

**ORIGINAL ARTICLE** 

# Assessment of quality of life in patients with neurogenic bladders who undergone urinary system reconstruction (Mitrofanoff)

Evaluación de la calidad de vida en pacientes con vejiga neurogénica que se sometieron a reconstrucción del sistema urinario (Mitrofanoff)

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#### **Abstract**

Objective: The purpose of this study was to evaluate the additional contribution of the Mitrofanoff channel to health-related quality of life (HRQoL). Methods: Between 2005 and 2009, we conducted a retrospective study on 10 pediatric patients who underwent Mitrofanoff surgery for neurogenic bladder and 11 control patients using urethral catheterization. We evaluated HRQoL using questionnaires tailored for various age groups, with higher scores indicating better QoL. Results: The mean age in the patient group was 12.8 years and 10.7 years in the control group (p = 0.103). Shunt use and wheelchair dependency were similar between groups (p = 0.217 and p = 0.505, respectively). Diaper use showed no significant difference (p = 0.256). Notably, 50% of the patient group performed self-catheterization compared to 9.1% in the control group, a significant difference (p = 0.038). Prophylaxis application was significantly higher in the control group (p = 0.049). HRQoL scores were not significantly different between surgery and control groups in children (p = 0.251) and adolescents (p = 0.831), with Cronbach's  $\alpha$ values indicating high reliability of the HRQoL scale. Conclusions: Although the procedure shows potential in enhancing independence, particularly in self-catheterization, the impact on overall HRQoL is not significantly different from the control group.

Keywords: Mitrofanoff. Quality of life. Neurogenic bladders. Urinary system reconstruction.

#### Resumen

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Objetivo: Evaluar la contribución adicional del canal de Mitrofanoff a la calidad de vida relacionada con la salud (CVRS). Método: Evaluamos la CVRS utilizando cuestionarios adaptados para varios grupos de edad, con puntuaciones más altas indicando una mejor calidad. Resultados: La edad media de los pacientes fue de 12.8 años y la del grupo control fue de 10.7 años (p = 0.103). El uso de derivaciones y la dependencia de silla de ruedas fueron similares entre los grupos (p = 0.217 y p = 0.505, respectivamente). Es notable que el 50% del grupo de pacientes realizaron autocateterización, en comparación con el 9.1% del grupo control (diferencia significativa, p = 0.038). La aplicación de profilaxis fue significativamente mayor en el grupo control (p = 0.049). Las puntuaciones de CVRS no fueron significativamente diferentes entre los grupos de cirugía y control en niños (p = 0.251) y adolescentes (p = 0.831), con valores alfa de Cronbach indicando una alta fiabilidad de la escala de CVRS. Conclusiones: Aunque el procedimiento muestra potencial en mejorar la independencia, en particular en la autocateterización, el impacto en la CVRS general no es significativamente diferente del grupo de control.

Palabras clave: Mitrofanoff. Calidad de vida. Vejiga neurógena. Reconstrucción del sistema urinario.

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## Introduction

In the United States, spinal dysraphism, particularly myelomeningocele, is one of the most common birth defects causing permanent disability, occurring in about 30 cases/100,000 live births<sup>1-3</sup>. More than 90% of patients with spina bifida develop neuropathic bladder dysfunction as a result; this can manifest as urinary incontinence, recurrent urinary tract infections, and, in the most severe cases, upper urinary system damage<sup>4,5</sup>. Unfortunately, up to 30% of adolescents in this condition experience some degree of kidney dysfunction.

Patients with neurogenic bladders often require minor or major surgical interventions to address urinary incontinence issues. Due to their inability to control urination, these children, often carrying the odor of urine and ostracized by their peers during childhood, experience a lack of self-confidence<sup>6</sup>. As adults, they continue to face similar challenges in finding and maintaining employment. In addressing this condition, the primary focus of assistance should be questioned: should it be on preserving the upper urinary tracts, or ensuring that the child remains dry? Both objectives are important, but the choice of focus can significantly impact the treatment approach and the patient's quality of life (QoL).

The QoL for patients with neurogenic bladders has significantly improved since the early 1970s with the introduction of the clean intermittent catheterization (CIC) method proposed by Lapides<sup>7</sup>. This method is considered a revolution in the treatment and management of neurogenic bladder. However, in some of these patients, despite having adequate bladder outlet resistance, bladder compliance and capacity may be low. Therefore, due to limited storage capacity, frequent CIC may be necessary to stay dry, which can complicate social life<sup>7,8</sup>. This highlights the complexity of managing neurogenic bladder conditions, where balancing medical needs with the impact on daily life is a critical part of treatment and care.

