

EFFICACY OF PHARMACOLOGICAL MANAGEMENT ON CYSTOMETRIC CAPACITY IN NEUROGENIC DETRUSOR OVERACTIVITY DUE TO SPINAL CAUSES IN ADULTS: SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

This research aims to evaluate the effects of pharmacological management on maximal bladder capacity (MCC) in patients with neurogenic detrusor overactivity (NDO) due to spinal causes. Literature searches were carried out in Pubmed and Scopus databases from the inception to November 2024. Randomized controlled trials on pharmacological treatments for storage symptoms compared to usual care or placebo (i.e., controls) in NDO patients with MCC as an outcome were included. Mean differences (MD) were pooled in meta-analyses. The results showed that MCC was significantly higher after treatment with antimuscarinics, intravesical vanilloids, and botulinum toxin type A injection (BONT-A) compared to controls, with MDs (95% confidence intervals) of 90.97 (57.30, 124.64), 90.70 (46.12, 135.29), and 158.55 (132.76, 184.34) ml, respectively. Subgroup analysis showed a dose-response relationship between BONT-A and MCC. This systematic review and meta-analysis supports the efficacy of antimuscarinics, intravesical vanilloids, and BONT-A in improving MCC in NDO patients due to spinal causes.

Keywords: Neurogenic Detrusor Overactivity, Spinal Causes, Pharmacological Management, Maximal Cystometric Capacity, Urodynamics

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INTRODUCTION

Adult patients with neurogenic detrusor overactivity (NDO) secondary to spinal cord lesions are at increased risk of incontinence and upper urinary tract damage compared to other etiologies (Panicker et al., 2015; Powell, 2016). Earlier studies revealed differences in urodynamic patterns in NDO between spinal and non-spinal causes. (Chiang et al., 2022; Khanna et al., 2009) Maximal cystometric capacity (MCC), a urodynamic parameter which reflects bladder capacity (Rosier et al., 2017), is used to monitor bladder storage function in NDO.

Pharmacological management aims to improve bladder storage function in these individuals. Current options include antimuscarinics, β_3 -adrenergic agonists (β_3 -agonists), and botulinum toxin type A (BONT-A) injections, α -adrenergic blockers (α -blockers), cannabinoids, intravesical vanilloids, and tricyclic antidepressants (Ginsberg et al., 2021; Romo et al., 2018; Sartori et al., 2024).

LITERATURE REVIEWS

Previous systematic reviews and meta-analyses (SRMA) have evaluated pharmacological management for NDO across all etiologies (Chen et al., 2023; Madhuvrata et al., 2012; Xu et al., 2022; Zhou et al., 2024) However, a comprehensive SRMA specifically focusing on all pharmacological treatments in patients with NDO due to spinal cord lesions remains lacking.

RESEARCH METHODOLOGY

Databases and Search Engines

A systematic search of MEDLINE (via PubMed) and Scopus was conducted from databases' inception to November 2024 to identify relevant studies. Search terms were developed based on the following concepts on participant, intervention, and study design: "neurogenic bladder", "neurogenic detrusor overactivity", "spinal cord diseases", "antimuscarinics", "alpha adrenergic blockers", " β_3 -adrenoreceptor agonists", "gabapentinoids", "tricyclic antidepressants", "cannabinoids", "vanilloid agonists", "botulinum" and "clinical trial". The search terms are provided in Supplementary Tables 1 and 2.

Selection of Studies, Data Extraction, and Risk of Bias Assessment

The retrieved articles were independently screened on title and abstract, and then selected on full text by two reviewers (SM and PT), based on the following inclusion criteria: randomized control trials (RCTs) of adult NDO patients whose majority were of spinal causes; pharmacological treatments for storage symptoms compared with placebo; and MCC as an outcome. Duplicate reports of the same studies were excluded. The data extraction and risk of bias assessment, using the Cochrane Risk of Bias Tool for Randomized Trials (RoB 2.0) (Sterne et al., 2019), were done independently by the same two reviewers. Disagreements were solved through discussion with a third reviewer (KT).

Statistical Analysis

Mean differences (MD) were pooled through meta-analysis on each intervention with at least three RCTs, using the DerSimonian-Laird random-effects model. Subgroup analysis was performed according to the route of administration (oral vs. intravesical) and BONT-A dose (Scaglione, 2016).

