

Spinal cord injury patients: Effect of urinary intervention therapy type on quality of life, questionnaire-based study

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ABSTRACT

Objective: The objective of the study is to assess the quality of life (QoL) with or without surgical intervention in patients with spinal cord injury (SCI) with neurogenic bladder.

Material and methods: A prospective study was conducted on SCI patients with neurogenic bladder. The questionnaires used to assess the QoL were the 36-Item Short-Form Health Survey questionnaire (SF-36), the Incontinence questionnaire [Urogenital Distress Inventory (UDI-6)], the International Index of Erectile Function (IIEF-5), and the Female Sexual Function Index (FSFI). Patients were categorized into two groups: the first group consisted of patients who underwent a surgical procedure and the second group included patients managed by a conservative treatment option: clean intermittent bladder catheterization.

Results: Total of 29 patients included in the study, 13 patients underwent urinary diversion (mean age: 45.84 ± 16.41 years) and 16 patients had a conservative treatment (mean age: 47.61 ± 13.90 years). The SF-36 questionnaire evaluation revealed that the bodily pain component was significantly lower in patients who underwent urinary diversion ($p=0.009$), whereas vitality ($p=0.045$) and social functioning ($p=0.005$) components were significantly lower in patients who underwent any type of urinary surgical procedure. The incontinence questionnaire (UDI-6) revealed significantly lower scores in patients who underwent urinary diversion (17.84 ± 5.2) than patients who underwent a conservative treatment (47.05 ± 5.8 ; $p=0.001$).

Conclusion: Urinary surgical intervention improved the QoL in SCI patients with neurogenic bladder as per the UDI-6 scores. However, contrasting results of the SF-36 assessment warrant its further validation by conducting studies with a larger sample size.

Keywords: Neurogenic bladder, clean intermittent catheterization, urinary diversion, quality of life

Introduction

Spinal cord injury (SCI), a devastating injury, occurs mainly due to traumatic or nontraumatic causes resulting in fracture and subsequent dislocation of the vertebral column. Studies suggested that currently there are around 2,32,000–3,16,000 people with SCI only in the United States, and around 50 million people are affected with SCI worldwide.^[1-3]

Genitourinary complications common in patients with SCI are urinary incontinence, repeated episodes of urinary tract infections, urinary stones, deterioration of upper urinary tract functions, and renal failure.^[3] The extent of neurological and bladder damage depends on the location and the severity (partial or com-

plete transection) of the cord injury. Neurogenic bladder is a very common complication of SCI and can significantly affect the quality of life (QoL) of the patients.^[4]

Following SCI, either storage or emptying of the bladder might be affected in the majority of the patients with SCI requiring surgical or medical management. However, in few individuals, the lower urinary tract function might rarely be spared.^[5-7]

The primary goal of management of neurogenic bladder is the maintenance of adequate renal function and prevention of urinary tract infection through regular emptying of the bladder. The next goal of management of neurogenic bladder is achieving as much control as possible over bladder function.

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Thus, in most patients, clean intermittent evacuation of the bladder and use of drugs are the initial lines of treatment. Early initiation of clean intermittent bladder evacuation and drug therapy can delay the need for surgical interventions for a long time. Surgery should be considered only after the conservative approach fails.^[8-11]

Bladder augmentation is used in patients with hyperactive bladder with incontinence, but with preserved upper urinary tract functions. Despite the adoption of this method, urinary incontinence might continue to bother 10%–20% of the patients. In patients with compromised upper urinary tract function due to ureteric obstruction or reflux, bladder substitution or reimplantation of ureters might be helpful.^[4, 8]

For patients with irreversible damage to sphincter and for those who cannot perform self-catheterization adequately, continent cutaneous diversion remains a viable option.^[4, 8] Again, colonic diversion is preferred in patients with chronic renal failure and in those unable to perform self-catheterization.^[4, 8]

A number of studies have assessed the QoL scores before and after an intervention (either surgical or conservative) in the group of patients with neurogenic bladder^[2-16]; however, to the best of our knowledge, we could not find any study comparing the QoL scores of patients managed with conservative and surgical methods.

This study investigated whether urinary diversion procedures offer a significant benefit in terms of QoL improvement and reduction of complications compared to clean intermittent catheterization (CIC).

