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The use of Botulinum toxin type A in various medical fields: A systematic review

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ABSTRACT

Clostridium botulinum bacteria produce neurotoxin called Botulinum toxin type A. The mechanism of action of Botulinum toxin is to block the release of the neurotransmitter. It causes temporary muscle paralysis. Since it was first applied in the 1970s, the use of Botulinum toxin has significantly increased and expanded. Botulinum toxin type A is a versatile therapeutic agent used across medical disciplines. The goal of this article is to review current medical applications of Botulinum toxin type A across specialties, focusing on mechanisms of action, dosage protocols, and safety.

Keywords: Botulinum toxin type A, off-label, neurotoxin, treatment option

1. INTRODUCTION

The mechanism-of-action of *Clostridium botulinum* producing neurotoxin Botulinum toxin type A is to block the SNARE proteins. The SNARE proteins enable the release of acetylcholine. The acetylcholine is crucial for muscle contraction. Botulinum toxin type A's effect is limited to the area of injection. The toxin does not impact sensory nerves. Over time, neuromuscular connections regenerate. To maintain the effect repeated injections are necessary (Brin and Burstein, 2023). Botulinum toxin type A had already been used in medicine in the 1980s. In 2002, the FDA approved Botulinum toxin for aesthetic purposes (Lorenc et al., 2013). Botulinum toxin type A is well tolerated by patients. The administration of botulinum toxin may cause local side effects, which are reversible and usually resolve spontaneously without treatment. Undesirable aesthetic effects result from the muscles' reaction to the toxin or from incorrect toxin administration. A possible serious complication is systemic spread of the toxin (Witmanowski and Błochowiak, 2020).

2. REVIEW METHODS

A review was conducted using scientific articles that matched the criteria. We used keywords such as Botulinum toxin type A, Botulinum toxin in medicine, Botulinum toxin in aesthetic medicine, Botulinum toxin indications, and Botulinum toxin

mechanism of action. The articles were searched in scientific databases, such as PubMed and Google Scholar. We set the time frame to 2025-2010 and included older publications if considered valuable. The articles were categorized by specialty: neurology, urology, stomatology, dermatology, gastroenterology, gynecology, and aesthetic medicine. The article screening process followed the PRISMA guidelines (Figure 1).

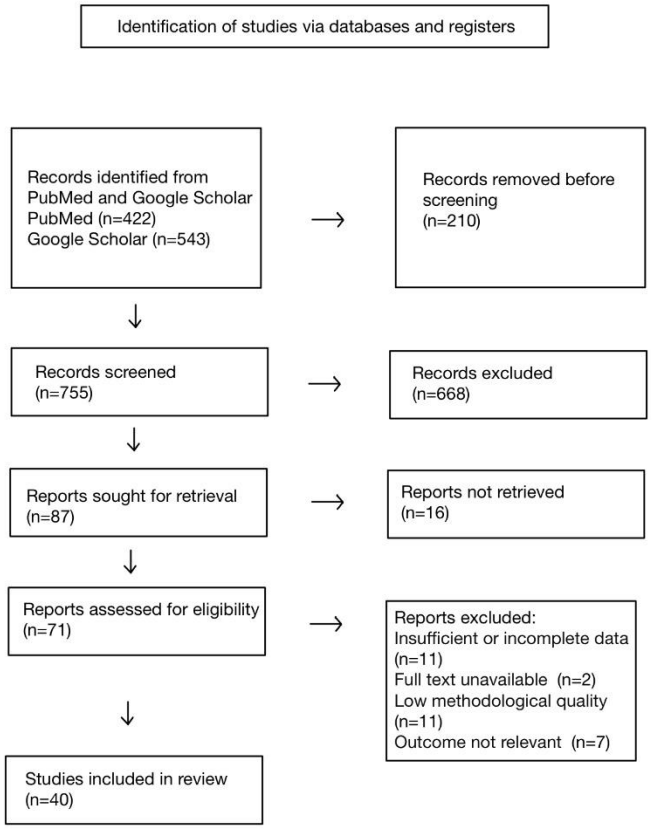

Figure 1. Flow chart

3. RESULTS AND DISCUSSION

The use of Botulinum toxin type A in neurology - Migraine

Migraine is a chronic neurological disorder. The main symptom is episodic headaches. The pain lasts 4-72 hours. It is often accompanied by nausea and photophobia. It affects women more often than men. Chronic migraine is diagnosed when pain occurs more than 15 days per month (Charles, 2018). The FDA approved the use of Botulinum toxin type A for the prevention of chronic migraine in 2010. It is not recommended for less frequent episodes. PREEMPT trials have been conducted to verify the effectiveness and safety of the use of Botulinum toxin injections as the treatment of chronic migraine (Diener et al., 2010; Dodick et al., 2010).

