Shifting to 4×1 intermittent catheterization without an early follow-up urodynamic study is possible in most patients with subacute spinal cord injury

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Objectives: We retrospectively evaluated the frequency of changing to 4/day intermittent catheterization (IC) in patients with subacute spinal cord injury (SCI) who had been initiated on IC 6 times a day and started oral anticholinergic treatment following urodynamic investigation for decreased maximum cystometric capacity and undergone a follow-up urodynamic study within 45 days. The goal of the study was to see if the second urodynamic study was necessary.

Methods: The frequency of shifting to 4/day IC was investigated retrospectively in 27 patients with subacute SCI who were prescribed 6/day IC.

Results: In 25 of 27 patients a bladder capacity of 400 ml or more was reached in urodynamic study carried out in the following 45 days and the patients were shifted to 4/day IC. There was a significant difference between the anticholinergic pre-treatment (293 ± 39 ml) and post-treatment (531 ± 81 ml) capacities ($P < 0.001$). The mean increase in bladder capacity in all patients was 237.6 ± 79.5 ml ($83.5 \pm 32.1\%$).

Conclusion: Patients with subacute SCI who were prescribed 6/day IC and were given an oral anticholinergic drug can be shifted to 4/day IC after 45 days without performing an early control urodynamic study if the patients use the drug properly. However in the long-run, periodic follow-up urodynamic studies should be carried out at appropriate intervals, according to the patients' clinical findings.

Keywords: Spinal cord injury, Anticholinergic therapy, Urodynamics, Intermittent catheter frequency

Introduction

Bladder dysfunction is a major problem in patients with spinal cord injury (SCI) and intermittent catheterization (IC) and anticholinergic agents occupy an important place in the treatment.¹⁻⁶

The IC frequency is selected according to the patient's conditions. Decreased frequency decreases the risk of urethral trauma,⁴ the time spent for catheterization, and the material cost, and also has a positive impact on sleep pattern and quality life.

In our standard practice, the decision to reduce frequency from 6/day to 4/day is deferred until the second urodynamic examination. If the decision could

be based on another method, then a second urodynamic investigation could be deferred, with savings to the patient and system.

Urodynamic investigations play a key role in determining the emptying method and IC frequency in this patient group.^{7,8} For urodynamic investigation, patients and health professionals spend time and labour, use consumables, and although rare, complications such as urinary tract infections can develop. These increase the cost of care for the disorder. When the state of disability in patients with SCI was considered, for the patients who have to perform urodynamic investigation especially at the centers outside the home city, performing the urodynamic investigation is more difficult and costly.

We retrospectively evaluated the frequency of changing to 4/day IC in patients with subacute SCI who

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had been initiated on IC 6/day and started oral anticholinergic treatment following urodynamic investigation for decreased maximum cystometric capacity and undergone a follow-up urodynamic study within 45 days. The goal of the study was to see if the second urodynamic study was necessary.

Materials and method

We included a total of 27 cases consisting of 22 males and 5 females with traumatic SCI were admitted to our hospital. Following urodynamic investigations carried out for lower urinary tract dysfunction, they had been put on 6/day IC and an oral anticholinergic (oxybutynin HCl) for overactive or hypocompliant detrusor and all had a follow-up urodynamic study within the following 45 days.

The patients taking anticholinergic agent apart from oxybutynin, with a time interval longer than 45 days between two urodynamic investigations, and having neurological diseases other than SCI or additional urinary system disease were excluded from the study.

Patient sex, age, duration of injury, SCI level and grade according to the American Spinal Cord Injury Association (ASIA) International Standards For Neurological Classification of Spinal Cord Injury (ISNCSCI) classification and oral anticholinergic (oxybutynin HCl) doses were recorded.

The approval of the Educational Planning and Coordination Committee of our hospital was obtained for this retrospective study.

Urodynamic studies were performed with the Libra⁺ (MMS, Enschede, the Netherlands) urodynamic measurement system using dual-lumen 8 F sterile urethral catheters and sterile saline at room temperature with a 50-ml/min constant fill rate. All urodynamic studies were conducted by the same person (first author).

