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Neurogenic bladder and bowel evaluation and intervention protocol in male patients with traumatic spinal cord injury

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We use this protocol and it's working

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Usamos este protocolo e está funcionando

Abstract

In 2013, the World Health Organization estimated that annually about 250,000 to 500,000 people are affected by spinal cord injury (SCI). In Brazil it is estimated that there are more than 10,000 new cases per year, trauma is the predominant cause. Eighty percent of the victims are male. Among the most common disorders, neurogenic bladder dysfunction and neurogenic bowel dysfunction stand out. Behavioural therapy, physiotherapy and neuromodulation are among the promising interventions to improve the signs and symptoms of those two dysfunctions. The evaluation protocol is composed of questions about the signs and symptoms of neurogenic bladder dysfunction and neurogenic bowel dysfunction, including issues related to motor and sensory impairment, functional independence and quality of life, as well as orientations and interventions for the treatment of the dysfunction. This protocol was approved by the Research Ethics Committee of the Alberto Santos Dumont Teaching and Research Institute (ISD) in September 2021, respecting the ethical aspects related to human subjects, according to resolution 466/2012 of the National Health Council and its complements. Registration number: CAAE: 46719121.3.0000.0129. It has been used in the development of studies and outpatient treatment at the Teaching and Health Research Centre Anita Garibaldi (CEPS).



Guidelines

To propose an evaluation and management protocol for bladder and bowel dysfunctions in traumatic spinal cord injured male patients with paraplegic/paraparetic and tetraplegic/tetraparetic involvement, by means of behavioural therapy and non-invasive paraspinal neuromodulation.

Safety warnings



Exclusion criteria

Failure to undergo the urological and proctological assessment and reassessment, failure to follow or answer the behavioural therapy, missing the appointment twice or giving up on participating in the research.

Before start

Inclusion criteria

Men diagnosed with traumatic spinal cord injury, aged between 18 and 50 years, without prostatic alterations and who did not receive non-invasive parasacral neuromodulation in the treatment of neurogenic bladder dysfunction and neurogenic bowel dysfunction in the last 12 months.

After confirming the inclusion criteria, the initial assessment includes the following steps:

1

Detailed clinical history related to bladder and bowel habits.

1.1 Bladder patterns

Semi-structured assessment form: toilet use, number of diapers used, catheterization, urine aspects, need of facilitating manoeuvre for urination, history of urinary infection and renal dysfunction will be addressed;

Voiding diary

It approaches information on micturition frequency, urinary quantity, presence of micturition urgency with or without incontinence, and fluid intake. This information guide bladder behaviour. The patient must fill-in, on a specific sheet provided: the time, amount of urine eliminated, if they use a nappy, report how many were used during the day, and the amount of liquid ingested for three consecutive days (Feldner Jr et al. 2006).

Neurogenic Bladder Symptom Score (NBSS)

A questionnaire of symptoms of congenital or acquired Neurogenic Lower Urinary Tract Dysfunction (NLUTD), validated for Brazil by Cintra (2019). Comprehensive assessment, measurement of multiple urinary symptoms and consequences of the dysfunction. It assesses three spectrum domains of neurogenic bladder dysfunction: 1- Incontinence (eight questions), 2- Storage and urination (seven questions) and 3- Consequences (seven questions). The total score can range from 0 to 74, where the higher the score, the more severe the symptoms of NLUTD. Two additional questions, directed to the form of bladder emptying and quality of life, complete the 24 questions of the NBSS (Cintra et al. 2019).

1.2 Intestinal pattern

Semi-structured assessment sheet: use of facilitating manoeuvres for bowel emptying, use of laxatives, suppositories and enemas, history of bowel washing, problems and side effects related to constipation (haemorrhoids, anal fissures and/or rectal bleeding), history of evacuation pattern.

Semi-structured assessment sheet: use of facilitating manoeuvres for bowel emptying, use of laxatives, suppositories and enemas, history of bowel washing, problems and side effects related to constipation (haemorrhoids, anal fissures and/or rectal bleeding), history of evacuation pattern.

Bristol Scale

It addresses information on the quality of stool, which has been recognised in the literature as a valuable tool in the assessment of intestinal diseases. It is composed of pictures representing seven types of stool associated with precise descriptions according to their shape and consistency, with the use of recognizable illustrations (Martinez and Azevedo 2012).