RESEARCH RESULTS

Study Selection and Characteristics of Included Study

Twenty-five RCTs were eligible. The selection process is shown in Figure 1 and the eligible studies' characteristics in Table 1. Of the 2,601 participants included, the mean age ranged from 29.8 to 53 years. The mean MCC at baseline ranged from 162.8 to 370 ml. Mean duration

of follow up urodynamics after initiating the medications ranged from two to 12 weeks. The interventions considered in the eligible RCTs include antimuscarinics, $\beta 3$ agonists, α -blockers, botulinum toxin injection, and intravesical vanilloids.

According to the RoB 2.0, ten studies showed low risk of bias (Apostolidis et al., 2013; Cruz et al., 2011; de Sèze et al., 2006; Denys et al., 2017; Ginsberg et al., 2012; Honda et al., 2021; Kennelly et al., 2022; Krhut et al., 2018; Schurch et al., 2005; Tullman et al., 2018), nine studies showed some concern (Abrams et al., 2003; Amarenco et al., 2017; de Sèze et al., 1998; Herschorn et al., 2011; Lehtoranta et al., 2002; Petersen et al., 1989; Stöhrer et al., 1999; Van Kerrebroeck et al., 1998; Welk et al., 2018), and six studies showed high risk of bias (Ehren et al., 2007; Ethans et al., 2004; Kim et al., 2003; Petersen et al., 1999; Silva et al., 2005; Stöhrer et al., 1991).

Antimuscarinics

Meta-analysis showed that antimuscarinic group had higher MCC than placebo group, with a pooled MD (95% confidence interval [CI]) of 90.97 (57.30, 124.64) ml. Subgroup analysis by the route of administration showed that oral antimuscarinics (from five RCTs) resulted in higher MCC than did intravesical antimuscarinics (from one RCT) (Figure 2). The funnel plot was symmetrical and Egger's test showed a non-significant p-value of 0.667, suggesting no publication bias.

$\beta 3$ -Agonists

Welk et al. (2018) showed that the mirabegron group had a median (interquartile range [IQR]) MCC of 291 (124-416) ml, which was not significantly different (p-value=0.20) from that of the placebo group, with a median MCC (IQR) of 282 (151-450) ml. Khut et al. (2018) showed that the mirabegron produced a non-significantly (p-value=0.06) higher mean \pm standard deviation (SD) MCC (238.81 \pm 150.56 ml) than did placebo (167.56 \pm 102.96 ml). Meta-analysis was not performed.

α -Blockers

Abram et al. (2003) reported that tamsulosin 0.4 mg/day, tamsulosin 0.8 mg/day, and placebo groups had no significant MCC change from baseline, with mean change \pm standard error of 7.3 \pm 12.6, 17.3 \pm 16.0, and 5.3 \pm 11.2 ml, respectively, which were also not significantly different. Petersen et al. (1989) showed that the change in MCC from prazosin was similar to that from placebo, with a mean difference \pm SD of 3 \pm 160 ml.

Intravesical Vanilloids

The meta-analysis results are shown in Figure 3. Kim et al. (2003) studied the effect of resiniferatoxin across seven different doses. A sensitivity analysis by excluding this study found that intravesical vanilloids led to significantly higher MCC than did placebo, with a pooled MD (95% CI) of 90.70 (46.12, 135.29) ml. The overall meta-analysis's funnel plot was asymmetrical although Egger's test showed a non-significant p-value of 0.523. The contour-enhanced funnel plot showed studies in both the significant and non-significant areas. This, along with the I^2 value of 72.6%, suggest that heterogeneity, but not publication bias, was the probable cause of the asymmetry.

Botulinum Toxin Type A Injection

The overall meta-analysis indicated that BONT-A produced higher MCC than did placebo after a single injection (pooled MD [95% CI] of 158.55 [132.76, 184.34] ml). Subgroup analysis, stratified by dose revealed a dose-response relationship for this treatment. The funnel plot was asymmetrical although Egger's test showed a non-significant p-value of 0.228. The contour-enhanced funnel plot showed that most studies were in the significant area but only one in the non-significant area, suggesting publication bias as the probable cause of the asymmetry.

