



USE OF BOTULINUM NEUROTOXIN FOR THE TREATMENT OF AUTONOMIC DISORDERS AND PAIN

This is a summary of the American Academy of Neurology (AAN) guidelines regarding recommended use and best practices for botulinum neurotoxin for non-motor functions.

Please refer to the full guideline for detailed findings and supporting evidence at www.aan.com.

RECOMMENDATIONS FOR USE OF BoNT IN AUTONOMIC DISORDERS AND PAIN

<i>Axillary hyperhidrosis</i>	Strong evidence supports	BoNT should be offered as a treatment option (Level A⁺).
<i>Palmar hyperhidrosis and drooling</i>	Good evidence supports	BoNT should be considered as a treatment option (Level B).
	Clinical context	Many physicians offer BoNT to these patients who are unresponsive to topical treatment as an alternative to iontophoresis or sympathectomy.
<i>Gustatory sweating</i>	Weak evidence supports	BoNT may be considered as a treatment option (Level C).
	Clinical context	The evidence for BoNT in gustatory sweating is suboptimal. There are not effective alternative treatments.
<i>Neurogenic detrusor overactivity</i>	Strong evidence supports	BoNT should be offered as a treatment option (Level A).
<i>Detrusor sphincter dyssynergia</i>	Good evidence supports	BoNT should be considered for detrusor sphincter dyssynergia (DSD) in patients with spinal cord injury (Level B).
	Clinical context	There are limited head-to-head comparisons of treatment options in DSD.
<i>Low back pain</i>	Weak evidence supports	BoNT may be considered as a treatment option of patients with chronic predominantly unilateral low back pain (LBP) (Level C).
	Clinical context	Evaluation and treatment of LBP is complicated by its diverse potential causes. In most clinical settings, it is difficult to diagnose the precise origin of pain and therefore creates challenges in study design, particularly in the selection of homogeneous subject populations.

<i>Chronic daily headache</i>	Insufficient evidence supports	There is insufficient evidence to support or refute a benefit of BoNT for the treatment of chronic daily headache (Level U).
<i>Chronic tension-type headache</i>	Good evidence supports	BoNT injections should not be considered (Level B).
<i>Episodic migraine</i>	Good evidence supports	BoNT injections should not be considered (Level B).
Clinical context		It is possible that underdosing and suboptimal muscle selection may account for some of the reported failures in studies of BoNT in headache.

This guideline summary is evidence-based. The AAN uses the following definitions for the level of recommendations and classification of evidence for therapeutic intervention.

The clinical context section is made available in order to place the evidence-based guideline(s) into perspective with current practice habits and challenges. No formal practice recommendations should be inferred.

***Classification of Recommendations:** **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. (Studies not meeting criteria for Class I-III).

*In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if (1) all criteria are met and/or (2) the magnitude of effect is large (relative rate improved outcome > 5 and the lower limit of the confidence interval is > 2).

AAN Classification of Evidence for Therapeutic Intervention: **Class I:** Randomized, controlled clinical trial 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. The following are required: (a) concealed allocation; (b) primary outcome(s) clearly defined; (c) exclusion/inclusion criteria clearly defined; and (d) adequate accounting for drop-outs (with at least 80% of enrolled subjects completing the study) and cross-overs with numbers sufficiently low to have minimal potential for bias. **Class II:** Prospective matched group cohort study in a representative population with masked outcome assessment that meets b-d above OR a RCT in a representative population that lacks one criteria a-d. **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, expert opinion, or a case report.

**Objective outcome measurement: An outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

This is an educational service of the American Academy of Neurology. It is designed to provide members with evidence-based guideline recommendations to assist with decision-making in patient care. It is based on an assessment of current scientific and clinical information and is not intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on the circumstances involved. Physicians are encouraged to review the full AAN guidelines carefully so they understand all recommendations associated with care of these patients.

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