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INTRACAVERNOSAL ONABOTULINUMTOXINA (BoNT-A) FOR THE TREATMENT OF ERECTILE DYSFUNCTION: A SYSTEMATIC REVIEW.

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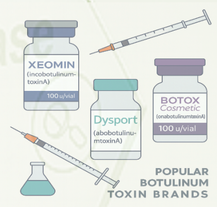
INTRODUCTION & AIM

Erectile dysfunction (ED) affects approximately 20% of men worldwide, significantly affecting their quality of life.

Phosphodiesterase type 5 inhibitors (PDE5-Is) are the standard **first-line treatment**, but a substantial number of patients are non-responders.

Second-line treatments, such as intracavernosal alprostadil, are effective but often limited by their invasive nature and the need for frequent injections.

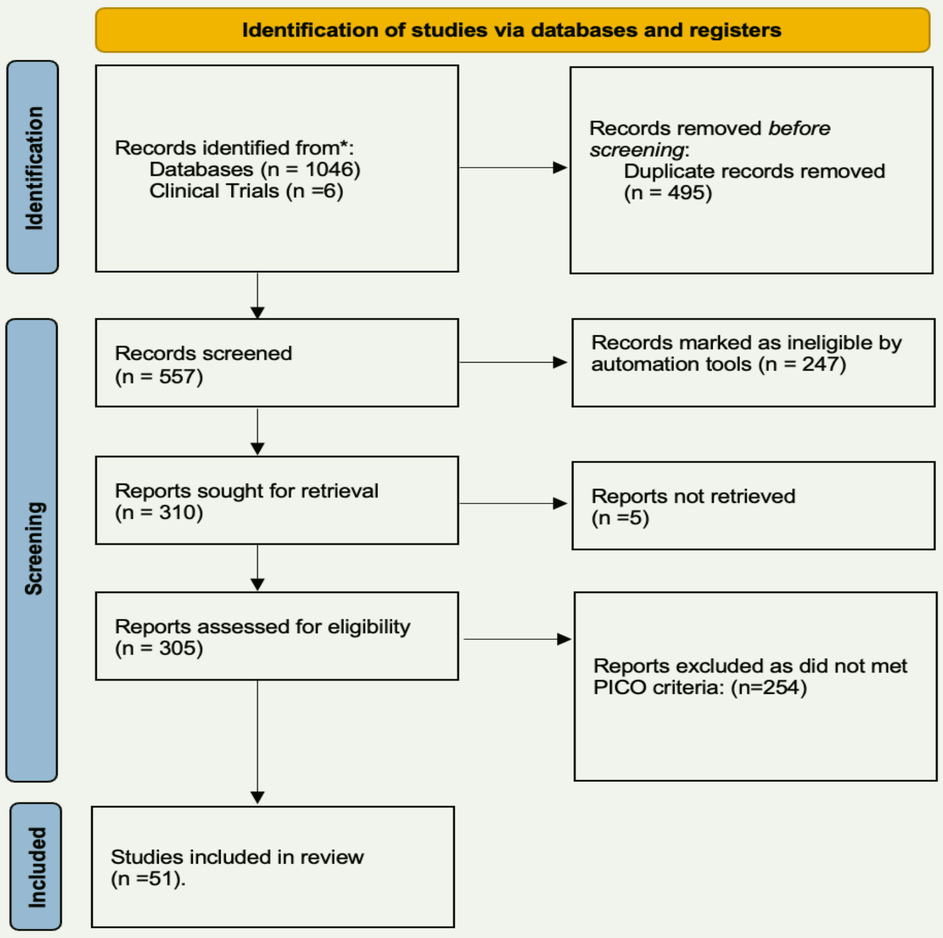
Intracavernosal **onabotulinumtoxinA (BoNT-A)** is a promising therapy for **refractory ED**.
By inhibiting the release of acetylcholine, norepinephrine, and other neurotransmitters involved in detumescence, it promotes cavernosal smooth muscle relaxation and enhances penile blood flow. A single injection can provide benefits for up to six months, potentially reducing treatment burden and improving adherence.



This systematic review critically evaluates the **current evidence** on the **therapeutic potential** and **risks** of intracavernosal BoNT-A for ED.

METHODS

A **systematic review** was performed in accordance with the **PRISMA** guidelines and registered in **PROSPERO** (CRD 420251087894). Literature searches were conducted in PubMed, Embase, Cochrane Library, Scopus, and Clinicaltrials.gov from inception until August 2025 using a combination of keywords and MeSH terms related to 'erectile dysfunction', 'intracaversonal injection' and 'botulinum toxin.'



Of the 1,052 records identified, 557 underwent screening, 305 were assessed for eligibility, and **51 studies** were included in the final review. Substantial heterogeneity was observed across interventions, patient populations, and outcome measures, precluding a meta-analysis. The evidence was therefore synthesized narratively.

RESULTS & DISCUSSION

Intracavernosal **BoNT-A** was associated with improvements in validated erectile function scores. Reported **response rates** ranged from **40 - 77.5%**. Efficacy was higher in patients with mild-to-moderate ED and with repeated administration of 100U doses.
Favorable safety profile. The most common adverse event was mild, transient penile pain (1.5%-6%). No studies reported serious systemic adverse events. The overall **strength of the evidence** was **limited** by significant heterogeneity among the included studies and their generally small sample sizes.

Claim	Evidence Strength	Reasoning
BoNT-A penile injection improves erectile function in men with ED refractory to standard therapies	Strong	Multiple RCTs and meta-analyses show significant improvements in IIEF/SHIM/EHS vs. placebo
BoNT-A injection is safe, with only mild, transient adverse events	Strong	Consistent safety profile across studies, no systemic side effects, rare serious events
Higher doses (100U) of BoNT-A are more effective and durable than lower doses (50U)	Moderate	Dose-comparison RCTs and case series show greater and longer-lasting effects with 100U
Repeated BoNT-A injections may enhance and prolong therapeutic response	Moderate	Observational data show increased response rates with multiple injections
Imaging biomarkers (e.g., shear wave elastography) may predict response to BoNT-A	Moderate	Pilot studies suggest correlation between tissue stiffness and treatment outcome
Long-term efficacy and safety of BoNT-A penile injection remain uncertain	Weak	Lack of large, long-term RCTs and standardized protocols

CONCLUSION

For patients with refractory ED, intracavernosal BoNT-A may provide a valuable treatment strategy offering the dual benefit of improved sexual function and a reduced need for invasive therapies.

FUTURE WORK

The path to standardizing this therapy requires validation through large-scale, placebo-controlled trials. **Key questions** that these studies must resolve include:
Optimal Patient Selection: Which etiological subgroups (e.g., vascular, neurogenic, diabetic) are the most responsive?
Dosing Optimization: What is the ideal dosing protocol to maximize efficacy?
Clinical Integration: What is its definitive role within the ED treatment algorithm?