

Healthcare Resource Utilization in Patients with Painful Diabetic Neuropathy Treated with 10-kHz Spinal Cord Stimulation: Results from a Randomized Controlled Trial

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Introduction

Painful diabetic neuropathy (PDN) affects around 20% of people with diabetes and is associated with higher healthcare resource utilization (HRU) compared with non-PDN patients with diabetes (Mehra 2014; Kiyani 2020). Conventional medical management (CMM) includes pharmacotherapy, which has limited efficacy and adverse side effects. High-frequency 10-kHz spinal cord stimulation (SCS) has demonstrated significant pain reduction in individuals with refractory PDN in a safe and effective manner (Petersen 2021).

Objective

The aim of this study is to determine the effect of 10-kHz SCS+CMM on HRU.

Methods

- HRU were collected during the SENZA-PDN randomized clinical trial (NCT03228420).
- HRU measures included hospitalizations, considered a serious adverse event, emergency department (ED) visits, physician office visits, and prescriptions at baseline, one, three, and six months follow up.
- HRU was compared between PDN patients treated with 10-kHz SCS+CMM and those treated with CMM alone. Results at 6-month follow up are reported as means ± standard deviations with 2-group student's t-test used to assess between group P-value.
- Patients who completed 6-month follow up were included in this study.

Results

Baseline characteristics of 216 randomized patients (CMM n=103; SCS+CMM n=113) are shown in Table 1. Of these randomized patients, 183 completed 6-month follow-up, (CMM n=95; SCS+CMM n=88).

Results (Continued)

- There was a trend towards a reduction in hospitalization rates for 10-kHz SCS+CMM patients compared to patients treated with CMM alone (0.08±0.27 vs. CMM-alone: 0.15±0.46; p=0.11) (**Figure 1**)
- There is evidence of lower average length of stay (LOS) per hospitalization for patients in the 10-kHz SCS+CMM arm than patients in the CMM alone arm (4.14±2.61 days vs. CMM-alone: 5.21±5.31; p=0.27) (**Figure 2**)

Table 1. RCT study patient demographics for patients in CMM vs. SCS+CMM arm

	CMM n=103	SCS+CMM n=113
Age in years, mean (SD)	60.8 (9.9)	60.7 (11.4)
Male, n (%)	66 (64%)	70 (62%)
Race		
White, n (%)	85 (82.5%)	87 (77.0%)
Black, n (%)	13 (12.6%)	18 (15.9%)
Native Hawaiian or Pacific Islander, n (%)	1 (1%)	3 (2.7%)
American Indian or Alaska Native, n (%)	0 (0%)	2 (1.8%)
Asian, n (%)	1 (1%)	1 (0.9%)
Other, n (%)	3 (2.9%)	2 (1.8%)
Diabetes		
Type 1, n (%)	3 (3%)	8 (7%)
Type 2, n (%)	100 (97%)	105 (93%)
Duration of Diabetes in years		
Diabetes, mean (SD)	12.2 (8.5)	12.9 (8.5)
Peripheral neuropathy, mean (SD)	7.1 (5.1)	7.4 (5.7)
Lower limb pain VAS in cm, mean (SD)	7.1 (1.6)	7.5 (1.6)
< 7.5 cm, n (%)	57 (55%)	54 (48%)
≥ 7.5 cm, n (%)	46 (45%)	59 (52%)
HbA1c, mean (SD)	7.4% (1.2%)	7.3% (1.1%)
< 7.0%, n (%)	40 (39%)	46 (41%)
≥ 7.0%, n (%)	63 (61%)	67 (59%)
BMI, mean (SD)	33.9 (5.2)	33.6 (5.4)

Figure 1. Hospitalization rates for patients observable at 6 months in CMM vs. SCS+CMM arm

