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Effects of Pseudoephedrine on Urinary and Voiding Function in Adults: A Systematic Review

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Keyword: Pseudoephedrine; Voiding Dysfunction; Lower Urinary Tract Symptoms; Urinary Retention;

Abstract
Introduction: *Pseudoephedrine is a sympathomimetic decongestant that may affect urinary function by increasing bladder outlet resistance.* ***Objective:*** *To synthesize clinical evidence on the effects of pseudoephedrine on urinary and voiding function in adults.* ***Method:*** *This systematic review was prospectively registered in PROSPERO (CRD420261485354). PubMed, Scopus, and ScienceDirect were searched on 19 August 2026. Eligible studies were original human studies of adults receiving systemic pseudoephedrine and reporting urinary or voiding outcomes. Findings were synthesized narratively because of clinical and methodological heterogeneity.* ***Result and Discussion:*** *Three prospective studies involving 387 participants were included. Overall, pseudoephedrine produced minimal changes in urinary function. In men, urinary symptom scores generally increased without significant overall deterioration. Men aged 50 years or older showed significant increases in total symptom scores, while higher baseline symptom severity was associated with greater deterioration and increased residual urine volume. In premenopausal women without urinary symptoms, short-term use did not significantly impair urodynamic or urethral neuromuscular parameters.* ***Conclusions:*** *Pseudoephedrine appears to have limited urinary effects in most adults, but older men and individuals with greater baseline urinary symptoms may require greater caution. Further studies are warranted.*

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Introduction

Pseudoephedrine is a commonly used sympathomimetic agent for the relief of nasal congestion associated with acute and chronic rhinitis. Because of its systemic adrenergic activity, it may also affect the lower urinary tract and potentially interfere with normal voiding function.(Diantini et al., 2024; Lee, Tam, Chang, Hsieh, & Shao, 2020; Shao et al., 2016) Given its widespread use among adults, understanding its potential urinary effects is clinically relevant. Lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH) affect approximately 25% of men in the United States, and nearly half experience symptoms of at least moderate severity.(Arnold, Gaillardetz, & Ohiokpehai, 2023) Storage symptoms include frequency, nocturia, urgency, and urge incontinence, whereas voiding symptoms include hesitancy, weak urinary stream, dribbling, and a feeling of incomplete bladder emptying.(Dawson, 2023) α1-Adrenoceptors are expressed in the bladder trigone and urethra, where their activation increases smooth-muscle tone and can contribute to bladder outlet resistance.(Hennenberg & Michel, 2024)

Pseudoephedrine may affect urinary function through adrenergic mechanisms. α1-Adrenoceptor stimulation can increase bladder outlet resistance through smooth-muscle contraction in the bladder neck, urethra, and prostate, although the clinical significance of these effects remains uncertain.(Hennenberg & Michel, 2024; Lee et al., 2020; Shao et al., 2016). Concerns about sympathomimetic-associated urinary symptoms are not new. Reports of dysuria and urinary retention associated with pseudoephedrine or ephedrine date back nearly a century, beginning with a report and followed by subsequent reports involving sympathomimetic decongestants. More recent literature continues to recognize urinary adverse effects as a potential concern with pseudoephedrine use.(Diantini et al., 2024; Shao et al., 2016)

Despite this history, product labeling has generally focused caution on men with diagnosed BPH or established urinary retention, while pseudoephedrine-associated urinary retention remains a recognized adverse effect.(Diantini et al., 2024; Lee et al., 2020; Shao et al., 2016). Clinical evidence specifically addressing pseudoephedrine and urinary function remains limited and somewhat inconsistent. Prospective studies using the International Prostate Symptom Score (IPSS) have generally found only modest and largely non-significant changes in urinary symptoms among adult men, consistent with the recognized potential for pseudoephedrine to affect urinary function as a sympathomimetic agent, while total IPSS increased significantly in men aged ≥50 years in both studies and higher baseline IPSS-voiding scores were associated with greater deterioration and increased residual urine volume.(Douhard, Humbert, Milon, & Pegahi, 2024; Lee et al., 2020; Shao et al., 2016)

In contrast, a randomized pilot study involving premenopausal women without LUTS found no significant changes in urethral sphincter electromyographic activity or pressure-flow parameters after pseudoephedrine administration, although urethral sensation increased during 5-Hz stimulation, consistent with the known role of urethral adrenergic mechanisms in urinary function.(Andersson & Uvelius, 2024; Greer et al., 2015) Taken together, the available studies have examined different populations and used a range of subjective and objective measures, making it difficult to determine the clinical magnitude of pseudoephedrine-related urinary effects or whether certain groups are more susceptible than others. To our knowledge, no previous systematic review has brought together the available evidence across sex, age, and study methodology.