The standard treatment protocol consists of 31 injections of a total of 155 units of Botulinum toxin type A administered to selected sites on the head and neck. Injections are repeated every 12 weeks. The administration of botulinum toxin type A reduces the secretion of pro-inflammatory substances, neurotransmitters, and neuropeptides in afferent fibers that conduct pain. It also affects ion channels that are sensitive to pain. In people with migraine, sensory nerve endings are overactive. The toxin blocks these nerve endings, reducing the number of pain signals reaching the brain. Clinical outcomes show significant quality-of-life improvements (Lew, 2002). After 12 weeks of therapy, 40% of patients with chronic migraine experienced a ≥ 30% reduction in pain (Lin et al., 2014).

The use of Botulinum toxin type A in neurology - Blepharospasm

Blepharospasm is a neurological motor disorder. It appears as involuntary contractions of the muscles around the eye and difficulty opening the eyelids. The first-line treatment is botulinum toxin. Treatment results in a reduction of symptoms by ≥ 50%. Most patients notice an improvement in 1-2 weeks after the injection. The standard dosage is 10-25 units per side. It is necessary to adjust the dose to

the severity of the symptoms. Injections are repeated every 3-4 months. Possible complications include ptosis and xerophthalmia (Skopljak-Salkica et al., 2024).

The use of Botulinum toxin type A in neurology - Hemifacial spasm

Hemifacial spasm is a neurological motor disorder. It manifests itself in involuntary muscle contractions on one side of the face. The affected muscles include: orbicularis oculi, corrugator supercilii, zygomaticus major, zygomaticus minor, levator labii superioris alaeque nasi, risorius, orbicularis oris, mentalis, depressor anguli oris, and platysma. The most common cause is pressure on the facial nerve from a blood vessel. The first-line therapy is Botulinum toxin type A injections. The effectiveness of 3 months of therapy ranges from 76 to 98 %. The standard dosage is 10-34 units of Botulinum toxin type A. It is recommended to repeat the injection every 3-4 months (Tambasco et al., 2021). Table 1 summarizes the use of Botulinum toxin type A in neurology.

Table 1. Main results of Botulinum toxin type A injections in neurology

Medical field	Condition	Main result	Dose
Neurology	Chronic migraine	≥30% pain reduction after 12 weeks	155 U; every 12 weeks
Neurology	Blepharospasm	≥50% symptôm reduction	10–25 U/side; every 3–4 months
Neurology	Hemifacial spasm	76–98% effectiveness	10–34 U; every 3–4 months

The use of Botulinum toxin type A in urology - Overactive bladder

An overactive bladder is a combination of symptoms such as urgent need to urinate, frequent urination, and nocturia. Abnormal contractions of the detrusor muscle occur when the bladder is filled. This leads to sudden urges. One of the treatment methods is Botulinum toxin type A injections. The recommended dose of Botox is 200 units (Juszczak et al., 2018). After treatment, a reduction in the frequency of urination and fewer episodes of urinary incontinence have been observed. Botulinum toxin type A injections significantly reduce symptoms in patients with an overactive bladder (Cui et al., 2013). The treatment provides positive change in patients' quality of life (Juszczak et al., 2018).

In 19 trials, Botulinum toxin type A at doses of 200 U and 300 U provided better results than placebo in decreasing loss of bladder control in neurogenic overactive bladder (Lew, 2002)

Observed side effects include urinary retention requiring catheterization and urinary tract infections (Cui et al., 2013). It is important to select patients appropriately, prevent bladder overflow, and treat infections to reduce the risk of complications (Apostolidis et al., 2020).

The use of Botulinum toxin type A in urology - Erectile dysfunction

Erectile dysfunction is the incapacity to achieve or maintain an erection adequate to permit sexual intercourse for at least 3 months (Rew and Heidelbaugh, 2016). It is estimated that ED affects approximately 19–52% of men aged 40–70 (Feldman et al., 1994).

