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URETHRAL SLEEVE SENSOR: A BETTER METHOD TO MEASURE URETHRAL PRESSURE DURING DYNAMIC CONDITIONS

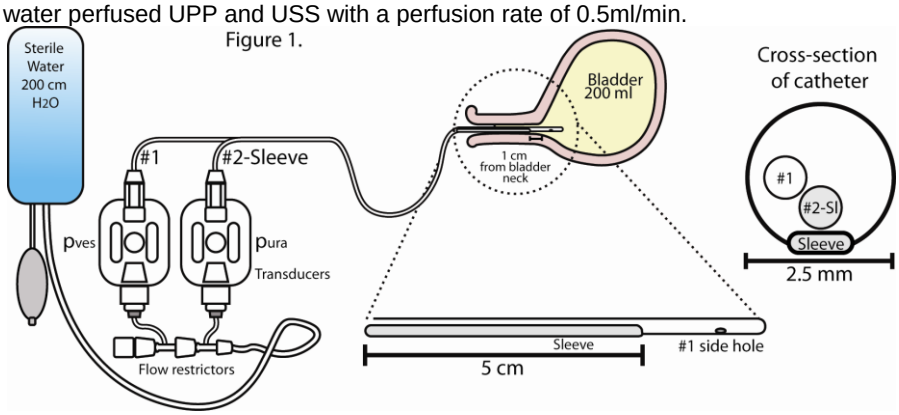
Hypothesis / aims of study

Current technology for measuring urethral pressure only measures discrete segments of the sphincter. For this reason, withdrawal techniques using a puller were developed to "map" a urethral pressure profile (UPP). Each profile typically requires at least 30 seconds and does not allow accurate measures during dynamic conditions which fatigue during that time period (e.g. valsalva or pelvic floor muscle contraction). If the catheter is placed in a stationary position at the peak of the UPP for dynamic measures, data is unreliable because even slight migration of the catheter produces erroneous decreases in maximum urethral closure pressure (MUCP). There is a need for a technology which measures MUCP during valsalva or pelvic floor muscle contraction (PFMC). Our goal is to evaluate the urethral sleeve sensor (USS), commonly used in GI manometry, as a technology for urethral pressure measures. The specific aims of this study are 1) to compare MUCP using the USS with water perfusion UPP, 2) to determine if USS measures respond appropriately during dynamic conditions such as valsalva or PFMC in normal and stress incontinent women, 3) to determine if there are axial variations with sleeve sensor technology in the urethra which affect the reliability of the measures, and 4) to determine patient tolerability with this technology compared to water perfusion UPP.

Study design, materials and methods

18 total subjects were needed to achieve a correlation coefficient of 0.8 with 80% power and □ =0.5 for comparison of USS and UPP; we recruited 18 continent women and 7 women with stress urinary incontinence. All subjects underwent assessments with water perfused UPP and USS with a perfusion rate of 0.5ml/min.

Figure 1.



This small (2.5 mm diameter) USS catheter is made of flexible silicone rubber with a 5 cm sleeve sensor positioned in the urethra and a second sensor (#1 side hole) at the distal end of the catheter positioned in the bladder (Figure 1). The catheter is not withdrawn. Figure 2a and 2b (below) are typical signals from a continent and an incontinent patient. Incontinent subjects were noted to leak during valsalva when p_{clo} became less than 0 cm H_2O.

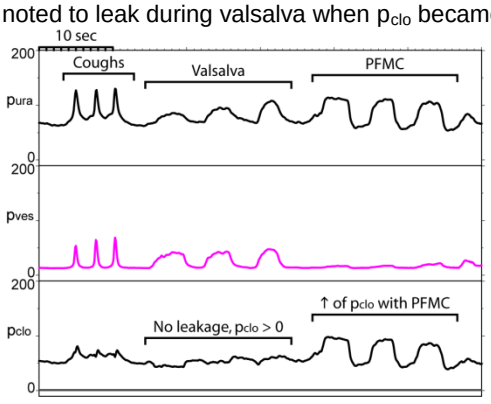


Figure 2a. Continent Subject

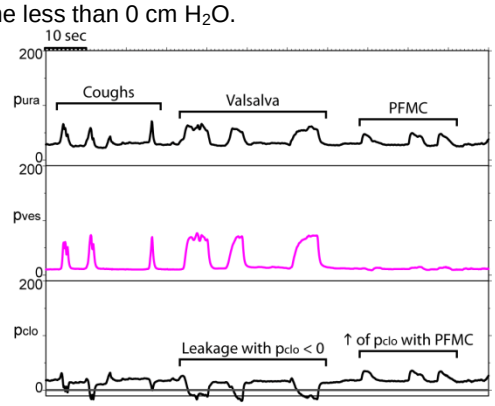


Figure 2b. Incontinent Subject

Measurements were obtained with subjects performing 3 coughs, 3 valsalva maneuvers, and 3 PFMCs with the sleeve oriented at 3, 6, 9, and 12 o'clock. Intravesical pressure (p_{ves}) and urethral pressure (p_{ura}) signals were collected continuously throughout the study and a third signal recorded urethral closure pressure (p_{clo}) by continuously subtracting p_{ves} from p_{ura}. UPPs were conducted with a 7Fr triple lumen water perfusion catheter withdrawn at 1mm/sec with a puller. All subjects completed a 0-100 mm visual analogue scale (VAS) scoring their discomfort for USS and UPP techniques.