Patients who have undergone augmentation cystoplasty, as well as those who have not, often require lifelong CIC<sup>9</sup>. Due to this, they may need a continent-catheterizable channel, which facilitates easier catheterization than the urethra. For patients who have difficulty with urethral catheterization due to physical or anatomical reasons, or simply for ease of use, a tube can be created from various tissues such as the appendix, narrowed ileum, segments of the colon,

distal ureter, bladder wall, or even fallopian tubes<sup>10</sup>. This tube is then implanted into the bladder wall using an anti-reflux method. Such a construction allows the patient to self-catheterize without assistance, greatly enhancing independence, and ease of living with their condition. This approach plays a significant role in improving the QoL for these patients by offering a more manageable and less invasive means of bladder management.

In our study, we conducted a QoL survey among patients with neurogenic bladders who underwent bladder augmentation and the Mitrofanoff procedure and subsequently performed CIC through this method. In addition, we surveyed patients with neurogenic bladders who performed CIC through the urethral route. The purpose of this study was to evaluate the additional contribution of the Mitrofanoff channel to HRQoL.

## Materials and methods

## Patients and design

Between 2005 and 2009, a retrospective study was conducted at the Pediatric Surgery Clinic and Pediatric Nephrology Outpatient Clinic of Şişli Etfal Hospital. It involved 10 patients between the ages of 5 and 20, who had undergone the Mitrofanoff operation due to neurogenic bladder. In addition, as a control group, 11 patients who performed CIC through the urethral route for the same reason were also included in the study. For evaluation purposes, these patients were asked to fill out a questionnaire.

The HRQoL developed by Parkin et al. evaluates patients across 10 fundamental life domains including social, emotional, mental, financial, medical, independence, environmental, physical, and occupational aspects. In practice, parents of children aged 5-12 were asked to complete a 44-item questionnaire, whereas patients aged 13-20 were given a 47-item questionnaire<sup>11</sup>. For patients with insufficient mental capacity, their parents completed the survey. Those who were unable to visit the hospital were surveyed over the phone. Higher scores obtained in the survey were interpreted as indicative of a higher health-related quality of life (HRQoL) (Tables 1 and 2).

In this study, higher scores obtained from the survey were indicative of a higher HRQoL. This survey aimed to provide detailed insights into the patients' perceptions of their continence post-surgery, a crucial aspect of their overall well-being and QoL.

Table 1. The health-related quality of life survey for children

Question no.	Question description
1	Is treated with respect + dignity by others?
2	Feels good about her/himself?
3	Is able to do some things as independently as possible?
4	Is able to get into the houses of his/her friends?
5	Accepts his/her physical limitations?
6	Will be able to choose a career of his/her own?
7	Has a chance to continue to study things in which he/she is interested?
8	Has a chance to learn to swim?
9	Participates in the same recreational activities as other children?
10	Has an opportunity to play indoors?
11	Has an opportunity to play outdoors?
12	Participates in games at recess?
13	Feels capable or skillful in some sport, hobby, or other activity?
14	Is stared at by others?
15	Is treated as if he/she were different?
16	Is healthy?
17	Is integrated into the school system?
18	Is able to use public washrooms that are accessible and private?
19	Has access to the community through ramps and elevators?
20	Is accepted and valued in our society?
21	Attends school that has a positive attitude toward children with disabilities?
22	Is in an environment that does not contain a lot of obstacles?
23	Has someone to confide in outside immediate family?
24	Has friends?
25	Has a supportive family?
26	Feels welcome in other children's homes?
27	Receives praise for things that he/she is able to do?
28	Feels important?
29	Is treated with respect by others?
30	Feels that she/he can accomplish her/his plans?
31	Expresses her/his emotions?
32	Has an opportunity to do everything other children do in school?

Table 1. The health-related quality of life survey for children (continued)

Question no.	Question description
33	Is able to learn well in an environment that is favorable to children with disabilities?
34	Is motivated to learn?
35	Is able to attend camp for children with disabilities?
36	Feels that examinations and treatments at a hospital or clinic are respectful?
37	Feels that examinations and treatments at a hospital or clinic are private?
38	Feels related to as a whole person by a doctor?
39	Is able to deal well with being in the hospital?
40	Feels in control of the situation in medical appointments and treatments?
41	Is learning to deal positively with his/her disability?
42	Is becoming appropriately independent in areas of self-care, mobility, and self-catheterization?
43	Will be able to live independently in the future?
44	Possesses self-confidence?