This systematic review therefore aimed to synthesize the clinical evidence on the effects of pseudoephedrine on urinary and voiding function in adults, with particular attention to age-related susceptibility, differences between subjective and objective outcomes, and comparisons with other decongestant or anticholinergic agents when available. The review included prospective clinical studies using cohort or randomized designs that evaluated pseudoephedrine in adult men or women and reported validated urinary symptom scores, postvoid residual urine volume, pressure-flow measurements, or urethral electrophysiological or sensory outcomes. Studies involving pediatric populations, animals, or non-clinical pharmacokinetic outcomes were excluded from the primary scope.

Method

Study Design

This systematic review evaluated clinical evidence regarding the effects of pseudoephedrine on urinary and voiding function in adults, including lower urinary tract symptoms, subjective voiding dysfunction, and objective urinary or urethral parameters. Randomized controlled and prospective observational studies were eligible. Studies were eligible when they included adults aged ≥18 years exposed to systemic pseudoephedrine, including oral formulations used for nasal decongestion. Eligible comparators included placebo, no exposure, baseline assessment, or another medication used for the same indication. Studies had to report at least one relevant outcome, including LUTS, IPSS, urinary retention, urinary flow, Qmax, PVR, urinary adverse events, or catheterization. Only original human studies published in English and available as full-text articles were included. Studies were excluded if they involved animals, in vitro experiments, pediatric populations, or conditions unrelated to urinary function. Reviews, systematic reviews, meta-analyses, editorials, letters, commentaries, and conference abstracts without sufficient clinical data were excluded, as were case reports and very small case series. Studies without pseudoephedrine exposure, relevant urinary outcomes, or sufficient methodological information were also excluded, as were duplicate publications.

Literature Search Strategy

A systematic search of PubMed, Scopus, and ScienceDirect was conducted on 19 August 2026 without publication-year restrictions. The strategy targeted pseudoephedrine in relation to LUTS, voiding dysfunction, urinary retention, and objective urinary parameters.

Table 1
Search Strategies

Database	Search strategy	Search limits	Records identified
PubMed	**#1:** ("Pseudoephedrine"[Title/Abstract] OR "pseudoephedrine sulfate"[Title/Abstract]); **#2:** ("Lower Urinary Tract Symptoms"[Title/Abstract] OR LUTS[Title/Abstract] OR "International Prostate Symptom Score"[Title/Abstract] OR IPSS[Title/Abstract] OR "voiding dysfunction"[Title/Abstract] OR "voiding function"[Title/Abstract] OR "urinary retention"[Title/Abstract] OR "postvoid residual"[Title/Abstract] OR "post-void residual"[Title/Abstract] OR "urinary flow"[Title/Abstract] OR "maximum urinary flow rate"[Title/Abstract] OR Qmax[Title/Abstract]); **#3:** #1 AND #2	No publication-year restriction; human studies; English-language publications; no full-text filter	**6**
Scopus	TITLE-ABS-KEY(pseudoephedrine OR "pseudoephedrine sulfate") AND TITLE-ABS-KEY("lower urinary tract symptoms" OR LUTS OR "International Prostate Symptom Score" OR IPSS OR "voiding dysfunction" OR "voiding function" OR "urinary retention" OR "postvoid residual" OR "urinary flow" OR Qmax)	No publication-year restriction; English-language articles	**49**
ScienceDirect	pseudoephedrine AND ("lower urinary tract symptoms" OR LUTS OR "International Prostate Symptom Score" OR IPSS OR "voiding dysfunction" OR "urinary retention" OR "postvoid residual" OR "urinary flow")	No publication-year restriction; research articles	**182**

Study Selection

A total of 237 records were identified: PubMed (n = 6), Scopus (n = 49), and ScienceDirect (n = 182). Records were imported into Rayyan for duplicate detection and screening. Rayyan identified 45 duplicate records. After duplicate resolution, 23 records were deleted as duplicates and 22 were resolved as not duplicate, leaving 214 records for title and abstract screening. The 214 records were screened against the predefined criteria and excluded when they did not evaluate pseudoephedrine, lacked relevant urinary outcomes, involved pediatric or non-human populations, were not eligible original research, or failed the predefined design or language criteria. Study selection was independently performed by two reviewers, with disagreements resolved through discussion and consensus.

