Effectiveness of intermittent urinary catheterization in patients with neurogenic bladder: a systematic review protocol

Lais Fumincelli1, Alessandra Mazzo1, José Carlos Amado Martins2, Fernando Manuel Dias Henriques2, Daniela Cardoso3, Manuel Alves Rodrigues3

1Ribeirão Preto College of Nursing, University of São Paulo, Ribeirão Preto, São Paulo, Brazil, 2Health Sciences Research Unit: Nursing, Nursing School of Coimbra, Coimbra, Portugal, and 3Health Sciences Research Unit: Nursing, Nursing School of Coimbra; The Portugal Centre for Evidence-Based Practice: a Joanna Briggs Institute Centre of Excellence, Coimbra, Portugal

Review question/objective: The objective of this review is to investigate the effectiveness of the use of intermittent urinary catheterization in improving the quality of life (QoL) of patients with neurogenic bladder.

Keywords: Intermittent urinary catheterization; intermittent urinary catheters; neurogenic bladder; quality of life; urinary catheterization

Background

The advancement of therapeutic practices has led to the improvement of the quality of care and an increase of life expectancy. In this regard, quality of life (QoL) has become an important indicator of treatment effectiveness.1 For patients with neurogenic bladder using intermittent catheterization, the catheter provides a better physical outcome2,3 but may also bring about difficulties in day-to-day activities. This fact can result in negative consequences to patients and/or their caregivers.4

The urologic problems of the neurogenic bladder include the inability to empty the bladder completely. This is due to nervous injuries or congenital defects that disrupt the process of communication between the nervous system and the urinary bladder, which leads to a voiding dysfunction of neurological origin.2,3 Neurogenic bladder affects adults in cases of traumatic injury (e.g. spinal cord injury) or non-traumatic (e.g. multiple sclerosis).4 For example, neurogenic bladder affects about 70% of persons with multiple sclerosis, 35–75% of those with Parkinsonism and 15% of those who have had a stroke. The incidence is higher in persons with spinal cord injuries where 80% or more have some degree of bladder dysfunction. It also affects newborns and children (e.g. spina bifida).5,6 Voiding difficulty is common in spina bifida that occurs approximately in one per 1000 live births, and in up to 61% of young adults with spina bifida, there is a possibility that urinary incontinence will occur.7,8

When undiagnosed or untreated, neurogenic bladder can cause urinary retention, urinary incontinence, urinary tract infection, dysuria and the formation of kidney stones due to urinary stasis and hydronephrosis.9 In addition, other issues such as restrictions, constraints and discomfort that could disrupt patients’ daily activities, and sexual, social, domestic and occupational activities could result.10,11 The prognosis of patients with neurogenic bladder is related to early diagnosis and appropriate treatment. The treatment goal is to maintain the urinary tract, reduce urinary tract infections, provide social adaptation of the patient and improve patients’ QoL.12,13 Treatment for neurogenic bladder usually consists of a combination of prescription drugs,12,14 maneuvers for bladder emptying (Valsalva and Crede),13 strengthening of the pelvic muscles15 and intermittent urinary catheterization.3,7,12

Intermittent urinary catheterization was introduced by Lapides et al.,15 which was a major breakthrough in the treatment of neurogenic bladders. This intermittent catheter has demonstrated a
significant reduction in complications of infection urinary caused by the indwelling catheter.

The current technique allows effective and safe emptying of the neurogenic bladder, and it is the first treatment option for patients with voiding dysfunction. For this reason, the intermittent catheterization enables the emptying of the bladder at periodic intervals by introducing a urinary catheter through the urethra. The intermittent catheter can be used at any age, including children and infants, as it prevents complications from bladder distension or residual urine post-voiding, and it improves the condition of the urinary tract. However, it is contraindicated in the absence of manual dexterity and in cases of morbid obesity and spasticity of the lower limbs. In order for this treatment to be effective, periodic use of urinary catheterization is recommended. The daily use of a urinary catheter can cause significant changes in daily activities of patients with neurogenic bladder and their families and/or caregivers, who generally provide assistance by performing the catheterization regularly.

The effectiveness of intermittent urinary catheterization has been evaluated in studies with samples of adult patients with neurogenic voiding dysfunction and who have used intermittent urinary catheters. In their initial treatment, these patients were identified by low scores in their overall QoL and physical domain. After four to six months’ treatment after using intermittent urinary catheters, the majority of these studies showed an improvement in QoL scores. showed that there was adherence to treatment and a significant increase in psychological and social domain scores after receiving educational training for intermittent urinary catheterization.