\*Patients were required to score from 1—a little to 5—a lot.

## Eligibility criteria

Patients who opted not to participate in our study were excluded. Only those who completed the questionnaire and provided complete data were included in the study. Patients over the age of 20 were not considered within the scope of the study.

## Surgical procedure

In many pediatric patients, a lower midline or transverse incision is made. A deep space is prepared on the right side of the bladder without opening the peritoneum. During this process, the umbilical artery remnant is ligated and cut, and the vas deferens are isolated and protected. Subsequently, the peritoneal cavity is entered, and the cecum and appendix are mobilized<sup>12</sup> (Fig. 1).

Sometimes, the cecum may be positioned high in the abdomen. Mobilization of the ascending colon along the Toldt line may be necessary to facilitate the mobilization of the appendix and its mesentery. An appendectomy is performed, preserving the vascular pedicle and including a portion of the cecal wall

Table 2. The health-related quality of life survey for adolescent

Question no.	Question description				
1	That you are treated the same as everyone else?				
2	That you have a supportive family?				
3	That you are accepted just as you are?				
4	That you are able to talk to 1 or both of your parents?				
5	That people enjoy being with you?				
6	That you are happy with yourself?				
7	That you are able to speak up for yourself?				
8	That there is hope for the future?				
9	Positive about yourself?				
10	That other people respect you?				
11	Satisfied with your school program?				
12	Able to participate in group activities?				
13	That you are able to have a special friend?				
14	Like you are treated the same as other kids?				
15	That you are able to take care of yourself, for example brushing your hair & teeth?				
16	That you are able to feed yourself?				
17	That you are able to help with some or all of your catheterization?				
18	That you are able to participate in some or all of your own bathing?				
19	That you have a lot of pain?				
20	That you can stand up for your rights?				
21	That you can make your own choices and decisions?				
22	That you are as independent as you are able to be?				
23	That you can use the telephone?				
24	That people listen to your opinions?				
25	That you are treated with respect and dignity at your medical appointments?				
26	That you have say in your medical treatment?				
27	That you understand what your medical condition will be like in the future?				
28	That you are getting good care at your spina bifida clinic?				
29	That your doctors, nurses+others who treat you know about spina bifida?				
30	That people see you + not only your disability?				
31	That you will have a suitable home in the future?				
32	That you have privacy + accessibility in public washrooms?				

Table 2. The health-related quality of life survey for adolescent (continued)

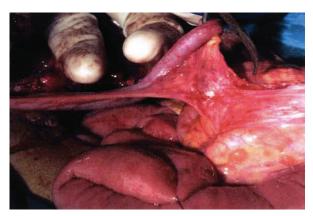
Question no.	Question description
33	That you are able to use kitchen at home?
34	That your present washroom is suitable for you?
35	That you are able to participate in outdoor activities?
36	That you have the physical strength to do sports such as swimming and skiing?
37	You are able to go out on dates + to parties?
38	Challenged and encouraged through sports?
39	Successful or skilled in some sport or other activity you like?
40	That there will be job opportunities for you in the future?
41	You are able to get an education for a job that interests you?
42	That you have a career goal in mind?
43	Able to hold down a part-time job?
44	That you will be able to have children in the future?
45	That you will marry?
46	That you have somebody with spina bifida to look up to + to have as
47	That you have a close friend who is like you in many ways?

<sup>\*</sup>Patients were required to score from 1—a little to 5—a lot.

making the stomal anastomosis easier and reducing the risk of stenosis. If the appendix is short, a portion of the cecal wall can be tubularized with the appendix. The defect in the cecum is closed, and the appendix, with its vascular pedicle, is transferred through the right mesocolon to the right side of the bladder. The peritoneum is then closed. The subsequent stages of the surgery continue extraperitoneally 12,13.

The bladder is opened in a vertical direction along the midline. If the bladder neck is to be closed, the incision is extended to the bladder neck, detached from the urethra, and the urethra is then closed. The closed end of the appendix is opened, and this end is implanted through an oblique or transverse submucosal tunnel in the trigone. The tunnel should be 3-4 cm in length (to maintain a 5:1 ratio). A Penrose drain is placed in the perivesical space to remain for several days<sup>14,15</sup> (Fig. 2).