Data Collection Process

Data were independently extracted using a standardized form. Variables included author and year, design, duration, population, sample size, age, pseudoephedrine formulation and dose, comparator, baseline urinary status, IPSS, voiding and storage scores, PVR, urinary flow or pressure-flow parameters, urinary adverse events, acute urinary retention, and main findings. Missing or unclear data were recorded as unavailable unless explicitly reported. Disagreements were resolved by discussion and consensus.

Result and Discussion

1. Result

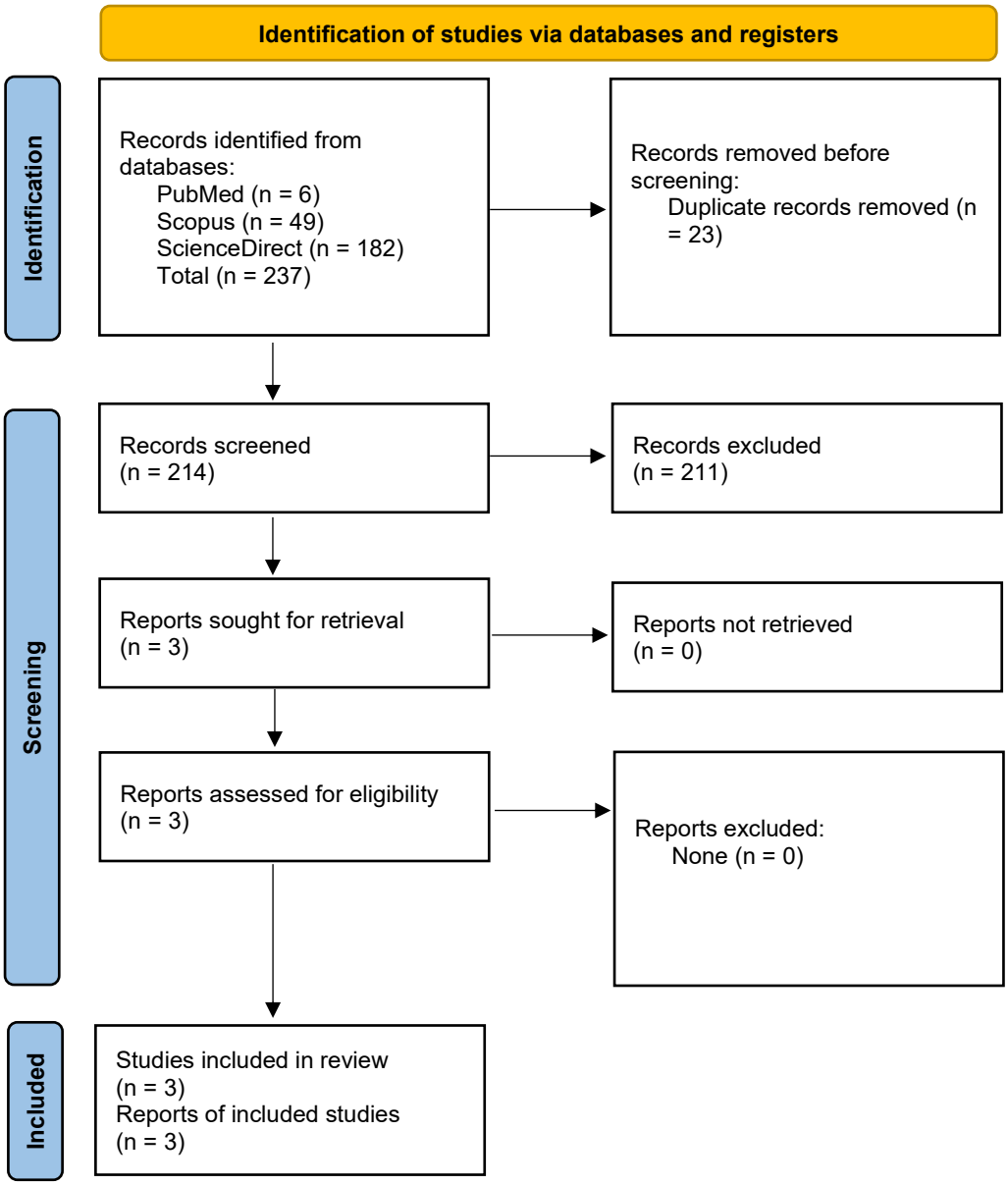

Figure 1. PRISMA 2020 Flow Summary

Risk of Bias Assessment

Risk of bias was assessed according to study design. Randomized controlled trials were evaluated using RoB 2 across the randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of reported results. The prospective observational study was assessed using the cohort Newcastle–Ottawa Scale, covering selection, comparability, and outcome domains. Assessments were based only on information reported in the original studies.

