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ORIGINAL ARTICLE

Lower urinary tract symptoms treatment constraints assessment (LUTS-TCA): a new tool for a global evaluation of neurogenic bladder treatments

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Abstract

Objectives To develop a new tool to assess constraints due to urinary treatments in neurological patients.

Materials and methods A prospective, monocentric study has been conducted from January to May 2017. Out-patients (multiple sclerosis, spinal cord injury, Parkinson disease) were included in a referral center if they had LUTS treatment for at least 3 months. To validate psychometric properties, we conducted a literature review, qualitative interviews, and discussion with a panel of six experts. Comprehension, acceptation, and pertinence were tested by a pilot study. A validation study, designed to calculate content validity, internal consistency reliability, and test–retest reliability [intraclass correlation coefficient (ICC)] has been conducted. The primary outcome was good psychometric properties defined with Cronbach's $\alpha > 0.7$ and ICC > 0.7.

Results Comprehension, acceptation, and pertinence were excellent. Validation study showed a perfect content validity (r2 = 1) and excellent internal consistency reliability (Cronbach' $\alpha = 0.90$). Total score was between 0 (best score) to 66 (maximal constraints). Test–retest reliability calculated using ICC was 0.81. Time to fill questionnaire was 4 min 20 s. The final version was composed by 22 items.

Conclusion LUTS TCA is the first validated tool to assess constraints of urinary treatment and has excellent psychometric properties.

Keywords Constraints · Neurogenic bladder · Questionnaire · Urinary treatment evaluation · Tool

Abbreviations

LUTS	Lower urinary tract symptom
CISC	Clean intermittent self-catheterization
OAB	Overactive bladder
ICC	Intraclass correlation coefficient
TSQM	Treatment Satisfaction Questionnaire for Medication
SATMED-Q	Treatment Satisfaction with Medicines Questionnaire
IPSS	International Prostate Symptoms Score
PGI-I	Patient global impression of improvement
OABSS	Overactive Bladder Symptom Score

Introduction

Lower urinary tract symptoms [1, 2] (LUTS) strongly impact daily life and quality of life [3–5]. To decrease their consequences, various and numerous treatments [6, 7] can be used (anticholinergics, beta3 agonists alpha-blockers, clean intermittent self-catheterization (CISC), surgery or intra detrusor injection of botulinum toxin A). In many cases, these treatments improve patient satisfaction and urinary symptoms, leading to better quality of life [8]. Numerous validated questionnaires can be used to evaluate these improvements, but also patient expectations or goals achievement [9]. In contrary, no specific tool is currently available to take into account the different constraints of the treatment(s).

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Yet, these constraints are very frequent and not only induced by the side effects of the different used drugs, especially anticholinergics (dry mouth, constipation, eye dryness, and blurred vision). Indeed, constraint is a general concept with all social, psychological, environmental, financial, beliefs, doubts, and patients feeling with the proposed treatment.

Moreover, these constraints are in balance with the positive effects of the treatments and thus explain the poor adherence and compliance of various treatments [10, 11]. However, even if constraints seem to be important to consider, there is no tool in the medical literature that allows its evaluation.

The aim of our study was to develop and validate a new tool to assess constraints due to urinary treatments in a neurologic population.

Materials and methods

We conducted a prospective, monocentric study in a Neurourology Department of a University Hospital. The study was conducted in three phases: qualitative interviews with patients, feasibility study and validation study. These steps allowed a full psychometric validation of a questionnaire [12]. Ethics approval was obtained from the local research ethics committee (ID-RCB: 2015-A00125-44). All patients gave their oral and written consent.

Patients were included from November 2016 to June 2017. The inclusion criteria were: to be aged > 18 years and to have been taking a urinary treatment for at least the last 3 months. All patients included suffered from neurogenic LUTS.

Review of literature and qualitative interviews

We conducted a review of the literature on Pubmed to explore and determine the different dimensions of constraints. All articles in English until March 2017 were reviewed with the following keywords: "tool", "questionnaire", "scale", "score", "benefit risk", "constraints", "side effects", "treatment" and "Lower Urinary tract symptoms". In addition to this review, semi-structured interviews were conducted from November 2016 to March 2017 on 29 patients suffering from various LUTS [overactive bladder (OAB), voiding dysfunction]. All the interviews were conducted by a single trained person. First part of the face to face determined the best term to define the constraints between discomfort, constraining, and boring. Mode of item wording was also chosen by the patients among ten propositions. Patients were asked to validate the mode of response for each item. A four-points Likert scale was proposed for each item, ranged: "A: not at all", "B: a little", "C: a lot", and "D: greatly".

