Optimization of the Application Procedure for the Brella SweatControl Patch

Authors:

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Topic:

Hyperhidrosis

Purpose:

The Brella® SweatControl Patch has been recently cleared by the Food and Drug Administration (FDA) for the treatment of axillary hyperhidrosis in adults. The Brella Patch consists of a layer of sodium and an adhesive backing. When placed on a dry underarm, the sodium interacts with the water from the sweat glands creating thermal energy in a reaction called Targeted Alkali Thermolysis (TAT). The thermal energy created by the patch is mediated by how much and how quickly the individual patient sweats. Therefore, the patch application time varies from patient to patient and is dictated by what the patient feels during treatment. The Brella treatment protocol directed clinicians to treat patients who are actively sweating until the patient felt pain greater than 7/10 for up to 3 minutes. Optimization of this protocol could allow for more individualized treatments to better accommodate the significant variations in sweating seen in this patient population.

Further, as in most aesthetic procedures, it is critical to both set patient expectations and monitor improvement after the treatment. In most circumstances, photographs are taken "before and after" procedures to serve as tangible evidence of improvement. As sweat reduction benefits are not visible by a photograph, a standard treatment record was developed to record and monitor Quality-of-Life (QoL) changes before and after a Brella treatment intended to demonstrate what sweat reduction looks like for each patient.

Thus, an in-market assessment was conducted to understand if the Brella Patch could effectively be administered to patients allowed to sweat naturally with the patch application time tailored to each patient and to assess the feasibility of the standard treatment record to visualize sweat reduction after a Brella Treatment.

Design:

Trained clinicians were instructed to apply the patch to a dry axilla and allow the patient to sweat naturally and treat to tolerability, meaning that the patch should be removed as soon as the patient reports feeling pain or burning indicating that their treatment has been completed. If the patch was still in place after 9 minutes, it was removed.

A total of six (6) practices agreed to implement this new treatment approach and to document treatment details. They were also asked to use the 5-question sweat-related QoL survey included in the standard treatment record immediately before and 2-3 weeks after treatment for all patients.

Findings:

Data on 30 patients treated shows that the optimized treatment approach was safe with no adverse events reported. Additionally, the consistent use of the "Before/After" treatment record demonstrated measurable changes in quality of life helpful to visualize the impact of Brella on an individual patient's sweat.

The average and median patch application time was 5.9 minutes and 5.5 minutes, respectively. A secondary finding was that the overall time needed by the practice to offer the Brella treatment was reduced during this assessment as the patients no longer needed to take the time to start actively sweating for the procedure.

The efficacy of the treatment was also confirmed with this approach. On average patients reported being bothered by 3.8 of the QoL sweat behaviors in the standard treatment record before Brella treatment with improvement shown in 3.6 of these behaviors after Brella. Importantly, QoL improvements were seen in 100% of patients with a reduction in at least 1 sweat-related behavior and most patients (87%) showing improvement in at least 2 sweat-related behaviors. It is important to note that even those patients that showed a reduction in only1 or 2 QoL factors were satisfied with their overall outcome after discussing the survey with their clinician.

Summary:

The optimized procedure for the Brella Patch is safe and effective. This updated protocol allows practices to deliver a more individualized treatment taking into account that everyone sweats differently and that patch application times will necessarily vary to be able to meet the needs of all patients. Finally, the assessment also established that a QoL survey can be used to create a "before and after picture" by identifying specific behaviors that are related to sweating before treatment and defining sweat reduction for each patient by assessing the change in these behaviors after treatment.