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Comparison Between Ambulatory and Conventional Urodynamics of the Modified Orthotopic Hautmann Neobladder

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Purpose: The aim of the present study was to determine the diagnostic accuracy of conventional and ambulatory urodynamic studies (UDS) in estimating neobladder function.
Methods: We evaluated 32 patients who underwent radical cystectomy and orthotopic Hautmann W neobladder with Abol-Enein-Ghoneim uretero-intestinal anastomosis for bladder cancer. The patients were initially examined by using both conventional and ambulatory UDS.
Results: Conventional UDS detected a very high mean intravesical pressure at maximum capacity (53.7 ± 17.5 cm H_2O). By contrast, the mean intravesical pressure detected by using ambulatory UDS (which reflects the dominant pattern of pressure variation during filling) was significantly lower (34.4 ± 5.2 cm H_2O, $P < 0.001$). The comparison between intravesical pressure at half of maximum capacity in conventional UDS and the mean value in ambulatory UDS did not show significant difference ($P = 0.152$). The mean voided volume in conventional UDS was greater than both the mean voided volume ($P < 0.001$) and the mean maximum voided volume in ambulatory UDS ($P = 0.001$). However, this difference did not affect the postvoid residual urine volume measured in both studies ($P = 0.207$). Moreover, incontinence episodes recorded in ambulatory UDS were more frequent but not statistically significantly different from those recorded in conventional UDS ($P = 0.332$).
Conclusions: The estimation of neobladder function by means of ambulatory UDS seems to provide interesting research data for the mode of lower urinary tract function in patients with orthotopic substitution after radical cystectomy. The great high value in ambulatory UDS, in cases in which conventional UDS had failed, is due to the exposure of daily and nocturnal incontinence episodes, confirming our patients' complaints.

Keywords: Urodynamics; Urinary Diversion; Urinary Incontinence

• **Conflict of Interest:** No potential conflict of interest relevant to this article was reported.

INTRODUCTION

During recent decades, orthotopic reconstruction after radical cystectomy for bladder cancer has been increasingly performed [1]. To date, different segments of the intestine and different techniques have been used to create a sufficient functional reservoir capacity and to reduce intravesical pressure for the protection of the upper urinary tract [2]. To assess neobladder function, conventional urodynamic studies (UDS) have been used. However, this method has been considered to be unable

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to mimic patients' symptoms as they occur in real life [3]. By contrast, ambulatory UDS, which use natural bladder filling, are believed to elicit more representative results [4].

According to our knowledge, no information is available in the literature on the comparison of these two methods in patients with orthotopic neobladder substitution after radical cystectomy. For this reason, recording and comparison of orthograde and retrograde filling cystometry findings was done for patients who had undergone modified orthotopic Hautmann substitution after bladder removal [5,6].

MATERIALS AND METHODS

From 2004 to 2011, 153 patients with bladder urothelial cell carcinoma (UCC) underwent radical cystectomy and orthotopic Hautmann W neobladder with Abol-Enein-Ghoneim uretero-intestinal anastomosis. All of the cystectomies and bladder substitutions were performed by a single surgeon. A 70-cm portion of the terminal ileum was isolated, 15- to 20-cm proximal to the ileocecal valve. The segment of the ileum was incised on the antimesenteric border and arranged into a W configuration, with the four limbs sutured to one another. Ureteral anastomoses were performed by using the Abol-Enein-Ghoneim antireflux technique, with a serous-lined extramural tunnel. Finally, a tension-free ileal-urethral anastomosis was created over a 20-Fr catheter.

To reliably compare the two urodynamic techniques, stringent inclusion and exclusion criteria were applied. The inclusion criterion was patients of all ages who underwent the procedure at least 1 year before the initiation of the study and have achieved better stabilization of the lower urinary tract function. Physical and mental conditions that ensure good cooperation between the physician and researcher were also required. By contrast, patients with urethral or urethrovesical anastomotic strictures, active urinary tract infections, or postoperative hernias; patients undergoing chemotherapy or radiotherapy for localized or systemic relapse at the time of the study; and patients with continuous urinary incontinence or severe comorbidities (chronic renal failure, cardiovascular diseases, etc.) were excluded. We eventually evaluated 32 patients who underwent the procedure. All of the participants provided written informed consent. The remaining patients were not included in the trial for the reasons shown in Table 1.