The cecal end of the appendix is anastomosed to the abdominal wall in the right lower quadrant or



**Figure 1.** Appendectomy for Mitrofanoff (schematic and operation image).



Figure 3. A view of Mitrofannoff in post-operative period.

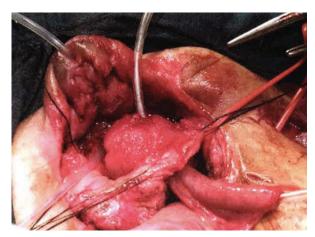


Figure 2. Mitrofanoff's anastomosis to the bladder (operation image).

umbilical pit, ensuring no tension is present at the site suitable for the patient. During this stage, care must be taken to ensure that the appendix and its mesentery pass through the anterior abdominal wall without kinking or angulation. To prevent kinking and problems with catheterization, a conduit as short as possible is recommended. Fixing the appendix and bladder wall beneath the fascia to the peritoneum helps reduce the problem of conduit angulation with bladder filling. Concealing the stoma at the skin level with the help of some flaps provides a more cosmetic result (Fig. 3). The catheter passing through the appendix is kept in place for at least 2 weeks<sup>15</sup>.

#### Statistical analysis

This study's statistical analyses were conducted using NCSS 2007 software. The Cronbach's  $\alpha$  coefficient

was chosen to determine the reliability of the HRQoL scale. In the analysis of the data, descriptive statistical methods (mean and standard deviation), the Mann–Whitney U-test for binary group comparisons, and the  $\chi^2$  test for qualitative data comparisons were used. A one-way analysis of variance was conducted to compare the study groups of Parkin and Mac Neily with the groups in this study. The results were evaluated at a significance level of p < 0.05.

#### Results

A total of 21 patients were included in this study. Table 3 presents demographic and medical information for 10 patients with various medical conditions and 11 control patients. While the ages of the patients ranged from 8 to 18, the gender distribution was equal between males and females. In the surgery group, there were six patients with meningomyelocele, one patient with both meningomyelocele and high-type anorectal malformation, one patient with caudal regression syndrome, and two patients who underwent surgery due to exstrophy of the bladder. The patients' age at surgery ranged from 6 to 16, and the post-operative follow-up period varied between 14 and 73 months.

The study was conducted on two different groups consisting of a total of 21 participants. When examining the age distribution between the patient group (n = 10) and the control group (n = 11), the mean age of the patient group was found to be  $12.8 \pm 3.03$  years, whereas the mean age of the control group was  $10.7 \pm 2.45$  years. The age difference between the two

Table 3. Demographic characteristics of patients undergoing Mitrofanoff procedure

Patient no.	Age	Gender	Etiology	Operation age (year)	Post-operative follow-up (months)
1	17	Male	Meningomyelocele	11	73
2	13	Female	Meningomyelocele	7	73
3	12	Male	Meningomyelocele and high-type anorectal malformation	9	34
4	18	Female	Operated exstrophy of the bladder	16	29
5	14	Female	Caudal regression	12	29
6	13	Female	Meningomyelocele	11	29
7	9	Female	Meningomyelocele	6	35
8	12	Male	Meningomyelocele	9	49
9	12	Male	Meningomyelocele	9	47
10	8	Female	Operated exstrophy of the bladder	7	14

groups was not statistically significant (p = 0.103). In terms of gender distribution, 60% of the patient group were female and 40% were male, whereas in the control group, 45.5% were female and 54.5% were male (p = 0.505). The use of shunts was found to be 20% in the patient group and 45.5% in the control group, and the difference between the groups was not statistically significant (p = 0.217). Regarding dependency on a wheelchair, 40% of the patient group and 54.5% of the control group used wheelchairs (p = 0.505). Diaper use showed no significant difference between groups (p = 0.256). When the frequency of urinary bladder catheterization was examined, it was observed that there was no prophylaxis applied by some participants in the patient group, whereas, in the control group, frequencies of  $2 \times 1$ ,  $3 \times 1$ ,  $4 \times 1$ ,  $5 \times 1$ , and  $6 \times 1$  were observed. Due to inconsistency among these frequencies, statistical analysis could not be conducted. However, the number of patients who performed self-catheterization was 50% in the patient group, whereas it was 9.1% in the control group, and this difference was statistically significant (p = 0.038). Furthermore, when looking at the prophylaxis application status, 30% of the patient group applied prophylaxis, whereas 72.7% of the control group applied prophylaxis, and this difference was statistically significant (p = 0.049) (Table 4).

