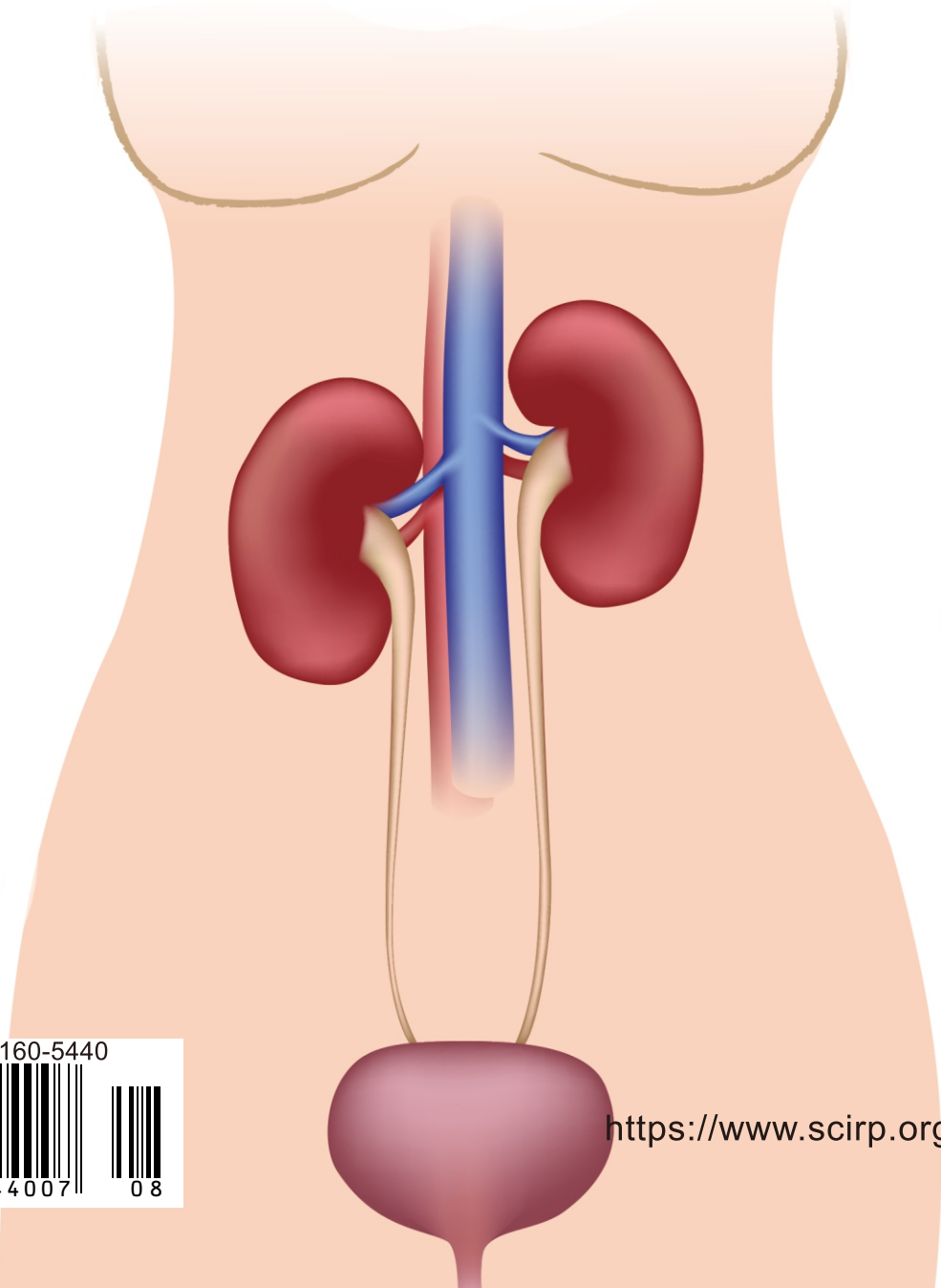


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# Initial Experience with Mirabegron for the Treatment of Neurogenic Lower Urinary Tract Dysfunction