Table 1. Patients excluded from the study and the reasons for the exclusion

Reason for the exclusion	No. of patients
Deceased	47
Active radiotherapy	4
Active chemotherapy	21
Urethral stricture	10
Postoperative hernia	3
Chronic renal failure	2
Urinary tract infection	3
Hospitalized for other reasons	2
Continuous urinary incontinence	1
Declined to participate	28

The clinical and demographic characteristics of the patients are summarized in Table 2. The percentage of the patients who were either overweight or obese was not notable at approximately 80%. However, their performance status was sufficient. Most of the patients had high-grade UCC (68.8%), and seven had positive lymph nodes

The design of the protocol, the performance of conventional and ambulatory UDS, and the interpretation of the results were based on two reports of the International Continence Society (ICS) [7,8]. Preparation for the UDS was started 2 days earlier,

Table 2. Demographic data and clinical characteristics (n = 32)

Characteristic	Value
Age (yr), mean ± SD	66.7 ± 8.3
Body mass index (kg/m^2), mean ± SD	29.3 ± 4.9
ECOG ≥ 1 (%)	25.0
Time from surgery (yr), mean ± SD	2 ± 1
Adjuvant or salvage chemotherapy (%)	15.6
Adjuvant or salvage radiotherapy (%)	0
Upper tract recurrence (%)	3.1
T stage (%)	
T0	3.1
T1	15.6
T2a	12.5
T2b	21.9
T3a	12.5
T3b	15.6
T4	0
In situ	18.8
N stage (%)	
N0	78.2
N+	21.8

SD, standard deviation; ECOG, Eastern Cooperative Oncology Group.

with prophylactic antibiotics (quinolones), laxatives, and a strict hydrate diet. At the beginning of the study, the patients underwent conventional UDS by using the Solar Silver urodynamic device (MMS, Medical Measurement Systems, Dover, NH, USA). The filling rate generally followed the formula of weight in kilograms divided by 4 mL/min, but this formula was adjusted accordingly [9]. All of the patients were in the sitting position during conventional UDS.

Ambulatory UDS were performed subsequently at a date different from that of conventional UDS in the hospital after admission to the ward because the cost of the device is high risking damage. In addition, the operator should have been under close surveillance at all times during the entire procedure (placement of the catheters, proper recording, and calculation of postvoid residual [PVR] volume). On average, the duration was approximately 18 hours. Orthograde filling cystometry was performed by using the Luna device (Wireless-Bluetooth) with microtip catheters (MMS). Proper placement of the intravesical catheter was checked on ultrasonography. During the ambulatory UDS phase, self-reported urine leakage episodes were also recorded in a voiding diary. The patients also brought diapers or pads, which were weighed to calculate the amount of urine leakage. Both, during the middle and at the end of the study, the PVR volume was estimated.

Statistical analysis was performed by using the IBM SPSS Statistics ver. 20.0 (IBM Co., Armonk, NY, USA). Regularity control of the variables with fewer than 50 cases was performed by using the Shapiro-Wilk test. For continuous variables that were not normally distributed, the nonparametric Wilcoxon rank test was used to compare the mean values of the same sample. To control the degree of correlation between the two continuous variables, we used the Pearson r and Spearman rho correlation coefficients. The values of dichotomous and categorical variables between two independent samples were estimated by using the statistical chi-square test, and those between the same samples were estimated by using McNemar test. The significance level was set at $P < 0.05$.

