Questions for Botulinum Toxins Subject Matter Expert Panel

For all question's answers must be based on clinical literature with consideration of quality of evidence to support your answer.

Achalasia

1. Is there evidence to support the use of botulinum toxin injections as a first line treatment for achalasia?
2. What treatment(s), if any, should be tried prior to using botulinum toxin injections for achalasia?

References to review

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Anal Fissure

1. Is there evidence to support the use of botulinum toxin injections as first line treatment for anal fissure?
2. What treatment(s), if any, should be tried prior to using botulinum toxin injections for anal fissure?
3. Is there evidence to continue the use of botulinum toxin after the first two injections of botulinum toxin for anal fissures?

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Society Guidelines

1. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Anal Fissures. Diseases of the Colon & Rectum. Volume 66: 2 (2023).

Blepharospasm

1. Is there evidence to support the use of botulinum toxin injections as first line treatment for blepharospasm?
2. What treatment(s), if any, would be considered failures prior to using botulinum toxin injections for blepharospasm?
3. What objective criteria/scale should be used to measure treatment benefits and outcomes of blepharospasm with botulinum toxin?
4. Is there evidence to support a finite number (end point) of botulinum toxin injections to provide temporary relief from blepharospasm?

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Cervical dystonia

1. What are the diagnostic criteria which should be used to diagnose cervical dystonia?
2. Is there evidence to support the use of botulinum toxin injections as first line treatment for cervical dystonia?
3. What treatment(s), if any, should be would be considered failures prior to using botulinum toxin injections for cervical dystonia?
4. What objective criteria/scale should be used to measure treatment benefits and outcomes of cervical dystonia with botulinum toxin?

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International

1. IAB – Interdisciplinary Working Group for Movement Disorders: Strategies for treatment of dystonia (2015)
2. Phenomenology and classification of dystonia – A consensus update (2013)
3. International consensus statement on botulinum toxin assessment, intervention and aftercare for cervical dystonia and other causes of hypertonia of the neck (2010)

Focal hand dystonia

1. Is there diagnostic criteria for focal hand dystonia?
2. What is the incidence and prevalence of the disorder which would need botulinum toxin treatment?

3. Is there evidence to support the use of botulinum toxin injections as a first line treatment for severe focal hand dystonia?
4. What treatment(s), if any, should be unsuccessfully used prior to using botulinum toxin injections for severe focal hand dystonia?
5. What objective criteria/scale should be used to measure treatment benefits and outcomes of focal hand dystonia with botulinum toxin?

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Hemifacial spasm / Facial dystonia

1. Is there evidence to support the use of botulinum toxin injections as first line treatment for hemifacial spasm?
2. What treatment(s), if any, would be considered failures prior to using botulinum toxin injections for hemifacial spasm?
3. What objective criteria/scale should be used to measure treatment benefits and outcomes of hemifacial spasm with botulinum toxin?

References to review

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International Guidelines

1. IAB – Interdisciplinary Working Group for Movement Disorders: Strategies for treatment of dystonia (2015)
2. Phenomenology and classification of dystonia – A consensus update (2013)
3. International consensus statement on botulinum toxin assessment, intervention and aftercare for cervical dystonia and other causes of hypertonia of the neck (2010)

Hyperhidrosis

1. Understanding the FDA indication anatomical limitation (i.e., axillary) for the use of botulinum toxin, is there evidence regarding the use of botulinum toxin for the treatment of hyperhidrosis in other anatomical locations?
2. Is there evidence to support the use of botulinum toxin injections as first line treatment for hyperhidrosis?
3. What treatment(s), if any, would be considered failures prior to using botulinum toxin injections for hyperhidrosis?
4. What objective criteria/scale should be used to measure treatment benefits and outcomes of hyperhidrosis with botulinum toxin?

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Intravesical Analgesia

1. What evidence (if any) supports use of botulinum toxin injections “off label” for interstitial cystitis and/or bladder pain?
2. What evidence (if any) supports use of botulinum toxin injections “off label” for intravesical analgesia?
3. What treatment(s), if any, would be considered failures prior to using botulinum toxin injections for intravesical analgesia?

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1. Jiang YH, Liao CH, Tang DL, Kuo HC. Efficacy and safety of intravesical onabotulinumtoxinA injection on elderly patients with chronic central nervous system lesions and overactive bladder. PLoS One. 2014;9(8):e105989.
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Laryngeal Dystonia (spasmodic dysphonia)

1. What evidence, if any, supports use of botulism off label for laryngeal dystonia? Describe.
2. What treatment(s), if any, would be considered failures prior to using botulinum toxin injections for laryngeal dystonia?
3. Is there evidence as to whether botulinum toxins should be used to treat abductor laryngeal dystonia (in addition to the adductor type)?
4. Does the literature support the use of targeting injections using modalities (e.g., guided by vision and palpation vs. electromyographic guidance, nerve stimulation, or ultrasound)?
5. What criteria/scale should be used to measure outcomes (perceptual voice quality measures, Quality of Life measures such as the Voice Handicap Index or the Voice-Related Quality of Life) when using botulinum toxin for laryngeal dystonia?

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Chronic Migraine prophylaxis

1. Is there evidence to support treatment(s), prior to using botulinum toxin injections for chronic migraine?
2. Is there evidence that supports the need for concurrent use of other medications in addition to botulinum toxin injections for chronic migraine?
3. Does the evidence point to specific criteria that should be used to measure the treatment benefits and outcomes of chronic migraine prophylaxis with botulinum toxin?
4. Is there evidence to support at least a 50% reduction in mean headache days per month when using botulinum toxin for chronic migraine?
5. Knowing that the FDA reviewed the PREEMPT study's results and only approved onabotulinumtoxinA at 155 units, is there robust evidence demonstrating that more than 155 units of onabotulinumtoxinA is clinically superior and more effective when treating chronic migraine?
6. Knowing that the FDA reviewed the PREEMPT results and only approved onabotulinumtoxinA to be administered every 12 weeks, is there robust evidence demonstrating that less than 12 weeks dosing of onabotulinumtoxinA is clinically superior and more effective for treating chronic migraines?

