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CAT Block 2

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**Reference Article:** Furyk, JS, et al. "Distal Ureteric Stones and Tamsulosin: A Double-Blind, Placebo-Controlled, Randomized, Multicenter Trial." *Annals of Emergency Medicine*: 67(1) Jan 2016, 86-95.

**Clinical Question:** Does Tamsulosin 0.4 mg daily aide in the spontaneous passage of distal ureteric stones less than or equal to 10 mm?

**Introduction:** Urinary tract stones have been known to affect humans since almost the beginning of recorded time. Mummies from ancient times have even been found to have urinary tract stones. Today, renal colic associated with ureteric stones affects approximately 1.2 million people each year and accounts for approximately 1% of the hospital admissions. Initial treatment may include pharmacologic agents like tamsulosin. However, data is currently limited on spontaneous passage rates of calculi with and without the use of certain "medical expulsive therapy." The goal of this study was to assess the efficacy of tamsulosin versus placebo in patients with distal ureteric stones less than or equal to 10mm in diameter.

**Methods:** RCT, double blind, placebo-controlled, multicenter trial of adults with distal ureteric stones confirmed by CT stone protocol. Study was conducted in 5 ED's in Queensland, Australia, with a combined annual census of greater than 300,000. Patients were recruited from Oct 2010 thru Mar 2014. Stone size and location were determined by the radiologist's read. The distal ureter was defined as distal to the SI joint on CT. Patients were dismissed if they had fever > 100.4, GFR < 60mL/minute, stones > 10mm, solitary kidney, pregnant (or trying), transplant patients, h/o ureter stricture or allergy to the meds. Other criteria for exclusion included if they were currently taking a calcium channel blocker or were hypotensive with a BP <100 mmHg. Subjects were given placebo or 0.4mg of Tamsulosin daily for 28 days. Primary outcomes measured were stone expulsion on CT at 28 days and time required for stone expulsion.

**Results:** Initially, 403 patients were randomized in the trial. 202 were in the treatment arm and 201 in the placebo. Three patients were excluded due to negative initial CT. Seven patients were excluded due to location of the stone. Six enrolled patients had GFR's less than 60 but were retained in the study. An additional 10 patients in the drug group and 15 in the placebo group were lost to follow-up. Ultimately, 316 patients received a CT scan at 28 days. Passage of the stone occurred in 140 of 161 (87%) in the treatment arm and 127 of 155 (81.9%) in the placebo, with a difference of 5% (95% CI -3.0% to 13%; p=.22). In subgroup analysis of the 77 patients who had a follow-up CT with 5 to 10 mm stones (large stones), 30 of 36 (83.3%) Tamsulosin group had stone passage compared to 25 of 41 (61.0%) placebo group, revealing a difference of 22.4% (95% CI 3.1% to 41.6%; p=0.03) and number needed to treat of 4.5.

**Discussion:** Based on this data, the authors suggest that the overall treatment with tamsulosin did not affect the passage of distal ureteric stones and there was no difference between the groups for urologic intervention. However, the stone appeared to pass more frequently in the patients taking the drug with large stones. In addition, there was no difference between groups concerning pain complaints, positive urine cultures or renal impairment.

**Limitations:** Several limitations to the study include: Australian study, possible selection bias in busy ED's, 17% of participants in both groups did not receive follow-up CT scans, poor compliance with taking trial medications was reported in both groups (5 patients reported not taking any medication at all).

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