Material and Methods

After obtaining Research Ethical Board (REB) (University Health network Research Ethics Board 11-0379-AE) approval from the ethics committee, medical records of all the patients with SCI admitted to our medical center from January 2012 to December 2014 were analyzed for patient selection.

Main Points:

- The QoL was assessed in SCI patients with neurogenic bladder with or without surgical intervention.
- In the QoL (SF-36) assessment, the bodily pain component was significantly lower in patients who underwent urinary diversion ($p=0.009$); vitality ($p=0.045$) and social functioning ($p=0.005$) components were significantly lower in patients who underwent a urinary surgical procedure.
- Urinary surgical intervention of SCI patients with neurogenic showed better urinary score in the UDI-6 questionnaire.

The inclusion criteria were any SCI patient with neurogenic bladder (characterized by urinary retention, incontinence, autonomic dysreflexia, and detrusor overactivity as evidenced by urodynamic studies) receiving either CIC or surgical intervention in the form of urinary diversions such as augmentation ileocystoplasty, Mitrofanoff (appendicovesicostomy), and ileal conduit (Indiana and Kock pouch). However, patients with associated dementia or active multiple sclerosis, quadriplegia, aphasia, and/or comatose were excluded from the study.

We used questionnaires to analyze the response from the patients; the questionnaires used for QoL assessment were 36-Item Short-Form Health Survey questionnaire (SF-36), the Incontinence questionnaire [Urogenital Distress Inventory (UDI-6)], International Index of Erectile Function (IIEF-5), and the Female Sexual Function Index (FSFI). The questionnaires were downloaded as the international validated form, and printed forms were then given to patients during their urology clinic visit. If patients agreed and signed a consent form, they were requested to return the filled questionnaires within 6 weeks to the clinic's address. A statistical analysis was conducted using IBM Statistical Package for the Social Sciences (IBM SPSS Corp.; Armonk, NY, USA) version 26.0 to calculate mean scores. The comparisons of categorical and continuous variables were conducted using Pearson's chi-square and t -test, respectively. Pearson's correlation was used for any correlations. Statistical significance was set at $p\leq 0.05$.

Questionnaires

Thirty-six-Item Short-Form Health Survey questionnaire

The Thirty-six-Item Short-Form Health Survey questionnaire (SF-36) is a set of generic, coherent, and easily administered QoL measures. These measures rely on patient self-reporting, and are now widely utilized by managed care organizations and by Medicare for routine monitoring and assessment of care outcomes in adult patients. The SF-36 consists of scores of eight scales, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0–100 scale on the assumption that each question carries equal weight. The lower the score, the more is the disability. The higher the score, the less disability, that is, a score of zero is equivalent to maximum disability, and a score of 100 is equivalent to no disability. The eight sections are vitality, physical functioning, bodily pain (BP), general health perceptions, physical role functioning, emotional role functioning, social role functioning, and mental health.

Urogenital Distress Inventory

Urogenital Distress Inventory (UDI-6) assesses life quality and symptom distress in patients with urinary incontinence. It com-

prises six questions with answers given in a scale of 0–3 (0=for not at all score, 1=a little bit, 2=moderately, and 3=greatly). The final score of UDI-6=(total raw score)/6×25. Lower scores correlate to better urine control.

International Index of Erectile Function

IIEF-5 assesses erectile dysfunction (ED) in men. The possible scores for the IIEF-5 range from 5 to 25, and ED was classified into five categories based on the scores: severe (5–7), moderate (8–11), mild to moderate (12–16), mild (17–21), and no ED (22–25).

Female sexual function index

FSFI is a validated questionnaire that assesses different domains of sexual function in females (desire, arousal, lubrication, orgasm, satisfaction, and pain) in addition to providing an overall score regarding sexual function. Possible FSFI total score ranges from 2.0 to 36.0. The scores of six domains belonging to the FSFI are summed to obtain the overall score. The rule of thumb for the overall result is that scores equal to or below 26.55 are classified as indicating female sexual dysfunction.

Results

There were 36 patients (n=36) with neurogenic bladder due to SCI; however, 29 (n=29) of them satisfied the inclusion criteria. Patients were categorized into two groups; the first group included patients who underwent any urinary diversion procedure and the second group consisted of a well-matched cohort of patients who had conservative management. SF-36, UDI-6, FSFI, and IIEF-5 were used to compare the QoL among the study groups.

