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Randomized Controlled Trial

Dual Stellate Ganglion Blocks for Managing Treatment-Resistant Anxiety Disorder: A Randomized, Double-Blind, Placebo-Controlled Trial

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Background: Anxiety disorders are associated with a high burden of illness. In patients with treatment-resistant anxiety disorder, management options can be limited. Stellate ganglion block has been reported to reduce anxiety symptoms in Posttraumatic Stress Disorder.

Objectives: We aimed to determine dual stellate ganglion block's effectiveness for reducing anxiety symptoms in moderate to severe treatment-resistant anxiety disorder.

Study Design: This double blinded, sham procedure, randomized controlled trial used a 2:1 active treatment to sham (control) treatment ratio.

Setting: Pain Medicine clinic at Sri Madhusudan Sai Institute of Medical Sciences & Research, a tertiary care medical college in the Republic of India.

Methods: Study patients were screened by an interdisciplinary team comprising a pain medicine physician, a psychiatrist, and a clinical psychologist. Participants and assessors were blinded. Adult patients with treatment-resistant moderate to severe anxiety disorder (a Generalized Anxiety Disorder-7 [GAD-7] scale score of ≥ 10) were included in the study. Patients with Posttraumatic Stress Disorder were excluded. Patients received either dual ultrasound-guided stellate ganglion blocks or a sham treatment.

Results: The primary outcome measure was the GAD-7 scale score at postintervention week 4. Of 87 screened individuals, 63 were eligible (72.4%); 20 were men and 43 were women; mean (SD) age, 38.4 (10.3) years. They were randomized (42 to the Stellate Ganglion Blocks Group and 21 to the Control (Sham) Group; 62 (98.4%) completed the study. In an intent-to-treat analysis, the mean total GAD-7 score change at postintervention week 4 was -9.6 points for the Stellate Ganglion Blocks Group, compared with -3.6 points for those receiving the sham/control treatment (mean difference -6.2; 95% CI,-9.3 to -3.2; $P < 0.001$).

Limitations: This was a single-center study with a limited follow-up period.

Conclusion: In this trial of patients with treatment-resistant anxiety disorder, dual stellate ganglion blocks were effective in reducing GAD-7 scores for 12 weeks postintervention. Further studies are recommended to assess the durability beyond 12 weeks and elucidate the mechanism of action of stellate ganglion block.

Key words: Anxiety disorder, treatment resistance, stellate ganglion block, dual SGB, autonomic dysfunction, ultrasound-guided

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Anxiety disorders constitute a variety of conditions. They include health anxiety, generalized anxiety disorder, social phobia, and panic disorders (1). They have a lifetime prevalence of approximately 34% in the United States (1). In 2017, it was reported that over 44 million people had an anxiety disorder in India (2). Poorly controlled anxiety disorders often cause significant dysfunction that can affect quality of life (3,4). The standard care for anxiety disorders includes pharmacological agents and psychotherapy (5). In patients who do receive care, poor compliance and treatment resistance are not uncommon.

Treatment-resistant anxiety disorders are diagnosed when patients fail to respond to an 8-week trial of at least one first-line medication and psychotherapy (5). These patients have limited options to manage their symptoms. In patients who do respond, recommendations suggest a 12-month medication course, making compliance challenging (6). In addition, there is a high risk of relapse when treatment is discontinued. The effectiveness of cognitive behavioral therapy for anxiety disorders is well recognized (6). However, there is minimal engagement with psychotherapy in rural India (7,8). In addition, there is inadequate implementation of mental health services with a high treatment gap in India (9). It is reported that people with poorly controlled mental health disorders die prematurely and have excess disability (10,11). Given the significant shortage of mental health personnel in India, innovative strategies and an integrated approach are needed to enhance mental health care delivery to patients with anxiety disorders (10-12).

In anxiety disorders, there is evidence of dysregulation and overactivation of the sympathetic nervous system (13-15). The stellate ganglion is a cervical sympathetic ganglion that has extensive connections with various parts of the brain involved in emotional regulation, including the amygdala, anterior cingulate, and insular cortex (16,17). A stellate ganglion block (SGB) produces a sympatholytic effect. SGBs have been shown to reduce anxiety in patients with Posttraumatic Stress Disorder (PTSD) as well as decrease night awakening in patients with breast cancer (18). The therapeutic effect of an SGB could be explained by the inhibition of complex neuronal connections between the stellate ganglion and the brain (18,19). SGBs have also been shown to benefit treatment-resistant mental health disorders, including bipolar disorder, tramadol addiction, and major depressive disorder (20,21).

