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Medina Lucena H[1], Tincello D[1]
***1.** University of Leicester*

TEST-RETEST AND RELIABILITY ANALYSIS OF A WATER LOAD PROTOCOL AS A TOOL TO ACHIEVE A FIXED DIURESIS RATE FOR INVESTIGATION INTO BLADDER SENSATION.

Hypothesis / aims of study

A forced diuresis protocol has been developed to evaluate bladder sensation during filling. The original protocol required consumption of 250-300 ml water every 15 minutes to achieve a steady diuresis rate, but the reliability of this protocol to produce a stable and predictable diuresis remains unproven. In recent work, we found the rate of diuresis to have a high variability, in some cases more than 5 ml/minute between tests in the same participant (unpublished). This study was designed to calculate and compare diuresis rates within cycles of each test, and between cycles and to confirm the consistency of voided volume between cycles to optimize the reproducibility of voided volume.

Study design, materials and methods

This study was the first of four parts of an observational and experimental study. Twelve volunteers were asked to undergo a previously designed diuresis and bladder sensation protocol (unpublished). The protocol allowed the visual recording of bladder sensation by the patient marking sensations on a 10 point visual analogue scale every 5 minutes while drinking an excess of water continually for the duration of the test.

Following ethical approval, informed consent was obtained from participants before obtaining serum to measure glomerular filtration rate to exclude undiagnosed kidney disease. Participants were asked to refrain from vigorous exercises on the day before the test session and not to have caffeine or a meal 2 hours before, and alcohol 12 hours before the beginning of the test. A biomedical impedance test was performed prior to the diuresis test to determine the participant's fluid status, to know if the participant was overhydrated or dehydrated. The volume drunk during the test was adjusted from 250ml to 300 ml based on the impedance to avoid any risk of water intoxication.

Participants were asked to drink 250 ml of water every 15 minutes 1 hour before the test. If participants were overhydrated (+500ml) on bioimpedance result they were asked to continue to drink 250 ml every 15 minute, but if they were under-hydrated this volume was increased to 300 ml. Participants were given a data-logging sheet to record their bladder sensations. No verbal cues were given other than to concentrate on the sensation in their bladder and to mark on the data-logging sheet the intensity of this sensation. When they reached the strongest sensation they could bear they were asked to hold on for up to 5 minutes and to remember this as their maximum sensation, marking it as a 10 on their sheet. They were then asked to void and this volume measured (V1). Immediately post void they recorded this as the minimal sensation.

Participants continued to drink and recorded bladder sensation for another entire filling cycle, where the voided volume was measured (V2) and for at least 30 minutes of the next cycle (voided volume V3). The first cycle allowed participants to fix the maximum and minimum sensations in their minds; cycle two was the core part of the experiment where analyses were done, and cycle three was used to confirm a steady diuresis rate has been achieved during cycles two and three (i.e. V2/t2 = V3/t3).

This test was performed twice within 14 days apart. The same instructions were read to participants at the beginning of each test. Data were presented as median (range) and compared by Wilcoxon signed rank test or Mann Whitney U test for paired and unpaired data.

Results

12 women were recruited. Median age was 26 years (19-37years), median BMI 29.1 Kg/m^2 (21.0 -42.4 kg/m^2). Nine were British, two Turkish and one from south East Asia. 11 out of 12 had the two tests within 14 days. One person withdrew after first test due to vomiting. All participants had a normal sodium level and glomerular filtration rate >60ml/min.

On the first test 11 out of 12 had a preload of 1000ml (one had drank 1250ml). Seven drank 250 ml every 15 min and 5 drank 300ml. Overall, there was no difference in median first void (V1) 735ml (386-1218ml) and median second void (V2) 678ml (420-1064ml) (p=0.433). The median diuresis rate of V2 was 12.1 ml/min (8.94-17.18) and 14.4 for V3 (8.13-20.0) (p=0.136), indicated a fixed diuresis rate was achieved during the test protocol (Table 1).

The diuresis rates during cycle 2 and cycle 3 achieved after drinking either 250 or 300 ml every 15 minutes were compared. The median differences were 2.36ml/min (0.01-6.30) with 250ml/15min and 3.03 ml/min (1.64- 4.63) after 300 ml (p=0.639). Because the variability of the calculated difference was less, we performed the second test with participants all drinking 300ml/15 minutes.

During second test all participants had a preload of 1000ml. Median first void (V1) was 618ml (482-1042ml) and median second void (V2) was 617ml (490-1026ml) (p=0.533). The median diuresis rate of V2 was 13.7 ml/min (8.90-16.36) and 13.5 for V3 (9.16-16.33) (p=0.477). The difference between diuresis rate in cycle 2 and cycle 3 where all participants drank 300 ml/15 min was 0.53ml/min (0.12-2.31).

Interpretation of results

The maximum bladder sensation was achieved at similar bladder volumes within cycles and between cycles, demonstrating that this test was reproducible. There was more variability in the diuresis rate when participants had drunk 250ml/15 min than when they had drunk higher volumes (300ml). The difference in the median diuresis rate in the second test was smaller with less variability than in the first cycle, where ingested volumes varied. This was probably due the larger volume providing a greater preload to the kidneys and helping to achieve a fixed diuresis rate. However, median diuresis rates were more similar in the second test experiment, suggesting a degree of "learning" was affecting the repeat test.

We analysed the data of participants who drank 300 ml every 15 min, to identify the upper limit of variability of the diuresis rate between cycles. At present we tentatively conclude that this should not be more than 4.5ml/min and anything above this will be rejected as invalid.

Concluding message

The water load protocol achieves a constant high diuresis with rapid, non-invasive bladder filling. The results from this study have validated previous work and allowed us to define the expected range of within test variability of diuresis rate. Variability is reduced with a water load of 300ml/15 minutes and we recommend rejection of any test where the variation in diuresis rate between the two test cycles exceeds 4.5 ml/min.

Table 1: Voids and diuresis rate at each test.

Factor	Test 1 (12)	Test 2 (11)	p value
Void 1 (ml)	735 (386-1218)	618 (482-1042)	0.593
Void 2 (ml)	678 (420-1064)	617 (490-1026)	0.929
Diuresis rate V2 (ml/min)	12.1 (8.94-17.18)	13.7 (8.90-16.36)	0.248
Diuresis rate V3 (ml/min)	14.4 (8.13-20.0)	13.5 (9.16-16.33)	0.656

Disclosures

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