Evacuation Diary

To observe the frequency of bowel emptying, eating habits and water intake. All evacuation and loss events must be recorded for 7 days, indicating the quality of the stools according to the Bristol Scale, and if there was difficulty in evacuating (Junior 2008).

2 Investigation of the relationship between bladder and bowel dysfunctions and SCI impairment.

2.1 Physical Evaluation

ASIA Scale (American Spinal Injury Association)

International gold standard for assessing and classifying the level of spinal cord injury. Examining the motor and sensory domain based on myotomes and dermatomes and anorectal examination, classifying the neurological level of the lesion and the type, complete or incomplete (Neves et al. 2007)

The tactile sensory examination uses a brush and a painful pin. It assesses and records 28 specific dermatomes bilaterally. A score of 0 denotes absent sensation, 1 denotes impaired or altered sensation, and 2 denotes normal sensation. In the motor examination, the major cervical and lumbar myotomes are assessed, being elbow flexors and extensors, wrist extensors and flexors, finger flexors and abductors, hip flexors, knee extensors, ankle dorsiflexors, plantar flexors, and toe long extensors. Motor strength is rated using the universal six-point scale rated 0-5, where 0 = total paralysis; 1 = palpable or visible contraction; 2 = active movement, complete arc of motion with gravity eliminated; 3 = active movement, complete arc of movement against gravity; 4 = active movement, complete arc of motion against moderate

resistance; 5 = (normal) complete arc of motion against resistance; NE = not examined. Motor strength is recorded for each muscle group bilaterally. Anorectal examination, digitally examined to assess voluntary sphincter motor contraction and bulbocavernosus reflex, both rated 0 for absent and 1 for present, important to determine the integrity of the lesion and assess the presence of spinal shock. The ASIA restraint scale uses the findings of the neurological examination to classify injury types within five categories: A = Complete Injury, no motor and sensory function exists in the spinal cord segments below the injury, including sacral segments; B = Incomplete Injury, sensibility (totally or partially) preserved with extension through sacral segments S4-S5, no motor function below neurological level; C = Incomplete Lesion, motor function preserved below the level of injury with most key muscles below the neurological level showing a degree of muscle strength less than 3; D = Incomplete injury, preserved motor function below the level of the lesion with most of the key muscles below the neurological level presenting a degree of muscular strength greater than or equal to 3; E = Normal, motor and sensory function. To determine motor level, the lowest key muscle should be grade 4 or 5, as this muscle will have both segments innervating it intact (Roberts et al. 2017, Kirshblum et al. 2014).

Modified Ashworth Scale (MAS)

It is a primary clinical measure of spasticity that makes it possible to measure the level of impairment (Santos et al. 2016). The scale has 5 categories ranging from normal tone to spasticity, according to muscle resistance against passive movement of the affected segment(s): 0 being normal tone; 1: slight increase in muscle tone with minimal resistance at the end of the movement; 1+: slight increase in muscle tone with minimal resistance in less than half the movement; 2: more marked increase in muscle tone for most of the movement, but passive mobilization is carried out with ease; 3: considerable increase in muscle tone, but passive movement is carried out with difficulty; 4: rigid affected segment in flexion or extension (Picon et al. 2013).

Thoracic-Lumbar Control Scale

It includes 10 items that evaluate: trunk extension in prone position, pelvis elevation, trunk flexion in dorsal decubitus, trunk rotation, sitting to supine, supine to sitting, sitting posture, trunk extension in sitting position, sitting balance and standing balance. The tasks are scored according to the patient's capacity to carry them out with minimum effort, varying from 0 to 5 points. The scores decrease as the use of compensatory strategies increases. In the first seven tasks, to obtain five points, the patient must be capable of carrying out the task in the proposed position with no evident effort and without assistance; the patient scores 4 if, when carrying out the task, some sign of effort is observed. If it is necessary for the patient to change position to carry out the task, the scores range from 3 to 0. If some contractile activity

is detected or if therapist assistance is given for most of the movement, the task is scored 1. In the absence of movement and muscle contraction, or assistance given to perform the task fully, the patient's score is 0 (Pastre et al. 2011).

The Spinal Cord Independence Measure III (SCIM III)

It specifically assesses a person with spinal cord impairment on levels of independence to perform the individuals' activities of daily living and mobility. It is divided into three complementary subscales: "self-care" (scored from 0 to 20) assesses six tasks ; "breathing and sphincter control" (score from 0 to 40) with four tasks and "mobility" (score from 0 to 40) with nine tasks. The final score ranges from 0 (most dependent) to 100 (most independent) (Riberto et al. 2014).