Studies with children and adolescents who use intermittent urinary catheterization showed that they had negative feelings during social activities, such as playing with siblings, school life, family and even sleeping over at a friend’s house, and consequently had low QoL scores. The intermittent urinary catheterization procedure represents an important alternative for the improvement of QoL in child patients, for example, by enabling them to be diaper-free.

Therefore, the regular use of intermittent catheterization has reduced the mortality and morbidity in these patients. This procedure has other beneficial effects, such as improved body image and self-confidence, and guarantees a good QoL. The QoL of patients using intermittent urinary catheterization can be increased by the improvement of urinary symptoms, independence, reduction of signs and symptoms of urinary incontinence and urinary infection, access to work activities and social inclusion. In this regard, multidisciplinary support is essential for the multidimensional needs of patients using urinary catheterization and/or their caregiver, which will lead to better adherence to the treatment.

The study of QoL is a meaningful way to assess the impact of neurogenic bladder dysfunction and its treatment in the life of patients and/or their caregivers. According to the concept adopted by the World Health Organization, QoL is defined as “the individual’s perception of their position in life, in the context of culture and value systems in which he lives, and in relation to their goals, expectations, standards and concerns”. Hence, studies on QoL of these patients and/or their caregivers can indicate the perception of these individuals on their position in life, culture, values, goals, perspectives, concerns and environment in which they live.

Through the understanding of their QoL, health professionals and health services policy-makers will also be able to determine suitable methods of treatment and therapies and evaluate the costs and benefits of proposed treatments. Patients, and in some cases their caregivers, are therefore able to gauge their overall QoL through the use of instruments for the measurement and identification of scores in different geographical regions.

A preliminary search of the JBI Database of Systematic Reviews and Implementation Reports, the Cochrane Database of Systematic Reviews, Prospero, CINAHL and MEDLINE has revealed that there are currently no systematic reviews (neither published nor in progress) on patients using intermittent urinary catheterization and their caregivers. Therefore, it is necessary to examine the effectiveness of the use of intermittent urinary catheterization in improving the QoL of patients with neurogenic urinary bladder, which will involve a thorough critical analysis based on scientific evidence.

Inclusion criteria

Types of participants

The current review will consider all studies that include newborns, children and adults diagnosed with neurogenic bladder according to the ICD-10 Diagnosis Code N31.9.
Types of intervention(s)
The current review will consider studies that assess the use of the intermittent urinary catheterization versus standard care. The standard care used in the scientific literature and adopted in this review are not using intermittent urinary catheterization, use of intermittent urinary catheter by supra-pubic, non-invasive methods (maneuvers for bladder emptying – Valsalva and Crede – and strengthening of the pelvic muscles), use of diapers due to urinary incontinence or indwelling urinary catheterization.

Outcomes
The current review will consider studies that include QoL as the primary outcome. This outcome will be measured by validated QoL instruments such as the World Health Organization Quality of life-Bref (WHOQOL-bref), the Short Form (SF-36) Health Survey and specific instruments to measure the QoL of patients who use intermittent urinary catheterization; however, these instruments have not been identified in the scientific literature.

The second outcome will be related to the voiding dysfunction that impacts QoL in patients: urinary infection rate during use of intermittent urinary catheter; urodynamic parameters, urine residual volume, use of drugs (e.g. anti-cholinergic treatment or botulinum toxin injections combined with intermittent urinary catheterization) and number of times to use urinary catheter; and urinary catheterization performed by caregivers.

Types of studies
The current review will consider both experimental and randomized controlled trials, non-randomized controlled trials, quasi-experimental studies, before and after studies, prospective and retrospective cohort studies, case-control studies and analytical cross-sectional studies.

Search strategy
The search strategy aims to find both published and unpublished studies. A three-step search strategy will be utilized in this review. An initial limited search of MEDLINE and CINAHL will be undertaken followed by analysis of the text words contained in the title and abstract, and of the index terms used to describe article. A second search using all identified keywords and index terms will then be undertaken across all included databases. Third, the reference list of all identified reports and articles will be searched for additional studies. Studies published in English, Spanish and Portuguese will be considered for inclusion in this review. All studies published since 1972 (as this was the year that intermittent urinary catheter was discovered by Lapides) to present day will be considered for inclusion in this review.

The published databases to be searched include: Cochrane Central Register of Controlled Trials Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus with Full Text Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS) PubMed Scopus Scientific Electronic Library Online (Scielo) Academic Search Premier (via platform EBSCO)

The unpublished databases to be searched will include:
Banco de teses da CAPES (www.capes.gov.br)
RCAAP – Repositório Científico de Acesso Aberto de Portugal
ProQuest Dissertation and Theses
TESEO – Base de Datos de Tesis Doctorales
OpenGrey

Initial keywords to be used will be:
patient' child' adult' old'
"intermittent urinary catheterization"
"urinary bladder neurogenic"
"neurogenic bladder"
"quality of life"
"health related quality of life"

Assessment of methodological quality
Quantitative papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI) (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion or with a third reviewer.