We conducted a randomized, double-blinded, placebo-controlled study that evaluated the effectiveness of dual SGBs for treatment-resistant anxiety disorder. A dual SGB was defined as a planned right SGB followed by a left SGB, performed within an interval of 1–7 days.

Methods

Our study was approved by the Institutional Ethics Committee at Sri Madhusudan Sai Institute of Medical Sciences and Research (IEC/Certificate/01/2024). It was registered at the Clinical Trials Registry of India (CTRI) and given the registration number CTRI/2024/02/063259. At enrollment, all patients provided written informed consent after receiving a complete description of the study.

Study Design and Patients

Patients were enrolled from February 2024 through April 2025. This study was conducted at Sri Madhusudan Sai Institute of Medical Sciences and Research, a newly established tertiary medical center in rural South India. The primary outcome measure, the Generalized Anxiety Disorder (GAD-7) scale, was assessed at baseline and at postintervention week 4.

Trial Patients

Adult patients presenting with treatment-resistant moderate to severe anxiety disorder (a GAD-7 score of ≥ 10) were included in the study.

Patients presenting with anxiety disorders were initially seen in a psychiatry clinic and offered medical management. Psychological therapy was offered to all. Patients presenting with moderate to severe anxiety disorders despite first-line management were reviewed by an interdisciplinary team comprising a pain medicine physician, a psychiatrist, and a clinical psychologist to confirm the diagnosis of treatment-resistant anxiety disorder and rule out PTSD.

Treatment-resistant anxiety disorder was defined as (5):

1. Failed pharmacotherapeutic treatment with at least one first-line treatment (selective serotonin reuptake inhibitor antidepressants, tricyclic antidepressents, or serotonin-norepinephrine reuptake inhibitor antidepressants) for at least 8 weeks and
2. Failed psychotherapeutic treatment with at least one first-line psychotherapeutic treatment (e.g., cognitive behavioral therapy) for at least 8 weeks.

Key exclusion criteria included PTSD, prior SGB treatment, recent myocardial infarction, dual antiplatelet therapy, glaucoma, and cardiac conduction block.

Trial Treatment

The research team, who were unaware of treatment allocation, administered 2 questionnaires (GAD-7 and the Hamilton Anxiety Rating Scale [HAM-A]). After completing the baseline questionnaires, patients were assigned to the pain medicine physician. Prior to their procedure, patients were assigned via block randomization to either the SGB Group or the Control (Sham) Group in a 2:1 allocation to ensure adequate numbers of patients in the SGB Group. Allocation was generated by a blinded statistician. Only the treating physician was aware of each patient's group allocation.

All interventions were performed in an outpatient setting using real-time ultrasound guidance with an in-plane technique; all patients had standard cardiovascular monitoring. Patients were premedicated with one mg of intravenous midazolam for sedation and to increase their seizure threshold.

For the SGB Group, an anterolateral approach was used after carefully scanning the neck anatomy with Doppler imaging to identify common structures and vascular anomalies. The needle was visualized under real-time ultrasound guidance through the sternocleidomastoid muscle until the needle tip penetrated the ventral fascia of longus colli, dorsal to the common carotid artery. Slowly, over a minute, 9 mL of a mixture (7 mL 0.2% ropivacaine, 1 mL 2% lidocaine, and a 20 mg depot of methylprednisolone) was injected (20). The procedure was repeated on the left side after 24 hours and within 7 days (20,22).

For the Control Group, the skin over the anterolateral neck was infiltrated with 2 mL of lidocaine. Thereafter, under ultrasound guidance, 2 mL of normal saline were injected into the musculature in the anterolateral neck.

Assessments at postintervention weeks 4 and 12 were completed by independent assessors who were blinded to the treatment allocation. As per the protocol, patients in the Control Group were offered dual SGBs when they completed the postintervention 12-week outcome measures.

Outcome Measures

The primary outcome was the change from baseline to postintervention week 4 in GAD-7 scores, which range from 0 to 21 points, with higher scores indicating greater anxiety symptom intensity.

