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Original Article

Clinical and economic consequences of volume- or time-dependent intermittent catheterization in patients with spinal cord lesions and neuropathic bladder

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Study design: Open comparative study.
Objective: To compare the impact of volume-dependent intermittent catheterization (VDIC) and time-dependent intermittent catheterization (TDIC) on financial burden and clinical outcomes in patients with spinal cord lesions (SCL).
Setting: Department of Spinal Rehabilitation, Loewenstein Rehabilitation Hospital, Israel.
Method: Economic and clinical outcomes were examined in 13 SCL patients treated with VDIC following bladder volume measurement by a portable ultrasound device (the study group), and in 11 patients treated with TDIC (the control group). Patients were followed for 12–30 days. Costs were calculated according to December 2003 prices at Loewenstein Hospital. The *t*-test and the Fisher's Exact Test were employed for comparisons between the groups.
Results: The number of catheterizations per patient per day, the time required to perform volume measurements and catheterizations, and their total cost, were approximately 44, 49, and 46% lower in the study group than in the control group. SCIMU (representing bladder management functioning) increased during the study in both groups, and the increase was 31% higher in the study group than in the control group. Urinary infection was found in three patients in the control group and in none in the study group.
Conclusion: VDIC has economic and probably also clinical advantages over TDIC.
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Keywords: volume-dependent intermittent catheterization; time-dependent intermittent catheterization; spinal cord lesions; economic consequences; outcomes

Introduction

Intermittent catheterization is an established method for voiding regulation in patients with spinal cord lesions (SCL) and a neuropathic bladder. It enables emptying the bladder while maintaining the bladder's ability to refill itself, and at the same time avoids the presence of a permanent foreign object within the bladder. Intermittent catheterization contributes to minimizing the danger of infection and damage to the urinary tract and may improve the patient's social functioning. It can serve as a permanent voiding technique or as a means of exercising the bladder during transition to another permanent method of regulating its function.[1–7]

Despite the advantages of intermittent catheterization, the repeated insertion of the catheter into the urethra and the bladder and the possible bladder over-filling between catheterizations can cause infection and structural damage. These include infections of the bladder, urethra, and prostate gland, urethral perforation (which may cause a false root), and strictures of the urethra and the meatus.[8] It is plausible that reduction of catheterization frequency can minimize these hazards. If an optimal frequency is achieved, both unnecessary catheterizations of a relatively empty bladder and bladder over-filling can be avoided. Avoiding unnecessary catheterizations might also reduce the burden of care.

Optimal frequency of intermittent catheterizations can be achieved by performing it during optimal bladder volumes, which are the maximal volumes that do not

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cause distress, autonomic dysreflexia, or over-filling. However, in the absence of a reliable means of measuring the volume of urine, catheterization is performed at fixed hours (time-dependent intermittent catheterization, or TDIC) and not necessarily when the bladder is at its optimal volume. Portable ultrasound devices may enable volume-dependent intermittent catheterization (VDIC), contributing to minimizing the side effects of intermittent catheterization.

Previous studies in patients with multiple sclerosis or neuropathic bladder of various etiologies demonstrated the accuracy of portable ultrasound devices and their contribution to reducing the number of catheterizations, to patient's satisfaction, and to improvement of bladder management according to Functional Independence Measure (FIM) scoring.[9–11]

This study focused on examining the effect of VDIC on the financial burden and on clinical results in patients with SCL.

Subjects and methods

In all, 24 patients with neuropathic bladder who required intermittent catheterization by a caregiver were included in the study. All had SCL, and no additional neurological problems or sores in the sphincteric region. The SCL severity according to the American Spinal Injury Association (ASIA) classification, was grade A in two patients, B in two patients, C in nine patients, and D in 11 patients.[12] Baseline ultrasound examination of the bladder and kidneys disclosed no structural bladder abnormalities or hydronephrosis, and blood creatinine level was normal in all the patients. Subjects were assigned at random into a study group treated by VDIC and a control group treated by TDIC. After excluding patients who switched to self-catheterization during the initial days of the study, 13 patients were included in the study group and 11 patients in the control group.

The two groups had similar characteristics. The study group comprised nine men and four women, eight patients with tetraplegia and five with paraplegia. The control group included six men and five women, five patients with tetraplegia and six with paraplegia. The delay from lesion onset to the experiment was less than 2 months in five patients of each group, 2–4 months in two patients of the control group and three patients of the study group, 4–6 months in two patients of each group, 6–12 months only in a control patient, and more than 12 months in one control patient and in three patients of the study group.

No significant differences were found between the groups in gender ($P = 0.675$), age, or in other characteristics that were examined at the beginning of the study, as specified in Table 1. These characteristics include the legs ASIA impairment scale Motor Score (AMS),[12] which represents the severity of lower body neurological deficit, SCIMU 1, which is the bladder management scoring by the Spinal Cord Independence Measure (SCIM)[13] at the beginning of the study, and the cystometric pressure (Cyst. Press) at the beginning of the study. Each subject participated in the experiment for 12–30 days (mean = 19 days in the study group and 20 days in the control group; the difference in follow-up between the groups was not significant $P = 0.605$).