Table 5, patients who underwent surgery in terms of the intestine segment used for augmentation, whether anti-reflux surgery was performed, whether bladder neck repair was done, and if done,

the method used, the preferred organ for the Mitrofanoff procedure, and the indications for surgical intervention are summarized.

The internal consistency of the scale used to assess HRQoL in the study was evaluated, and the Cronbach's  $\alpha$  value was calculated as 0.964 for the adolescent surgery group, 0.909 for the control group, 0.864 for the child surgery group, and 0.950 for the child control group. When looking at HRQoL scores, in children, patients who underwent surgery had a score of 180, whereas the control group had a score of 153, and the difference between them was not statistically significant (p = 0.251). However, although the difference may not be significant, a higher and better QoL score was obtained in the surgery group. On the other hand, when looking at HRQoL scores in adolescents, patients who underwent surgery had a score of 188, whereas the control group had a score of 190, and the difference between them was not statistically significant (p = 0.831) (Table 6 and Fig. 4).

#### Discussion

In this study, the effect of the Mitrofanoff procedure on HRQoL in patients with neurogenic bladder dysfunction was evaluated. Spinal dysraphism, especially myelomeningocele, is one of the most common birth defects in the United States, leading to permanent disability, and over 90% of spina bifida patients with neurogenic bladder dysfunction experience problems such as urinary incontinence, recurrent urinary tract

Table 4. Comparison of the groups

Patients' characteristics	Patients group (n = 10)	Control group (n = 11)	p-value
Current age (year)	12.8 ± 3.03	10.7 ± 2.45	0.103
Age at operation (year)			
Gender	. (	0 (5 4 50()	0.505
Male	4 (40%)	6 (54.5%)	
Female	6 (60%)	5 (45.5%)	
Shunt			0.217
Yes	2 (20%)	5 (45.5%)	
No	8 (80%)	6 (54.5%)	
Wheelchair dependency			0.505
Yes	4 (40%)	6 (54.5%)	0.000
No	6 (60%)	5 (45.5%)	
Diaper use			0.256
Yes	3 (30%)	6 (54.5%)	
No	7 (70%)	5 (45.5%)	
Clean intermittent catheter frequency			N/A
None	2 (20%)		
2 × 1		2 (18.2%)	
3 × 1		1 (9.1%)	
4 × 1		3 (27.3%)	
5 × 1	5 (50%)	2 (18.2%)	
6 × 1	3 (30%)	3 (27.3%)	
Self-catheterization	5 (50%)	1 (9.1%)	0.038
Profilaxis			0.049
Yes	3 (30%)	8 (72.7%)	
No	7 (70%)	3 (27.3%)	

Table 5. Detailed data of patients who underwent surgery

No	Segment of intestine used for augmentation	Anti-reflux procedure	Bladder neck repair	Organ used for Mitrofanoff	Indication for surgery
1	lleum	No	No	Appendix	Upper urinary tract disruption and incontinence despite medical treatment
2	lleum	No	No	Appendix	Upper urinary tract disruption despite medical treatment
3	lleum	Politano Lead Better	Bladder neck sling with detrusor flap	lleum	Upper urinary tract disruption and incontinence despite medical treatment
4	lleum	Cohen	No	Appendix	Upper urinary tract disruption despite medical treatment
5	lleum	Politano Lead Better	Young-Dees	lleum	Upper urinary tract disruption and incontinence despite medical treatment
6	lleum	No	Young-Dees	lleum	Urinary incontinence
7	lleum	Politano Lead Better	Young-Dees	Appendix	Urinary incontinence
8	lleum	No	Young-Dees	Appendix	Urinary incontinence
9	lleum	Cohen	Young-Dees	Appendix	Urinary incontinence
10	lleum	Politano Lead Better	No	Appendix	Upper urinary tract disruption despite medical treatment

Table 6. Comparison of the HRQoL between groups

HRQoL domains	HRC	p-value	
	Patients (n = 10)	Controls (n = 11)	
Children (< 12 years)	180.75 ± 22	153.43 ± 36	0.251
Adolescent (> 12 years)	188.67 ± 35	190 ± 26	0.831

HRQoL: health-related quality of life.