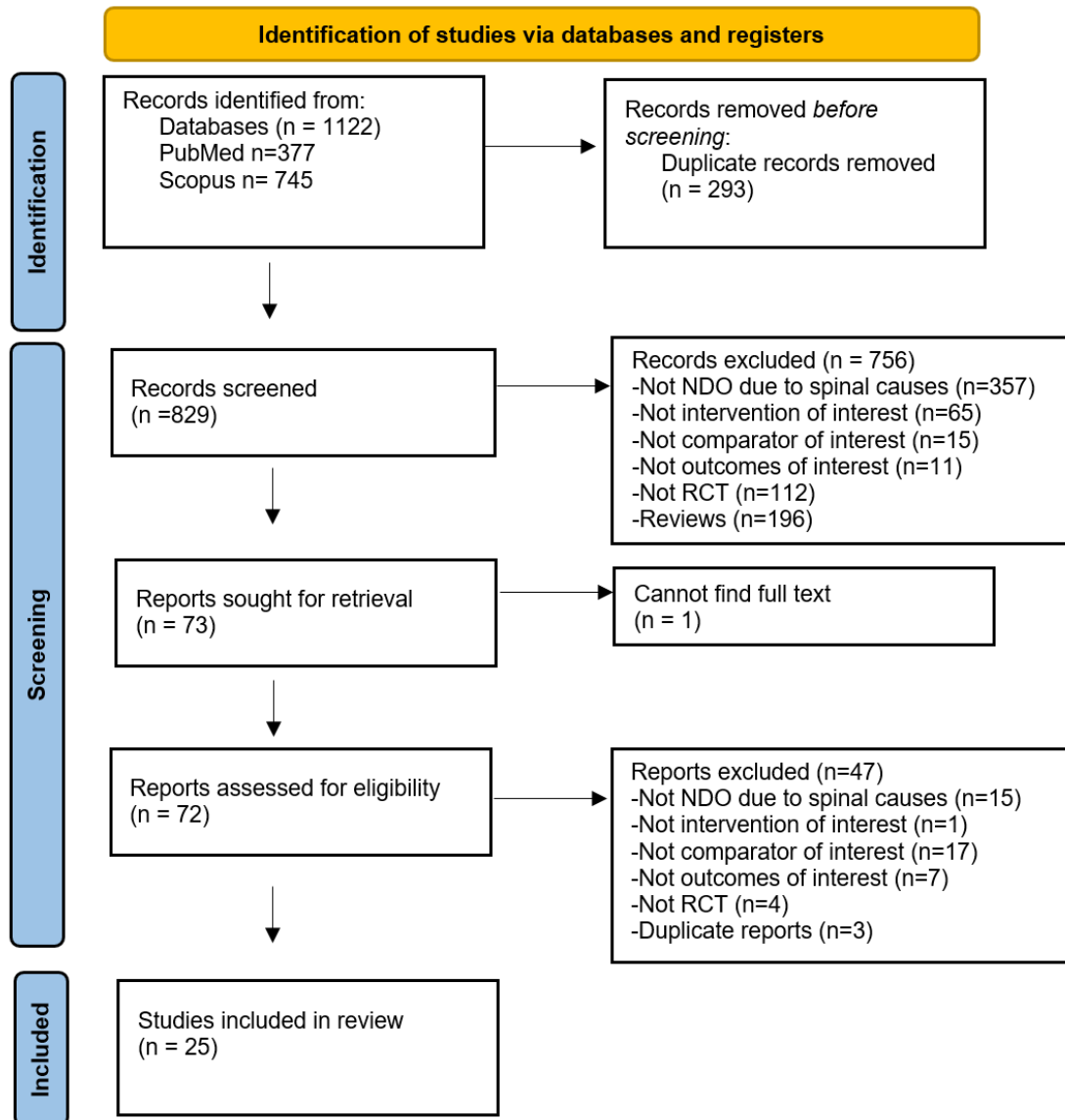


Figure 1 PRISMA flow diagram

Table 1 Characteristics and details of population and intervention of the included studies