3 Complementary examinations to investigate the anatomical and functional structures of the urinary tract and rectal ampulla.

3.1 Examinations to assess the functionality of the urinary tract.

Urodynamic Testing

It is a valuable exam for the evaluation and treatment of the lower urinary tract, enabling the dynamic study of the transport, storage, and emptying of urine by the urinary tract. It evaluates maximum bladder capacity, bladder compliance, involuntary detrusor contractions (IDC), amplitude of involuntary contractions, and bladder volume that triggers the onset of IDC. The patient is positioned in the supine position, and a probe is passed through the external ostium of the urethra and rectal balloon introduced into the anus. Saline solution at body temperature is used at a rate of 20 ml/min to fill the bladder through the urethral tube until the detrusor contraction pressure is reached or the patient has the sensation of urination or craving. Intravesical pressure is recorded by the 8F double-lumen transurethral probe and abdominal pressure is recorded by a rectal balloon. If signs of autonomic dysreflexia occur, bladder filling is stopped immediately (KOCHERet al., 2020).

Ultrasound

Used to identify the presence of alterations in the urinary tract. Ultrasound allows the determination of the size and thickness of the kidney, being useful in the evaluation of renal parenchyma disease and hydronephrosis, evaluation of residual bladder volume and bladder wall thickness, detection of calculi and bladder tumours, rectal ampulla, providing the measurement of the transverse diameter of the rectum and the evaluation of fecal retention. The supra pubic transabdominal approach is most commonly used. The exam is performed with the patient in dorsal decubitus, with the

water-based conductive gel applied to the abdomen, and the transducer passed with a frequency around 3.5 MHZ to 5MHZ, described for adults. The examination is performed first with a full bladder after emptying (Romero 2008, Fonseca 2016).

4 **Quality of life assessment.**

4.1 *Qualiveen Short Form (Qualiveen-SF)*

It is a validated questionnaire to measure the quality of life of individuals with urinary dysfunction of neurological origin such as SCI and multiple sclerosis, translated and validated for Brazil by Nader et al. It is composed of 8 questions and divided into 4 domains: Concerns about limitations (2 items), Frequency of limitations (25 items), Fears (2 items), and Feelings related to urinary problems (2 items). For each question, only one answer is accepted. The answers are graduated on a Likert scale ranging from always, frequently, sometimes, rarely and never. Qualiveen SF scores range from 0 to 34 points, where for each answer a value from 0 to 4 is determined. From questions 1 to 6. No = 0, Mildly = 1, Slightly = 2, Moderate Amount = 3, Extreme = 4, question 7 is Never = 0, Rarely = 1, Once in a while = 2, Frequently = 3 and Always = 4, question 8 is Never = 4, Rarely = 3, Once in a while = 2, Frequently = 1, Always = 0. Therefore, the higher the score, the better the voiding function, thus having less impact on quality of life (Nader et al. 2016).

5 **Guidelines for assessing progress at home.**

The Micturition Diary and Evacuation Diary along with the Bristol Scale will be requested when necessary and assigned to the patient and caregiver, with guidance on how to complete, observe and report the act of urination and defecation, as well as the aspects of urine and faeces, for a given period of time.

6 **Management and Monitoring.**

In the first consultation an initial evaluation should be done and the exams of the protocol should be scheduled.

The patient presenting the clinical manifestations of Neurogenic bladder dysfunction and Neurogenic Bowel dysfunction, as well as the corresponding results in performed

exams, will begin the treatment with the behavioral therapist. This treatment will be initiated for both groups, and the non-invasive paraspinal neuromodulation will be performed in addition to only one of the groups.

7 Treatment

7.1 Behavioural Therapy

To perform the behavioural therapy, the patient should follow the guidelines for water intake, nutrition, bowel movements and urination, as well as guidelines for positioning on the toilet to facilitate elimination, pre-determined according to the evaluation performed.

Guidance on water intake is based on information reported by patients, micturition and evacuation diaries, to schedule the indicated daily consumption. However, it is thought together with the programming of urinary frequency or the daily catheterization, maintaining a relationship of fluid consumption with bladder compliance, followed by guidance of micturition pattern.

