Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache

Report of the Guideline Development Subcommittee of the American Academy of Neurology.

Neurology. 2016;86: 1818-26

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Methods:

Guideline development procedure:

According to the AAN Systematic Review and Guideline Development Process (https://www.aan.com/Guidelines/Home/Development)

Comprehensive, systematic review of the literature

A systematic review was performed to identify relevant studies published since the prior guidelines. In general, only randomized, masked trials (RMTs) were considered. To assess long-term outcomes, including safety, we used evidence from nonrandomized trials. Twenty-three articles on blepharospasm, 23 on CD, 86 on spasticity, and 28 on headache met inclusion criteria. Table 1 summarizes the conclusions from this review.

Classification of evidence based on quality of the study design

Results of the systematic review are published as supplement to the original article.

Class I

A randomized, controlled clinical trial of the intervention of interest with masked or objective outcome assessment, in a representative population. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class II

A randomized, controlled clinical trial of the intervention of interest in a representative population with masked or objective outcome assessment that lacks one criteria a–e above or a prospective matched cohort study with masked or objective outcome assessment in a representative population that meets b□e above. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class III

All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.

Class IV

Studies not meeting Class I, II, or III criteria, including consensus or expert opinion.

Recommendations are based on peer-reviewed evidence or expert consensus and are directly linked to the evidence and weighted based on the strength of the evidence:

According to the AAN Systematic Review and Guideline Development Process (https://www.aan.com/Guidelines/Home/Development), a modified form of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach should be used.

A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)

B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

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Reference to the original guideline:

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