Data extraction
Quantitative data will be extracted from papers included in the review using the standardized data.
extraction tool from JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. For missing information or need to clarify unclear data the authors of primary studies will be contacted. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

**Data synthesis**

Quantitative papers will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated. Heterogeneity will be assessed statistically using the standard chi-square and also explored using subgroup analyses based on the different quantitative study designs included in this review and based on types of intermittent urinary catheter (e.g. standard intermittent catheter, hydrophilic-coated catheter and catheter lubricant) and overall score of QoL from selected studies and their classification in domains (e.g. physical, emotional, social and psychological). Where statistical pooling is not possible, the findings will be presented in narrative form including tables, graphs and figures to aid in data presentation where appropriate.

**Acknowledgements**

The authors would like to thank the support provided by Health Sciences Research Unit – Nursing (UICISA: E), hosted by the Nursing School of Coimbra (ESEnFC). This review will contribute toward a PhD degree for the main author and is funded by São Paulo Research Foundation (FAPESP).

**References**

Appendix I: Appraisal instruments

MAStARI appraisal instrument

### JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the assignment to treatment groups truly random?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Were participants blinded to treatment allocation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Was allocation to treatment groups concealed from the allocator?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Were the outcomes of people who withdrew described and included in the analysis?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Were those assessing outcomes blind to the treatment allocation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Were the control and treatment groups comparable at entry?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Were groups treated identically other than for the named interventions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Were outcomes measured in the same way for all groups?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Were outcomes measured in a reliable way?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Was appropriate statistical analysis used?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Overall appraisal:**

- Include □
- Exclude □
- Seek further info. □

**Comments (Including reason for exclusion)**

________________________________________________________________________

________________________________________________________________________
JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer __________________ Date ____________________

Author __________________ Year ______ Record Number ______

1. Was study based on a random or pseudo-random sample? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable
2. Were the criteria for inclusion in the sample clearly defined? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable
3. Were confounding factors identified and strategies to deal with them stated? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable
4. Were outcomes assessed using objective criteria? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable
5. If comparisons are being made, was there sufficient descriptions of the groups? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable
6. Was follow up carried out over a sufficient time period? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable
7. Were the outcomes of people who withdrew described and included in the analysis? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable
8. Were outcomes measured in a reliable way? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable
9. Was appropriate statistical analysis used? [ ] Yes [ ] No [ ] Unclear [ ] Not Applicable

Overall appraisal: Include [ ] Exclude [ ] Seek further info [ ]

Comments (including reason for exclusion)

________________________________________________________________________

________________________________________________________________________
### JBI Critical Appraisal Checklist for Comparable Cohort/Case Control

**Reviewer**  
**Date**  

**Author**  
**Year**  
**Record Number**  

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is sample representative of patients in the population as a whole?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Are the patients at a similar point in the course of their condition/illness?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Has bias been minimised in relation to selection of cases and of controls?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Are confounding factors identified and strategies to deal with them stated?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Are outcomes assessed using objective criteria?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Was follow up carried out over a sufficient time period?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Were the outcomes of people who withdrew described and included in the analysis?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Were outcomes measured in a reliable way?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Was appropriate statistical analysis used?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Overall appraisal:**  
- Include [ ]  
- Exclude [ ]  
- Seek further info. [ ]

**Comments (Including reason for exclusion)**

---

©2016 Joanna Briggs Institute. Unauthorized reproduction of this article is prohibited.
Appendix II: Data extraction instruments

MAStARI data extraction instrument

**JBI Data Extraction Form for Experimental / Observational Studies**

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>Year</td>
</tr>
<tr>
<td>Journal</td>
<td>Record</td>
</tr>
</tbody>
</table>

**Study Method**

- [ ] RCT
- [ ] Quasi-RCT
- [ ] Longitudinal
- [ ] Retrospective
- [ ] Observational
- [ ] Other

**Participants**

<table>
<thead>
<tr>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Sample size**

- Group A ____________________
- Group B ____________________

**Interventions**

<table>
<thead>
<tr>
<th>Intervention A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intervention B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Authors Conclusions:**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Reviewers Conclusions:**

<p>| |</p>
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
</table>
### Study results

#### Dichotomous data

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
<th>Intervention ( ) number / total number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Continuous data

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention ( ) number / total number</th>
<th>Intervention ( ) number / total number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>