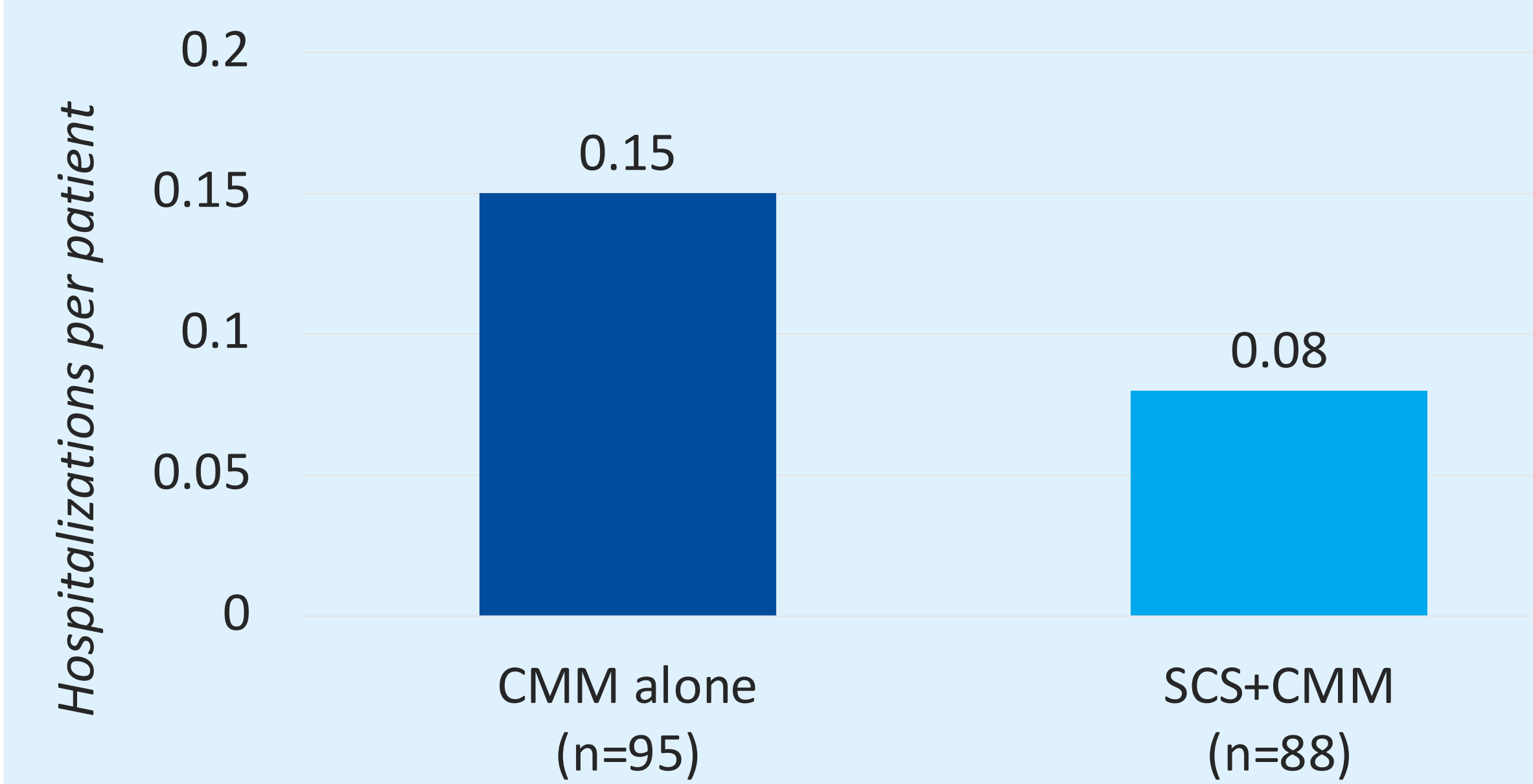


Figure 2. Average LOS per hospitalization for patients observable at 6 months in CMM vs. SCS+CMM arm