The urodynamic study was ended if the patient reported a severe need to urinate, in case of significant leakage development, intravesical pressure exceeding 40 cmH₂O, or autonomic dysreflexia findings during the urodynamic study and the bladder capacity at that time was recorded as the maximum cystometric capacity. Detrusor overactivity and hypocompliance were evaluated in the reviewed urodynamic records and recorded.⁷

The criteria for shifting catheterization frequency from 6/day to 4/day safely is described as a maximum cystometric capacity of 400 ml and over observed in the follow-up urodynamic study. If we summarize, the criteria is a cystometric capacity of 400 ml reached before the patient reported a strong desire to void,

before a significant leakage developed, before intravesical pressure exceeded 40 cmH₂O due to detrusor overactivity or detrusor hypocompliance, and before autonomic dysreflexia findings occurred during the urodynamic study.

A cystometric capacity of 400 ml and over in cases who underwent a follow-up urodynamic study within 45 days after treatment initiation was looked for and the ratio of patients who could be changed to 4/day IC was determined.

Statistical analyses were performed using the SPSS version 15 software (SPSS Inc., Chicago, IL, USA). Descriptive statistics were expressed as mean ± standard deviation, range and median for variables with continuous measurement and as the number of cases for the nominal and ordinal variables. Compliance of variables with the normal distribution was examined by using the Kolmogorov-Smirnov/Shapiro-Wilk tests. Since the maximum cystometric capacity values did not show a normal distribution of values, the Wilcoxon test was used for the comparison of pre-treatment and post-treatment maximum cystometric capacity values. Results with a P-value < 0.05 were considered to be statistically significant.

Results

The 27 traumatic SCI cases included in the study consisted of 22 males and 5 females with a mean age of 35 ± 11 (range: 18–54, median: 38) years. The mean duration from the injury to the examination was 110 ± 11 (range: 53–222, median: 94) days and the mean duration from the first urodynamic examination to the follow-up urodynamic examination (oxybutynin HCl treatment duration) was 30 ± 9 (range: 17–45, median: 29) days. The study group included 3 patients with cervical, 19 patients with thoracic, and 5 patients with lumbosacral spinal cord lesions. The ASIA ISNCSCI classification was A in 19 cases, B in 1 case, C in 6 cases and D in 1 case. The oxybutynin HCl dose was 10 mg/day in 15 cases and 15 mg/day in 12 cases. The demographic and clinical characteristics of the patients are presented in Table 1.

Based on the second urodynamic study, 25/27 (92.6%) met the criteria of changing their IC frequency from 6/day to 4/day. Among the 2 cases that could not make the change, one had taken the medication after meals instead of on an empty stomach while the other's maximum cystometric capacity had increased from 250 ml to 350 ml (40% increase) but had not reached a capacity of 400 ml for 4/day intermittent catheterization. The follow-up urodynamic study had

Table 1 Demographic and clinical features of the patients (*n* = 27)

Age (years) (mean ± SD, median, min-max)	35 ± 11, 38, 18–54
Disease duration (days) (mean ± SD, median, min-max)	110 ± 11, 94, 53–222
Oxybutynin HCl treatment duration (days) (mean ± SD, median, min-max)	30 ± 9, 29, 17–45
Sex (female/male)	5/22
Level of lesion (cervical/thoracic/lumbosacral)	3/19/5
ASIA ISNCSCI Grade (A/B/C/D/E)	19/1/6/1/0

ASIA ISNCSCI: American Spinal Cord Injury Association International Standards For Neurological Classification of Spinal Cord Injury.

Table 2 Comparison of pre and post-treatment maximum cystometric capacities

	Pre-treatment	Post-treatment	P
Maximum cystometric capacity (ml) (mean ± SD, median, min-max)	293 ± 39, 300, 230–370	531 ± 81, 550, 350–600	<0.001
Increase in maximum cystometric capacity (ml) (mean ± SD)		237.6 ± 79.5	
Increase in maximum cystometric capacity (%) (mean ± SD)		83.5 ± 32.1	

been performed on the 35th day in the second patient, so treatment duration was 35 days.

