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Botulinum Toxin Type A Injection for Cervical Dystonia in Adults with Dyskinetic Cerebral Palsy

You Gyoung Yi[1*], Moon Suk Bang[1†], Kee Won Kim[1], You Ho Myung[1]
Seoul National University Hospital, Department of Rehabilitation Medicine[1]

Objective:
We aimed to evaluate the efficacy and safety of injecting botulinum toxin A (BoNT-A) into the neck muscles to treat cervical dystonia (CD) in patients with dyskinetic cerebral palsy (CP).

Method
This was a randomized, double-blinded, placebo-controlled trial with cross-over design. We prospectively enrolled adults with dyskinetic CP who were over 20 years old and had been clinically diagnosed with CD for more than one year. The primary outcome measure was the change in Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) at four weeks from the baseline TWSTRS.

Results
Seventeen patients were initially enrolled, but one patient was excluded after the final evaluation because of a violation of the study protocol. Demographic and clinical data for the sixteen participants included in the study are presented in Table 1. - Changes on the TWSTRS after the Injection TWSTRS total scores at baseline, four weeks, and 12 weeks are presented in Figure 1. At four weeks, the BoNT-A injections showed significant improvement in the TWSTRS total score (Figure 1A) compared to the saline injections ($p = 0.0286$ for ANCOVA). At 12 weeks, the BoNT-A injections had a tendency to show greater improvement than the saline injections, but this difference was not statistically significant ($p = 0.0783$). There was no significant difference between the two injections on the TWSTRS severity score (Figure 1B). At four weeks there was a significant improvement in the TWSTRS disability score (Figure 1C) for the BoNT-A injections compared to the saline injections ($p = 0.0152$), but there was no significant difference after 12 weeks ($p = 0.6444$). On the TWSTRS pain score (Figure 1D), the BoNT-A injections showed statistically significant improvement compared to the saline injections at both four and 12 weeks ($p = 0.0013$ and 0.0200, respectively). - Changes in Numerical Rating Scale (NRS) after the Injection Figure 2 presents the NRS for both pain and disability at baseline, four weeks, and 12 weeks and the NRS for satisfaction at four weeks and 12 weeks. On the pain NRS (Figure 2A), the BoNT-A injections had a tendency toward lower pain at four and 12 weeks, but there was no statistically significant difference between the two treatments ($p = 0.0603$ and 0.1796, respectively). On the disability NRS (Figure 2B), the BoNT-A injections had a tendency toward lower disability at four weeks, but there was no statistically significant difference between the two treatments ($p = 0.1466$). On the satisfaction NRS (Figure 2C), which was not obtained at the baseline, the BoNT-A injections scored higher at four weeks and 12 weeks. This difference reached statistical significance only at four weeks ($p = 0.0176$).

Conclusion

BoNT-A injection for CD in adults with dyskinetic CP is relative safe and improves pain and disability.

Table 1. Baseline characteristics and clinical status of the study participants.

	Items	Number = 16
Demographics	Male/Female, number	8/8
	Age (years), mean (SD)	46.00 (6.44)
	Retrocollis/Anterocollis, number	7/9
	GMFCS level, number (%)	
	I	4 (25.00)
	II	7 (43.75)
	III	0 (0)
	IV	4 (25.00)
	V	1 (6.25)
	Maximal Kellgren score for cervical spondylosis, number (%)	
	0	0 (0)
	1	2 (12.50)
	2	3 (18.75)
	3	8 (50.0)
	4	3 (18.75)
Clinical data	TWSTRS total score at baseline, mean (SD)	41.69 (13.36)
	TWSTRS Severity score, mean (SD)	20.63 (11.13)
	TWSTRS Disability score, mean (SD)	11.13 (5.66)
	TWSTRS Pain score, mean (SD)	9.94 (4.47)
	JOA score at baseline, mean (SD)	11.34 (2.84)
	NRS pain score at baseline, mean (SD)	4.25 (2.08)
	NRS disability score at baseline, mean (SD)	5.19 (2.46)

TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale; JOA, Japanese Orthopedic Association Score; NRS, Numerical Rating Scale; GMFCS, Gross Motor Function Classification System.