Table 2. Main results of Botulinum toxin type A injections in urology

Medical field	Condition	Main result	Dose
Urology	Overactive bladder	Reduced urinary incontinence; improved quality of life	200 U
Urology	Erectile dysfunction	40% of patients achieved a 2–7 point improvement in IIEF-EF/SHIM score	50-100 U

One month after Botulinum toxin type A injections, 40% of patients achieved a 2–7-point increase in the IIEF-EF/SHIM score (Pang, 2025). A positive change was noticed in patients with erectile dysfunction who underwent Botulinum toxin type A injections into the

corpus cavernosum. The administered doses were 50-100 units, with a higher dose providing a longer-lasting effect (Barros, 2022). Adding Botox injections into the corpus cavernosum to therapy may increase the effectiveness of treatment with PDE5 inhibitors. The treatment is safe; however, it is off-label and requires further research (Giuliano et al., 2019). Table 2 summarizes the use of Botulinum toxin type A in urology.

The use of Botulinum toxin type A in stomatology - Bruxism

Bruxism is a condition in which there is uncontrolled grinding or clenching of the teeth, especially at night during sleep. It can also occur during the day, especially in stressful situations. The injections of Botulinum toxin type decrease the suffering of patients with bruxism and recurrence of episodes (Fernández-Núñez et al., 2019). The treatment may be beneficial to the patients who face trouble using oral splints frequently (Chen et al., 2023). The recommended injection protocol is 50-60 units divided between both sides of the face. The injections are inserted into the masseter and temporal muscles (Long et al., 2020).

The use of Botulinum toxin type A - Hyperhidrosis

Hyperhidrosis is a condition defined by immoderate sweating. It is caused by excessive stimulation of sweat gland receptors. The highest concentration of sweat glands is found on the palms, soles, and armpits, which is why these areas are treated with Botulinum toxin type A injections. The injections are effective in reducing the symptoms of hyperhidrosis. The toxin blocks the stimulation of sweat glands (Obed et al., 2021).

The recommended dosage is 50-75 units per armpit, divided into several injections (Lowe et al., 2007). For the palms, the dosage is higher, up to 200 units per palm (Wollina and Karamfilov, 2001). A randomized, double-masked, placebo-controlled trial of botulinum A toxin for severe axillary hyperhidrosis (200 U) in which toxin was administered in one armpit and a placebo in the other, showed sweat reduction 34.5% ($p < 0.001$) after 3 weeks, and 36.9% after 8 weeks (Schnider et al., 1999).

Botulinum toxin type A injections provide reduction of hyperhidrosis symptoms and an improvement in patients' quality of life (Obed et al., 2021). Four weeks after Botulinum toxin type A injections, 75% of treated patients show a 2-point improvement on the Hyperhidrosis Disease Severity Scale (Lowe et al., 2007). Compared to other treatments for hyperhidrosis, Botulinum toxin type A injections have fewer side effects (Sun et al., 2025). The duration of the effect varies between 4 and 12 months, depending on the injection site (D'Epiro et al., 2014).

The use of Botulinum toxin type A in gastroenterology

Botulinum toxin type A treatment has been proven effective in gastroenterological conditions such as achalasia, sphincter of Oddi dysfunction, esophageal motor disorders, or gastroparesis. Botulinum toxin type A can be used in the short-term treatment of achalasia. Injections reduce symptoms in 70% of patients. It is not applicable in long-term treatment due to the need for repeated doses and reduced efficacy. It is the preferred method in older patients for whom surgery carries a higher risk (Zepeda-Gómez and Valdovinos-Díaz, 2002).

Botulinum toxin type A injections after biliary sphincterotomy in patients with sphincter of Oddi dysfunction may help reduce the incidence of pancreatitis after endoscopic retrograde cholangiopancreatography (Gorelick et al., 2004). Botulinum toxin type A may also be used to treat chronic anal fissure, anismus, or oropharyngeal dysphagia (Zepeda-Gómez and Valdovinos-Díaz, 2002). Botulinum toxin type A has been proven effective in the treatment of esophageal motor disorders, including esophagogastric junction outflow obstruction, hypercontractile esophagus, and diffuse esophageal spasm (Calderon et al., 2025). Botulinum toxin type A injections for gastroparesis were effective in 64% of patients after one month, and the effect lasted up to 6 months (Reichenbach et al., 2020). Botulinum toxin type A injections in gastroenterology are used off-label.

The use of Botulinum toxin type A in gynecology

Botulinum toxin type A has been proven effective in gynecological conditions such as refractory myofascial pelvic pain, vaginismus, dyspareunia, vulvodynia, and urinary incontinence (Carruthers et al., 2014). Vaginismus is a condition defined by unintentional contraction of the perineal muscles. These contractions may occur during sexual intercourse or a gynecological examination (Lew, 2002).

