

PP-109

Prospective randomized controlled trial for patient with renal stone undergoing extracorporeal shockwave lithotripsy (ESWL) using Tamsulosin as adjuvant medical expulsive therapy: Are there any added benefits?

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Objectives: The primary objective of the study is to assess the effectiveness of Tamsulosin as Medical Expulsive Therapy (MET) for patients presented with renal stones undergoing ESWL up to three times. The secondary objective is to assess the respective pain control status using Tamsulosin compared with the control group.

Method: This is a prospective randomized controlled trial. KWE cluster ethics committee approved the study in 6/2011. We recruit patient presented with renal stone in any position with the size limited between 5 and 20mm. They received up to 3 sessions of ESWL after they were randomized into MET and the control based on computer generated random number. For MET group, they will receive Tamsulosin 0.4mg daily for 4 weeks plus analgesic for 1 week on if necessary basis. For the control group, they will receive analgesic if necessary for 1 week only. We will follow up the patient 4 weeks after the ESWL session and reassess in our out-patient clinic with KUB X-ray to check for stone clearance and stone progress. Bedside USG will also be done to rule out presence of ureteric obstruction. Pre- and post-ESWL serum creatinine level, haemoglobin and urine culture were saved. Moreover, all the adverse events from the drugs were charted as well as the erect and supine BP before ESWL and during follow up. Clearance of stone is defined as clinically insignificant stone of size 4mm or below.

Results: Based on power of 80% and alpha error of 5%, we aim at 100 patients in MET group and 100 patients in control group. Currently we analyzed 94 patients including 32 female and 62 male. The age ranged from 28 to 75 with 45 patients in MET and 49 in control group. The mean size was 9.4mm (range 5 to 20mm). 55.3% stone from lower pole, 14.9% from upper, 14.9% from middle, 7.4% from PUJ and 7.4% from renal pelvis. 67 patients, 19 patients and 8 patients completed one, two and three ESWL respectively. The stone clearance rate for the MET group was 37.5%, 37.5% and 20% after first, second and third ESWL respectively whereas the control group was 37.1%, 0% and 0% respectively.

Conclusion: Apparently the MET group did not show advantage for the first ESWL to the renal stone but there is a trend of improved clearance rate with multiple ESWL given. However the sample size so far was too small and further data collection and analysis will be required to give any concrete conclusion.

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