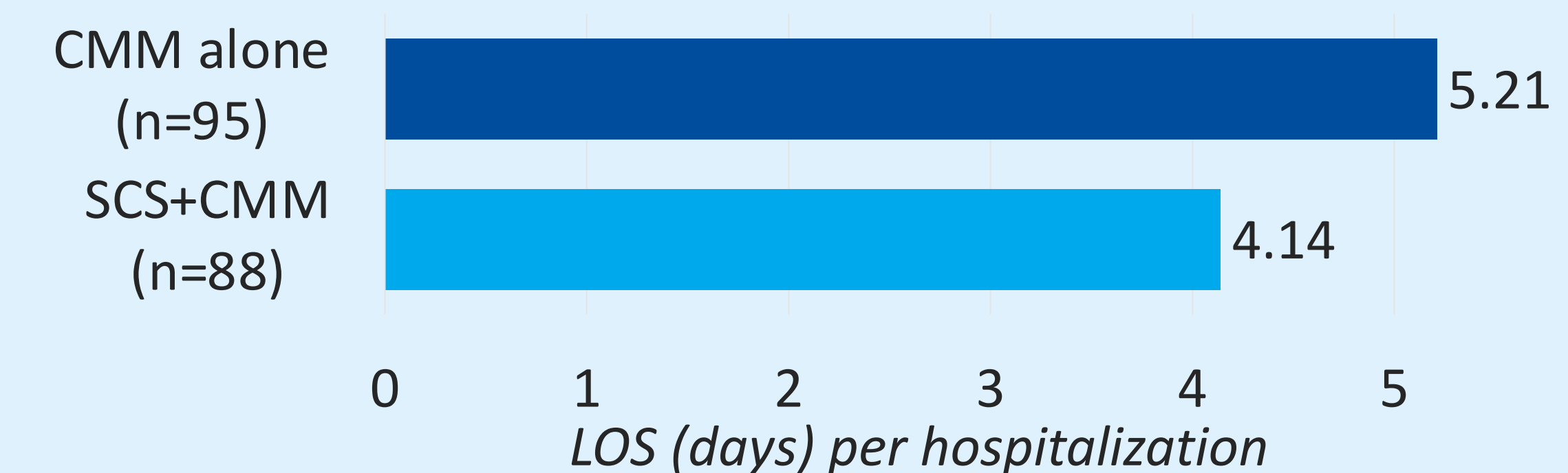
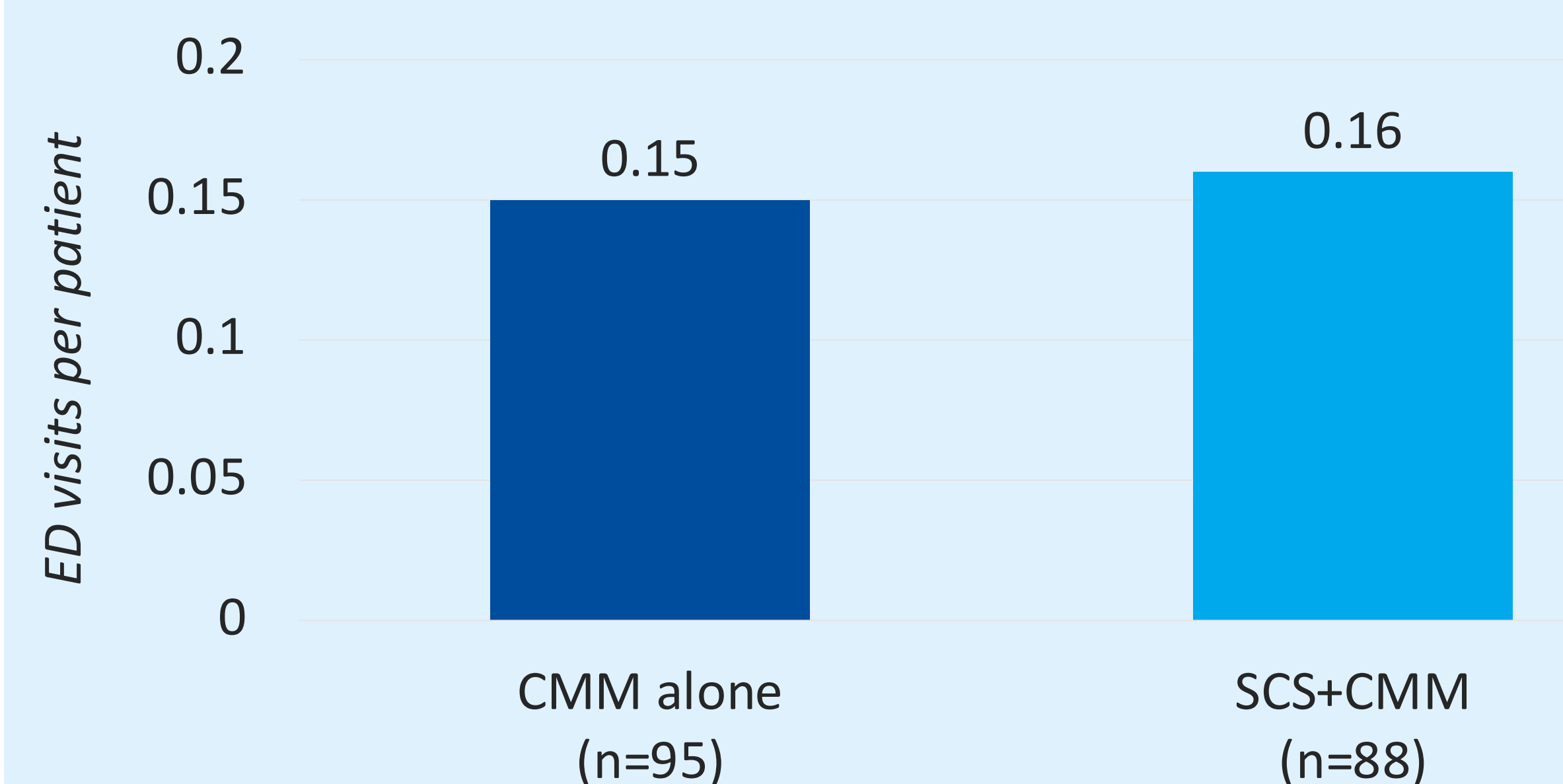