Table 2
RoB 2 Traffic-Light Summary

Study	D1. Bias arising from the randomization process	D2. Bias due to deviations from intended interventions	D3. Bias due to missing outcome data	D4. Bias in measurement of the outcome	D5. Bias in selection of the reported result	Overall risk of bias
Greer et al. (2015)	Some concerns	Low risk	Some concerns	Low risk	Some concerns	**Some concerns**
Lee et al. (2020)	Some concerns	Some concerns	Low risk	Some concerns	Some concerns	**Some concerns**

Legend: Low risk; Some concerns; High risk.

The randomized study by(Greer et al., 2015) was judged to have some concerns overall. The randomization process raised concerns because computer-generated randomization was reported but allocation concealment was insufficiently described. Deviations from intended interventions were low risk because the study was double-blinded. Missing outcome data raised some concerns because not all randomized participants completed every follow-up assessment. Outcome measurement was judged low risk because standardized physiological assessments were used and investigators were blinded. Selection of the reported result also raised some concerns because prespecified analyses were insufficiently documented.

The study by(Lee et al., 2020) was also judged to have some concerns overall. Sequence generation and allocation concealment were insufficiently described, while blinding was unclear. The measurement-of-outcome domain raised some concerns because IPSS is subjective and the extent of blinding was uncertain. Missing outcome data were judged low risk based on available follow-up information, whereas selective reporting raised some concerns because multiple subgroup analyses were reported without adequate documentation of a prespecified analysis plan.

The prospective study by(Shao et al., 2016) received an NOS score of 6/9. The study had clear eligibility criteria, prospective exposure ascertainment, confirmation that the outcome was absent at baseline, standardized IPSS assessment, and complete follow-up. Comparability points were not awarded because no control group was included, limiting adjustment for confounding and causal inference. The short follow-up also limited assessment of longer-term outcomes.

Table 3
Newcastle–Ottawa Scale assessment of the observational study

Study	Selection of cohorts	Comparability of cohorts	Outcome	NOS score
Shao et al. (2016)	4/4	0/2	2/3	**6/9**

No RoB 2 domain in either randomized study was judged high risk. Both were therefore classified as having some concerns overall, mainly because of incomplete reporting of allocation procedures, blinding, missing data, and prespecified analyses. For selection, (Shao et al., 2016) received points for cohort representativeness, exposure ascertainment, and confirmation that the outcome was absent at baseline. No point was awarded for selection of a non-exposed cohort because none was included. No

comparability points were awarded because there was no control group, preventing meaningful adjustment for confounding. For outcome, points were awarded for outcome assessment and adequate follow-up. All 131 participants completed the study, and symptoms were assessed using IPSS. However, the 1-week follow-up limited assessment of longer-term effects.

Effect Measures

For continuous outcomes such as IPSS, PVR, Qmax, and pressure-flow parameters, baseline changes or between-group differences were considered where available. Dichotomous outcomes, including urinary retention, dysuria, difficulty urinating, and catheterization, were reported as frequencies or proportions. Where effect estimates could not be calculated, findings were presented as reported by the original studies.

Data Synthesis

A narrative synthesis was undertaken because participant characteristics, study design, pseudoephedrine dose and formulation, treatment duration, comparators, and outcome measures were heterogeneous. These differences prevented meaningful quantitative pooling or meta-analysis. The synthesis therefore focused on changes in urinary symptoms, IPSS, PVR, urinary flow, pressure-flow parameters, urethral sensory and neuromuscular measures, urinary retention, and adverse events. No subgroup, meta-regression, or sensitivity analysis was performed because of the small number of studies and substantial heterogeneity.

Reporting Bias and Certainty of Evidence

Formal assessment of publication bias or small-study effects was not performed because only three studies were included. Certainty of evidence was also not formally assessed using GRADE because the evidence base was small, heterogeneous, and unsuitable for quantitative synthesis.