Results

Similar to other reports on axial variation of the urethra [1-2], our study demonstrated higher pressures at 12 o'clock than 3, 6, and 9 o'clock. Mean difference between the three other orientations and 12 o'clock were between 10-17cm H_2O with correlation coefficients of <0.83 but differences between the other three positions was less than 7 cm H_2O with correlation coefficients >0.84. Because the 12 o'clock position produced less reliable results than the three other positions, we excluded the 12 o'clock position from all later presented data. The correlation coefficient of MUCP for UPP and USS was high at 0.86 ($p<0.001$) and 74% of the variation can be explained by the model (Figure 3).

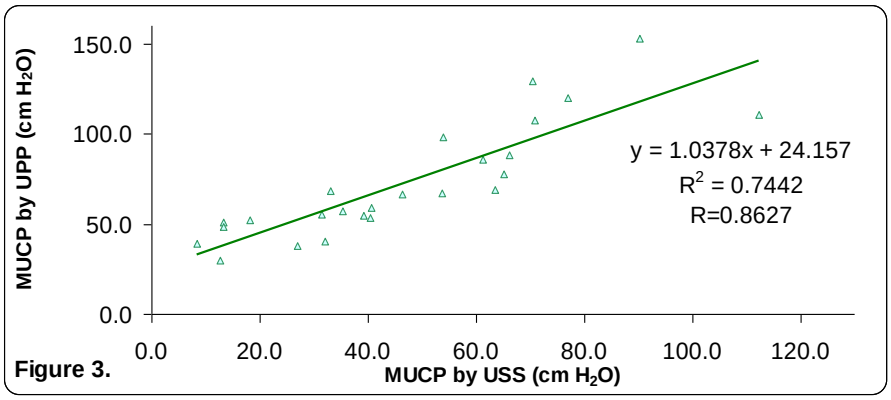


Figure 3.

Continent subjects demonstrated significantly greater values of p_{clo} baseline, p_{clo} with PFMC and change in pressure than incontinent subjects (Table 1).

Table 1.	Continent n=16 mean (SD)	Incontinent n=6 mean (SD)	p-value
p_{clo} baseline (cm H_2O)	59 (22)	19 (8)	**<0.001**
p_{clo} w/ PFMC (cm H_2O)	83 (27)	28 (10)	**<0.001**
Change in pressure w/ PFMC (cm H_2O)	23 (15)	8 (4)	**0.024**

Table 2 is a 2x2 table which demonstrates sleeve urodynamic findings of a urethral closure pressure declining to 0 during a valsalva maneuver in the continent and incontinent groups. Note the excellent sensitivity and specificity of this urodynamic finding with clinical findings in both groups.

Table 2.	Clinically demonstrated leakage with valsalva.	
Sleeve urodynamic findings	Continent (no leakage with valsalva)	Incontinent (leakage with valsalva)
Valsalva MUCP>0	18	0
Valsalva MUCP<0	0	7

The mean discomfort measured by visual analogue scale was 22±18 mm for the USS compared to 51±27 mm for the UPP (p<0.001).

Interpretation of results

The MUCP measurements from the urethral sleeve sensor correlate highly with the measurements from the UPP. For the best reliability, the catheter should be oriented to 3, 6, or 9 o'clock when taking measurements. Continent subjects demonstrate higher baseline urethral pressures and increases in pressure during PFMC compared to incontinent subjects. This technique reliably discriminates continent from incontinent subjects. The USS is significantly more tolerable (less discomfort) than the UPP.

Concluding message

The USS correlates highly with conventional MUCP measures, but does not require a puller and has the advantage of measuring MUCP during dynamic conditions, such as valsalva or PFMC. The USS MUCP during valsalva discriminates between stress continent and incontinent subjects. Current methods of biofeedback use vaginal pressure as a surrogate for urethral pressure, but this well-tolerated technology allows direct measurement of urethral pressure during PFMC for a true measure of urethral function.

References

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2. Dompeyre, P., et al., Comparative study of 230 women to determine the maximum closure pressure and functional length of the urethra at 0, 3, 6 and 9 o'clock. Prog Urol, 1999. 9(6): p. 1090-5; discussion 1095-6

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Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The study was approved by the institutional review board at the University of California, San Diego.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**