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## Abstract

**Background:** Though anticholinergic drugs are considered the standard treatment for neurogenic detrusor overactivity, it is far from an ideal tool, because of their adverse effects such as Constipation or not respond sufficiently for a substantial proportion of patients. Recently mirabegron has become a commonly used overactive bladder medication in the general population, but few studies about mirabegron for the treatment of neurogenic detrusor overactivity. **Objective:** To evaluate the efficacy and safety of mirabegron for the treatment of neurogenic lower urinary tract dysfunction. **Study Design:** Prospective study. **Methods:** This prospective study included 13 adult patients with neurogenic lower urinary tract dysfunction as a result of spinal cord injury. All patients receiving mirabegron treatment (50 mg once daily) at least 6 weeks. The effective outcomes included the mean urine volume per catheterization, urinary incontinence episodes and Incontinence Specific Quality of Life Instrument. We monitored the blood pressure and heart rate to assess the cardiovascular safety, other adverse events were also recorded. **Results:** A total of 13 patients were included. After 6 weeks of treatment, all patients experienced a significant increase in the mean volume of per catheterization from  $238.46 \pm 65.43$  ml to  $327.69 \pm 59.04$  ml ( $p = 0.001$ ). There is a significant reduction in the volume of urine leakage ( $463.85 \pm 247.98$  ml VS  $180.00 \pm 190.96$  ml,  $p = 0.003$ ) and incontinence episodes per 24 h ( $4.46 \pm 2.03$  VS  $1.92 \pm 1.50$ ,  $p = 0.001$ ). Significant improvement in mean Incontinence Specific Quality of Life Instrument was also found ( $p = 0.001$ ). No patients reported dry mouth during the study, and the cardiovascular safety were acceptable. **Conclusion:** Mirabegron is safe and effective in the treatment of neurogenic lower urinary tract dysfunction. It might be a good choice for reducing the cessation of clean intermittent catheterization.

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## Keywords

Neurogenic Lower Urinary Tract, Mirabegron, Detrusor Overactivity, Spinal Cord Injury

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## 1. Introduction

Detrusor overactivity (DO) is characterized by spontaneous or provoked involuntary detrusor contractions during storage phase in urodynamic investigation [1] [2]. Neurogenic DO (NDO) is DO caused by various neurogenic diseases such as brain tumors, dementia, multiple sclerosis, Parkinson's disease, stroke and spinal cord injury (SCI) [3]. NDO can cause a variety of long-term complications such as urinary incontinence (UI), stones, hydronephrosis, recurrent urinary tract infection and Vesicoureteral reflux (VUR); the most dangerous being damage of renal function. These complications may markedly impact the quality of life of people with SCI, including limiting their behavior, causing social embarrassment and possibly threatening their life [4].

Anticholinergic drugs are considered the standard treatment for NDO. The positive effects of oxybutynin, trospium chloride, tolterodine, propiverine, and imidafenacin in increasing the bladder capacity and reducing the intravesical pressure have been documented in several studies [5]. Nevertheless, treatment with antimuscarinic drugs is frequently discontinued due to side effects (dry mouth and constipation) or a lack of efficacy [6]. In particular in patients with SCI, who suffer from a neurogenic bowel dysfunction, the concomitant antimuscarinic treatment will worsen the constipation. Therefore, there is a need for therapy alternatives.

In recent years, mirabegron, a  $\beta$ -adrenoreceptor agonist, was developed to target sympathetic nerve stimulated relaxation of the bladder, a mechanism of action that improves the storage capacity of the bladder without inducing anticholinergic-associated adverse events [7] [8].

Clinical trials have demonstrated its efficacy and safety [9] [10] and observational studies suggest improved persistence and adherence when compared to antimuscarinics [11]. As such, it has become a commonly used overactive bladder medication in the general population [12]. But few studies were carried on the treatment of mirabegron for NDO. The aim of this study was evaluated to evaluate the efficacy and safety of mirabegron for the treatment of neurogenic lower urinary tract dysfunction (NLUTD).