Thirteen patients underwent urinary diversion; the mean age being 45.84±16.41 years. Sixteen patients had a conservative treatment; the mean age being 47.61±13.90 years. In the QoL (SF-36) questionnaire, the scores for the BP component were significantly lower (p=0.009) in patients who underwent urinary diversion. Similarly, the scores for the vitality (p=0.045) and social functioning (p=0.005) components were also significantly lower in patients who underwent urinary diversion. However, there was no significant difference in the scores between the group scores regarding physical functioning. In contrast, the incontinence questionnaire (UDI-6) revealed that the patients who underwent urinary diversion had significantly lower scores (17.84±5.2) than patients who had conservative treatment (47.05±5.8; p=0.001). This suggested improved QoL of patients with SCI who underwent urinary diversion by lowering the BP and improving the urinary dysfunction symptoms. FSFI and IIEF-5 did not show any significant difference between both groups (Table 1).

Table 1. Patients in each group

| Variable | CIC group | Surgical intervention group | p-value |
|--|------------|-----------------------------|---------|
| Number of patients | 16 | 13 | 0.153 |
| Age in years | 47.61±13.9 | 45.84±16.41 | 0.136 |
| Gender | | | |
| Male | 13 | 11 | 0.093 |
| Female | 3 | 2 | 0.764 |
| SF-36 | | | |
| Physical functioning | 25.4±12 | 26.5±11 | 0.098 |
| Role limitations due to physical health problems | 40.1±8.1 | 42.2±5 | 0.071 |
| Bodily pain | 39.01±1.8 | 22.5±10 | 0.009 |
| General health | 43.6±10 | 42.5±9 | 0.761 |
| Vitality | 40.2±8.9 | 29.6±6.7 | 0.045 |
| Social functioning | 38.6±9.3 | 23.1±15.3 | 0.005 |
| Role limitations due to emotional problems | 50±5.6 | 48.5±8.9 | 0.901 |
| Mental health | 47.8±12 | 47.1±11 | 0.776 |
| UDI-6 | 47.05±5.8 | 17.84±5.2 | 0.001 |
| FSFI | | | |
| Desire | 3.89±1.2 | 4.02±0.2 | 0.129 |
| Arousal | 7.9±0.04 | 6.9±1.04 | 0.067 |
| Lubrication | 7.35±4.5 | 7.05±4.22 | 0.084 |
| Orgasm | 6.34±1.9 | 6.00±2.2 | 0.231 |
| Satisfaction | 9.2±1.76 | 8.2±2.56 | 0.332 |
| Pain | 5.76±2.61 | 4.34±3.55 | 0.054 |
| Total score | 50.33±10.5 | 55.33±6.5 | 0.067 |
| IIEF-5 | 7.3±2.3 | 7.9±1.6 | 0.800 |

Discussion

Neurogenic bladder is a common sequel of injury or trauma to the spinal cord. The management of neurogenic bladder poses quite a challenge for the urologist notwithstanding the injury to the spinal cord is acquired or congenital. Besides trauma (SCI), some other congenital conditions such as neural tube defects and other spinal birth defects may lead to neurogenic bladder.

In this questionnaire-based study, we analyzed the responses of the patients with neurogenic bladder (due to SCI). The patients were categorized under two categories; one group of patients was managed using the conventional methods such as CIC and medications (anticholinergics), the other group of patients was managed with surgical interventions such as urinary diversion

methods such as augmentation ileocystoplasty, Mitrofanoff (appendicovesicostomy), and ileal conduit (Indiana and Kock pouch).

Interestingly, the UDI-6 scores suggested an improved QoL in patients who underwent urinary diversion by lowering the BP and improving the urinary dysfunction symptoms compared to those who were managed with a conservative treatment. In contrast, the scores of three indices, the BP component, vitality, and social functionality in the SF-36 questionnaire, were significantly lower in patients who underwent urinary diversion compared to those who were managed with a conservative method. This suggested poorer QoL for patients undergoing urinary tract intervention; and therefore, warrants further analysis involving a larger sample size to confirm the information. No significant differences were observed in the scores of physical functioning between the two groups.

In 2017, Best KL et al.^[12] published a systematic review to classify and identify the QoL tools for neurogenic bladder function after SCI. They used search engines such as Medline/PubMed, CINAHL, and PsycInfo to search for the keywords SCI, neurogenic bladder, and QoL. They found that of all the QoL tools, the SF-36 questionnaire was the most frequently used tool. In our study, we also used this questionnaire, SF-36, besides other questionnaires namely UDI-6, IIEF-5, IIEF-5, and FSFI.

