

A moderate dose of botulinum toxin type A for the relief of chronic orofacial pain: a randomized, controlled, double-blind clinical trial

Victoria Sitnikova: Department of Oral and Maxillofacial Diseases, Faculty of Medicine, University of Helsinki, Helsinki victoria.sitnikova@helsinki.fi
 Pentti Kemppainen: Department of Oral and Maxillofacial Diseases, Faculty of Medicine, University of Helsinki, Helsinki
 Olli Teronen: Private Practice Mehiläinen, Helsinki, Finland
 Antti Kämppi: Department of Oral and Maxillofacial Diseases, Faculty of Medicine, University of Helsinki, Helsinki,

INTRODUCTION: Injections of botulinum toxin type A (BoNT-A) have been proposed as an additional treatment modality for patients suffering chronic orofacial myofascial pain (MFP). Along with its analgesic effect, it impairs muscle function, and minimal effective dose should be used.

THE AIM OF THE STUDY: The aim of this study was to evaluate whether a moderate dose of BoNT-A is more efficient than saline solution (SS) when treating chronic orofacial MFP.

METHODS: The study was conducted as a double-blind cross-over trial. Fifty-seven patients diagnosed with myalgia and myofascial pain were allocated into two groups: one which received saline solution first and another which received BoNT-A first. A total dose of 50 U of BoNT-A was injected in masseter and temporal muscles bilaterally. Follow-ups were performed 2, 11 and 16 weeks after the injections. Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) instruments were used to evaluate Characteristic Pain Intensity (CPI) and pain-related disability based on Graded Chronic Paint Scale (GCPS).

