

Urodynamic and continence assessment of orthotropic neobladder reconstruction following radical cystectomy in bladder cancer; a prospective, blinded North Indian tertiary care experience

Vishwajeet Singh, Swarnendu Mandal, Sachin Patil, Rahul Janak Sinha, Dheeraj Kumar Gupta, Satya Narayan Sankhwar

Abstract

Aim: The aim of this study is to compare urodynamic and continence parameters among patients undergoing orthotropic neo-bladder substitution with sigmoid or ileal segments. Variations in the Urodynamic parameter between the continent and incontinent patients were also evaluated. **Patients and Methods:** From January 2008 to March 2012, 44 patients underwent ileal neobladder (IN) reconstruction and 36 patients underwent sigmoid neobladder (SN) reconstruction. Evaluation of Urodynamic and Continence parameters was performed at 12 months after surgery. **Results:** The average capacity of IN and SN was 510 ml and 532 ml respectively. The voiding pressure, mean peak flow rates and post void residual urine (PVRU) for IN and SN were 27.5 cm H₂O versus 37 cm H₂O, 15ml/s versus 17ml/s and 36 ml versus 25 ml respectively. Daytime continence for IN and SN was 93% (41/44) and 89% (32/36), and night-time continence was 91% (40/44) and 78% (28/36) respectively. The compliance, maximum cystometric capacity and PVRU in the daytime continent (versus incontinent) were 61 (versus 41), 471 (versus 651) and 22 (versus 124) and in the night-time continent (versus incontinent) were 57 (versus 43), 437 (versus 654) and 18 (versus 105) respectively. **Conclusion:** A neobladder constructed from detubularized ileum or sigmoid achieves urodynamically proven adequate capacity and compliance with 89-93% daytime and 78-91% night time continence. Continent men when compared with incontinent (both daytime and night time) were more likely to have comparatively higher compliance, lower maximum cystometric capacity and lower PVRU. Urodynamic study could predict which incontinent men would improve with pelvic floor exercises and clean intermittent catheterization (CIC).

Key words: Ileal neobladder, nonrandomized, prospective, sigmoid neobladder, urodynamic

Introduction

Orthotropic neobladder (ONB) has become the most common type of continent urinary diversion performed after radical cystectomy (RC).^[1] ONB can be offered to 60-70% of patients undergoing cystectomy.^[2] Urodynamic evaluation is the most objective method in assessing the functional outcome of neobladder. The objective of this prospective, nonrandomized study was to compare urodynamic and continence parameters in sigmoid neobladder (SN) or ileal neobladder (IN) ONB. Variations in the Urodynamic parameter between the continent and incontinent patients both during the day-time and night-time were also evaluated.

Patients and Methods

In this prospective nonrandomized study, all patients undergoing RC and ONB from January 2008 to March 2012 were included. Ethical clearance was obtained from Institutional Review Board and written informed consent was obtained prior to urodynamic evaluation. All procedures were performed by a single surgeon (VS).

Surgical Technique

Standard techniques were used for ONB reconstruction. The reservoir was spherical and configured from detubularized 40 cm sigmoid colon in SN and 50-60 cm ileal segment in IN. Care is taken to preserve the external striated sphincter and preserving neurovascular bundles.^[3]

Patient was seen initially at 1 month after surgery, then every 3 months for 2 years and finally every 6 months. Patients underwent urodynamic and continence evaluation at 12 months after surgery.

Urodynamic Assessment

Initially patient was allowed to void and was then catheterized to empty the reservoir to determine post void residual

volume (PVRU). Using a 7-Fr. transurethral catheter and 10 Fr rectal balloon catheters, standard three-channel filling cystometry was performed using Medtronic duet^[4] logic G/2 device. The pouch was filled at a rate of 20-50 ml/min with normal saline at room temperature until any of the following occurred; discomfort, leakage or volume of 1000 ml was reached. If the patient failed to void due to mucous plugs, bladder wash was performed for three days and urodynamic repeated.

The parameters noted were compliance, maximum capacity, Pdet at max capacity, voided volume, flow rate and residual volume. The methods, definitions, and units conformed to the standards recommended by the International Continence Society (ICS).^[2-3]

Continence Assessment

Information was obtained about the voiding status, including voiding posture, desire to void, need for catheterization and state of daytime or night-time urinary continence, using a questionnaire at 12 months of follow-up. Continence was scored according to standards recommended by the ICS^[2] [Table 1].