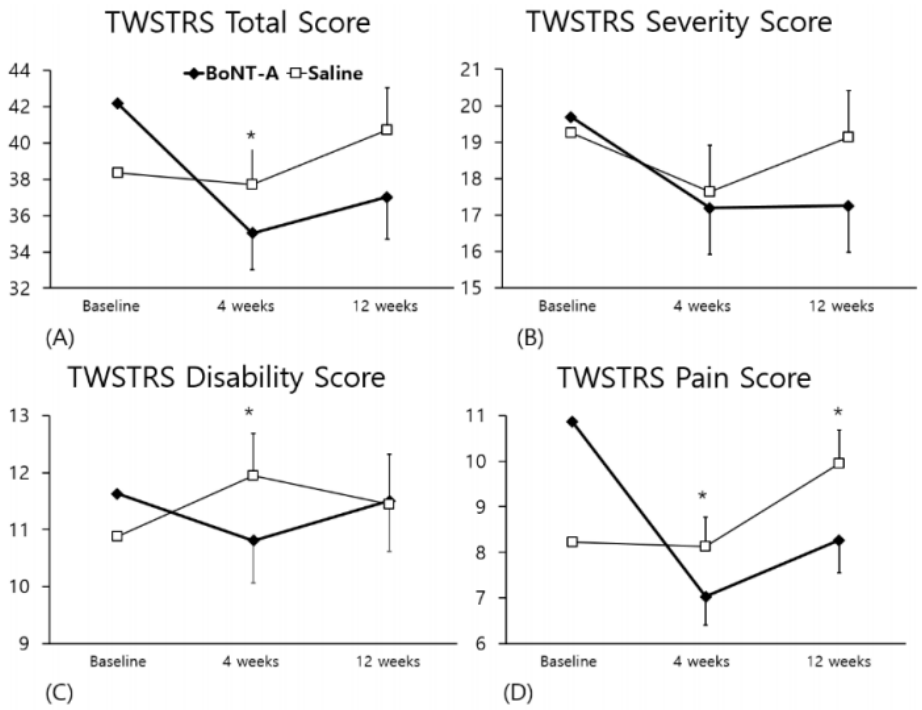

Figure 1. Comparison of the TWSTRS change between the BoNT-A and the Saline injection. * $p < 0.05$ for ANCOVA. The error bar indicates the SE for LS mean change from baseline. BoNT-A Botulinum toxin A, ANCOVA, Analysis of covariance, SE standard error, LS least-squares. (**A**), TWSTRS total score change, scale ranges from 0 to 85, (**B**), TWSTRS severity subscale change, scale range from 0 to 35, (**C**), TWSTRS disability subscale change, scale range from 0 to 30, (**D**), TWSTRS pain subscale change, scale range from 0 to 20, TWSTRS; Toronto Western Spasmodic Torticollis Rating Scale.

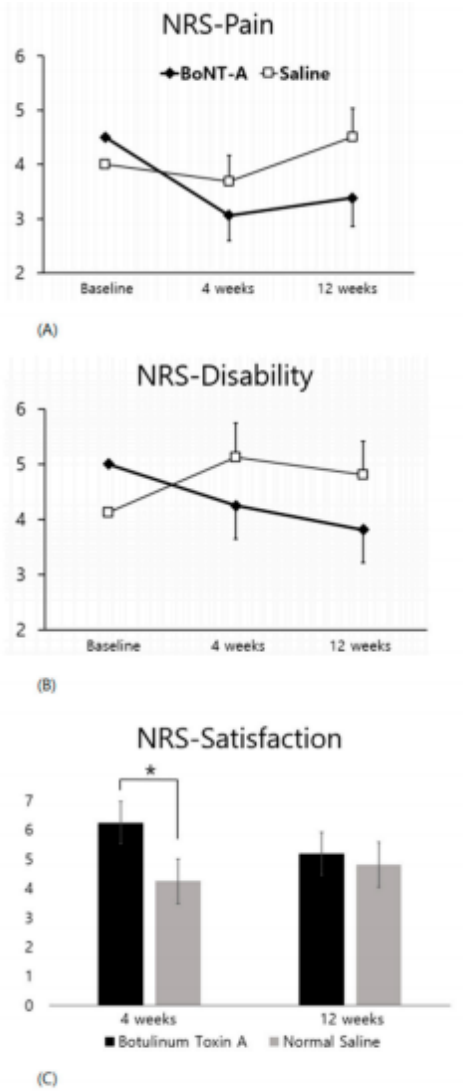

Figure 2. Comparison of NRS scores between the BoNT-A and the saline injection. Comparison of the NRS score at four weeks and 12 weeks between the BoNT-A and the saline injection, * $p < 0.05$ for ANCOVA (**A**,**B**) and Wilcoxon signed-rank test (**C**), In Figure 2A,B, the error bar indicates the SE for LS mean change from baseline. In Figure 2C, the error bar indicates the standard deviation. NRS Numeric rating scale, BoNT-A Botulinum toxin A, ANCOVA, Analysis of covariance, SE standard error, LS least-squares.