Drug class	Author, year	Age	SCI %	MS %	MCC* (ml)	Intervention and dose	Control	Follow-up (weeks)
Antimuscarinics	Amarenco 2017	44	45	55	222	solifenacin 5-10 mg and oxybutynin 15 mg	placebo	4
	Ethans 2004	41	70	20	244	tolterodine 4 mg	placebo	2
	Stohrer 1999	30	100	0	279	propiverine 45 mg	placebo	2
	Van Kerrebroeck 1998	42	43	26	176	tolterodine 1-8 mg	placebo	2
	Stohrer 1991	33	100	0	178	tropium 40 mg	placebo	3
	Lehtoranta 2002	37	33	22	232	intravesical oxybutynin 15 mg	saline	2
β3 agonists	Welk 2018	53	60	41	274	mirabegron 50 mg	placebo	10
	Krhut 2018	44	74	26	197	mirabegron 50 mg	placebo	4
α-blockers	Abrams 2003	37	100	0	238	tamsulosin 0.4-0.8 mg	placebo	4
	Petersen 1989	51	0	70	370	prazosin 4.5-9 mg	placebo	4
Intravesical vanilloids	De Seze 2006	41	21	79	218	capsaicin 1 mM + glusidic solvent	glusidic solvent	4
	Silva 2005	38	39	29	194	resiniferatoxin 0.05 μM in 10% ethanol	10% ethanol +saline	12
	Kim 2003	42	56	19	222	resiniferatoxin 0.005-1 μM in 10% ethanol	10% ethanol +saline	3
	Petersen 1999	45	42	58	210	capsaicin 1 mM in 30% ethanol	saline	4
	De Seze 1998	43	40	60	163	capsaicin 1 mM in 30% ethanol	30% ethanol + saline	4
Botulinum toxin type A injection	Kennelly 2022	42	70	30	221	abobotulinum 600-800 units	saline	6
	Honda 2021	49	100	0	246	onabotulinum 200 units	saline	6
	Tullman 2018	52	0	100	246	onabotulinum 100 units	saline	6
	Denys 2017	46	39	62	254	abobotulinum 750 units	saline	6
	Apostolidis 2013	34	100	0	195	onabotulinum 100-200 units	saline	6
	Ginsberg 2011	46	45	55	255	onabotulinum 200-300 units	saline	6
	Cruz 2011	46	44	56	248	onabotulinum 200-300 units	saline	6
	Herschorn 2011	43	67	34	284	onabotulinum 300 units	saline	6
	Ehren2007	36	65	19	262	abobotulinum 500 units	saline	6
	Schurch 2005	41	90	10	269	onabotulinum 200-300 units	saline	2

Note: SCI, spinal cord injury; MS, multiple sclerosis; MCC*, maximal cystometric capacity at baseline