Patients were encouraged to void spontaneously, ideally by pelvic floor relaxation alone, failing which they were taught to use abdominal straining. Clean intermittent catheterization (CIC) was recommended only if they failed to void with above maneuvers or when PVRU was >100 ml. Alarm clock was used at night after 4 hours, initially. Pelvic floor exercises and CIC were encouraged in men who were incontinent.

The urodynamic study and continence questionnaire was administered by an urologist (SM) who was blinded to all surgical works and type of neobladder reconstructed.

Statistical Evaluation

Data were maintained and entered in Microsoft Excel computer program and analysis was carried by using SPSS (version 16) software. The results are presented in mean (\pm standard deviation) and percentages. Chi-square test was used to compare the dichotomous/categorical variables. The unpaired *t*-test was used to compare two means. The *P* < 0.05 was considered as significant.

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Department of Urology, King George's Medical University (erstwhile Chattrapati Shahuji Maharaj Medical University), Lucknow, Uttar Pradesh, India
Correspondence to: Prof. Vishwajeet Singh,
 E-mail: drvishwajeeturo@sify.com

Results

The mean age of patients was 54.45 ± 11.67 years. The mean body mass index (BMI) was 23.80 ± 2.13 kg/m². Mean follow up was 23.4 ± 7.9 months. The IN reconstruction (Studer pouch) was done in 44 and SN in 36 patients respectively.

Mean urodynamic values and continence parameters between IN and SN are enumerated in Table 2. The average reservoir capacity, voided volume, voiding pressure, compliance, mean peak flow rates and PVRU for IN and SN were 510 ml versus 532 ml, 398 ml versus 477 ml, 27 cm H₂O versus 37.5 cm H₂O, 53.5 ml/cm H₂O versus 45.5 ml/cm, 13.5 ml/s versus 17 ml/s and 36 ml versus 25 ml respectively. All patients voided with abdominal valsalva maneuver. CIC was

required by 18% in IN and 16% in SN. Daytime continence was achieved in 41/44 (93%) patients of IN and 32/36 (89%) patients of SN. Night time continence was achieved in 40/44 (91%) of patients with an IN and 28/36 (78%) of patients with an SN. There was no statistical significant difference between IN and SN in urodynamic or continence parameters.

On comparing the urodynamic parameters [Table 3] between the daytime continent ($n = 73$) versus daytime incontinent ($n = 7$) patients (combined IN and SN), it was found that continent patients (as compared to incontinent) had statistically significantly high compliance (61 vs 40.5 ml/cm H₂O), low maximum cystometric capacity (471 vs 652 ml) and low PVRU (22 vs 124 ml).

Similarly, on comparing the urodynamic parameters [Table 3] between night-time continent ($n = 68$) versus night-time incontinent ($n = 12$) patients (combined IN and SN), it was found that continent patients (as compared to incontinent) had statistically significantly low maximum cystometric capacity (437 versus 654 ml) and low PVRU (18 versus 105 ml). Pelvic floor exercises and CIC were encouraged in men who were incontinent and improvement in continence was noted.

Discussion

Currently there is no consensus about the urodynamic assessment of the intestinal neobladder. The same parameters applied to an intact bladder are used without considering that the intestine was not originally conceived to store or void urine. Mean maximum capacity of IN varies between 400 and 500 ml and that of SN from 480 to 580 ml.^[5,6] Mean maximum capacity in our study for IN was 510 ml and for SN was 530 ml. Urodynamic results depend on the type, length and configuration of intestinal segment used. They are also dependent on time elapsed after surgery since overall capacity seems to increase during first 6-9 months.^[1-5]

Table 1: Definitions of day and night time continence according to ICS

Characteristics	Continence status	Voiding status
Day time continence		
Completely dry without need for protection	Continent	Good
Completely dry, protection for safety	Continent	Good
No more than 1 pad a day, damp once or twice a week	Socially continent	Satisfactory
No more than 1 pad a day, damp	Socially continent	Satisfactory
More than 1 pad a day, wet or soaked	Incontinent	Unsatisfactory
Night time continence		
Dry with no sanitary pad required	Continent	Good
Dry with one awakening	Continent	Fair
Wet, leakage and incontinence during sleep	Incontinent	Poor