Secondary outcomes included estimated differences in mean GAD-7 scores at baseline and postintervention week 12. The estimated differences in mean HAM-A scores at baseline, and at postintervention weeks 4 and 12 were also assessed. In addition, the Patient Global Impression of Change (PGIC) measure was recorded at postintervention weeks 4 and 12.

We collected information on adverse events via patient report. All reported adverse events were tabulated. Formal statistical analyses of these adverse events were not performed.

Statistical Analysis

The sample size was based on showing a difference in the primary outcome, the GAD-7 score, between groups. A difference of 5 units between groups was considered a clinically important difference. Based on previous research, the standard deviation of the GAD-7 questionnaire scores is estimated to be 6.2 units (23). Assuming a 2:1 allocation in favor of the SGB Group, and a 5% significance level and 80% power, it was calculated that 19 patients were required for the Control Group and 38 for the SGB Group. Allowing for a 10% attrition rate, it was proposed to recruit 63 patients (42:21) for the study. We analyzed the primary outcome and the secondary outcomes with an Analysis of Covariance (ANCOVA). The outcome variable was the score at either postintervention week 4 or 12, with the equivalent at baseline included as a covariate in the analysis. Patient Global Impression of Change scores were analyzed using the Mann-Whitney U test. Missing data for both the primary and secondary outcomes were treated as missing at random for all analyses. All analyses were done using Stata version 15.1 (StataCorp LLC).

Results

Patient Disposition and Characteristics

The first patient was recruited on February 28, 2024. A total of 87 patients were screened and 63 patients were randomized to treatment; (72.4%). Of these, 20 were men and 43 were women. Their mean (SD)age was 38.4 (10.3) years. Their group allocation was 42 to the SGB Group and 21 to the Control Group. Of these, 62 patients (98.4%) remained in the study through the postintervention 12-week assessment (Fig. 1). One patient (1.6%) withdrew from the study.

Table 1 details demographic and clinical characteristics. Baseline characteristics were similar in the 2 treatment groups. In particular, initial GAD-7 scores were similar. Mean (SD) baseline HAMA-A scores (SGB Group, 26.4 [16.9]; Control Group, 24.6 [5.1]) were also similar.