The water consumption program is built in relation with urine and feces quality and frequency. It is done through analysis of the micturition and evacuation diary and programs hydric intake as well as urination and evacuation schedule. It allows to condition the bladder to keep stored urine with low compliance for the programmed period, so that, at the end of the day, the patient has urinated around five to seven times a day. It also improve the constipation and feces aspects.

■ *Management of neurogenic bladder symptom*

Bladder emptying should be done as a priority at the scheduled time for urination, either voluntarily or using intermittent bladder catheterization, under medical supervision, as an effective intervention to prevent and treat complications (FEDERAL).

Material required to perform clean intermittent catheterization:

1. Catheter of a gauge indicated by the doctor or nurse;
2. Gel lubricant (if the catheter is not lubricated);
3. Liquid soap or a non-alcoholic wet wipe;
4. Towel, paper towel or gauze (does not need to be sterile);
5. Measuring bottle to discard urine, or use a plastic bottle if you are not near the toilet.

Technique to perform catheterization:

1. Wash your hands with running water and liquid soap;
2. If you are out of the house and do not have a sink nearby, use alcohol gel;
3. Expose the penis and retract the foreskin (skin covering the penis) with your nondominant hand;
4. Wipe with gauze soaked in water and a small amount of liquid soap or the moistened tissue and wipe the orifice of the urethra towards the base of the penis;
5. Do this cleaning three times, change the gauze/wipe every time;
6. Remove the soap with gauze moistened with water. Wash your hands;
7. Open the catheter packaging properly and remove the catheter without contaminating it;
8. Lubricate the catheter with 15 to 20 cm gel (if you are not using a lubricated catheter), without touching the tip or extension of the catheter;
9. Position the penis by bringing it close to the abdomen and retract the foreskin with your non-dominant hand;
10. Hold the lubricated catheter in your dominant hand and slowly introduce it through the urethral orifice until urine comes out;
11. With your dominant hand take the previously prepared catheter and introduce it slowly through the urethra;
When urine comes back through the catheter, stop introducing it and wait for it to come out completely;
12. When the urine stops coming out, push the catheter deeper one to two centimetres, if urine comes out again, wait for it to stop coming out;
13. The catheter may encounter resistance in passing through the curvature of the prostate, in the urethra. In this case, lower the penis, reducing its initial angulation and continue inserting carefully;
14. When the urine stops flowing into the collection container, remove the catheter slowly, stopping whenever new urine drainage appears;
15. Lift the catheter by its tip to finish draining the urine that has remained inside it into the collection bottle and onto clothes;

Wash your hands.

Management of the neurogenic bowel syndrome

For bowel emptying, it is indicated that the patient should choose a period of the day after a standard meal, whether breakfast, lunch or dinner and preferably at a time when he/she can dedicate him/herself to the act of evacuating. With the bladder emptied, the patient should start the stimulation of the peristaltic movements and the intestinal transit with massage and body movements, whether they are active, active-assisted or passive, always do diaphragmatic breathing (pulling air through the nose

and releasing it through the mouth with labial frenum) during the exercises (Thom é et al. 2013, Furlan et al. 2005).

Following the following steps:

1. Step:

- Triple Flexion of lower limb: Patient lying on the back, caregiver holding ankle and knee at key points, performs flexion-extension movements of the lower limb (LL). 10 rhythmic repetitions;
- Pelvic Girdle Mobilization: Patient lying on the back, caregiver half kneeling in front of the patient, with the patient's feet resting on the caregiver's abdomen, holding the knee and ankle at key points, making circular movements. 1 minute each side;
- Massage to activate the colonic transit: Patient lying on the back, the caregiver or the patient positions the hands with fingers adducted above the right iliac crest, performs the sliding with wave-like movements with light pressure against the abdominal wall, toward the ribs, sliding below them until reaching the left side. Then sliding downward, toward the left iliac crest, finishing the movement. Mobilisation of the intestinal mass up to the portion of the sigmoid colon, following the route of the large intestine. From 5 to 10 minutes.

2. Step

- Positioning for evacuation: Sitting on the toilet or shower chair, with feet flat on the floor, to keep the knees at a 45° angle, so that gravity helps the emptying of the rectum. If the patient does not sit or prefers another position, they should lie on the left side of their body;
- Body movement: stand up and bend over. If the patient has good trunk stability: stand up as if releasing pressure from the buttocks;
- Lateral trunk movements: Sitting, one should try to put one's hand against the ground, on the right and left side.