There was a significant difference between the anticholinergic pre-treatment (293 ± 39 ml) and post-treatment (531 ± 81 ml) capacities (*P* < 0.001). The mean increase in maximum cystometric capacity in all patients was 237.6 ± 79.5 ml (83.5 ± 32.1%) (Table 2).

Discussion

We observed that 25 (92.6%) of the 27 cases with SCI in the subacute period who were put on 6/day IC as a result of a urodynamic study and were started treatment with oral anticholinergic (oxybutynin HCl) for an overactive or hypocompliant detrusor could be changed to 4/day IC within 45 days after the treatment was started. Among the 2 cases that could not make the change to 4/day intermittent catheterization, one had taken the medication after meals instead of on an empty stomach while the other's maximum cystometric capacity had increased from 250 ml to 350 ml but had not reached a capacity of 400 ml for 4/day intermittent catheterization. Considering that the treatment duration in the second patient was only 35 days, it seems highly likely that the capacity that increased to 350 ml in 35 days will increase to 400 ml at 45 days. These results suggest that intermittent catheterization frequency can be decreased from 6/day to 4/day after 45 days without first performing a second follow-up urodynamic examination.

The advantages of not performing this additional urodynamic evaluation will be avoiding a financial burden, not exposing the patient to extra medical intervention, saving time for the healthcare staff and the related unit, and protection from complications that might develop due to the examination such as urinary tract infections, etc. The decrease of IC frequency in the

early period will decrease the risk of urethral trauma,⁴ the time spent on catheterization, and the cost of material and will contribute positively to the sleep pattern and life quality. However periodic follow-up urodynamic studies should be carried out in SCI patients in appropriate intervals according to the patients' clinical findings. New studies in which urinary tract imaging is conducted may clarify possible positive effect of reduction of catheterization frequency in urinary tract in long term. Similarly new studies in which UTI frequencies are compared in patients conducting IC 6/day or 4/day may demonstrate the effect of decreased IC frequency from 6/day or 4/day on the risk of urinary tract infection.

The most important point here is to consider that the response of the bladder muscle to anticholinergic treatment may decrease in cases with SCI in the chronic period and to therefore determine the IC frequency in such patients according to the follow-up urodynamic studies to be performed as appropriate.

Significant increases have been reported in bladder capacity in cases with detrusor overactivity⁹ and in patients with SCI¹⁰ after 2–3 weeks of oral oxybutynin HCl treatment.^{9,10} In a review examining the results of 30 studies performed with a total of 1,479 patients with neurogenic detrusor overactivity, it was shown that antimuscarinic drugs (most commonly studied drugs; oxybutynin HCl, trospium chloride and propiverine) are effective after 2–3 weeks of therapy.¹¹ We also observed a significant increase in mean bladder capacity in our patients with SCI who had been put on 6/day IC and oral anticholinergic therapy for an overactive or hypocompliant detrusor.

A retrospective study evaluating the effectiveness of anticholinergic drugs within a mean duration of 1 month (21–46 days) in 231 patients with overactive

detrusor who were undergoing intermittent catheterization has reported an increase in maximum cystometric capacity from 225 ml to 441 ml and a significant decrease in involuntary detrusor contractions but the incontinence continued in 67% of the patients.¹² That study with a larger number of patients had results similar to ours as regards the significant increase in the maximum cystometric capacity and it was emphasized that urodynamic follow-up was mandatory as full continence was not achieved in most patients and anticholinergic treatment could not always adequately suppress neurogenic detrusor overactivity. We found in our study that patients who were undergoing IC 6 times a day and used anticholinergic treatment appropriately could go on to a catheterization frequency of 4/day after a mean duration of approximately 30 days in 92.6% of the cases. We therefore believe that the IC frequency can be decreased to 4/day without performing an early follow-up urodynamic study in patients who meet these criteria but would like to emphasize that regular urodynamic follow-up is mandatory. The retrospective design and the small number of cases are the limitations of our study. Prospective new studies with larger sample sizes may increase knowledge on this area.