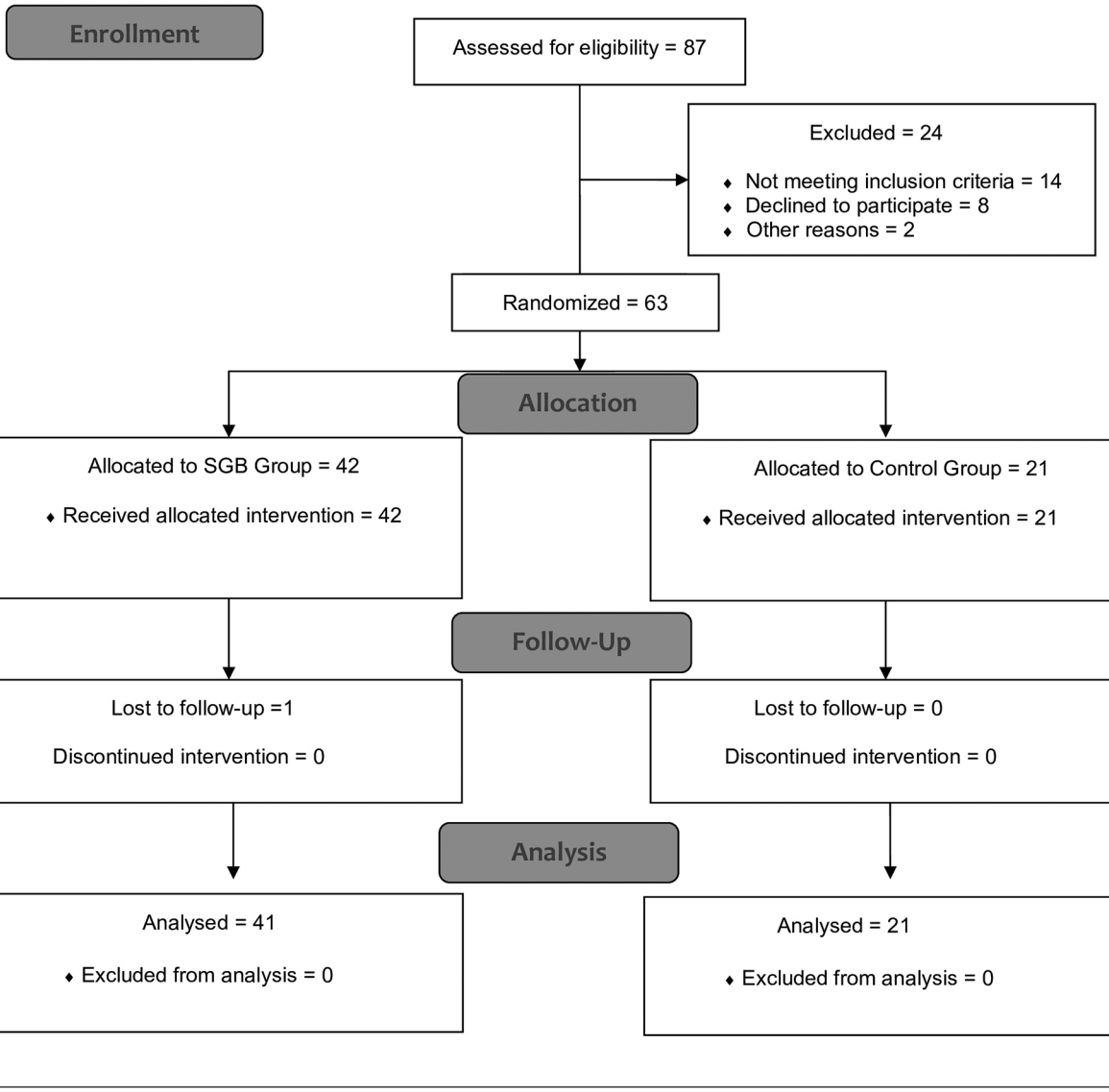

Fig. 1. *Consolidated Standards of Reporting Trials (CONSORT) flow diagram.*

First Line Management

The mean number of medication failures was 2.4 in this cohort. Forty-six patients (73%) had trialed at least 2 or more medications. These included first-line antidepressants—serotonin-norepinephrine reuptake inhibitors, selective serotonin reuptake inhibitors, and tricyclics— as well as gabapentinoids, and benzodiazepines.

Psychotherapy was offered to all patients. Only 20 (32%) underwent this therapy, while the remaining declined.

Efficacy Outcomes

There was a significant reduction in GAD-7 scores from baseline at the primary as well as secondary endpoints. Table 2 presents the primary and selected secondary outcomes by group. The reduction in the GAD-7 score at postintervention week 4—the primary endpoint—among those in the SGB Group was greater than the reduction in those in the Control Group (mean group difference -6.2; 95% CI, -9.3 to -3.2; $P < 0.001$).

The secondary outcome measure provides evi-

dence of the effectiveness of SGBs for anxiety disorders at postintervention week 12 (Table 2). Those in the SGB Group, compared to the Control Group, had both clinically and statistically improved HAM-A scores at postintervention weeks 4 and 12 as well as their GAD-7 scores at postintervention week 12.

There was a clinically significant group difference in Patient Global Impression of Change scores at postintervention weeks 4 and 12. At both timepoints, the scores in the SGB Group were superior to that in the Control Group. At postintervention week 4, 61% of patients in the SGB Group had definitive improvement or were a great deal better when compared to 10% of patients in the Control Group. The group differences were similar at postintervention week 12. Only 16% of patients in the SGB Group reported no change or were almost the same. In contrast, 63% of the Control Group reported no or a minimal change in anxiety symptoms.

Blinding Index

The blinding success was calculated using the James index, which was 0.68 (95% CI, 0.56 to 0.80).

Crossover

Five patients in the Control Group reported a clinically significant benefit. The remaining 16 patients in the Control Group chose to receive dual SGBs at the end of the study period. A clinically significant benefit was reported by 14 patients (88%) at the 12-week follow-up, while 2 patients reported no change in anxiety symptoms.

Safety Outcomes

Safety outcomes are an important consideration. Of the 15 events reported in the SGB Group, none were serious. Transient voice hoarseness lasting between one to 3 hours was reported by 14 (33%) patients. One patient reported upper limb numbness that resolved in 6 hours.