Table 4
Characteristics and findings of included studies

Study	Design	n	Intervention vs Comparator	Main Results
Shao et al. (2016)	Prospective	131	Pseudoephedrine sulfate 120 mg BID vs baseline	IPSS increased significantly in men ≥50 years (9.95 to 11.45), suggesting subclinical voiding dysfunction. No significant change in men <50 years. Dysuria occurred in 3/131 (2.3%); no acute urinary retention.
Greer et al. (2015)	Prospective, randomized, double-blinded pilot study	56 randomized; 10 received pseudoephedrine	Pseudoephedrine ER 120 mg vs placebo	Pseudoephedrine increased urethral sensation but did not significantly alter neuromuscular or pressure-flow parameters.
Lee et al. (2020)	Prospective, randomized study	200	Pseudoephedrine sulfate 120 mg BID vs desloratadine 5 mg QD	Total IPSS increased significantly in men ≥50 years receiving pseudoephedrine. PVR increased in participants with baseline IPSS >7. No acute urinary retention.

2. Discussion

This systematic review synthesized clinical evidence regarding pseudoephedrine and urinary function in adults. Three prospective studies involving 387 participants were identified, comprising one uncontrolled before-and-after observational study and two randomized studies, with outcomes assessed using symptom scores, PVR, and objective urodynamic or electrophysiological measures. Overall, pseudoephedrine produced modest and largely non-significant changes in urinary function, but age- and baseline symptom-related differences were evident in men. Both(Lee et al., 2020; Shao et al., 2016) reported significant increases in total IPSS among men aged ≥50 years. Significant increases in voiding and storage subscores were observed only in.(Shao et al., 2016) Similarly, (Lee et al., 2020) also reported a significant increase in PVR among participants with higher baseline IPSS. In contrast,(Greer et al., 2015) found no significant impairment of urodynamic or urethral neuromuscular parameters in premenopausal women without LUTS. These findings suggest that urinary effects may depend more on age, baseline symptoms, and sex-specific characteristics than on a uniform drug effect.

Up to 40% of men older than 50 years experience LUTS, including urgency, nocturia, and weak urinary stream.(Wei, Dauw, & Brodsky, 2025) BPH is a common cause of LUTS in aging men and may substantially affect quality of life.(Zekraoui, Bhojani, Zorn, Elterman, & Chughtai, 2025). The present synthesis adds prospective symptom-score evidence to this background. In(Shao et al., 2016), 51.8% of men aged ≥50 years showed an increase in IPSS-T after pseudoephedrine exposure, which was considered subclinical voiding dysfunction despite the absence of subjective complaints at baseline. To our knowledge, this specific evidence has not been previously synthesized systematically. Nevertheless, the concordant increase in total IPSS across two studies suggests a possible age-dependent association, although the limited evidence prevents firm conclusions. Overall, substantial urinary deterioration was not observed in most adults, but older men and those with greater baseline symptom burden may warrant greater caution. These mechanisms contribute to both detrusor overactivity and underactivity, providing a unifying framework for storage and voiding symptoms.(Papanikolaou et al., 2026)

However, statistical significance should not be interpreted as equivalent to clinical significance. Although increases in IPSS and PVR were statistically significant in selected subgroups, the included male studies did not report acute urinary retention or catheterization. Therefore, the available evidence suggests that the observed changes may represent mild or subclinical worsening of urinary function rather than consistent clinically overt urinary obstruction. Because the included studies did not provide sufficient data to determine whether the observed changes exceeded established thresholds for clinically meaningful deterioration, the magnitude of their patient-level clinical impact remains uncertain. Baseline urinary status also appeared relevant. Men with higher premedication IPSS-voiding scores were more likely to show subclinical deterioration after pseudoephedrine exposure (Shao et al., 2016), while(Lee et al., 2020) found a significant PVR increase among men with baseline IPSS >7 but not among those with lower scores. This suggests that baseline urinary symptoms may complement age when identifying individuals potentially more vulnerable to pseudoephedrine. Interestingly, desloratadine produced a different pattern, with worsening IPSS-V among men younger than 50 years, whereas pseudoephedrine-associated deterioration was concentrated in older men.(Lee et al., 2020) In women, pseudoephedrine was associated

with increased urethral sensation rather than clinically evident dysfunction.(Greer et al., 2015) These contrasting findings indicate that age, baseline urinary status, and sex may modify drug effects, although the small number of studies prevents treatment-specific recommendations.

