Tamsulosin for kidney stones: The evidence keeps shrinking

Written by The Life Science Feed Editorial Team · Published 28 September 2026 · Edited by Mara Voss

Ureteral stones are a common cause of excruciating acute renal colic, frequently presenting in emergency departments and general practice across Europe. For years, medical expulsive therapy (MET) with alpha-1 adrenergic receptor blockers like tamsulosin has been a standard conservative management strategy, particularly for smaller distal stones, aiming to facilitate stone passage and reduce the need for surgical intervention. However, a growing body of robust evidence now challenges the previously accepted efficacy of tamsulosin, suggesting its benefit may be far less significant than once believed.

KEY TAKEAWAYS

- The Pivot: Larger, more robust randomised controlled trials increasingly show no significant benefit of tamsulosin for medical expulsive therapy in patients with ureteral stones.
- The Data: A 2019 meta-analysis of placebo-controlled trials found no statistically significant difference in stone passage rates with tamsulosin (e.g., Tao RZ et al., Urol J. 2019;16(3): 224-231).
- The Action: Re-evaluate the routine use of tamsulosin for medical expulsive therapy, particularly for smaller distal ureteral stones where spontaneous passage rates are already high.

Ureteral stones, particularly those causing acute renal colic, represent a common presentation in emergency departments and general practice. The pain is often excruciating, driven by obstruction and subsequent hydronephrosis. Management strategies traditionally aim to relieve pain, facilitate stone passage, and prevent complications such as infection or renal damage. For smaller stones, especially those located in the distal ureter, conservative management has long been the initial approach, often coupled with analgesia and hydration. The concept of medical expulsive therapy (MET) emerged as an adjunct to this conservative strategy, seeking to actively promote stone expulsion.

Alpha-1 adrenergic receptor blockers, such as tamsulosin, became the primary candidates for MET. These agents work by relaxing the smooth muscle in the ureter, particularly at the ureterovesical junction, which is a common site for stone impaction. The rationale was that by reducing ureteral spasm and resistance, tamsulosin would increase the rate of spontaneous stone passage, decrease the time to passage, and potentially reduce the need for surgical intervention or hospitalisation. This physiological mechanism seemed plausible, leading to widespread adoption in clinical guidelines and routine practice across Europe and beyond. Many clinicians, consulting resources like the Oxford Handbook of General Practice, would have found this approach listed as a standard option.

The Shifting Sands of Evidence

Initial studies, often smaller and less rigorously designed, did suggest a benefit for tamsulosin in facilitating stone passage. These early trials frequently reported higher rates of stone expulsion and reduced pain scores in patients receiving tamsulosin compared to placebo or standard care. This positive signal drove the rapid integration of tamsulosin into clinical algorithms. The drug's relatively benign side effect profile, primarily orthostatic hypotension and ejaculatory dysfunction, further contributed to its appeal as a low-risk intervention for a high-morbidity condition.

But as larger, more robust randomised controlled trials began to emerge, the picture grew less clear. These studies, designed with greater statistical power and more stringent methodologies, started to challenge the previously accepted efficacy of tamsulosin. Many of these trials focused on patients with distal ureteral stones, typically those less than 10 mm, as this was the population where MET was theoretically most beneficial and where spontaneous passage was already more likely. The primary endpoint in most of these investigations was the rate of spontaneous stone passage, often within a defined period, such as four weeks.

A recurring theme in these later, larger trials was the lack of a statistically significant difference in stone passage rates between the tamsulosin group and the placebo group. While some studies still showed a numerical trend towards improved passage with tamsulosin, these differences often failed to reach statistical significance. This was particularly true for smaller stones, where the natural history of spontaneous passage is already high. The effect size, if any, appeared to be marginal at best, raising questions about the clinical meaningfulness of any observed benefit.

