Evaluation of Efficacy and Safety of Low Dose Glycopyrrolate in Management of Primary Hyperhidrosis---An Open Label Single Arm Study

Sir,

Hyperhidrosis can hinder the social life of patients, lower their quality of life, and may even result in psychological problems such as depression.[1] Therefore, treatment is essential for these patients, and various treatment methods are being attempted. We conducted an open label prospective interventional study on 50 patients with primary hyperhidrosis at our tertiary care centre for a period of one year (October 2018 to September 2019).

After designing appropriate inclusion and exclusion criteria, oral glycopyrrolate 2 mg daily was given to every patient for a duration of 6 weeks and cases were followed weekly till the end of 6th week to note the response and any adverse events. Hyperhidrosis Disease Severity Scale (HDSS) and Dermatology Life Quality Index (DLQI) were used to assess the severity of hyperhidrosis and impact of disease on QOL respectively. The response was considered "excellent" when the HDSS score decreased by 2 points (which correlated with an 80% improvement in hyperhidrosis), or when a final score of 1 was achieved. A "partial response" was defined as an improvement of 1 point. The treatment was considered as failure when the HDSS score remained similar or worsened, or if there was intolerance to treatment. HDSS and DLQI were calculated at baseline and at the end of 6 weeks. The response to treatment were assessed by comparing pre-treatment and posttreatment scores using appropriate statistical tools. P value <0.05 was considered as cut off value for significance.

Out of total 50 patients, 39 (79%) had severe hyperhidrosis and 11 (21%) had moderate hyperhidrosis. One patient dropped out from the study due to dryness of mouth, constipation, and abdominal pain. Thus, a total of 49 patients were available for the final analysis. Demographic and clinical characteristics are shown in Table 1. The areas where hyperhidrosis occurred most frequently were, in descending order, the hands, feet, axillae, and craniofacial. 18.4% of the patients were confirmed to have symptoms in only one area, while 71.4% had symptoms in two areas and 10.2% had symptoms in three or more areas simultaneously. 85% of females had severe hyperhidrosis as compared to 75.86% of male patients. A total of 37 patients (75.5%) showed excellent response to treatment. Out of remaining 12 patients, 6 (12.2%) showed partial response and 6 patients (12.2%) did not responded to treatment. The palmar and plantar hyperhidrosis responded better as compared to axillary and craniofacial hyperhidrosis. The mean time taken for improvement of hyperhidrosis being 4.26 days after starting treatment. The HDSS score at the baseline (3.22 ± 0.77) was significantly improved at the end of study (i.e., at 6 weeks) (1.63 ± 0.72) (Z score 5.71; $P < 0.0001$). This corresponds to actual decrease in perspiration in 87.75% of patients [Figure 1]. The pre-treatment DLQI (19.32 ± 5.5) improved to (8.02 ± 4.76) after medication, providing confirmation that the discomfort level in everyday life had also decreased (Z score 6.03; $P < 0.0001$) [Figure 2]. The correlation between HDSS score and DLQI score were sought both before and after treatment. There

Table 1: Patient characteristics

No. of patients	49
Mean age, years	19.59±7.76
Gender	Male 29 (59.18%)
	Female 20 (40.82%)
Sites affected	
Palmar	7 (14.3%)
Palmoplantar	31 (63.3%)
Axillary	1 (2%)
Palmar, axillary	3 (6.1%)
Craniofacial	1 (2%)
Palmar, Craniofacial	1 (2%)
Palmoplantar, Craniofacial	5 (10.2%)
Duration of disease, year	7.80±6.94
Time for improvement, days	
Male	4.37±1.04
Female	4.10±1.11

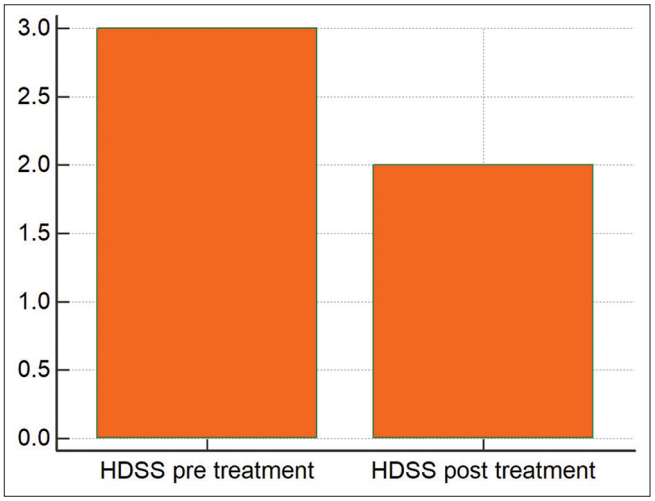

Figure 1: Bar diagram showing comparative analysis of pre and post treatment HDSS. The scores at the baseline was significantly improved at the end of study (i.e., at 6 weeks)

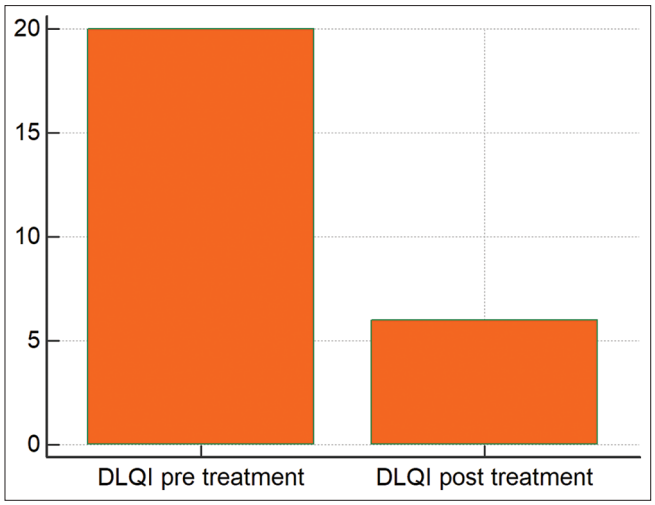

Figure 2: Bar diagram showing comparative analysis of pre and post treatment DLQI. There was statistically significant improvement in quality of life of patients after treatment

was statistically significant positive correlation in both pre-treatment scores (r = 0 0.89; P value <0.0001) and posttreatment scores (r = 0.79; P value <0.0001). Out of 49 patients, 18.3% patients experienced side effects (dryness of mouth 16.3% and palpitation 2%).

Primary hyperhidrosis results due to idiopathic overactivity of sympathetic tone to sweat glands, which in turn due to a higher expression of acetylcholine and alpha-7 nicotinic receptors in sympathetic ganglia.[2] Approximately, 3% of world's population are suffering from this medical condition.[3] Various studies have shown the efficacy of systemic agents in the treatment of hyperhidrosis. The drugs most commonly studied are oxybutynin, clonidine, and glycopyrrolate and sedatives but none is approved for this condition.[4] Non-invasive treatment possibilities include topical agents, botulinum toxin, iontophoresis, and microwave thermolysis. Glycopyrrolate is an anticholinergic having better affinity at muscarinic receptors and structural properties rendering it less permeable through the blood-brain barrier, thus the central nervous adverse effects are significantly reduced, thus it seems a good oral agent to be considered in the cases of primary hyperhidrosis.[5,6]

Despite the limitations of our study as small sample size, open label study design and lack of objective assessment of efficacy, the results from our study are encouraging and we consider low dose glycopyrrolate as cost effective, efficacious, and safe option in management of primary hyperhidrosis.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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