RESULTS

Conventional UDS

The urodynamic parameters found in conventional UDS are

Table 3. Urodynamic findings

Variable	Conventional	Ambulatory	P-value
Sensation (mL)			
Volume at first sensation	244.2±122.2	-	
Volume at normal desire	351.9±158.2	-	
Maximum cystometric capacity	496.8±234.4	-	
Intravesical pressure (cm H_2O)			
Maximum intravesical pressure (at maximum capacity)	53.7±17.5	50.2±9.2	0.264
Mean intravesical pressure	31.4±9.6[a]	34.4±5.2	0.152
Neobladder wall (subtracted) pressure (cm H_2O)			
At first sensation	14.4±9.1	-	
At normal desire	22.1±13.5	-	
Maximum	24.9±13.9	39.2±13.5	0.001
On neobladder contractions	31.2±11.1	-	
On contractions without urine leakage	-	28.6±9.0	
On contractions with urine leakage	-	18.2±7.3	
Voiding phase			
Maximum flow rate (mL/sec)	10.3±5.2	8.6±2.9	0.035
Voided volume (mL)	406.0±210.6	204.8±58.1	0.001
Maximum voided volume (mL)	-	259.9±77.8	
Postvoid residual volume (mL)	95.0±36.4	120.0±83.2	0.207
Patients with incontinence			
During the day	13 (40.6)	18 (56.2)	0.332
During the night	-	28 (87.5)	

Values are presented as mean±standard deviation or number (%).
[a] At half of maximum capacity.

presented in Table 3. Evaluation of the patients during the filling phase revealed a maximum cystometric capacity of 496.8±234.4 mL and maximum filling pressure of 53.7±17.5 cm H_2O. During voiding, the maximum flow rate (Qmax) was 10.3±5.2 mL/sec, with a mean voided volume of the neobladder of 406±210.6 and a PVR urine volume of 95.0±36.4 mL. Of the patients, 40.6% (13 of 32) had at least one episode of incontinence during the study.

Ambulatory UDS

The total recording time for the portable urodynamic measurement was 17.6±0.9 hours, and the mean patient walking time was 114.6±62.2 minutes. Thirteen of the 32 patients (40.6%) terminated the ambulatory recording early. The main reasons for the early termination were defecation, fatigue, and catheter migration.

The minimum and maximum intravesical pressures during the test were 18.7±4.2 and 50.2±9.2 cm H_2O, respectively. The minimum and maximum pressures of the neobladder wall were 4.0±2.4 and 39.2±13.5 cm H_2O, respectively. The mean maximum urine flow during ambulatory UDS was 8.6±2.9 mL/sec, and the mean urination volume was 204.8±58.1 mL (Table 3). Concerning incontinence, of the 32 patients, 18 (56.2%) and 28 (87.5%) experienced urine leakage during the day and night, respectively, in ambulatory UDS (P=0.002).

Comparison Between the Findings of Conventional and Ambulatory UDS

In our comparison of the maximum intravesical pressure between conventional and ambulatory UDS, we did not find any statistically significant difference (P=0.264). Moreover, no statistically significant differences in mean intravesical pressure at half of maximum capacity were observed between conventional and ambulatory UDS (P=0.152). However, to explain the integrity of the upper urinary tract despite high maximum intravesical pressures in conventional UDS, we compared it with the mean intravesical pressure in ambulatory UDS. In each of the patients, the mean intavesical pressure formed almost a stable and continuous dominant pattern of imperceptible pressure variation during filling. It was found to be significantly lower than that during conventional UDS (34.4±5.2 cm H_2O, P<0.001).

Concerning the wall pressure during neobladder contractions, the following parameters were assessed: The subtracted pressure (neobladder wall pressure) on neobladder contractions without urine leakage or feeling of urgency during ambulatory UDS (28.6±9.0 cm H_2O) was higher than the pressure (14.4±9.1 cm H_2O) recorded during conventional UDS at the first desire to void (P=0.001). This last comparison was performed to demonstrate the subjectivity of sensation as a parameter in UDS of neobladder. Higher wall pressures during neobladder contractions in ambulatory UDS did not produce a voiding effect on the patients. Moreover, the pressure of the neobladder wall during urine leakage in ambulatory UDS (18.2±7.3 cm H_2O) did not differ significantly from the following measurements of wall pressure in conventional UDS: at first desire (UDS: 14.4±9.1 cm H_2O, P=0.304), at normal desire (22.1±13.5 cm H_2O, P=0.326); and at maximum capacity (24.9±13.9 cm H_2O, P=0.137).