## 2. Material and Methods

In this prospective observational study, a total of 13 patients who received treatment with mirabegron 50 mg once daily at least 6 weeks from April to June 2021 in our SCI center were included. All eligible inpatients over 18 years of age with non-acute SCI (*i.e.* no progression in neurological symptoms in the previous 3

months) were screened for enrollment. The main inclusion criteria were: 1) urodynamic presence of DO; 2) bothersome urinary symptoms (frequency, urgency, urgency incontinence) and at least one episode of urgency/unaware incontinence during the 3-day voiding diary; 3) Patients or their caregivers agreed to perform clean intermittent catheterization (CIC); 4) Patients with previous injection of onabotulinumtoxin were included, if the last injection was at least 12 month before mirabegron treatment.

Exclusion criteria were: 1) intravesical botulinum toxin use within the last year; 2) clinically significant stressUI; 3) specific potentially complicating conditions (such as pelvic radiation, bladder cancer, or painful bladder syndrome), and the use of certain other medications; 4) subjects with symptomatic urinary tract infections (asymptomatic bacteriuria was not considered an exclusion criterion); 5) patients with severe cardiovascular (CV) disease (untreated hypertension, defined as a systolic blood pressure (SBP) > 180 mmHg or diastolic blood pressure (DBP) > 110 mmHg, or untreated arrhythmia); 6) significant renal or liver dysfunction. Before treatment, all patients underwent urodynamic examination according to the International Continence Society standard.

The bladder management was oral mirabegron 50 mg once daily combined with CIC 4 - 6 times each day. The mean urine volume per catheterization, UI episodes and complete dryness were determined from 3 consecutive days of the patient's bladder diary. Complete dryness is defined as less than one incontinence episode per 24 h. The severity of incontinence was determined using the 24 h pad-weight test (24 PWT). All patients were asked to complete the Incontinence-Specific Quality-of-Life Instrument (I-QoL). Patients were monitored for significant changes in their blood pressure (BP), heart rate (HR), and liver or renal function.

Student's paired samples t-test was used as appropriate to compare and I-QoL, of pre-treatment and post-treatment. The results are shown as mean values and standard deviation (SD). All statistical tests were 2-sided, and a p-value of 0.05 or less was considered statistically significant. Statistical analyses were performed with SPSS 13.0 software (SPSS Inc., Chicago, IL, USA).

### 3. Results

A total of 13 patients included in our study, the mean age was  $41.62 \pm 11.98$  years, mean injury duration  $0.86 \pm 0.61$  months (**Table 1**). The distribution of SCI levels was 6 (46%) cervical, 6 (46%) thoracic and 1 (8%)Lumbar. The distribution of the American Spinal Injury Association Impairment Scale (AIS) scores were: 6 (46%) Grade A, 1 (8%) Grade B, 4 (31%) Grade C and 2 (15%) Grade D.

**Table 2** shows that the significant improvement in the mean volume of per catheterization from  $238.46 \pm 65.43$  ml to  $327.69 \pm 59.04$  ml ( $p = 0.001$ ). There is a significant reduction in the volume of urine leakage ( $463.85 \pm 247.98$  ml VS  $180.00 \pm 190.96$  ml,  $p = 0.003$ ) and UI episodes per 24 h ( $4.46 \pm 2.03$  VS  $1.92 \pm 1.50$ ). Significant in the I-QoL from 54.15 to 69.92 ( $p = 0.000$ ).

**Table 1.** The characteristics of the evaluated patients.

Variables	n = 13
Age-years (mean $\pm$ SD)	41.62 $\pm$ 11.98
Time since SCI (years)	0.86 $\pm$ 0.61
Gender-N (%) Male/Femal	11(85%)/2(15%)
Level of injury-N (%) Cervical/Thoracic/Lumbar	6 (46%)/6(46%)/1(8%)
AIS-N (%) A/B/C/D	6 (46%)/1(8%)/4(31%)/2(15%)

SD, standard deviation; SCI, spinal cord injury; AIS, American Spinal Injury Association Impairment Scale.