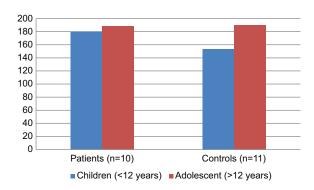


Figure 4. Graph of health-related quality of life between groups.

infections, and in the most severe cases, upper urinary tract damage<sup>1,2</sup>. This study examined the impact of this condition requiring surgical intervention and the addition of the Mitrofanoff channel on the QoL of these patients.

Although the success of surgical interventions in child-hood incontinence has been extensively examined in many reports, there are few studies that evaluate the impact of such interventions on HRQoL. In recent years, there has been an increased interest in measuring HRQoL in adult urology. Criteria have been developed for benign prostatic hyperplasia, prostate cancer, bladder cancer, and overactive bladder<sup>16-18</sup>. In chronic diseases such as spina bifida, which make up a significant portion of the patients in this study, treatment success will increase not only through the eradication of the disease but also through the improvement of QoL.

The attainment of social continence marks a pivotal point in the lives of patients with these conditions. Being a continent is a socially expected norm<sup>19</sup>. It is widely believed that incontinence adversely affects the development of self-confidence and self-esteem in children. However, the challenges faced by these patients extend beyond the surgical procedure. Surgeons should recognize that although the surgery successfully achieves "dryness," the lifelong

commitment to intermittent catheterization could potentially be seen as substituting one issue for another<sup>20</sup>. This situation often extends its impact to include family members or caregivers, who not only accompany patients during their treatment but are also responsible for managing the intricacies of the procedure.

Lima et al. conducted an assessment of QoL in individuals with neurogenic bladder who underwent urological reconstructive procedures. They utilized the SF-36 Health Survey and the Qualiveen questionnaire to measure patient-reported outcomes and found notable enhancements across all domains, which were statistically significant<sup>21</sup>.

In the study conducted by Macneil et al., the postoperative average HRQoL scores of patients with neurogenic bladder problems due to spina bifida were not found to be higher than those of the control group<sup>22</sup>. Similarly, in a study conducted by Parkin and colleagues in 1997, they assessed the QoL of spina bifida patients and did not find that patients with neurogenic bladder problems had higher HRQoL12. In our study, when assessing the internal consistency of the scale used to evaluate HRQoL, the Cronbach's  $\alpha$ value was calculated as 0.964 for the adolescent surgery group, 0.909 for the control group, 0.864 for the child surgery group, and 0.950 for the child control group. When looking at the HRQoL scores, in children, patients who underwent surgery had a score of 180, whereas the control group had a score of 153, and the difference between them was not statistically significant (p = 0.251). However, even though the difference may not be statistically significant, a higher and better QoL score was obtained in the surgery group. Particularly, the significant difference in the proportion of patients who can self-catheterize suggests that surgical intervention may increase the independence levels of patients. These findings emphasize the importance of surgical interventions in the management of neurogenic bladder dysfunction. Furthermore, the lower rates of prophylaxis application in the surgical group compared to the control group also indicate that this group requires less medical intervention. In this regard, looking at the patients who underwent the Mitrofanoff procedure, their ability to perform CIC on their own and their independence in this regard, as well as their advantages in various aspects, including prophylaxis, are evident.

The limitations of our study with a total of 21 patients, the sample size is relatively small. This small cohort may not fully represent the broader population

of patients with neurogenic bladders, potentially affecting the generalizability of our findings. Addressing these limitations in future research would significantly enhance the understanding of the impact of the Mitrofanoff procedure on the QoL of patients with neurogenic bladders.

## **Conclusions**

Our study, assessing the HRQoL in patients with neurogenic bladders post-Mitrofanoff procedure, reveals nuanced insights. Although the procedure shows potential in enhancing independence, particularly in self-catheterization, the impact on overall HRQoL is not significantly different from the control group. This suggests that while surgical advancements such as the Mitrofanoff procedure offer technical benefits, their holistic impact on patient QoL remains complex and multifaceted. Future research, addressing the limitations of our small-scale, retrospective study, is crucial to deepen understanding in this vital area of patient care.

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#### Conflicts of interest

The authors declare no conflicts of interest.

#### Ethical disclosures

**Protection of human and animal subjects.** The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

**Confidentiality of data.** The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of

the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript nor for the creation of images, graphics, tables, or their corresponding captions.

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