The mean voided volume (406 mL) in conventional UDS was greater than both the mean voided volume (204.8 mL, P<0.001) and mean maximum voided volume in ambulatory UDS (259.9 mL, P=0.001), with the latter volumes being 50% and 64% of the first, respectively. Finally, no statistically significant difference in PVR urine volume was observed between the two urodynamic methods (P=0.207), although the maximum urine flow rate during conventional UDS was higher (10.3±5.2 mL/sec) than the mean flow rate during ambulatory UDS (8.6±2.9 mL/sec, P=0.035).

The comparison of urine leakage events between conventional and ambulatory UDS during the daytime showed that the episodes recorded in the latter were more frequent. In detail, of the 32 patients, 13 had incontinence in conventional UDS (40.6%) and 18 experienced urine leakage in ambulatory UDS during the day (56.2%). However, this difference was not statistically significant (P=0.332).

Diary and Comparison of Urine Leakage During Ambulatory UDS

When findings from the patient diaries on ambulatory UDS (self-reported urine leakage episodes) were compared with the urine leakage episodes according to conductance electrodes during ambulatory UDS, a statistically significant difference was found in favor of conductance during the night and the entire 18-hour incontinence (night: 0.8±0.01 vs. 3.2±2.4, P<0.001; 18 hours: 2.7±1.3 vs. 5.0±3.2, P<0.001) but not for day incontinence (1.7±0.3 vs. 1.8±0.3, P=0.083).

DISCUSSION

The goal of orthotopic neobladder substitution should be to

improve patient quality of life, ensuring both continence and minimal residual urine volumes, while simultaneously maintaining the integrity of the upper urinary tract [10]. Hautmann et al. [11] described neobladder formation with the small intestine in 1988, and because then, the ileum has been the most commonly used segment due to easier reconstruction, lower storage pressures and less production of mucus. It seems that the orthotopic neobladder is safer than the commonly used ileal conduit, but with similar preoperative complications and long-term morbidity [12]. The technique of orthotopic neobladder substitution applied in this trial was that of Abol-Enein-Ghoneim. This technique retains the advantages of implanting different ureter sizes, allowing for endoscopy of the upper tract at any time and simultaneously preventing vesicoureteral reflux, thereby reducing pyelonephritis episodes [13].

In our study, we found a mean intravesical pressure at maximum capacity of 53.7 ± 17.5 cm H_2O in conventional UDS, which was among the highest values reported in the literature [14]. Pressures up to 40 cm H_2O are known to be considered acceptable to preserve the function of the upper urinary tract. However, the maintenance of the upper urinary tract function in our patients (normal creatinine levels and absence of hydronephrosis), despite this high pressure in conventional UDS, might be explained by the mean intravesical pressure being 34.4 ± 5.2 cm H_2O in ambulatory UDS, consistent with literature reports. This value was statistically significantly lower than the aforementioned value in conventional UDS ($P < 0.001$), demonstrating the usefulness of ambulatory UDS to clarify the actual variance of intravesical pressure during the day.

By contrast, the result of the comparison of intravesical pressure at half of maximum capacity between conventional and ambulatory UDS did not show statistical significance ($P = 0.152$), possibly indicating that filling up to the point of maximum capacity only has relevance as research interest because in everyday clinical practice, patients' neobladders most likely function at intermediate filling volumes, which are lower than the maximum capacity. This finding was also confirmed by the voided volumes recorded by using the two methods, presenting a statistically significant difference (406.0 mL vs. 204.8 mL, $P < 0.001$). However, these higher volumes measured using conventional UDS seemed not to affect the PVR measured using the conventional and ambulatory UDS ($P = 0.207$).

Regarding neobladder sensation, the filling volumes during conventional UDS were close to that of the normal bladder, that is, 244.2 mL at first desire, 351.9 mL at normal desire, and 496.8 mL at maximum capacity. Despite approximately half of the contractions during conventional UDS being associated with some degree of sensation, this sensation is not always connected to neobladder contractions, as also demonstrated by means of ambulatory UDS.