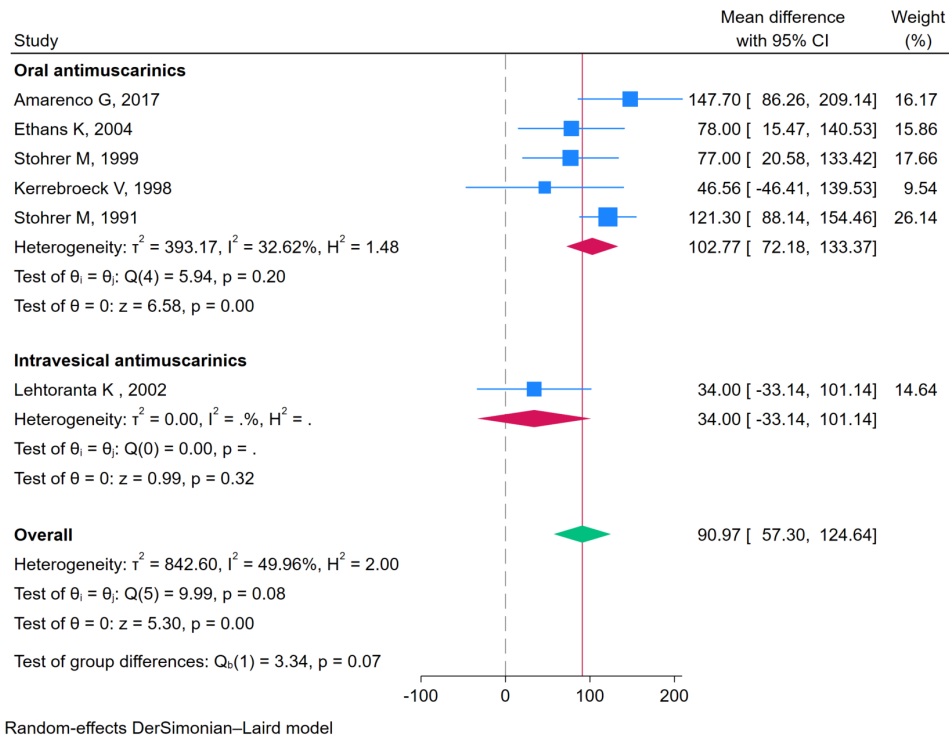


Figure 2 Forest plot of MCC after receiving antimuscarinics

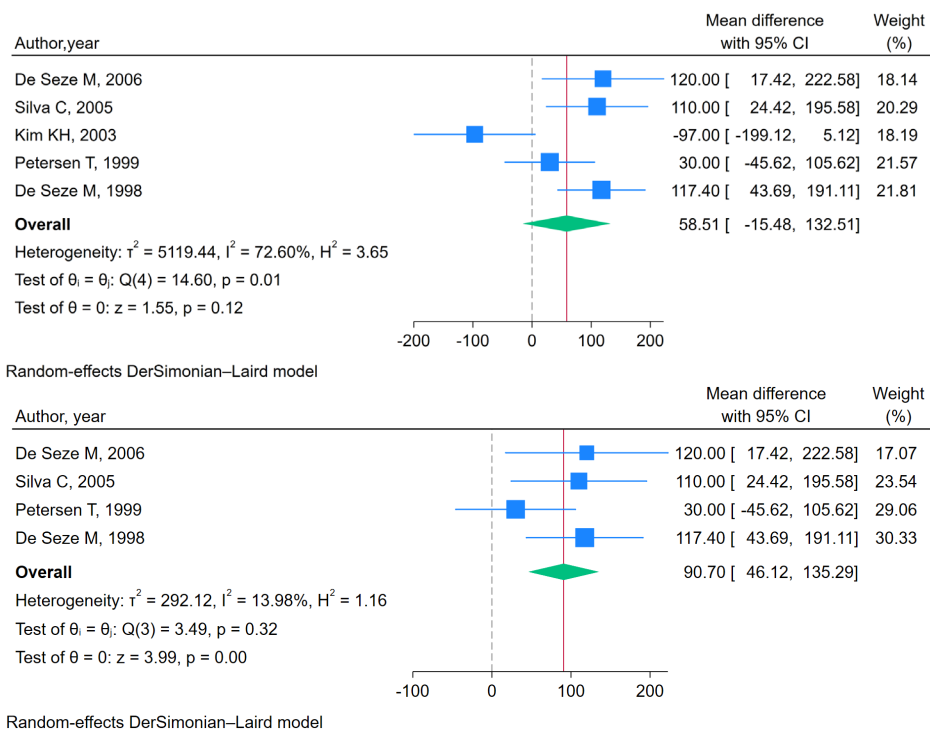


Figure 3 Forest plot of MCC after receiving single dose of intravesical vanilloids and after sensitivity analysis