All exercises should be performed together with diaphragmatic breathing

7.2

Neuromodulation

he application of neuromodulation will be done by the physiotherapist using the Neurodyn Portable TENS from Ibramed, which is a transcutaneous neuromuscular stimulator indicated for treatments and physical rehabilitation. It is composed of TENS current (Transcutaneous Electrical Nerve Stimulation), by means of individualized self-adhesive electrodes, measuring 5×5 cm, fixed bilaterally in the sacral region (S2-S4). The current will have pulse width parameters of 200 ms, frequency of 10 Hz and intensity before the activation of the motor point of the region for 30 minutes (LORDÊLO et al., 2010; JÁCOMO, 2019; RIBEIRO, 2019).

After one month of sessions with the behavioural therapist, the neuromodulation applied by the physiotherapist will be implemented twice a week for a period of one month, totaling 16 sessions.

8 Treatment

After the participant has signed the Free and Informed Consent Form (FICF) and the Institute has given its consent, the evaluation will begin with the tools and exams for data collection. When the diagnosis of Neurogenic bladder dysfunction and Neurogenic Bowel dysfunction is obtained after the first evaluation, which will include all the tools and evaluation exams, the behavioural therapy (BT) will be designed for all patients, according to the particularities of each one. The BT will be followed by each participant. When one month of intervention is completed, each will be reassessed with the evaluation tools (voiding and voiding diary, NBSS, Rome Criteria, Bristol Scale, SF-Qualiveen, and randomized through the Random.org site, two groups will be formed, the experimental and the control. In the experimental group, patients will continue to undergo BT for another month, and non-invasive parasacral neuromodulation will be added to the BT, applied in 10 sessions. The control group will continue to perform BT for the same period and neuromodulation will be added for 10 sessions, applied in sham mode (without application of electrical current). A new reevaluation will be done using all the tools and evaluation exams. In total, each participant will undergo an initial evaluation and two reevaluations, in two months of intervention and 10 sessions of following pattern:

- Control group: one month of behavioural therapy alone, and one month of BT associated with neuromodulation in sham mode for 10 sessions which should be applied by the physiotherapist twice a week;
- Experimental group: one month of behavioural therapy alone, and one month of BT associated with neuromodulation for 10 sessions which should be applied by the physiotherapist twice a week.

Considering the BT to be performed with both groups, the bowel management will be based on the bowel re-education protocol for people with spinal cord injury and on the Practical Guide for the management of neurogenic bowel syndrome in people with spinal cord injury - Part I. It includes diaphragm release, triple flexion of the lower limbs, mobilization of the pelvic waist and trunk, colonic transit activation massage (Thom é et al. 2013, Furlan et al. 2005).

The physiotherapist will accompany the BT in order to reinforce and certify that the orientations are being followed correctly. Both groups, at the end of the treatment, will be submitted to a final re-evaluation so that the effects of the behavioural therapy and of the non-invasive parasacral neuromodulation can be evaluated.

Flowchart

9

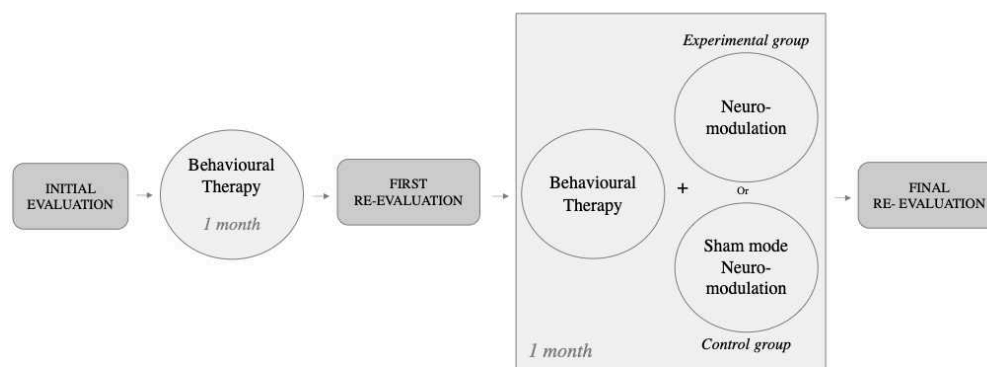


Figure 1. Flowchart of the protocol steps