Discussion

We conducted the first randomized controlled trial evaluating the effectiveness of dual SGBs for managing treatment-resistant anxiety disorder. Our study shows that dual SGBs with steroids are effective for significant symptom reduction at postintervention weeks 4 and 12 when compared to a Control Group who received a sham procedure (Fig. 2). To date SGBs have been formally evaluated in PTSD and depression (21,23,24). These studies reported the effectiveness of a single-sided (right side) SGB with local anesthetic agent; the follow-up period was 8 weeks (21,23,24). In addition, Lynch et al (22) reported that an SGB reduced anxiety by half in a large case series. However, this retrospective, single-cohort study included patients with PTSD; both single and dual SGBs were performed with only a local anesthetic and outcomes were reported at only at postintervention week 4 (22). In contrast, our study on dual SGBs with a local anesthetic and steroid

Table 1. *Study patients' demographics.*

	Control (Sham Group) (n = 21)	SGB Group (n = 42)	Total (N = 63)
Age (y)	38.5 (11.1)	38.3 (10.1)	38.4 (10.3)
Gender (n [%])			
Men	7 (33%)	13 (31%)	20 (32%)
Women	14 (67%)	29 (69%)	43 (68%)
BMI (kg/m²)	24.7 (6.9)	23.1 (4.3)	23.7 (5.2)
Duration since diagnosis	4 (2–7)	3 (1–8)	4 (1–8)
Medications trialed (N)	2 (1–3)	2 (1–3)	2 (1–3)
Co-morbidities			
0	17 (81%)	34 (81%)	51 (81%)
1	1 (5%)	5 (12%)	6 (10%)
> 2	3 (14%)	3 (7%)	6 (10%)

Data are presented as mean (SD); median (interquartile range); or number (percentage). SGB, stellate ganglion block.

Table 2. *Change in Generalized Anxiety Disorder-7 (GAD-7) and Hamilton Anxiety Rating Scale (HAM-A) scores at postintervention weeks 4 and 12.*

Outcome	Timepoint	Control (Sham) Group		SGB Group		Group Difference	
		n	Mean (SD)	n	Mean (SD)	Mean difference (95% CI) (*)	*P* Value
GAD-7	Baseline	21	16.9 (1.8)	42	16.6 (2.9)		
	4 weeks	21	13.4 (6.3)	41	7.0 (5.5)	-6.2 (-9.3 to -3.2)	< 0.001
	12 weeks	20	13.5 (5.9)	41	7.0 (6.2)	-6.2 (-9.3 to -3.0)	< 0.001
HAMA-A	Baseline	21	24.6 (5.1)	41	26.4 (6.9)		
	4 weeks	21	18.5 (7.8)	41	12.4 (8.2)	-6.5 (-10.9 to -2.2)	0.004
	12 weeks	20	17.6 (7.8)	41	12.8 (9.1)	-5.4 (-10.1 to -0.6)	0.03

(*) Group differences calculated as the outcomes for the Stellate Ganglion Block (SGB) Group minus the outcomes for the Control Group adjusted for outcome values at baseline.

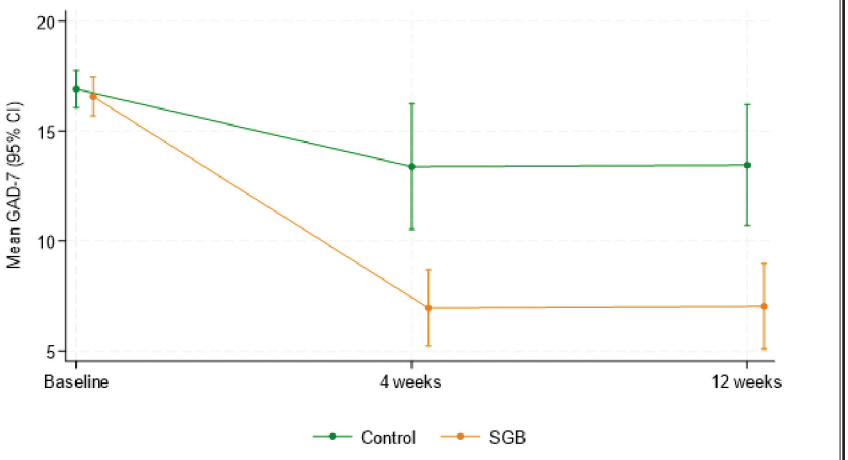

Fig. 2. *Generalized Anxiety Disorder-7 (GAD-7) scores over time.*

mixture excluded patients with PTSD, and the follow-up period was 12 weeks. Our results are congruent with case series that have reported SGB's benefit for mitigating anxiety symptoms in patients with heterogenous mental health disorders (20,22,23).

