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OVERACTIVE BLADDER PHENOTYPES USING ELECTRONIC DATA CAPTURE

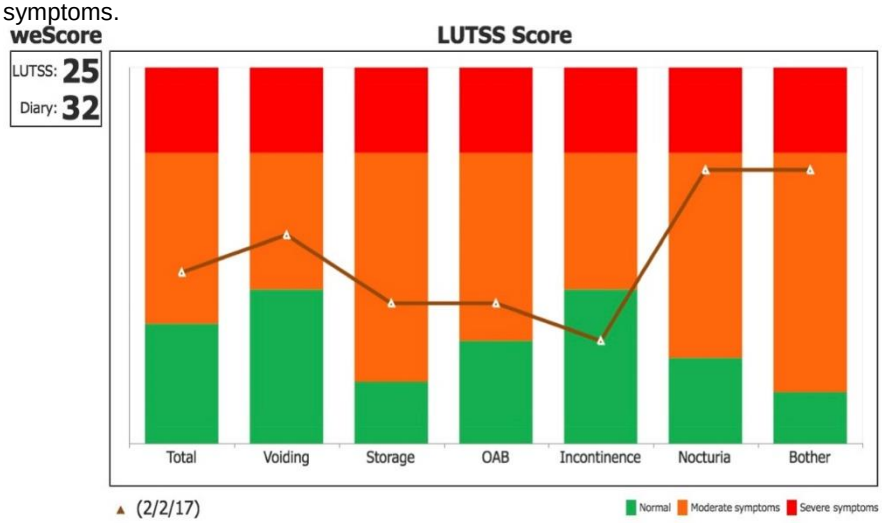
Hypothesis / aims of study

Overactive bladder (OAB) is a clinical diagnosis based on lower urinary tract symptoms (LUTS). Once remediable pathology has been excluded, most treatment algorithms recommend empiric treatment based on a monolithic, one-size-fits-all approach. The purpose of this study is to refine the OAB diagnosis further by developing phenotypes that can be used to promote more individualized treatment and to offer clues to search for underlying causes.

Study design, materials and methods

This is a retrospective multicenter observational study of patients evaluated for LUTS who completed a 24 hour bladder diary (24HBD) and lower urinary tract symptoms score (LUTSS) on a mobile app, website and/or paper. The results appeared on the doctor portal (figure 1).

Figure 1. The total LUTSS and 5 sub-scores are color coded to represent normal (green), moderate (orange), and severe (red) symptoms.



Bladder Diary:

Dairy Date	2/2/17
Voided Volume (ml)	
24 hours	3974
Daytime	3005
Nighttime	969
# Voids	
24 hours	17
Daytime	12
Nighttime	5
Maximum Voided Volume	386
# Incontinent Episodes	0
# Urgency Voids	0
# Difficulty Voiding Episodes	7
Nocturnal Polyuria Index	0.24
Nocturia Index	2.51
Urge Void Correlation	0.54

Those with an overactive bladder symptom sub-score (OABSS) ≥ 8, which has been validated to correspond to a clinical diagnosis of OAB, were included. When multiple diaries or scores were completed, the earliest was used. Maximum voided volume (MVV), 24 hour voided volume (24HV) and, when available, contemporaneous uroflow (Q) and post-void residual (PVR) were recorded. Patients with incomplete LUTSS or 24HBD were excluded. Subjects were first divided into three major phenotypes according to the 24HV as follows: Phenotype 1 = polyuria (P) [24HV > 2.5 L]; Phenotype 2 = normal (N) [24HV 1L – 2.5 L]; Phenotype 3 = oliguria (O) [24HV < 1L]. Each major phenotype was then categorized according to the MVV resulting in 9 intermediate phenotypes: small MVV (S-MVV) [MVV < 150 mL]; large MVV (L-MVV) [MVV > 350 mL]; normal MVV (N-MVV) [150 mL<N-MVV<350 mL]. Finally, each of the 9 intermediate phenotypes was subdivided according to the Q and PVR data as follows: normal (Q>12 mL/s and PVR ≤100 mL) or abnormal (Q ≤12 mL/s and/or PVR >100 mL), resulting in a total of 18 minor phenotypes.