The second part of the interview was free and patient expressed the constraints they felt. Verbatim transcripts were analyzed to emerge the different themes of constraints.

During this phase, a panel of six experts was selected, composed of neurourologists and urologists.

Feasibility study

This pilot study was conducted from April 1st to 31 April 2017. For this feasibility study, 31 patients were included. They had to rate each item to evaluate comprehension, acceptation, and pertinence with a four-point Likert scale from response "A: not at all" to "D: perfectly".

Validation study

We conducted the validation study from May 2017 to June 2017 to determine the psychometric properties of the questionnaire.

Content validity was tested by a univariate logistic regression between the generic item of the questionnaire (generic item: "Eventually, the possible constraints or side effects caused by urinary treatment are encouraging me not to pursue it") and the total score resulting from all the independent items.

Internal consistency reliability was calculated using the α coefficient of Cronbach. Each response has been transformed in a numeric value to perform this test. Alpha coefficient of Cronbach was considered as very good if > 0.7 [12].

Test–retest reliability was tested using the intraclass correlation coefficient (ICC) which was significant over 0.7 [12]. The first questionnaire was filled at the end of the first consultation and patients had to mail a second questionnaire (filled at home) 7 days after the first consultation.

Statistical analyses

For item reduction, we performed a descending stepwise logistic regression. The dependent variable was the generic item and the independent variables were the other items. An exact test of Fisher was used for the univariate phase. All variables with $p < 0.1$ were included in the multivariate phase. All statistical analyzes were performed with the R-studio version 3.3.1 and Statviews (SAS institute V5.0).

For analysis, response to the generic item were binarized as 0 (for patients who answered none or a little) or 1 (for those who answered a lot or greatly).

Results

Phase 1: review of literature and qualitative interviews

Twenty-nine interviews were conducted on patients followed in the unit for LUTS of various etiologies with different treatments (anticholinergics, alpha-blockers, botulinum toxin with or without CISC, and tibial nerve stimulation). Interviews and review of the literature allowed to produce 34 items to explore constraints. From the 29 patients, interviewed 22 (76%) considered the best term as "constraining". Four-points Likert scale has been validated by all patients interviewed and the best mode of item wording was constructed as: "To take a daily treatment for urinary symptoms is constraining".

After this phase, a first experts meeting allowed to reduce the number of items to 25. The test version of the tool was composed of 23 independent items and two generic items. The generic items were constructed to sum the total score. These items were constructed to be used as a single question which could explain the domain of constraints.

Phase 2: feasibility study

We included 31 patients. Comprehension and acceptation were good or perfect for all patients and each item. Pertinence of each item was good or perfect for 97% of patients. There were only two missing data for question 13. A second experts' meeting allowed to reduce the questionnaire to 22 independent items and one generic item.

Phase 3: validation study

Eighty-six patients were included (Table 1), with urologic and neurologic diseases and a combination of different treatments.

The average time to fill the questionnaire was 4 min and 20 s (SD 1 min 19 s).

Content validity: we performed a univariate logistic regression between response to the item 23 (0 or 1) and the total score and the explained variance (R2) were 100%. The item 23 explore perfectly constraints fields.

Internal consistency reliability has been calculated on the 22 independent items. The Cronbach's α was 0.90. No ceiling or floor effect was detected.

Table 1 Patients' characteristics

Age mean (SD)	55.4 (14.2)
Gender *N* (%)	
Male	32 (37.2)
Female	54 (62.8)
Medications *N* (%)	
Clear intermittent catheterization	60 (69.8)
Anticholinergics	34 (39.5)
Intra detrusor injection of botulinum toxin A	31 (36.0)
Posterior tibia nerve stimulation	19 (22.1)
α Blockers	12 (13.9)
Pathology	
Multiple Sclerosis	37 (43.0)
Spinal cord injury	22 (25.6)
Brain lesion	7 (8.1)
Idiopathic	6 (7.0)
Parkinson's disease	5 (5.8)
Urologic disease	4 (4.7)
Others	5 (5.8)

Test–retest reliability has been tested by ICC between total score of the first questionnaire and total score of the second questionnaire fulfilled at day 7. Seventy-five patients were included for test–retest reliability and 55 (73.3%) questionnaires were returned by mail. From the 55 questionnaires completed, two were excluded for missing data. Finally, 53 questionnaires were included to evaluate ICC. On the 22 independent items, ICC was 0.81.