Wall pressure during neobladder contractions without urine leakage, recorded in ambulatory UDS, was statistically significantly higher than the relevant pressure at first desire in conventional UDS, without any recording at the points of urgency reported by the patients. Moreover, the subjectivity of neobladder sensation was evidenced by the lack of significant difference in urine leakage wall pressure recorded during ambulatory UDS and that recorded during conventional UDS, as well as by the mean wall pressure during bladder contraction in conventional UDS being statistically significantly higher than each sensation pressure. Obviously, this neobladder sensitivity could be interpreted as a filling sensation or as pressure on the lower abdominal wall, as also described in the literature [15].

Regarding voiding parameters, although the patients' voiding volumes were similar to those in other reports with low PVRs, the Qmax recorded with both methods were among the lowest reported in the literature (10.3 ± 5.2 mL/sec in conventional UDS and 8.6 ± 2.9 mL/sec in ambulatory UDS) [16-18]. Urethral stricture could be responsible for this deviation. However, all of the patients were controlled before enrollment in the study by catheterization of the neobladder, and they were excluded in cases of positive results. Although the statistically significant difference in Qmax was in favor of the conventional study, which could be attributed to the larger filling volume, this value was far from similar to those reported in the literature. Perhaps, to some extent, this difference could be related to the degree of inadequate education regarding neobladder emptying among the patients in our country.

With the PVR limit of 100 mL proposed by Hautmann to undergo intermittent self-catheterization, in this study, 18% of the patients in the conventional UDS group (6 of 32) and 21% of the patients in the ambulatory group (7 of 32) were found to have exceeded the above limit. In a retrospective study of 2000 orthotopic neobladders, the percentage of patients who required self-catheterize ranged from 4% to 25%, consistent with our results [19].

Finally, between the two methods, we also observed differences in incontinence events in the same patients. However, although the patients seemed to have more urine leakage episodes during ambulatory UDS than during conventional UDS

(13 of 32 vs. 18 of 32), this difference was not statistically significant. Possibly, with a larger number of patients, the usefulness of ambulatory UDS for this proportion of patients would become more obvious. The short duration of the conventional UDS method, in combination with the uncomfortable sedentary and stationary position of the patient and the presence of physiological stress, could explain the limitations of this study in determining the true number of incontinence episodes. In addition, the great value of ambulatory UDS in detecting incontinence was further established at night, when 87.5% of patients were found to have incontinence, a percentage far greater than that reported in the international literature [20]. Diary-reported incontinence was proven to be lesser in extent compared with true leakage episodes according to conductance electrodes during 18 hours and night recordings. However, diary-recording of leakage episodes in ambulatory UDS simulates a simple 24-hour diary that is generally used to assess incontinence in daily practice.

All of these benefits of ambulatory UDS and mainly its potential to identify abnormalities, which can be misleading with conventional UDS, must be evaluated. However, the technical difficulties that patients may face during the ambulatory method perhaps constitute an obstacle to the widespread use of ambulatory UDS in all patients requiring assessment.

Some drawbacks of the present study should also be mentioned. One limitation was the rather small number of patients (n=32) included in the study who underwent both conventional and ambulatory UDS. However, the initial pool (n=153), and the stringent inclusion and exclusion criteria allowed us to draw firm conclusions about the functional behavior of the neobladder in a representative group of patients. Furthermore, the subjectivity in assessing the results of ambulatory UDS surely demonstrated another limitation. In particular, what is considered an artifact, a true neobladder contraction, or only a patient's movement cannot yet be fully defined. If we also add the possible patient negligence to press the button in case of an event due to long-term recording, the previously mentioned subjectivity becomes more obvious.

In conclusion, the estimation of neobladder function by means of ambulatory UDS seems to provide interesting research data for the mode of lower urinary tract function in patients who undergo orthotopic substitution after radical cystectomy. First, the mean intravesical pressure during ambulatory UDS explains the integrity of the upper urinary tract despite high mean intravesical pressures at maximum capacity. Second, in everyday clinical practice, the functional capacity of the orthotopic neobladder is almost 50% of the maximum cystometric capacity in conventional UDS. Moreover, neobladder contractions do not seem to affect neobladder sensation, which is totally a feeling of fullness of the intestinal reservoir. Finally, the great value of ambulatory UDS in cases in which conventional UDS have failed lies in the accurate exposure of daily and nocturnal incontinence episodes, confirming our patients' complaints.

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