In the control group, the bladder was emptied at preset times according to the number of catheterizations set for each day. Before each catheterization the patient was asked to pass urine voluntarily, without manual assistance, with the assistance of a 'trigger', or by applying pressure to the lower abdomen (Crede maneuver), following urodynamic findings, according to the European Association of Urology guidelines.[14] The volume of the urine the patient was able to pass was measured with a urine collecting device. The residual urine volume, which was evacuated by catheterization, was measured by the same means after the catheterization. The prevoiding bladder volume was calculated by summing the voided and the residual urine volumes. Time-dependent intermittent catheterization was performed every 6 h on the first day of the subject's participation in the experiment. Later, one catheterization was performed every 24 h for each 100 ml of residual urine volume. The residual urine volume was taken as the smaller among the frequent volumes on the previous day. For example, when the residual volumes were 100, 150, 150, and 400 ml, only one catheterization was performed the next day, however, if the residual volumes were 100, 300, 350, and 400 ml, three catheterizations were performed.

In the study group, bladder emptying followed measurement by the portable ultrasound device (PCI 5000 Bladder Manager TM from Diagnostic

Table 1 Patient characteristics at the beginning of the study

	Mean-CG	*SD-CG*	*Mean-SG*	*SD-SG*	P
Age	42.7 years	20.6 years	53.46 years	17.9 years	0.18
AMS (legs)	18.9	18.3	27.6	16.3	0.23
SCIMU 1	2.18	2.75	1.61	2.14	0.576
Cyst. Press	47.1 cm/H_2O	21 cm/H_2O	63.6 cm/H_2O	27.8 cm/H_2O	0.095

SD = standard deviation; SG = study group; CG = control group; P = significance of the difference between the groups; AMS (legs) = Legs ASIA Motor Score (representing the severity of lower body neurological deficit according to ASIA impairment scale);[11] SCIMU 1 = scoring of the bladder management by SCIM scale (Spinal Cord Independence Measure);[12] at the beginning of the study; Cyst. Press = cystometric pressure at the beginning of the study

Ultrasound). In the first 3 days of participation in the experiment, ultrasound measurements were performed five or six times a day. From day 4 on, to allow a reasonable chance of detecting maximal residual urine volumes, the number of daily measurements was determined by dividing the maximum residual urine volume of the previous day by 100 ml.

The urine volume measured with the portable ultrasound device varied according to fluid intake and bladder properties. Each time it was greater than 300 ml, the patient was asked to pass urine voluntarily, without manual assistance, with the assistance of a 'trigger', or by applying pressure to the lower abdomen (Crede maneuver), according to urodynamic findings.[14] After voiding, residual urine volume was measured. Intermittent catheterization was performed each time the prevoiding bladder volume was greater than 300 ml, and the residual urine volume was greater than 250 or 100 ml times the number of catheterizations performed during the previous 24 h. If total bladder volume was greater than 500 ml, drinking regimen was changed (fluid intake reduced or distributed differently), or catheterizations were added. Instructions were given to add catheterizations to all subjects when a bladder volume of over 400 ml was expected because of a significant increase in fluid intake or urine output on that day, or for clinical reasons, such as abdominal distress or signs of autonomic dysreflexia.

For all subjects, a standard technique of sterile catheterization was used. The catheterizations and the ultrasound measurements were performed by a nurse, when the patient was in supine position. The volumes measured by the PCI 5000 Bladder Manager were highly accurate, as demonstrated in a previous publication.[10]

The following items were recorded every day for each patient: the number of urine volume and residual volume measurements, the number of catheterizations performed, and the duration of measurements and catheterizations. All the measurements performed before or after passing urine, or an attempt to pass urine with or without catheterization, were counted as one measurement. In the control group, the recorded time included the measurement performed by a collecting device and the catheterization that followed each measurement (the number of catheterizations being equal to the number of measurements). In the study group, the recorded time included the measurements performed with the portable ultrasound device and the catheterizations that followed some of the measurements. In addition, daily notes specified whether a clinical urinary infection has appeared. At the beginning and the end of the study, urinary function was assessed by the subscale for bladder management of the SCIM scale (SCIMU 1 and 2),[13] and blood creatinine level was obtained.

Costs were calculated according to prices obtained from the administration of the hospital in December 2003: NIS 10 ($\sim$\$2.2) for the equipment used in each catheterization and NIS 34.23 ($\sim$\$7.6) for 1 h of a nurse's time devoted to measurement of urine volume and catheterization.

Daily average values were calculated for each patient in each group. The comparisons between the groups were performed by *t*-test for all the variables except gender and the frequency urinary tract infections, for which the Fisher's Exact Test was employed.

Results

The frequency of catheterizations (No Cat) and urine volume measurements (No MS), the time required to perform them (Time MS + Cat), and their cost by type of intermittent catheterization (Cost Eqip, Cost Nurse, Total Cost) are shown in Table 2. The use of VDIC in the study group reduced the number of catheterizations per patient per day by 1.6 on average (a reduction of approximately 44%). The time required to perform volume measurements and catheterizations was reduced by 20 min (49% reduction). The total cost of measurements and catheterizations per patient (including equipment and nurse salary but not including the portable ultrasound device), was reduced by NIS 27.74 ($\sim$\$6.2) per day (a reduction of 46%).