In conclusion, our findings suggest that the catheterization frequency can be reduced to 4/day in a short period such as about 45 days without performing an early follow-up urodynamic examination for monitoring the effect of anticholinergic therapy in patients with subacute SCI originally put on 6/day IC as a result of a urodynamic study and started treatment with oral anticholinergic therapy for overactive or hypocompliant detrusor. However, periodic follow-up urodynamic studies should be carried out at appropriate intervals according to the clinical findings.

Disclaimer statements

Contributors None.

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Conflicts of interest The authors declare no conflict of interest.

Ethics approval The approval of the Educational Planning and Coordination Committee of our hospital was obtained for this retrospective study.

References

- 1 Neurogenic Bladder Turkish Research Group, Yıldız N, Akkoç Y, Erhan B, Gündüz B, Yılmaz B, Alaca R, *et al.* Neurogenic bladder in patients with traumatic spinal cord injury: treatment and follow-up. *Spinal Cord* 2014;52(6):462–7.
- 2 Hansen RB, Biering-Sørensen F, Kristensen JK. Bladder emptying over a period of 10–45 years after a traumatic spinal cord injury. *Spinal Cord* 2004;42(11):631–7.
- 3 Siroky MB. Pathogenesis of bacteriuria and infection in the spinal cord injured patient. *Am J Med* 2002;113(Suppl 1A):67S–79S.
- 4 Lindehall B, Abrahamsson K, Hjalmas K, Jodal U, Olsson I, Sillen U. Complications of clean intermittent catheterization in boys and young males with neurogenic bladder dysfunction. *J Urol* 2004;172(4 Pt 2):1686–8.
- 5 Diokno A, Ingber M. Oxybutynin in detrusor overactivity. *Urol Clin North Am* 2006;33(4):439–45.
- 6 Dahlberg A, Perttälä I, Wuokko E, Ala-Opas M. Bladder management in persons with spinal cord lesion. *Spinal Cord* 2004;42(12):694–8.
- 7 Pannek J, Stöhrer M, Blok B, Castro-Diaz D, Del Popolo G, Kramer G, *et al.* Guidelines on neurogenic lower urinary tract dysfunction. European Association of Urology 2013. Available at: http://uroweb.org/wp-content/uploads/20_Neurogenic-LUTD_LR.pdf. Accessed September 7, 2015.
- 8 Nosseir M, Hinkel A, Pannek J. Clinical usefulness of urodynamic assessment for maintenance of bladder function in patients with spinal cord injury. *Neurourol Urodyn* 2007;26(2):228–33.
- 9 Madersbacher H, Stöhrer M, Richter R, Burgdörfer H, Hachen HJ, Mürtz G. Trospium chloride versus oxybutynin: a randomized, double-blind, multicentre trial in the treatment of detrusor hyperreflexia. *Br J Urol* 1995;75(4):452–6.
- 10 Stöhrer M, Mürtz G, Kramer G, Schnabel F, Arnold EP, Wyndaele JJ. Propiverine compared to oxybutynin in neurogenic detrusor overactivity—results of a randomized, double-blind, multicenter clinical study. *Eur Urol* 2007;51(1):235–42.
- 11 Madersbacher H, Mürtz G, Stöhrer M. Neurogenic detrusor overactivity in adults: a review on efficacy, tolerability and safety of oral antimuscarinics. *Spinal Cord* 2013;51(6):432–41.
- 12 Hadji N, Previnaire JG, Benbouzid R, Robain G, Leblond C, Miesusset R, *et al.* Are oxybutynin and trospium efficacious in the treatment of detrusor overactivity in spinal cord injury patients? *Spinal Cord* 2014;52(9):701–5.