To reduce items number, we performed a multivariate logistic regression between the set of items and the generic item (*n* 23) (Table 2). Seven items were included in the multivariate phase (Table 2) and only one remained significant (item 22) with an explained variance (r2) equal to 0.18.

The final version of the questionnaire was composed of 22 items. Each item was rated from 0 (for response not at all) to 3 (for greatly). Total score ranged 0 to 66 meaning the biggest constraint.

Discussion

To our knowledge, LUTS-TCA is the first validated questionnaire which allows treatment constraints' evaluation, for a neurologic population. This tool has excellent psychometric properties. Indeed, the Cronbach's α is very high (0.90), meaning that it explores successfully the domain of constraints. Likewise, the intraclass correlation coefficient is good (0.81), meaning that the questionnaire is reproducible. These good psychometric properties and the time to

Table 2 Univariate and multivariate analyzes between item 23 (scored 0 if response was "not at all" and 1 if response was "yes a little; yes a lot or yes greatly") and each independent item

Items	Univariate analysis (*p*)	Multivariate analysis			
		Initial table r2 = 1.00, *n* = 86		Final table r2 = 0.18, *n* = 86	
		p	OR (CI 95%)	*p*	OR (CI 95%)
Q1	0.32				
Q2	0.22				
Q3	0.2				
Q4	0.13				
Q5	0.25				
Q6	0.09*	0.23	2.27 (0.59–9.46)		
Q7	0.12				
Q8	0.33				
Q9	0.11				
Q10	0.21				
Q11	0.23				
Q12	0.04*	0.32	1.98 (0.48–8.03)		
Q13	0.03*	0.21	2.68 (0.61–14.49		
Q14	0.03*	0.27	2.04 (0.58–8.25)		
Q15	0.02*	0.83	0.84 (0.14–3.45)		
Q16	0.87				
Q17	0.57				
Q18	0.26				
Q19	0.14				
Q20	0.16				
Q21	0.51				
Q22	0.002*	0.03	4.98 (1.32–26.53)	0.03	0.175

* Variable with $p < 0,1$

fill LUTS TCA (4 min 20 s) allow a quick and an objective evaluation of treatment constraints.

Two questionnaires exist in medical literature, including in a small part, constraints domains, but they have not been specifically validated to totally explore this dimension unlike LUTS-TCA. These two questionnaires are the Treatment Satisfaction Questionnaire for Medication (TSQM) [13] and the Treatment Satisfaction with Medicines Questionnaire (SATMED-Q) [14]. The TSQM, developed by Atkinson et al. in 2004 [13], was composed of 13 items exploring four fields (effectiveness, side effects, convenience, and overall satisfaction). The SATMED-Q validated in 2008 by Ruiz et al. [14] contained six domains including treatment effectiveness, convenience of use, impact on daily living activities, medical care, undesirable side effects, and global satisfaction. The TSQM and the SATMED-Q are the unique tools which partially include constraints impact (side effects, convenience to use, and quality of life) in satisfaction evaluation. As explained by Shikiar et al. [15], treatment satisfaction depends on many variables. Thus, Shikiar et al. described a pyramidal model of satisfaction. The base of this pyramidal model was satisfaction with health care, health department. The second level of the pyramid was the treatment satisfaction in terms of convenience to use, dietary limitations or daily activities. The top of this model was the satisfaction with medication that means the different impacts on symptoms and side effects.

In fact, in most studies and in clinical practice, satisfaction evaluation is focused on symptoms relief and/or quality-of-life improvement. Tools like International Prostate Symptoms Score (IPSS), Patient Global Impression of Improvement (PGI-I), or Overactive Bladder Symptom Score (OABSS) are useful but not sufficient. They only evaluate one side of the satisfaction (the benefits on symptoms and the improvement of quality of life/bother) and do not consider the negative sides of the proposed treatment. However, several fields have a real impact on adherence, compliance, and acceptance of the treatments. The field of constraints is wider than quality of life or side effects and needs to be explore by specific tools. Indeed, constraints can express themselves under numerous and various forms. It could be represented by a daily take of a tablet or the necessity to realize several CISC in a day. This daily constraint could be felt as a dependence on the treatment. Moreover, the necessity, every day, not to forget the treatment can be perceived as restrictive and difficult for patients with neurologic condition. Most of the proposed treatments for urinary symptoms are not curative and patients have to take them every day to obtain symptoms relief. This particularity can send back to the patients the image to be sick.