The observed patterns may plausibly reflect pseudoephedrine's mixed adrenergic effects. α1 stimulation can increase tone at the bladder neck, proximal urethra, and prostate, whereas β2 activity may promote smooth-muscle relaxation. The relative contribution of these mechanisms to clinically meaningful voiding dysfunction remains uncertain and was not directly examined in the included studies.(Lee et al., 2020; Shao et al., 2016) In younger individuals without prostate-related obstruction, these effects may remain clinically tolerated, with limited impact on overall voiding function.(Shao et al., 2016) In older men, age-related prostatic enlargement and changes in detrusor function may reduce functional reserve, making additional outlet resistance more clinically apparent. This interpretation is compatible with the worsening symptom scores in older men and increased PVR among participants with higher baseline IPSS.(Lee et al., 2020) Similarly, (Greer et al., 2015) also reported electrophysiological trends compatible with increased sphincter tone, although these did not reach statistical significance. Dysuria was reported in the prospective male study, but no acute urinary retention occurred in either male cohort.(Lee et al., 2020; Shao et al., 2016)

Thus, the biological mechanism provides a plausible explanation for the observed subgroup pattern, but it should be regarded as mechanistic interpretation rather than direct evidence of causality. The included studies did not directly measure α1- or β-adrenoceptor activity at the bladder outlet, and therefore the contribution of these pathways to the clinical findings cannot be established from the available data. BPH is highly prevalent with aging, and medical treatment remains a major approach for bothersome symptoms.(Te, Ramaswamy, & Kaplan, 2025) Objective assessment with uroflowmetry and PVR can complement symptom-based evaluation when voiding dysfunction is suspected.(Gravas et al., 2023) Changes in bladder outlet resistance may affect urinary symptoms and treatment response, supporting the potential clinical relevance of adrenergic effects on voiding function.(Koneval, Sommer, & Schneidewind, 2025) Because IPSS measures subjective symptom burden and may not directly correspond to objective urinary parameters, symptom changes should be interpreted together with measures such as PVR.(Kohler & Kausik, 2023)

From a clinical perspective, these findings suggest that pseudoephedrine is unlikely to cause substantial urinary deterioration in most adults, particularly in populations without baseline urinary symptoms. Nevertheless, clinicians may need to exercise greater caution when prescribing it to older men or individuals with pre-existing voiding symptoms, particularly when additional increases in outlet resistance could be poorly tolerated. The available evidence supports clinical awareness and symptom monitoring rather than routine avoidance of pseudoephedrine in all adults. Several strengths and limitations should be considered. All three studies were prospective and used validated or objective measures, including IPSS, PVR, pressure-flow studies, and electromyography. However, the evidence base comprised only three studies, with small samples and short follow-up of one to two weeks. The pseudoephedrine group in(Greer et al., 2015) was particularly small.(Shao et al., 2016) used an uncontrolled before-after design, limiting causal attribution and comparability. Both randomized studies had some concerns under RoB 2 because of incomplete reporting of randomization or allocation procedures, unclear blinding in (Lee et al., 2020), incomplete follow-up for some

outcomes in (Greer et al., 2015), and limited information regarding prespecified analyses. Generalizability is also limited because the male studies excluded established BPH or LUTS, while the female study was a small pilot in a predominantly African American population. The findings therefore support further investigation but do not justify firm clinical recommendations.

Conclusion

This systematic review found no substantial deterioration of urinary or voiding function in most adults exposed to pseudoephedrine. However, total urinary symptom scores increased in men aged ≥50 years, and higher baseline IPSS was associated with greater PVR increase. These findings suggest possible age- and symptom-dependent vulnerability, although causality cannot be established because of the small evidence base and uncontrolled design of one study. In premenopausal women without LUTS, short-term pseudoephedrine did not significantly alter urodynamic or urethral neuromuscular parameters. Further studies with larger samples, longer exposure and follow-up, standardized dosing, validated symptom measures, and objective urodynamic outcomes are needed.

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Limitations

This review included only three studies with small samples, short follow-up, and substantial clinical and methodological heterogeneity, preventing meta-analysis. One study used an uncontrolled before-and-after design, limiting causal inference, and both randomized studies had some concerns regarding risk of bias. The exclusion of men with established BPH or LUTS also limits generalizability to symptomatic populations.

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