacy of suction curettage showed a 75% decrease in the sweat rate which was similar to our study. Bechara *et al*.[12] conducted a study comparing one hole liposuction cannula, three hole liposuction cannula and a sharp suction curettage cannula, and found that sharp suction curettage cannula resulted in highest reduction of sweat rates. In our study, we used three hole liposuction cannula with similar efficacy and no adverse events.

With regards to the treatment-related adverse events, both BtxA and subcutaneous curettage had no major adverse events. However, the few minor adverse events that occurred was with subcutaneous curettage. Apart from the normal physiological scar, two patients had post-operative echymoses and one of them had bridle formation. The adverse event profile was comparable with previous studies[23] and none of them were severe. Patients were fully satisfied with the procedure and had no long lasting complaints.

There have been no controlled studies in the past regarding duration of action of suction curettage. Various studies have mentioned the different duration of action because of the difference in the operative technique used. None of the cohorts were followed beyond a year. In our study patients were followed up for duration of 6 months. Although there was an increase in the HDSS score compared to the score at 3rd month, in both the treatment arms, it was not statistically significant. Patients were still satisfied with the response of both treatment modalities.

Limitations and Conclusion

The limitation of our study was that patients were followed up for only 6 months duration to avoid loss to follow-up. Follow-up after 6 months showed that both BtxA intradermal injections and subcutaneous curettage of sweat glands in the axilla were equally effective as per the objective gravimetry analysis and subjective HDSS score. Few minor adverse events were observed with the surgical modality alone. In view of the expenses involved with BtxA injections, considering the affordability in Indian setup, the tumescent subcutaneous curettage technique can be a preferable option with long-lasting efficacy.

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Conflicts of interest

There are no conflicts of interest.

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