In 2015, Lima DX et al.^[13] published an article to assess the QoL in patients with neurogenic bladder undergoing reconstructive urological surgeries.

Unlike our study where comparisons were made between two different groups (one group underwent surgical intervention, and the other group was managed with CIC, conservative method), Lima DX et al.^[13] retrospectively evaluated the QoL in the same group of patients ($n=67$) before and after undergoing surgical intervention (bladder augmentation and eventual complementary procedures). However, similar to our study, they also used the SF-36 questionnaire besides the QoL Qualiveen questionnaire.

Similar to our study, the analysis of the results of their study revealed that bladder augmentation resulted in significant improvement in QoL as the scores of functional capacity, general health, vitality, social aspects, emotional aspects, and mental health in the SF-36 questionnaire were significantly higher in the postoperative period.

Kuo HC published another study on the assessment of the QoL in neurogenic bladder patients following SCI.^[14] This prospective study was conducted on 251 patients attending the urology department between 1988 and 1996. The author assessed the satisfaction rate and QoL before and after active urological man-

agement. It was found that both the satisfaction rate (84.4%) and the mean QoL index improved (from -1.27 ± 0.39 to 1.54 ± 0.38) after active treatment. Similar to the study published by Lima DX et al.,^[13] our study has also compared the QoL scores and satisfaction scores before and after surgical intervention.

Vajda P et al.^[15] also published a similar study in 2009.^[15] Their study assessed the QoL after surgery in 1- to 10-year-old children ($n=61$) using a multimodality treatment-specific questionnaire consisting of 38 questions. They found significant improvement in the QoL ($p<0.05$) after surgery; it was also found that 90% of the patients would prefer surgery compared to their previous state.

A literature review on QoL assessment among patients with neurogenic bladder revealed that only a few studies compared the QoL scores before and after conservative management. Tang F et al.^[16] published a study evaluating the effect of continuous care intervention such as conservative management, including clean intermittent self-catheterization, drinking guidance, and bladder training guidance on the QoL of patients with neurogenic bladder following SCI.^[16] In their study, the researchers compared the QoL scores (using the World Health Organization Quality of Life-BREF) in the same group of patients before and after the continuous care intervention.

They concluded that following a 3-month continuous care intervention, patients' compliance and QoL scores were significantly higher than the scores measured before continuous care intervention.

However, unlike our study none of the studies compared the QoL scores among neurogenic bladder patients managed with a conservative method, and those managed with surgical interventions.

Similar to other published studies, we also conclude that although there is an obvious improvement of QoL among patients with neurogenic bladder, there are some well-recognized complications of surgical interventions namely mucous secretion, loose stool formation, abdominal pain, etc.^[14] In addition, the reconstruction of the urinary tract might prove to be quite challenging for the surgeon.

As per the study published by Herschorn S and Hewitt RJ in 1998, long-term outcome assessment of augmentation cystoplasty for neurogenic bladder revealed the incidence of complications despite a high degree of patient satisfaction. Thus, the need for reintervention should be kept in mind. The reported reoperation rate was 36%.^[17]

The QoL in patients with neurogenic bladder is one of the important factors to be considered. Although conservative treatment is

found to be sufficient to manage the condition depending upon the patient's profile, his or her expectations, surgical interventions give highly satisfactory results in patients with neurogenic bladder. Like other studies, we also found similar improvements in the QoL in patients of the neurogenic bladder. However, limitations of our study include the small study groups and the fact that the long-term surgery-related complications were not considered in the patients who underwent surgery.

Hence, in the future, similar studies need to be planned in patients with neurogenic bladder for assessing the QoL with or without surgical interventions with special mention of the complications faced by the patients managed both by conservative and surgical interventions both on short- and long-term basis.

Urinary surgical intervention improves the QoL in SCI patients with neurogenic bladder as per the UDI-6 scores. However, contrasting results of SF-36 assessment warrant further validation for recommending surgical intervention to these patients.

Ethics Committee Approval: Ethics Committee approval for the study was obtained Research Ethical Board (REB) (University Health network Research Ethics Board 11-0379-AE).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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Conflict of Interest: The authors have no conflicts of interest to declare.

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