ICS=International continence society

Table 2: Urodynamic and continence parameters in the mean between IN and SN

	Ileal neobladder (n=44)	Sigmoid neobladder (n=36)	P value
Urodynamic parameters			
Compliance (ml/cm H ₂ O)	53.54 [SD=51.04]	45.38 [SD=43.55]	0.729
Max capacity (ml)	509.60 [SD=207.38]	532.63 [SD=95.06]	0.776
P reservoir (cm H ₂ O)	27.30 [SD=12.32]	37.44 [SD=12.05]	0.088
Voided volume (ml)	467.80 [SD=76.76]	503.44 [SD=96.44]	0.071
Max flow rate (ml/s)	13.27 [SD=10.92]	17.06 [SD=4.23]	0.652
Residual volume (ml)	36.37 [SD=24.22]	25.42 [SD=15.10]	0.8001
Continence parameters			
Posture on voiding			
Sitting	36	28	0.656
Standing	8	8	
Desire to void			
Present	24	16	0.828
Absent	20	20	
CIC			
Yes	8 (18%)	6 (16%)	0.860
No	36 (82%)	30 (84%)	
Day time continence			
Continent	41 (93%)	32 (89%)	0.890
Incontinent	3	4	
Night time continence			
Continent	40 (91%)	28 (78%)	0.860
Incontinent	4	8	

IN=Ileal neobladder, SN=Sigmoid neobladder, SD=Standard deviation, CIC=Clean intermittent catheterization

Table 3: Urodynamic parameters between day and night time continent and incontinent (combined IN and SN)

	Continent (n=73)	Incontinent (n=7)	P value
Day time continent and incontinent			
Compliance (ml/cm H ₂ O)	61.25 [SD=50.75]	40.36 [SD=36.78]	0.028
Max capacity (ml)	471.13 [SD=103.11]	651.5 [SD=184.5]	0.003
P reservoir (cm H ₂ O)	32.13 [SD=12.64]	28.4 [SD=5.59]	0.37
Voided volume (ml)	442 [SD=104.36]	404 [SD=48.4]	0.22
Max flow rate (ml/s)	15.3 [SD=11.35]	13.2 [SD=4.1]	0.56
Residual volume (ml)	22.25 [SD=12.26]	124.5 [SD=62.5]	0.002
	Continent (n=68)	Incontinent (n=12)	
Night time continent and incontinent			
Compliance (ml/cm H ₂ O)	57.25 [SD=57.2]	43.36 [SD=38.7]	0.028
Max capacity (ml)	437.6 [SD=73.88]	654.5 [SD=171.5]	0.0015
P reservoir (cm H ₂ O)	31.13 [SD=12.64]	33.7 [SD=5.59]	0.37
Voided volume (ml)	436 [SD=104.36]	434 [SD=48.4]	0.22
Max flow rate (ml/s)	14.9 [SD=11.35]	13.7 [SD=4.1]	0.56
Residual volume (ml)	18.25 [SD = 11.67]	105 [SD = 51.3]	0.001

SD=Standard deviation, IN=Ileal neobladder, SN=Sigmoid neobladder

Because sigmoid colon are richly supplied by parasympathetic nerves, they can produce strong contractions.^[6-7] This could be why SN patients are better voiders than IN patients.^[6-7] Moreover, for the same reason, some SN patients reported having the feeling of a full bladder just as they had before operation.^[7] Thus, differences exist in voiding function of neobladder constructed using the IN and SN. The results obtained from this study showed that compliance of IN (53 ml/cm H₂O) was greater than that of SN (43 ml/cm H₂O). This is consistent with the results reported by Berglund and Kock.^[4] The lower relative compliance of SN might derive from the longitudinal layer of colonic segment, which is relatively non-distensible.^[5] An additional factor attributing to the lower compliance might be the greater number of involuntary contractions in SN compared with IN, because the frequency was greater and amplitude of pressure was higher in SN on urodynamic study.^[5]

Schrier *et al.*^[6] have reported a significantly larger maximal capacity, lower pressure at maximal capacity, and greater compliance for IN than for SN. Koraitim *et al.*^[7] showed that, compared with SN, the IN provides a greater-capacity, lower-pressure reservoir with greater compliance and less frequent involuntary contractions. Moreover, the IN showed no remarkable change in voiding function within 10 years postoperatively.⁵ However, Shimogaki *et al.*^[8] noted that the number of IN patients who needed CIC to evacuate the bladder tended to increase with time.