Dissecting the Discrepancy

The discrepancy between earlier positive findings and later negative or equivocal results can be attributed to several factors. Many initial studies suffered from methodological limitations, including small sample sizes, lack of proper randomisation or blinding, and heterogeneity in patient populations and stone characteristics. These issues can lead to an overestimation of treatment effects. Larger, multicentre trials, with their improved design and greater statistical power, are better equipped to detect true differences, or the absence thereof, between interventions.

Another factor is the natural history of ureteral stones. Many small, distal ureteral stones will pass spontaneously without any intervention beyond hydration and analgesia. This high baseline rate of spontaneous passage makes it challenging to demonstrate a significant additional benefit from a medical therapy unless that therapy has a very substantial effect. If a drug only marginally increases an already high passage rate, a very large sample size is needed to detect that small increment, and even then, its clinical utility might be debatable. This is a common challenge in trials for conditions with a high rate of natural resolution, where the bar for demonstrating efficacy is inherently higher.

The specific characteristics of the stones themselves also play a role. Stone size, location, and composition are all critical determinants of spontaneous passage. Tamsulosin's mechanism of action targets smooth muscle relaxation, which might be more relevant for stones impacted at specific anatomical narrowings, such as the ureterovesical junction. But for larger stones, or those lodged in areas less amenable to smooth muscle relaxation, the drug's utility would naturally diminish. The heterogeneity of stone characteristics across different trials could therefore contribute to varying results.

Beyond Stone Passage: Other Endpoints

Beyond the primary endpoint of stone passage, researchers also investigated other clinically relevant outcomes, such as time to stone passage, pain scores, need for analgesia, and rates of surgical intervention. Here too, the evidence for tamsulosin has been inconsistent. While some studies reported a reduction in time to passage or a decrease in pain, these

benefits were not universally observed across all trials. The impact on the need for surgical intervention, a patient-centred outcome, also failed to show a consistent, significant reduction with tamsulosin in many of the larger studies.

The safety profile of tamsulosin, while generally favourable, still includes potential adverse events. Orthostatic hypotension, though often mild, can be problematic, especially in older patients or those with cardiovascular comorbidities. Ejaculatory dysfunction, a common side effect, can impact quality of life and adherence, particularly in younger male patients. If the clinical benefit is marginal, then even a relatively mild side effect profile becomes a more significant consideration. Clinicians must weigh these potential harms against an increasingly uncertain benefit, a dilemma that also arises in discussions around sexual side effects of BPH treatment.

Implications for Clinical Practice

The accumulating evidence suggests a need to re-evaluate the routine use of tamsulosin as medical expulsive therapy for distal ureteral stones. While it remains a guideline-recommended option in some regions, the strength of that recommendation is weakening. For smaller stones, where spontaneous passage is highly likely, the addition of tamsulosin may offer little to no additional benefit, exposing patients to unnecessary medication and potential side effects. This is particularly relevant in primary care settings, where tamsulosin is often prescribed empirically without extensive urological evaluation.

For larger stones, or those with features suggesting a lower likelihood of spontaneous passage, the role of MET becomes even more questionable. In these cases, early urological consultation and consideration of definitive interventions, such as ureteroscopy or lithotripsy, may be more appropriate. The focus should shift towards identifying patients who genuinely benefit from active medical intervention versus those who can be managed expectantly with pain control alone. This approach requires careful patient selection and shared decision-making, moving away from a blanket prescription strategy.

The ongoing debate highlights the importance of continually scrutinising established clinical practices with robust, contemporary evidence. What once seemed like a clear-cut benefit has, under closer examination, become far less certain. This evolution in understanding shows the dynamic nature of medical evidence and the need for clinicians to remain critical consumers of research, even for therapies that have been widely adopted. The field of urology, like many others, continues to refine its approaches to common conditions, as seen in discussions around new BPH therapies and their long-term outcomes.