**Table 2.** The significant improvement in clinical parameter.

	Pre-treatment	Post-treatment	p-value
Vcic	238.46 $\pm$ 65.43	327.69 $\pm$ 59.04	0.001
UI episodes	4.46 $\pm$ 2.03	1.92 $\pm$ 1.50	0.001
UI volume	463.85 $\pm$ 247.98	180.00 $\pm$ 190.96	0.003
I-Qol	54.15 $\pm$ 6.61	69.92 $\pm$ 9.73	0.000

Vcic, urine volume per catheterization; UI, urinary incontinence; I-Qol, Incontinence Specific Quality of Life Instrument.

Change from baseline in BP and HR were showed in **Table 3**. Though the increase in the SBP (75.54 VS 79.08,  $p = 0.152$ ) was slightly larger than DBP (116.31 VS 117.46,  $p = 0.786$ ) and HR (77.69 VS 78.15,  $p = 0.759$ .), all of them were not significant differences from baseline.

Though there is a little increase in the BP and HR, no one described headache, palpitation, dry mouth, constipation and other side effects.

#### 4. Discussion

After SCI, most individuals develop NLUTD, which in the majority of cases requires assisted bladder emptying rather than volitional voiding. CIC is recommended for bladder management after SCI since it has the lowest complication rate [13] [14] [15]. However, transitions from CIC to other less optimal strategies, such as indwelling catheters (IDCs) are common [16] [17]. Darshan P. Patel *et al.* revealed that convenience (36%), urinary leakage (20%), and the number of urinary infections (19%) were the most common reasons for CIC cessation [17]. So, improve the patient's QoL is also an important aim in the treatment of NLUTD [18].

In our study mirabegron treatment significantly reduce the number of patients suffering from incontinence and the number of absorptive pads used. Especially 3 patients developed complete dryness after mirabegron treatment, they are less likely to worry about the disturbance from UI, which affects their physical activities, social relationships and feelings. The improve the IQoL might be beneficial for patients persist in carry out CIC.

**Table 3.** Change from baseline in blood pressure and heart rate.

	Pre-treatment	Post-treatment	p-value
SBP	116.31 ± 11.03	117.46 ± 10.40	0.786
DBP	75.54 ± 6.86	79.08 ± 5.22	0.152
HR	77.69 ± 3.97	78.15 ± 3.63	0.759

SBP, systolic blood pressure; DBP, diastolic blood pressure; HR, heart rate.

The  $\beta$ -adrenergic agonist mirabegron was introduced into the treatment of iOAB in 2012. Its safety and efficacy in the treatment of this condition have been confirmed in a large number of well-designed studies [12]. In this study we also found improvement in the mean volume of per catheterization.

In human bladder,  $\beta$ -adrenoceptors account for 97% of total  $\beta$ -adrenoceptor messenger RNA [19], and they are thought to be the main subtype mediating relaxation of detrusor smooth muscle during the storage phase [20]. However,  $\beta$ -adrenoceptors are also expressed in CV tissues, so the treatment with  $\beta$ -adrenoceptor agonists may have “off-target” effects on regulation of the heart and vasculature [21]. In our study, there is a little increase in SBP, DBP and HR, but none of them were significant differences from baseline, similar to the previous studies [22] [23]. And no patients reported dry mouth during the study, so regarding safety, we did not observe severe side effects.

There is no doubt some limitations in the present study. The small number of patients included and the lack of a control group for comparison. Furthermore, we had no use urodynamic to evaluated the efficacy of 50 mg mirabegron for the treatment of NLUTD.

## 5. Conclusion

Mirabegron is safe and effective in the treatment of neurogenic lower urinary tract dysfunction. It might be a good choice for reducing the cessation of clean intermittent catheterization.

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## Conflicts of Interest

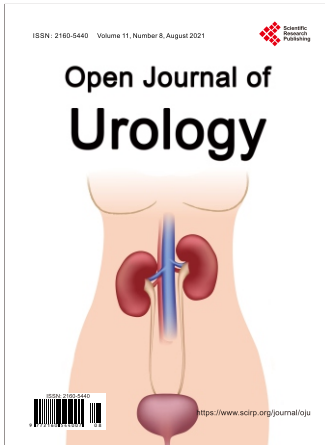
The authors declare no conflicts of interest regarding the publication of this paper.

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