Overall daytime continence rates in literature vary between 77% and 100% and nighttime continence rates from 66% to 80%.^[9,10] In our study daytime continence of IN and SN were 93% and 89% respectively and nighttime continence were 91% and 78% respectively. The rate of CIC after neobladder varies broadly in literature from 4% to 43% at 5 years, but seems dependent on which cutoff the authors considers PVRU as clinically significant. CIC is recommended when the PVRU routinely exceeded 100 mL.^[3,9] The rate of CIC in our study for IN and SN were 18% and 16% respectively at 1 year.

Over distension with loss of wall tension should be avoided, because it can produce incomplete emptying. Porru *et al.* found that only patients with a capacity >700 mL had a significant PVRU (150 mL).^[11] The IN, being larger, accommodates larger volumes at pressures similar to those in smaller reservoirs,

but with the generation of a higher wall tension. The lower pressures in large capacity neo-bladders result in a better degree of resistance across the continence zone, thereby improving continence. This was apparent in the present series, with IN having the best continence.

Radical Cystectomy interrupts the nervous reflex loop and destroys the anatomic structure responsible for voiding control by resection of the bladder neck and prostatic urethra.^[10] Therefore, continence after ONB is dependent on an intact urethral sphincter mechanism and pelvic floor, which are able to maintain a resistance pressure across the urethral continence zone.^[9] Additional factors that might influence continence include urethral length and sensitivity, patient age and mental status, and an intact pelvic nerve supply to rhabdosphincter.^[10]

Nocturnal incontinence in these patients has been attributed to several causes, including loss of vesicourethral reflex, which normally permits an increase in urethral sphincter tone as the bladder distends, decreased muscle tone and urethral closure pressure during sleep, high amplitude involuntary contractions of the reservoir, decreased sensitivity of membranous urethra after radical cystectomy and decreased vigilance of patient during sleep.^[7] At night, the intraurethral pressure decreases during sleep.^[10] Nocturnal incontinence might occur when the neobladder pressure exceeds the urethral resistance.^[10]

In the only study^[12] available in literature on the differences in the urodynamic parameters between the continent and incontinent patients, it was found that incontinent groups ($n = 17$) had higher PVRU, higher pressure values and lower compliance than continent men ($n = 50$). In addition, men with incontinence had lower flow rates and less efficient sphincter function than continent men. A similar finding in our study reflects that we could obtain similar results and that Indian men behave similarly to western population [Table 3]. With the introduction of rigorous pelvic floor exercises and strict implementation of CIC, even incontinent men who had their compliance, maximum cystometric capacity and PVRU at a closer range to normal (as compared to continent men) than those whose compliance, maximum cystometric capacity and PVRU were at the higher range, could achieve continence at later follow-up. Thus urodynamic study could help us to predict which men could improve with pelvic floor exercises

and CIC. The improvement in continence rate after 1 year of reservoir construction for up to 4 years.^[12,13] raises questions about the underlying mechanism, and about which patients will improve.^[12] Various explanation for late improvements are better understanding by the patient of his micturition habit,^[12] development of conditioned reflexes that help men to perceive sensory output from their posterior urethra, helping to raise their outlet resistance,^[13] increase in reservoir capacity and improved compliance with progressive reservoir dilatation and the sphincter mechanism might improve in men whose neurovascular bundle was incompletely damaged and has regenerated.^[14] However, it is interesting to note that compliance in these patients is much higher than that reported by Burkhard *et al.*^[15] and may be explained by large percentage of patients with incomplete emptying (20%) in this study.

Our study has provided significant information about urodynamic and continence parameters in men undergoing ONB. Our study is among very few studies which are prospective, longitudinal and including heterogeneous group of patients in terms of age, BMI, socio-economic status. The only limitation is that the present study is nonrandomized. however it must be understood that pre-operative randomization into either IN or SN is difficult because the type of neobladder to be reconstructed depends on intra-operative anatomy of bowel. For this reason only one study^[9] is available in literature which is randomized. To decrease bias the operation was performed by a single surgeon (VS) and follow-up urodynamic study and functional evaluation by another urologist (SM) who was blinded to the type of ONB.

Conclusion

Ileal or sigmoid neobladders achieve urodynamically proven adequate capacity and compliance. They void with adequate abdominal pressure, with acceptable PVRU and good flow rate. There were no significant urodynamic difference between IN and SN. Daytime continence was excellent and night time continence was good. There were no significant difference between IN and SN as regards to continence or need of CIC. There is no perceived superiority of IN over SN. It can be offered to all suitable Indian men undergoing radical cystectomy.

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