RESULTS

FIGURE 1 CPI at baseline and after BoNT-A and SS injections

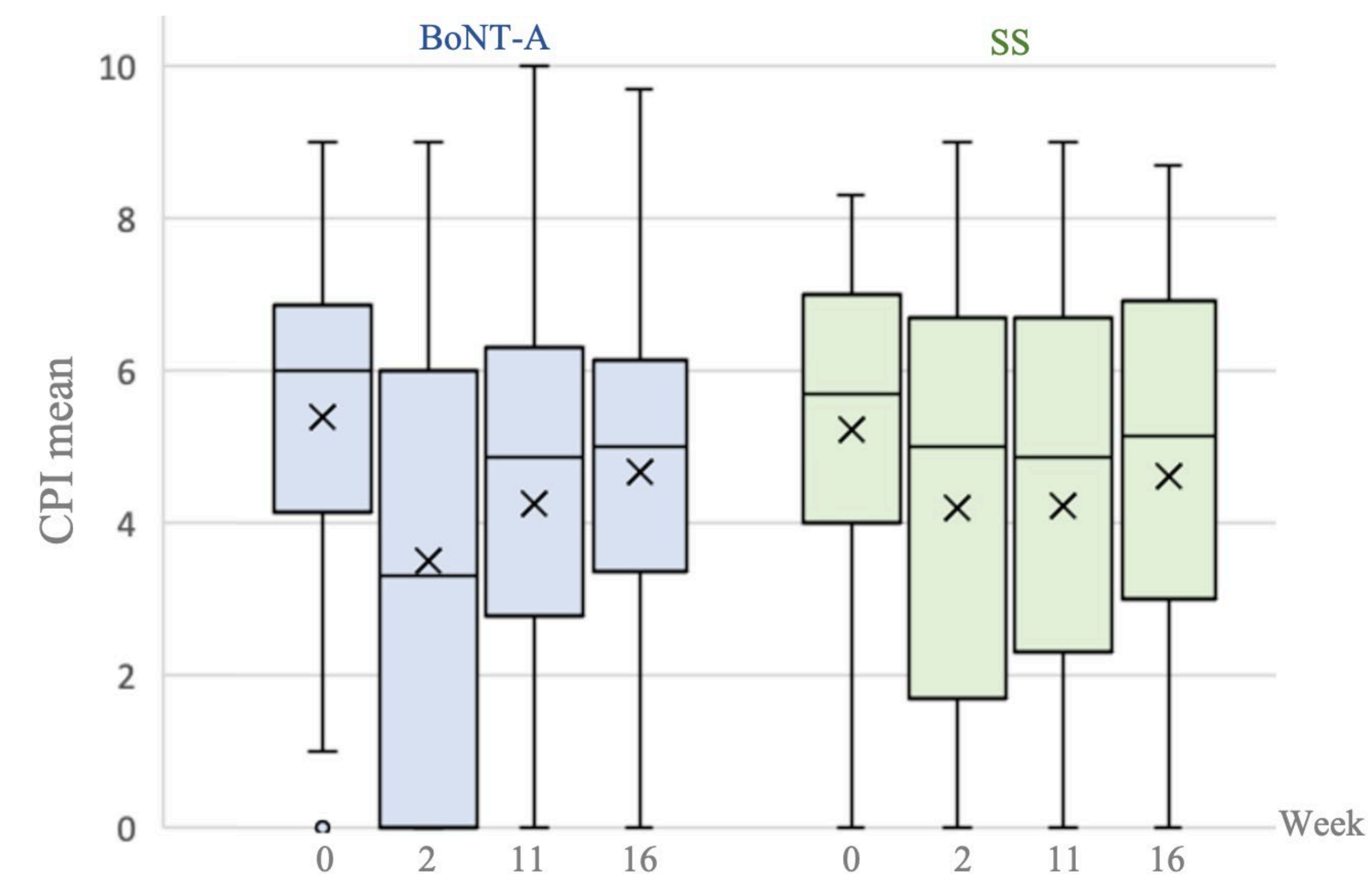


TABLE 1 Comparison of CPI and GCPS scores within one group between time-points

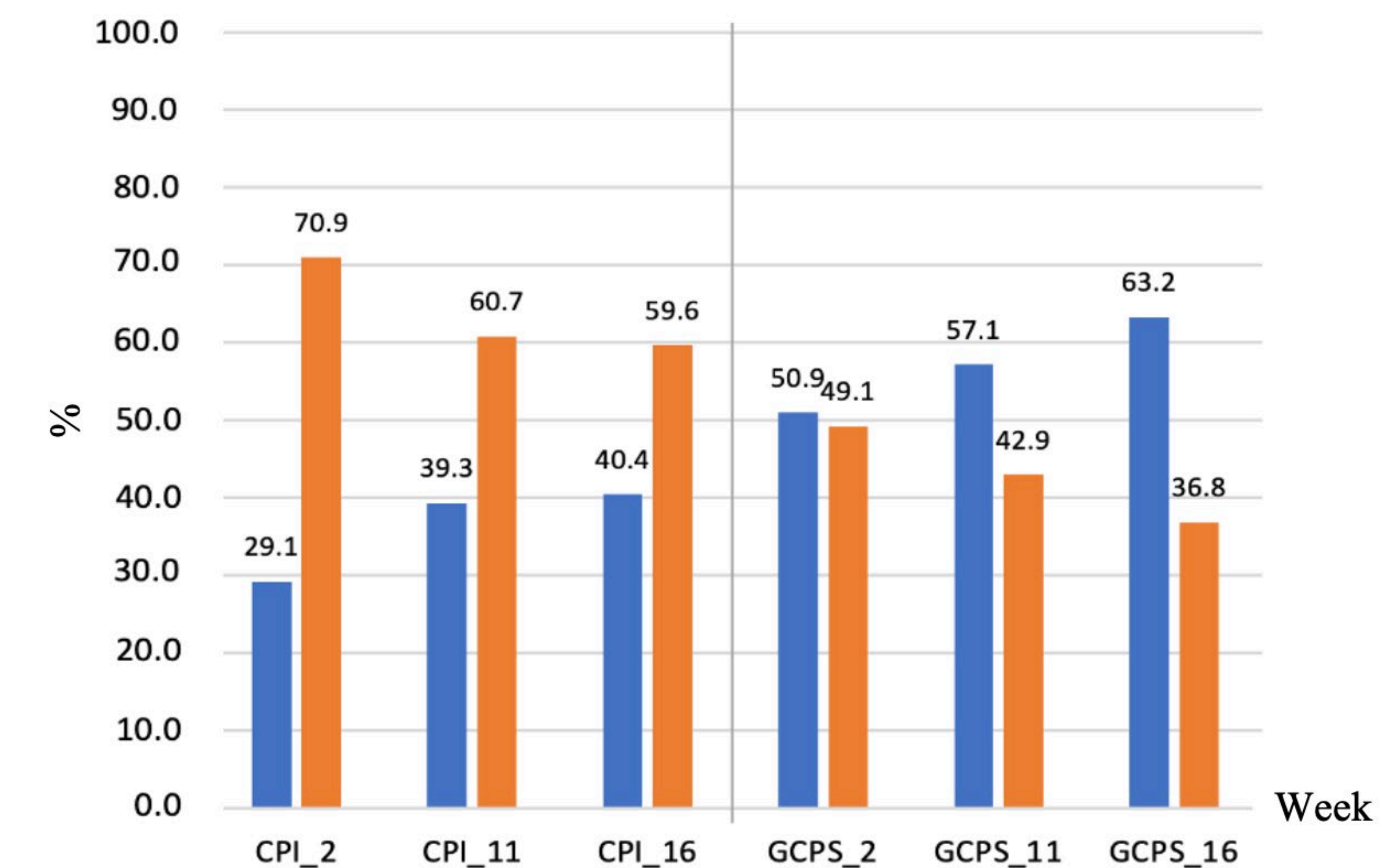
		p values		
		Time range		
		0-2	0-11	0-16
BoNT-A	CPI	<0.001	0.005	0.011
	GCPS	<0.001	0.003	0.017
SS	CPI	<0.001	0.412	0.397
	GCPS	0.265	0.343	0.436

Wilcoxon test

TABLE 2 Characteristics of the participants

Pain characteristics	% (n)
GCPS	
0	5.3 (3)
I	21.1 (12)
II	56.1 (32)
III	15.8 (9)
IV	1.8 (1)
Pain chronicity	
1 to <5 years	24.6 (14)
5 to <10 years	24.6 (14)
≥10 years	47.4 (27)
Not reported	3.5 (2)
Pain frequency	
Persistent	40.4 (23)
Recurrent	54.4 (31)
Once only	1.8 (1)
Not reported	3.5 (2)

FIGURE 2 Proportion of those who benefited from the BoNT-A injections (red) compared to those who did not (blue)



CONCLUSION: The pain-relieving effect of 50 U of BoNT-A is longer lasting compared to the effect of SS alone. However, the placebo effect is also evident.