SCIMU values increased in both groups during the experiment. In the study group, the increase in SCIMU was 31% greater than in the control group, although this difference (dSCIM U) was not statistically significant (Table 3). Blood creatinine level also increased

Table 2 Economic consequences of VDIC *versus* TDIC

	Mean-CG	*SD-CG*	*Mean-SG*	*SD-SG*	P
No MS	3.62	0.74	2.53	0.65	<0.001
No Cat	3.62	0.74	2.02	0.67	<0.0001
Time MS + Cat	*41.17 min	16.20 min	21.16 min	12.06 min	<0.005
Cost Eqip	NIS 36.19	NIS 7.38	NIS 20.18	NIS 6.75	<0.0001
Cost Nurse	*NIS 23.49	NIS 9.24	NIS 12.07	NIS 6.88	<0.005
Total Cost	*NIS 59.99	NIS 16.64	NIS 32.25	NIS 12.35	<0.001

VDIC = volume-dependent intermittent catheterization; TDIC = time-dependent intermittent catheterization; SD = standard deviation; SG = study group; CG = control group; *P* = significance of number of catheterizations per patient per day; Time MS + Cat = total time of measurements and catheterizations per day per patient; Cost Equip = cost of equipment per catheterization per patient; Cost Nurse = Cost of nurse's labor for measurements and catheterizations per day per patient; Total Cost = total cost for measurements and catheterizations per day per patient; min = minutes; NIS = New Israeli Shekel, *$n = 9$

Table 3 Clinical consequences of VDIC *versus* TDIC

	Mean-CG	*SD-CG*	*Mean-SG*	*SD-SG*	P
dSCIMU	4.82	3.25	6.32	4.28	0.129
dCr	0.036	0.102	0.023	0.072	0.715

VDIC = volume-dependent intermittent catheterization; TDIC = time-dependent intermittent catheterization; SD = standard deviation; SG = study group; CG = control group; *P* = significance of difference between the groups; dSCIMU = the increase in SCIMU values during the experiment; dCr = the increase in blood creatinine level during the experiment

during the experiment in both groups. This increase was 36% lower in the study group. However, this difference (dCr) was statistically nonsignificant either, and the creatinine value remained within the normal range in both groups (Table 3). No clinical urinary infection was found in any of the patients in the study group, however, infections were found in three patients of the control group ($P = 0.49$).

Discussion

Although the advantages of VDIC were demonstrated in previous publications,[9,10] the number of SCL patients included in these studies was limited and more data were needed in order to demonstrate its economic and clinical significance. Therefore, we have studied additional VDIC patients and we have taken into consideration economic and clinical aspects, which to the best of our knowledge have not been examined before in this context.

The results show that switching from TDIC to VDIC results in a significant 44–49% decrease in the number of catheterizations per day, in the duration of measurement per patient per day, and in the costs of measurement, catheterization, and equipment for each catheterization. The average daily cost per patient at Loewenstein hospital was lower by NIS 27.74 (~$6.2). There are at least five patients in the department who need intermittent catheterizations at any given time, and therefore switching from TDIC to VDIC can save NIS 50 625 per year ($27.74 \times 5 \times 365$) (~$11 250), which is more than the cost of a portable ultrasound device in Israel.

We could not demonstrate a significant impact of the intermittent catheterization type on clinical variables. This may be due to the sample size, which was too small, or to the follow-up period, which was too short. However, although injuries in the study group were not significantly milder than those in the control group, the improvement in SCIMU values was 31% greater. The relative increase in the SCIMU index may express better bladder emptying ability, less reliance on aids, and less incontinence. In addition, the patients in the study group experienced no clinical urinary infections during the follow-up period, while in the control group three patients had clinical urinary infections.

Although results are significant and impressive, the relatively small number of patients examined limits their implications. A larger number of subjects might demonstrate a significant difference in patient characteristics between the two groups, for example, in intravesical pressure. A higher intravesical pressure in the study group could contribute to the faster decrease in the number of catheterizations. Another bias could be the result of the exclusion of patients who switched to self-intermittent catheterization. Some of these patients may have started self-catheterization earlier because they required less catheterizations even with TDIC, and their exclusion may have artificially increased the average number of catheterizations per day in the control group. Another limitation of the research was the relatively short follow-up. A longer follow-up could have allowed the detection of an additional decrease in catheterizations in the control group and might reduce the difference between the groups. Finally, the calculation of the costs is based on given prices of equipment and labor. These may change depending on when and where the costs are calculated.

Despite the limitations of the study, the findings demonstrate the statistically significant economic advantages of VDIC over TDIC. The clinical advantages are reflected only in the average values of variables that represent function and medical complications, but they support our impression that lower-frequency intermittent catheterization and bladder emptying at suitable volumes are likely to improve damaged bladder functioning and minimize medical complications.

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