Results

1189 patients completed the LUTSS. 331 patients, 197 men and 134 women, completed the LUTSS and a contemporaneous 24HBD. OAB, as defined by OABSS ≥ 8, was present in 235 (71%) of these patients (128 male and 107 female). Of these, 115 (31 male and 84 female) had contemporaneous Q and PVR data inputted. Prevalence data for the 18 phenotypes is seen in table 1.

Interpretation of results

We have identified three major phenotypes based on a 24HBD that are further subdivided according to MVV, Q & PVR for a total of 18 subtypes. In the next phase of investigation we will focus on developing and testing individualized diagnostic and treatment algorithms based on the phenotypes. For example, we hypothesize that OAB patients with polyuria, large capacity bladder and normal Q & PVR are optimally treated with behaviour modification; whereas those with oliguria, small capacity bladder and high PVR require advanced diagnostic evaluation and treatment. Further, by combining the phenotypic data with other parameters such as urgency and incontinence episodes, we hope to tailor our electronic and clinical data gathering into a user friendly, efficient and cost-effective means of caring for patients with OAB. By combining both subjective and objective data gathering into a central electronic repository, we will be able to more proactively identify patients that will benefit from specific treatments and, more importantly, develop new and more effective treatments.

Concluding message

The stratification of OAB variants into 18 phenotypes provides the substrate for further research into the etiology of OAB, new treatments and more precise treatment algorithms.

Table 1: Major phenotypes and MVV subtypes are based on the OAB patients who completed both a 24HBD and LUTSS (n=235). Q and PVR subtypes are based on those with Q and PVR data entered (n=115).

OAB Phenotypes with Q & PVR 24h Bladder diary + LUTSS ***n*=235**																	
Phenotype 1 Polyuria 24HV>2.5L n=43 (18%)						**Phenotype 2** Normal 1L<24HV<2.5L n=143 (61%)						**Phenotype 3** Oliguria MVV<150mL n=49 (21%)					
1.1 S-MVV <150mL n=0* (0%)		**1.2** N-MVV 150- 350mL n=7 (16%)		**1.3** L-MVV >350mL n=36 (84%)		**2.1** S-MVV <150mL n=3 (2%)		**2.2** N-MVV 150-350mL n=91 (64%)		**2.3** L-MVV >350mL n=49 (34%)		**3.1** S-MVV <150mL n=18 (37%)		**3.2** N-MVV 150- 350mL n=29 (59%)		**3.3** L-MVV >350mL n=2 (4%)	
1.1.1 n=0 0%	**1.1.2** n=0 0%	**1.2.1** n=3 3%	**1.2.2** n=1 1%	**1.3.1** n=11 10%	**1.3.2** n=11 10%	**2.1.1** n=0 0%	**2.1.2** n=0 0%	**2.2.1** n=21 17%	**2.2.2** n=23 20%	**2.3.1** n=13 11%	**2.3.2** n=98 8%	**3.1.1** n=3 3%	**3.1.2** n=4 3%	**3.2.1** n=98 8%	**3.2.2** n=65 5%	**3.3.1** n=0 0%	**3.3.2** n=11 1%

In subtype "_._.1," Q and PVR are normal (Q > 12 mL/s, PVR ≤ 100 mL)
In subtype "_._.2," Q and/or PVR are abnormal (Q ≤ 12 mL/s and/or PVR>100 mL)
*In some of the phenotypes, such as this one, there were no patients who fulfilled the criteria, but it is expected that there will be patients with these phenotypes in larger studies.

Disclosures

Funding: Institute for Bladder and Prostate Research **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Western IRB approved **Helsinki:** Yes **Informed Consent:** No