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DOXAZOSIN VERSUS TIZANIDINE FOR THE TREATMENT OF DYSFUNCTIONAL VOIDING IN CHILDREN: A PROSPECTIVE RANDOMIZED OPEN-LABELED TRIAL

Hypothesis / aims of study
Currently there is no approved pharmacological therapy for dysfunctional voiding in children**.** In the current study, an imidazoline (Tizanidine); a drug used for management of spasticity, was compared with alpha blocker (Doxazosin) for the treatment of dysfunctional voiding in children in a prospective, randomized, open labeled, parallel group trial.

Study design, materials and methods
Children' evaluation was carried out in accordance with ICCS guidelines**.** Severity of symproms, main bother symptom, and presence of constipation was recorded. Urine analysis, urine culture, renal ultrasound and voiding cystourethrogram were carried out in all patients. Three consecutive non-invasive flowmetry (NIF) with skin-patch perineal EMG and US estimation of PVR were conducted before commencing invasive urodynamic. Eligible children were randomly divided into 2 groups: Group A received alpha blocker (Doxazosin 0.5 mg/once daily before bed-time) while group B received Tezanidine 2mg/once daily before bed-time). Children were followed after one week, and then monthly for 6 months**.** Statistical analysis: Mann-Whitney U test and independent-t test were used to compare means of 2 groups. Fisher's exact test (2-tailed) was utilized for comparison between categorical variables. Wilcoxon signed rank test was executed for nonparametric statistical comparisons before and after treatment in both cohorts. Statistical significance was determined at $p < 0.05$.

Results
Forty patients (37 girls and 3 boys) with a mean±SD age of 7±2.6 (range 4-12 years) were randomllay allocated into 2 groups (20 children in each arm). At last follow up, both groups gave rise to similar improvement in severity of symptoms, satisfaction scale and NIF parameters. In Doxazosin group, urge episodes was the only symptom that showed significant reduction compared to base line ($p = 0.028$). While incidence of nocturnal enuresis, urge and daytime incontinence were significantly reduced compared with base line in Tizanidine group ($p = 0.003$, 0.008 and 0.017 respectively). However, there was no significant difference in NIF parameters between the two groups**.** Epigasteric pain was reported in 2 (10%) children received Doxazosin. In Tizanidine group, loss of appetite was noticed in 2 (10%) children, epigastric pain in one (5%) and headache in one (5%).

Interpretation of results
Both treatment groups showed improvement on subjective basis. However, objective improvement was not significant.

Concluding message
Tizanidine is safe and effective drug for management of children with DV owing to pelvic floor/skeletal sphincter dysfunction (PFSD). A new phenotype sub classification for the current ICCS definition of DV is needed to differentiate between Bladder neck dysfunction (BND) and pelvic floor/skeletal sphincter dysfunction (PFSD).

Specify source of funding or grant	**Institutional : Urology and Nephrology Center, Mansoura University**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Local ethical committe, Urology and Nephrology center, Mansoura University**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**