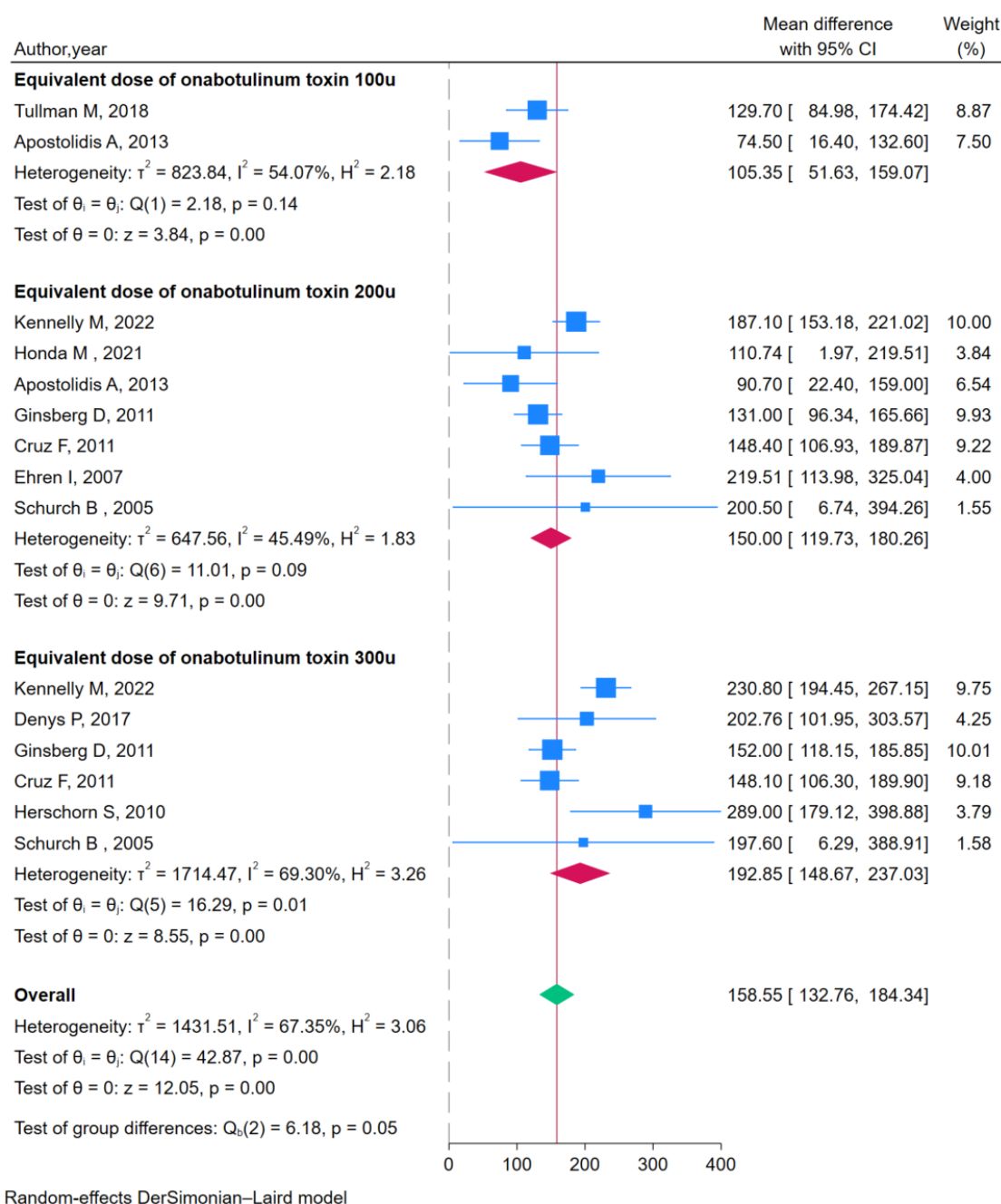


Figure 4 Forest plot of MCC after receiving botulinum toxin A intradetrusor injection

DISCUSSION & CONCLUSION

This SRMA was performed to investigate the efficacy of pharmacological management on MCC in NDO patients due to spinal causes. Preliminary results showed that β 3-agonists and α -blockers might not significantly increase MCC relative to placebo; meta-analysis was not feasible due to insufficient studies. However, significant increases in MCC were observed following treatment with antimuscarinics, intravesical vanilloids, and BONT-A injection. These findings are consistent with a previous SRMA on antimuscarinics in NDO of all etiologies (Madhuvrata et al., 2012), but inconsistent with another SRMA that included RCTs alongside observational studies on β 3-agonists (Yuanzhuo et al., 2022). Concomitant antimuscarinic use in observational studies might be involved in this difference. Our findings on intravesical vanilloids, based on five RCTs in patients with NDO due to all spinal causes, are also different from a previous SRMA whose fewer primary studies focused on NDO owing

to multiple sclerosis only (Phé et al., 2018). Meanwhile, despite the presence of previous SRMAs (Chen et al., 2023; Xu et al., 2022; Zhou et al., 2024), our meta-analysis which included three more RCTs on BONT-A (Denys et al., 2017; Ehren et al., 2007; Kennelly et al., 2022) could demonstrate its dose-response relationship with MCC.

The strength of this study is its focus on NDO patients due to spinal causes, which is a population with complex bladder dysfunction different from other neurogenic causes. The findings may support the use of antimuscarinics, intravesical vanilloids, and BONT-A injection in improving MCC. However, there are also some limitations. First, the number of RCTs on some interventions was small. Second, there was heterogeneity observed in the meta-analyses. The possible causes could be the difference in spinal cause (e.g., spinal cord injury and multiple sclerosis), neurological level of injury (cervical, thoracic, or lumbar), and concomitant treatment with antimuscarinics. However, the available data were not sufficient for subgroup analysis. Third, the findings on the efficacy of BoNT-A injection should be interpreted with caution due to the influence of publication bias. Fourth, some pharmacological therapies used for more specific symptoms in NDO patients, such as desmopressin for nocturnal polyuria and phosphodiesterase-5 inhibitors for erectile dysfunction, were not included. Lastly, MCC was the only urodynamic parameter considered in this SRMA. Future studies may include other clinically relevant urodynamic outcomes such as the maximal detrusor pressure and bladder compliance.

In conclusion, the findings of this SRMA support the efficacy of antimuscarinics, intravesical vanilloids, and BONT-A injection in improving MCC in NDO patients due to spinal etiologies. However, the evidence is insufficient to conclude the effects of β 3-agonists and α -blockers in this population.

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