Maine Medical Center
Department of Emergency Medicine

Journal Club / Research Article Summary
Date: ______10/23/13________
Presenter: ______Kevin Kralik________

ARTICLE:

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PURPOSE:
The purpose of the study was to evaluate the efficacy of tamsulosin for treatment of ureteral stones in a general emergency department population. Since use of tamsulosin has proved effective in decreasing pain and time to stone passage in other studies of patients referred to urologists, it was hypothesized that it would do the same in a general ED population with ureterolithiasis. Specifically, the hypothesis of 30% or greater difference in proportion of subjects passing the stone at 14 days was tested based on the results of earlier studies.

DESIGN:
The study was designed as a randomized controlled trial comparing the treatment (tamsulosin) with standard analgesic therapy (oxycodone and ibuprofen). The primary outcome measured was successful spontaneous stone passage at 14 days. Secondary outcomes were time until stone expulsion, number of colicky pain episodes, number of return visits to ED or PCP, amount of opioid analgesic used, number of days of missed work/function, adverse events, and pain scores.

SETTING / SUBJECTS:
Study was conducted at Maine Medical Center, a northeastern urban academic ED. Subjects included were over 18, able to consent, and had a CT confirmed single calculus in distal third of the ureter. Exclusion criteria included allergy or sensitivity to the study drug or sulfa allergy, renal failure, infection, fever, multiple stones, pregnancy, breastfeeding or current treatment with alpha lytic drugs, CCBs, or nitrates. Patients had to speak and understand English. The study was powered to detect a 30% difference between groups in rate of stone expulsion. This would require 34 in each group, 39 were enrolled in the treatment group and 41 in the control. 3 subjects were lost to follow up in the tamsulosin group and 1 in the standard therapy group. One subject withdrew from the study in the standard group. One standard therapy subject was started on tamsulosin by
their follow up MD and was excluded. One subject had a stone too proximal in the standard therapy group and was excluded.

METHODS:

Patients were randomized to either the standard therapy group or the treatment group. Those in the standard therapy group were instructed in the use of 800 mg ibuprofen TID and 5 mg oxycodone every 4-6 hours as needed for pain. The treatment group received the same interventions as well as 0.4 mg tamsulosin hydrochloride for 10 days. Two, five and 14 day follow up telephone calls were conducted to evaluated stone passage as well as secondary outcomes of time until stone expulsion, number of colicky pain episodes, number of return visits to ED or PCP, amount of opioid analgesic used, number of days of missed work/function, adverse events, and pain scores. Pain was rated on 1-20 Numeric Rating Scale.

DATA ANALYSIS:

Descriptive statistics were used for study populations and demographics. Univariate analyses were conducted with independent samples t-test to compare means in normally distributed variables, Mann-Whitney U-test was used for non-normally distributed variables. The hypothesis of 30% or greater difference in proportion of subjects passing the stone at 14 days was tested. 8 subjects were uncertain whether they passed their stone, so additional analyses were conducted for the assumption the at 1) all passed by 14 days (best case), 2) none passed (worst case) 3) 3/5 of standard and 2/3 of experimental passed (mid-case) and 4) all tamsulosin passes (best case tamsulosin). Nominal parameters evaluated with Fisher’s exact test. Kaplan Meier analysis was used for time to stone passage with log rank analysis for group comparison. Confounding variables were controlled by randomization of the study groups.

RESULTS:

For the primary outcome, 77.1% of the tamsulosin group and 64.9% of the standard therapy group passed the stone by 14 days, a difference of 12% with p=0.54. Median number of days to stone expulsion was 1 in tamsulosin group and 3 in standard therapy group (Figure 2). Between groups p=.3372. During follow up 6 in the tamsulosin group and 8 in standard therapy had return visits, with an intergroup difference of 4.5%, also non-significant (p=0.634). There were no differences in number of colicky pain episodes (Table 3). No adverse medication events were recorded in either group. In the hypothetical case sensitivity analysis no differences between expulsion at 14 days were significant. Limitations included relatively small study size (although powered correctly), lack of blinding of participants to their treatment/lack of placebo, difference in average size of stones from previous studies. Additionally, straining urine or even repeat CT would be better ways to determine passage of stone. Follow up info was also not
obtained for all subjects. Tamsulosin does not appear to decrease time to stone expulsion, pain, or repeat visits, at least in this population with this stone size (approx 3.6 mm avg).

IMPLICATIONS FOR PRACTICE:

The study is highly applicable to our practice, it was conducted in our ED, and it is a commonly encountered situation and easy to implement tamsulosin treatment. No adverse events were recorded, so downside of treatment is low except perhaps for cost, but there was no benefit. However, given other studies that have shown benefit it seems reasonable for stones >5mm.

LEVEL OF EVIDENCE / DECISION FOR USE:

- Ready for use

- *Level of Evidence:*
  - Ib Evidence obtained from at least one RCT