In 2021, more than 350 million people in the world were diagnosed with anxiety disorder, making anxiety disorders the most common of all mental health disorders (25). India, with a population of 1.4 billion, has over 44 million with anxiety (2). Anxiety disorders come with a significant illness burden (6). In India, the current management of anxiety disorders relies primarily on pharmacotherapy with very few centers offering psychological therapy. The scenario is far worse in rural India, where more than 60% of the population resides. The mental health professional to patient ratio is skewed toward urban centers. Innovative treatment strategies are required for enhancing mental health care delivery across the subcontinent (2).

Interdisciplinary collaboration among psychiatrists, clinical psychologists, anesthesiologists, and pain medicine physicians has the potential to enhance mental health delivery. Currently, there is minimal interaction among these specialties in routine practice, with the exception of electroconvulsive therapy. In our study, all patients were assessed by an interdisciplinary team comprising a pain medicine physician, psychiatrist, and a clinical psychologist. This close collaboration has vastly improved the quality of care provided to patients with heterogenous treatment-resistant mental health disorders at our center (20).

The therapeutic effect of an SGB could be explained by the inhibition of complex neuronal connections between the stellate ganglion and the brain (18,19). It is proposed that an SGB could downregulate sympathetic overactivity, thereby reducing the affective fight or flight symptoms seen in anxiety disorders (26). Emotional reasoning and anxiety sensitivity are 2 constructs reported in developing anxiety disorders (26). Emotional or ex consequentia reasoning is the phenomenon whereby individuals with elevated anxiety infer threat from their subjective anxious experiences (i.e., "If I'm anxious, there must be danger") (27). Emotional reasoning and anxiety sensitivity are reported to be causally involved in the persistence of anxiety disorders and PTSD (26,28). Mitigating these phenomena could explain the effectiveness of an SGB in both PTSD and anxiety disorders (29).

An ultrasound-guided SGB is a safe procedure that can be performed in an outpatient setting (20,22,30,31). However, the technique requires significant skill and care. Ultrasound guidance can mitigate the side effects reported following an SGB (23,30).

Strengths and Limitations

Our study supports the effectiveness of dual SGBs for treatment-resistant anxiety disorders. The strengths of our study include its interdisciplinary collaboration among 3 heterogeneous specialties, high internal validity, and an adequately powered study with an excellent retention rate. In addition, it is the first trial evaluating the effectiveness of an SGB in treatment-resistant anxiety disorder.

Limitations include that it is a single-center study with a limited follow-up period. Only a third of the patients received psychotherapy. A majority of our cohort were from rural India; they were not interested in engaging with psychotherapy. This is congruent with other published reports (7,8). The durability of dual SGBs for anxiety disorders requires further evaluation. The addition of steroids might have a role in enhancing the durability of SGB (20). However, using particulate

steroids in an SGB requires an assiduous technique, as inadvertent intravascular injection can cause significant neurological adverse effects.

Conclusion

Dual SGBs are a treatment option for patients with moderate to severe treatment-resistant anxiety disorder. Multidisciplinary collaboration among medical specialities has the potential to enhance mental health care delivery, especially for patents with treatment-resistant disorders. Further studies are recommended to confirm these findings, assess the durability of SGBs beyond 12 weeks for treatment-resistant disorders, and identify the precise mechanism of action of an SGB. The role of steroids in an SGB requires further evaluation.

Data Statement

The authors confirm that redacted identifiable patient data are available on email request addressed to the corresponding author.

Author Contributions

1. G Niraj: conception and design, intervention performance, data interpretation, drafting the article, and final approval of the submitted version.
2. Varsha Karanth: conception and design, data collection, data interpretation, drafting the article, and final approval of the submitted version.
3. N Charan: study design, drafting the article, and final approval of the submitted version.
4. Shruti Niraj: conception and design, data collection, data interpretation, drafting the article, and final approval of the submitted version.
5. A Aiswarya: study design, data collection, drafting the article, and final approval of the submitted version.
6. Paul Bassett: conception and design, data analysis, drafting the article, and final approval of the submitted version.

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