Capsaicin 8% Patch Compared with Pregabalin in the Treatment of Nondiabetic Peripheral Neuropathic Pain: Elevate Trial

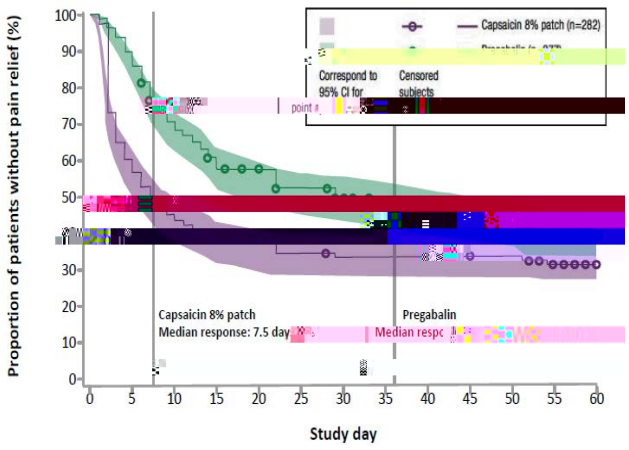
persisting for ≥3 months) were included. Patients with HIV-associated neuropathy (HIV-AN) were excluded [15].

Following the screening period, patients were randomized to receive the capsaicin 8% patch (n=282) or oral pregabalin (n=277). e capsaicin 8% patch (up to four patches) was given as a single 30-min application to the feet or as a single 60-min application to any other part of the body. Oral pregabalin was initiated at 75 mg/day and was increased by 75 mg every 3-4 days, up to the highest tolerated dose or 600 mg/day over the rst 4 weeks (one down-titration was allowed). From weeks 4-8, patients remained on an optimised pregabalin dosage of 150-600 mg/day as two or three divided doses. Noninferiority was achieved if the two-sided 95% con dence interval (CI) for the odds ratio (OR) of the capsaicin patch versus pregabalin was > 0.693 in both the full analysis set (FAS) and per protocol set (PPS) (Figure 1) [15].

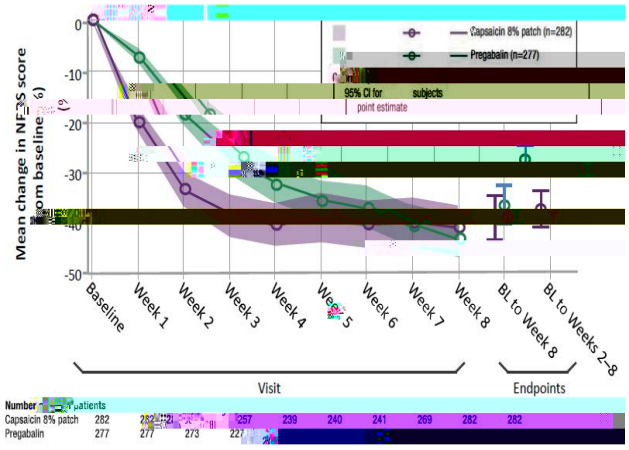
e capsaicin 8% patch was noninferior to an optimized dose of oral pregabalin in relieving pain in patients with moderate-to-severe peripheral neuropathic pain. e proportion of patients who achieved a ≥30% decrease in the average NPRS score from baseline to week 8 (primary endpoint) was 55.7% in the capsaicin 8% patch group compared with 54.5% in the pregabalin group. e between-group di erence (capsaicin 8% patch - pregabalin) was 1.2% (OR 1.03; 95%CI 0.71-1.49) in the FAS analysis and 0.3% (OR 1.03; 95% CI 0.70-1.52) in the PPS analysis. e median time to pain relief (where 50% of subjects had a 30% reduction in average daily NPRS score) was 7.5 days in capsaicin 8% patch recipients compared with 36.0 days in pregabalin recipients (adjusted hazard ratio 1.68; 95% CI 1.35-2.08; , <0.0001). Mean NPRS scores were reduced by 37.1 and 27.5% from baseline to between weeks 2-8 in the capsaicin 8% patch group and the pregabalin group, respectively (no signi cant between-group di erence) (Figure 2) [15].

According to a prespeci ed subgroup analysis, the proportion of capsaicin 8% patch recipients versus pregabalin recipients achieving a ≥30% decrease in the average NPRS score was 53.4 vs. 40.9% (treatment di erence +12.5%; 95% CI 1.0-24.1) in patients with peripheral nerve injury (n=283), 71.4 vs. 76.7% (-5.3%; 95% CI -20.1 to 9.5) in patients with PHN (n=136) and 46.6 vs. 58.2% (-11.6%; 95% CI -28.1 to 4.8) in patients with non-diabetic painful peripheral polyneuropathy (n=140). Of note, ELEVATE was not adequately powered for subgroup analyses [15].

Capsaicin 8% patch treatment signi cantly improved mean treatment satisfaction scores at week 8, as assessed by the Treatment



: Median time-to-onset of pain relief (FAS) [15].



BL: baseline; FAS: full analysis set;

NPRS: Numerical Pain Rating Scale

: Mean change in NPRS from baseline (FAS) [15].

Satisfaction Questionnaire for Medication scale, for patient perception of e ectiveness (59.1 vs. 54.8; treatment di erence 4.3; 95% CI 0.4-8.1), side e ects (95.3 vs. 74.1, treatment di erence 21.2; 95% CI 17.5-24.9) and global satisfaction (59.6 vs. 52.9; treatment di erence 6.7; 95% CI 2.3-11.2) compared with pregabalin treatment; there were no between-group di erences in convenience score (71.8 vs. 72.8) [15].

In summary, the capsaicin 8% patch was shown to be noninferior to oral pregabalin in nondiabetic adult patients with a variety of types of peripheral neuropathic pain. Importantly, the time to onset of pain relief was signi cantly shorter in the capsaicin than the pregabalin group. As patients with HIV were excluded, the comparative e cacy of capsaicin versus pregabalin in patients with HIV-AN is unknown.

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