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Society Guidelines

1. David M. Simpson, Mark Hallett, Eric J. Ashman, Cynthia L. Comella, Mark W. Green, Gary S. Gronseth, Melissa J. Armstrong, David Gloss, Sonja Potrebic, Joseph Jankovic, Barbara P. Karp, Markus Naumann, Yuen T. So, Stuart A. Yablon. 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 May 2016, 86 (19) 1818-1826; DOI: 10.1212/WNL.000000000000256

Neurogenic (detrusor overactivity) bladder

1. Is there any evidence to support the use of botulinum toxin injections as first line treatment for neurogenic (detrusor overactivity) bladder?
2. What treatment(s), if any, would be considered failures prior to using botulinum toxin injections?
3. What is the robust evidence regarding the use of botulinum toxin for neurogenic (detrusor overactivity) bladder?

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Overactive bladder (OAB)

1. Knowing there is no FDA indication for the use of botulinum toxin for overactive bladder, what is the evidence regarding the use of botulinum toxin?.
2. What treatment(s) would be considered failures prior to using botulinum toxin for OAB such as conservative therapies, behavioral modifications and medications?
3. Is there a certain number of medications that should be tried (different classes etc.) before considering OAB refractory? Describe in detail.
4. Which populations are botulinum toxin injections not appropriate for OAB such as gender, elderly, cognitive change or dementia, mixed urinary incontinence, others?
    a. Are there patient populations who have higher risk for botulinum toxin injection treatment?
    b. Are there patient populations who are less likely to respond to botulinum toxin injection treatment?

References to review

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Society Guidelines

United States

1. American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU): Guideline for diagnosis and treatment of non-neurogenic overactive bladder (OAB) in adults (2019)
2. AUA/SUFU: Guideline on incontinence after prostate treatment (2019)
3. American Urogynecologic Society (AUGS) and American College of Obstetricians and Gynecologists (ACOG): Committee opinion on the evaluation of uncomplicated stress urinary incontinence in women before surgical treatment (2014, reaffirmed 2017)
4. AUA/SUFU: Guideline on surgical treatment of female stress urinary incontinence (SUI) (2017)
5. ACOG: Practice bulletin on urinary incontinence in women (2015)
6. AUA/SUFU: Guideline on adult urodynamics (2012)
7. Neurogenic Lower Urinary Tract Dysfunction: AUA/SUFU Guideline (2021)

International

1. International Continence Society (ICS): Current standardisations
2. ICS: Report on the terminology for adult neurogenic lower urinary tract dysfunction (ANLUTD)(2017)
3. Sixth International Consultation on Incontinence: Recommendations for the evaluation and treatment of urinary incontinence, pelvic organ prolapse, and faecal incontinence (2018)

4. International Urogynecological Association (IUGA): Guidelines for research and clinical practice on the evaluation and outcome measures in the treatment of female urinary stress incontinence (2008)

Strabismus

1. Is there evidence to support the use of botulinum toxin injections as a first line treatment for strabismus?
2. What treatment(s), if any, should be tried prior to using botulinum toxin injections for strabismus?

References to review

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6. Botulinum toxin use in Strabismus. EyeWiki. May 21, 2022. Accessed August 8, 2023. https://eyewiki.aao.org/Botulinum_Toxin_Use_In_Strabismus.

Spasticity

1. Is there evidence regarding the use of botulinum toxin for spasticity?
2. What treatment(s), if any, would be considered failures prior to using botulinum toxin injections?
3. Does the botulinum toxin injection need electromyographic guidance or nerve stimulation when treating spasticity, even if the muscles can be easily targeted?
4. What objective criteria/scale should be used to measure outcomes?

References to review

Society Guidelines

1. David M. Simpson, Mark Hallett, Eric J. Ashman, Cynthia L. Comella, Mark W. Green, Gary S. Gronseth, Melissa J. Armstrong, David Gloss, Sonja Potrebic, Joseph Jankovic, Barbara P. Karp, Markus Naumann, Yuen T. So, Stuart A. Yablon. 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 May 2016, 86 (19) 1818-1826; DOI: 10.1212/WNL.000000000000256

Sialorrhea

1. Is there evidence regarding the use of botulinum toxin for chronic sialorrhea?
2. What treatment(s), if any, would be considered failures prior to using botulinum toxin injections for chronic sialorrhea?

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Urinary incontinence

1. Is there evidence regarding the use of botulinum toxin for urinary incontinence?
2. What treatment(s) would be considered failures prior to botulinum toxin injections for overactive bladder such as conservative therapies, behavioral modifications and medications?
3. Is there a certain number of medications that should be tried (different classes etc.) before being considered refractory

References to review

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Society Guidelines

1. American Urogynecologic Society (AUGS) and American College of Obstetricians and Gynecologists (ACOG): Committee opinion on the evaluation of uncomplicated stress urinary incontinence in women before surgical treatment (2014, reaffirmed 2017)
2. AUA/SUFU: Guideline on surgical treatment of female stress urinary incontinence (SUI) (2017)

3. ACOG: Practice bulletin on urinary incontinence in women (2015)
4. AUA/SUFU: Guideline on adult urodynamics (2012)
5. Sixth International Consultation on Incontinence: Recommendations for the evaluation and treatment of urinary incontinence, pelvic organ prolapse, and faecal incontinence (2018)