Where the Evidence Falls Short

Despite the numerous trials, several gaps in the evidence remain. Most studies have focused on a relatively narrow range of stone sizes and locations. The efficacy of tamsulosin for very small stones (e.g., The cost-effectiveness of tamsulosin as MET is another area that warrants further investigation. If the clinical benefit is minimal, then the cost of the medication, even if relatively low, combined with the potential for side effects and follow-up visits, might not justify its routine use. Health economic analyses, integrating the latest efficacy data, are important for informing guideline development and resource allocation. Without clear evidence of benefit, the default should be to avoid unnecessary polypharmacy.

The role of other alpha-blockers, or indeed other classes of drugs, in medical expulsive therapy also requires ongoing evaluation. While tamsulosin has been the most studied agent, other alpha-blockers exist, and their efficacy profile might differ. Similarly, other pharmacological approaches, such as phosphodiesterase-5 inhibitors or calcium channel blockers,

have been explored, but none have consistently demonstrated superior efficacy to warrant widespread adoption. The search for an effective, well-tolerated MET continues, but for now, the evidence for tamsulosin is simply not compelling enough to maintain its previous standing as a universally recommended therapy.

CLINICAL IMPLICATIONS

The most striking consequence of this evolving evidence is the need for a significant re-evaluation of medical expulsive therapy (MET) guidelines, particularly those from bodies like the European Association of Urology (EAU). For years, tamsulosin has been a cornerstone of conservative management for distal ureteral stones. Now, the robust data from larger trials indicates its benefit is, at best, marginal. This calls for a shift away from routine prescription for most patients.

For clinicians, this means moving beyond ingrained habits. The Oxford Handbook of General Practice, and similar resources, must reflect this updated understanding. Prescribing tamsulosin for small, distal stones without strong justification may expose patients to unnecessary medication and potential side effects, however mild. The focus should return to robust pain management and vigilant monitoring for spontaneous passage, which is often high for these stones anyway.

The pharmaceutical industry, particularly manufacturers of alpha-blockers like Boehringer Ingelheim (Flomax) and Astellas Pharma (Harnal), must acknowledge this shift. While these drugs remain vital for other indications, their role in kidney stone management is diminishing. Patients, in turn, should be counselled on the limited evidence for tamsulosin in this context. Shared decision-making, based on current data, is paramount.

REFERENCES

1. 1. Tao RZ, Qin ZQ, Liu FD, Lv JL. Efficacy and Safety of Tamsulosin in the Medical Expulsion Therapy for Distal Ureteral Calculi: A Systematic Review and Meta-Analysis of Placebo-Controlled Trials. Urol J. 2019;16(3):224-231. doi:10.22037/uj.v0i0.4758
2. 2. Li JK, Qiu S, Jin K, et al. Efficacy and safety of phosphodiesterase type 5 inhibitors for the treatment of distal ureteral calculi of 5 to 10 mm in size: A systematic review and network meta-analysis. Kaohsiung J Med Sci. 2019;35(5):257-264. doi:10.1002/kjm2.12048
3. 3. Ge H, Zheng X, Na Y, et al. Bilateral Same-Session Ureteroscopy for Treatment of Ureteral Calculi: A Systematic Review and Meta-Analysis. J Endourol. 2016;30(11):1169-1179. doi:10.1089/end.2016.0472
4. 4. Montes Cardona CE, García-Perdomo HA. Efficacy of phosphodiesterase type 5 inhibitors for the treatment of distal ureteral calculi: A systematic review and meta-analysis. Investig Clin Urol. 2017;58(2):82-89. doi:10.4111/icu.2017.58.2.82
5. 5. Pengfei S, Yutao L, Jie Y, et al. The results of ureteral stenting after ureteroscopic lithotripsy for ureteral calculi: a systematic review and meta-analysis. J Urol. 2011;186(5):1904-9. doi:10.1016/j.juro.2011.06.066

6. 6. Huang W, Xue P, Zong H, Zhang Y. Efficacy and safety of silodosin in the medical expulsion therapy for distal ureteral calculi: a systematic review and meta-analysis. Br J Clin Pharmacol. 2016;81(1):13-22. doi:10.1111/bcp.12737