Quality of Life Improvement Shown During Sahara Clinical Study on the TAT Patch for the Treatment of Primary Axillary Hyperhidrosis or Excessive Axillary Sweating

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Background

Hyperhidrosis, or excessive sweating, has been shown to limit social or work life, inhibit physical or leisure activities, and impair emotional and mental well-being.[1] In fact, it has been reported that 71% of individuals with excessive sweating experience anxiety from sweating.[1] As such, the use of patient-reported outcomes that evaluate effectiveness of treatments based on the quality-of-life (QoL) factors for individuals impacted by sweating are of high importance in assessing the success and benefits of any sweat reduction treatment.

Targeted Alkali Thermolysis (TAT) is a new technology that has been developed for sweat reduction by using localized thermal energy to target sweat glands and reduce excessive sweat production.

Methods

The Sahara Study was a randomized, double-blind, sham-controlled pivotal study to evaluate a TAT patch (Brella™ SweatControl Patch, Candesant Biomedical, Nashville, TN) for the treatment of primary axillary hyperhidrosis, or excessive axillary sweating.

110 adults with Hyperhidrosis Disease Severity Scale (HDSS) scores of 3 or 4 and Gravimetric Sweat Production (GSP) greater than 50 mg/5 minutes were treated bilaterally with either an active (TAT) or sham patch for up to 3 minutes.

HDSS, GSP, and QoL Assessments were measured through 12 weeks, with responders followed for 24 weeks. The additional QoL measures included: Degree of Bother from sweating, Level of Impact of Sweating (both measured on a 5-point Likert scale), and the LIFe-7 (Life Impact Factors-7), a series of 7 binary (Yes/No) questions designed to assess the impact of sweating on both physical activities (e.g., number of showers, changing clothing) and psychosocial factors (e.g., levels of frustration, embarrassment, and confidence). The factors are listed in Figure 1.

Results

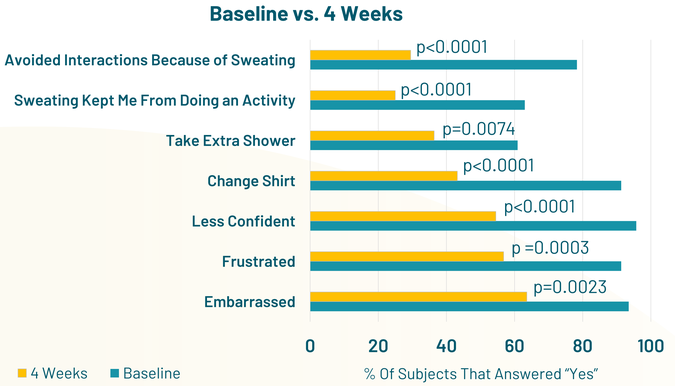
The TAT Patch was recently cleared by the FDA based upon the safety and efficacy endpoints from the Sahara Study; these data were previously reported.[2] In summary, efficacy was established by significant improvements in HDSS and GSP in subjects treated with TAT compared to a sham patch, and safety was demonstrated with the report of only mild or moderate adverse events (AEs), most of which resolved within 2 weeks. Duration of effect of 3 to 4 months was observed after the single treatment.

The additional QoL data collected during the Sahara Study are being presented here for the first time; the results further support the potential benefits of this technology. On average, the Degree of Bother from sweat was reduced by 1.52 points for active subjects vs. 0.61 points for sham subjects (p=0.0005), indicating the TAT-treated subjects went from being extremely/very bothered to being a little/moderately bothered by their sweat. Also, Impact of Sweating on daily activities was reduced by 1.44 points vs. 0.57 points (p=0.0004) in the active and sham groups, respectively. This demonstrated that daily activities were impacted a great deal or an extreme amount before treatment with the TAT Patch were only impacted a little bit or a moderate amount after treatment. Finally, LIFe-7 data (shown in Table 1) further confirm that treatment with the TAT Patch had a favorable effect on quality of life. For all 7 measures, there was a significant improvement compared to Baseline at both 4 and 12 weeks post-treatment with the TAT Patch. Of particular note was the significant improvement in confidence at (p<0.0001 and p=0.0001 at 4 and 12 weeks, respectively), significant reduction in limiting activities because of sweating (p<0.0001 at both time points) and the need to change shirts was significantly reduced (p<0.0001 at both time points).

Conclusion

Given the negative impact of sweating, patient perception on quality-of-life improvement is an essential measurement of success. Improvements in the emotional state and in the ability to engage in daily activities or social interactions were seen following treatment with the TAT Patch for patients in the Sahara Study for up to 12 weeks post-treatment. These data strongly support use of the TAT Patch for sweat reduction in subjects that suffer from excessive axillary sweating associated with primary axillary hyperhidrosis.

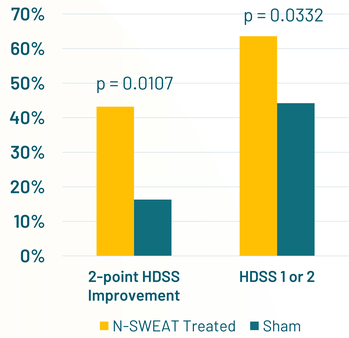
Figure 1. LIFe-7 Outcomes Summary



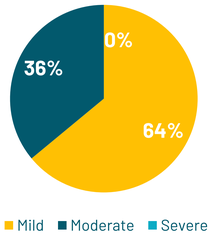
Pivotal Study: Achieved All Endpoints

Endpoints	TAT Patch n=44	Sham Control n=43
Mean Improvement QoL (Bother)	-1.52	-0.61
	p=0.0005	
Mean Improvement QoL (Impact)	-1.44	-0.57
	p=0.0004	

HDSS Improvement at 4-Weeks



Adverse Event Severity



References

[1] Doolittle J, Walker P, Mills T, Thurston J. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res. 2016;308(10):743-749. doi:10.1007/s00403-016-1697-9

[2] Glaser DA, Green L, Kaminer M, Smith S, Pariser D. Outcomes from the SAHARA Clinical Study on the TAT Patch for Excessive Axillary Sweating or Primary Axillary Hyperhidrosis. Late-breaking oral presentation at: American Academy of Dermatology annual meeting; March 17-21 (presented March 18, 10:10 am CT), 2023; New Orleans, Louisiana.

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Brella™ Duration of Effect is 3 to 4 months

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