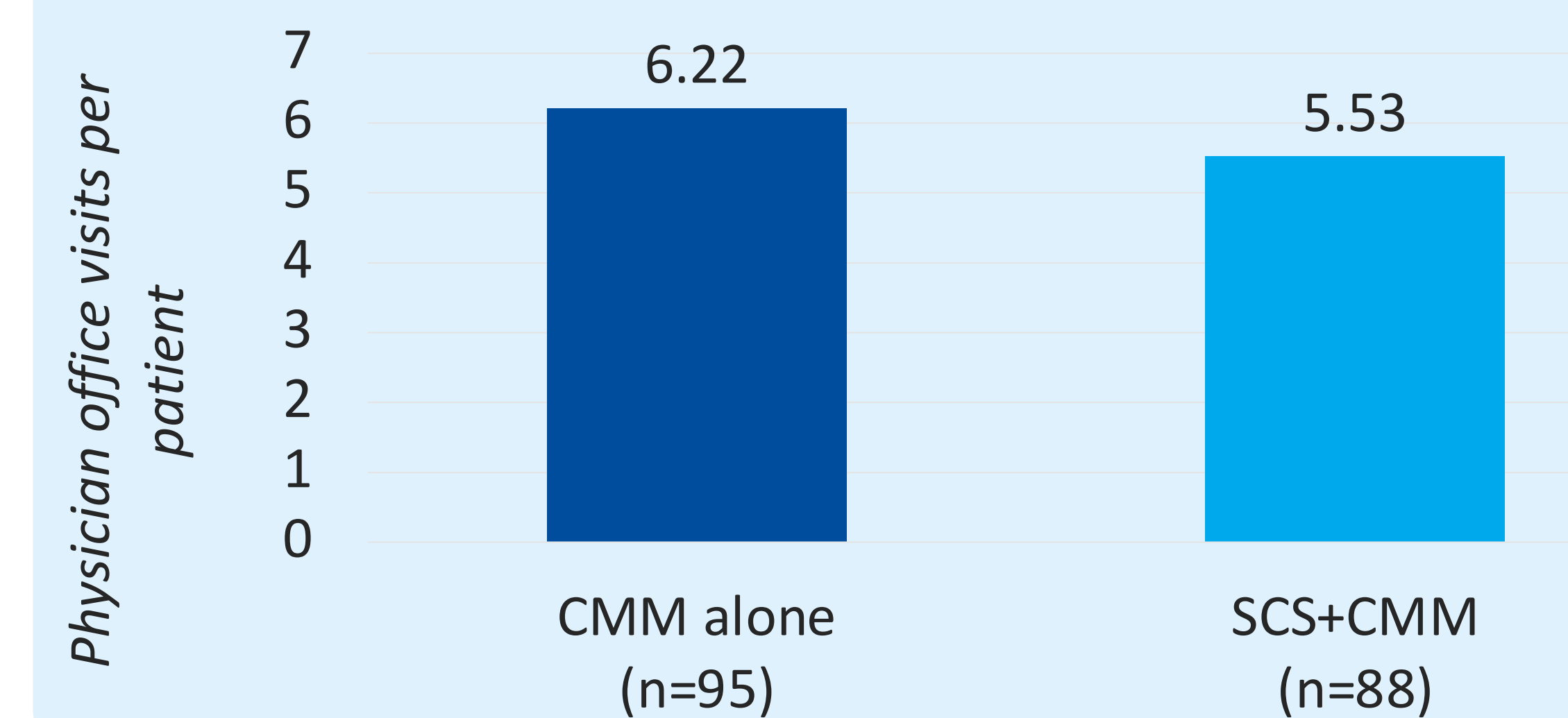
Figure 3. ED visits for patients observable at 6 months in CMM vs. SCS+CMM arm



Results (Continued)

- Self-reported ED visits (0.16±0.447 vs. CMM-alone: 0.15 ±.366; p=0.5) (**Figure 3**) and physician office visit rates appeared similar between the two treatment arms (5.53±3.59 vs. CMM-alone: 6.22±3.87; p=0.1) (**Figure 4**)

Figure 4. Physician office visits for patients observable at 6 months in CMM vs. SCS+CMM arm



Conclusions

High-frequency 10-kHz SCS appears to result in a reduction in hospitalization rates and length of stay in patients with refractory PDN at 6-month. Longer term data is needed.

References

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ABBREVIATIONS CMM, Conventional medical management; ED, Emergency department; HRU, Healthcare resource utilization; LOS, Length of stay; PDN, Painful diabetic neuropathy

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