After applying a dose of 150-400 units of Botulinum toxin type A injected into the puborectalis muscles in 3 spots on each side of the vagina, 95.8% of patients had vaginal examinations after 1 week that showed little or no vaginismus. Up to 75% had intercourse after

the first injection (Ghazizadeh and Nikzad, 2004). Vulvodynia is a dysfunction characterized by chronic pain or discomfort in the vulvar area.

A dose of 20-40 units of Botulinum toxin type A was used in the treatment. Injection areas were the vestibule, levator ani muscle, and the perineal body. After the injection, all patients experienced relief from pain (Yoon et al., 2007). Myofascial pelvic pain is a dysfunction characterized by persistent pelvic pain. The cause of the pain is contraction of the pelvic muscles. Myofascial pain is defined by the existence of hypersensitive points, which when triggered, cause pain. The 100-300 units doses of Botulinum toxin type A were used in the treatment. A reduction of pain was observed in 79.3% of patients (Lew, 2002).

The use of Botulinum toxin type A in aesthetic medicine

Botulinum toxin type A inhibits the release of acetylcholine, causing temporary paralysis of the facial muscles, which leads to reduced muscle tension and smoothing of wrinkles. Botulinum toxin type A injections were approved by FDA as treatment for glabellar frown lines in 2002 (Satriyasa, 2019).

Glabellar frown lines

In a randomized, double-masked, placebo-controlled study, the use of 20 U of Botox at five glabellar points resulted in a significant reduction in wrinkle depth both at maximum frown and at rest. Some patients experienced mild cases of blepharoptosis (5.4%) (Carruthers et al., 2014). Data analyzed from four trials (621 subjects) showed that after treatment of glabellar lines with 20 U of Botulinum toxin type A, more than 50% of patients maintained clinical effect for 120 days (Glogau et al., 2012). In a 2-year study involving 801 people, adverse reactions were rare and mild. No serious events or development of neutralizing antibodies has been reported. Botulinum toxin type A is an effective and well-tolerated treatment for glabellar frown lines (Prager, 2013).

Crows' feet lines

Botulinum toxin type A works by blocking the release of acetylcholine at the injection site, which leads to relaxation of the muscles around the lateral corner of the eye and smoothing of wrinkles (Carruthers et al., 2014). In a multicenter, double-masked, placebo-controlled study (24 U), 66.7% of physicians and 58.1% of patients reported no or mild wrinkles when smiling maximally. In the placebo group, the values were 6.7% and 5.4% ($p < 0.001$). Most side effects were mild and did not require discontinuation of treatment (Carruthers et al., 2002).

Forehead lines

The optimal protocol consists of 10 injection points: 5 in the frontal muscle and 5 in the glabellar complex. For a more effective, natural treatment outcome, potential variations in anatomy should be considered (De Boulle et al., 2020). 30 days after injection, the effect of no or mild wrinkles was achieved in 91.2% (40 U) and 86.4% (30 U) of the patients according to the doctors' evaluation and 89.5% and 81.4% according to the patients' evaluation. Botulinum toxin type A resulted in significantly higher responder rates than placebo ($p < 0.001$) (Solish et al., 2016).

4. CONCLUSION

Botulinum toxin type A is a safe and effective treatment option with a broad spectrum of medical applications. It has broad therapeutic indications across medical specialties. It is utilized in neurology, urology, gynecology, gastroenterology, stomatology, dermatology and aesthetic medicine. The use of Botulinum toxin type A continues to increase. The indications approved by FDA represent only small part of the Botulinum toxin type A applications. The use of Botulinum toxin type A continues to expand, but most of the applications remain off-label. Although the use of Botulinum toxin type A show promising results ongoing research is necessary to define its long-term effects, optimal doses of the toxin, and patient selection criteria.

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Authors' Contributions

Conceptualization - NS, DB, KK;

methodology NS, KJ, AK;
Check - AK, NS, WM, JK, OD, KT;
Formal Analysis - NS, KK;
Investigation – NS, KK, AK, JK;
Resources - KJ, DB, WM;
Data Curation – KK, AK, KT;
Writing Rough Preparation - NS, KJ;
Writing, review and editing - NS, KJ, OD, WZ;
Visualisation – JK, AK, KK, AB;
Supervision - DB, JW, KS;
Project Administration – NS.

Informed consent

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Ethical approval

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Conflict of interest

The authors declare that they have no conflicts of interest, competing financial interests or personal relationships that could have influenced the work reported in this paper.

Data and materials availability

All data associated with this study will be available based on the reasonable request to corresponding author.

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