DEM Journal Club

Article Appraisal

Article: Medical expulsive therapy in adults with ureteric colic: a multicentre, randomised, placebo-controlled trial

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Background and Study Objective(s):

Previous meta-analyses have suggested a potential benefit to using medical expulsive therapy in adults with ureteric colic, however the component studies included were small, had varied inclusion and exclusion criteria, and were deemed to be of low to moderate quality. This study aimed to overcome these limitations by designing a large multicentre randomized controlled trial where the primary outcome was the proportion of participants who did not need further intervention for stone clearance within 4 weeks of randomisation.

Study Design:

This study was a randomised, placebo-controlled trial, conducted in 24 UK NHS hospitals and included 1167 adults aged 18–65 years with one stone of 10 mm or less in either ureter, as identified by CT. The study excluded patients with sepsis, a GFR <30, and those unable to take the study medications. The patients were randomized to receive either 30 mg nifedipine, 30 mcg of tamsulosin, or placebo, using stone size and location as minimization covariates. They were then followed for four weeks to look for the primary outcome of need for additional intervention to facilitate stone passage in 4 weeks. Other outcomes included were analgesic use, as VAS pain scale at 4 weeks, a functional score assessed by a SF-36 questionnaire, date of imaging showing no stone, and patient reported adverse outcomes.

Results:

Spontaneous stone passage, defined by absence of need for intervention to assist stone passage during the 4 weeks after randomisation, did not differ between groups. These findings were consistent across the predefined subgroups of sex, stone size, and stone location. No differences were recorded in the secondary outcomes of days of analgesic use, time to stone passage, and health status between the groups.

Validity of Results:

The study had a had good internal validity as it had relatively low loss to follow up rate with a sound statistical analysis and adequate power for the primary outcome.

Generalizability of Results:

The need for intervention at 4 weeks as a primary outcome was thought to have been a poor surrogate for the rate of stone passage and somewhat limited the study generalizability as it seems to be fairly variable in between centres

in Canada. It was felt at Journal Club, that number of days of analgesic use would have been a more interesting primary outcome since we know that the intervention rate on all comers with renal colic is fairly low and centre specific. It was also felt that the study did not answer the question of whether we should be using this therapy in patients with larger and more distal stones.

The Bottom Line:

The group consensus at the Journal Club meeting was that the study did answer the question it set out to answer; however, it wasn't the question most people were interested in having answered. Overall, we were still left wondering whether prescribing MET to patients improved patient outcomes with larger and more distal stones.