Moreover, lots of LUTS are caused by neurologic disease or aging [5] and patients already have other treatments to take every day, with other constraints and side effects. If urinary treatment adds new constraints, it could lead to treatment discontinuation. This phenomenon is frequent for antimuscarinics, where side effects (constipation, blurred vision, and dry mouth) [10, 16] result in additional therapeutics (for instance, laxative to decrease constipation). It is the same problem for the need of CISC resulting from intra detrusor injection of botulinum toxin A [17] which subsequently intensify the general care constraints.

In addition, patients with intra-detrusor injection of botulinum toxin A have to repeat injections every 6 months. This rhythm of consultation has a real impact on patient's organization, whatever their social conditions are. It can be problematic for work organization (absenteeism is a part of socio economic burden of OAB [3]) or for family life.

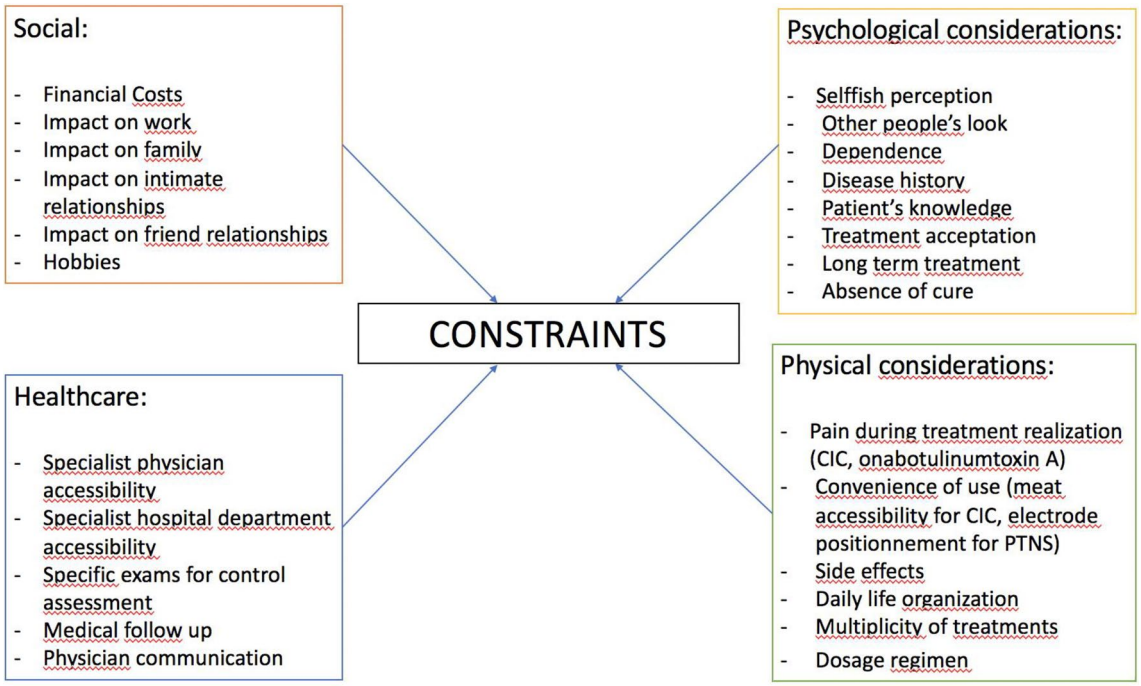

Fig. 1 List of care constraints

Treatments like CISC have good acceptance and convenience to use at home but are more problematic when patients plan to travel or for outdoor activities. CISC could appear to be embarrassing and patient always have to plan all their activities depending on treatment logistics (number of urinary catheters).

Difficulties can exist to provide treatment because of its availability in the pharmacy or its cost which could be the first reason for treatment discontinuation whatever its efficiency is. Constraints are increased for population with cognitive impairment or physical deficiencies and therapeutic decision should be well considered in this population usually suffering from LUTS [5]. As suggested by these examples, constraints exist for all sorts of treatment and have different expressions depending on etiology of LUTS, age or patient's life. Figure 1 lists all the different domains of care constraints. Our study population is mainly represented by patients suffered from neurogenic disease. This specificity, due to a recruitment from a tertiary center of neurourology, can influence patient's response. Patients already have lot of treatment and have more care constraints (numerous specialists or consultation frequency in a year). This specific population can feel more constraints than people consulting only for urologic or gynecologic disease. They are also more exposed to a treatment combination to control LUTS caused by neurologic disorder. Indeed, the medical objectives are different for neurogenic population and constraints could be more accepted for these patients. For example, patients with spinal cord injury are more susceptible to accept invasive treatment because of renal prognosis or urinary infectious risk.

LUTS treatment is very wide and different. Surgical treatment which can cure urological disease or LUTS were not studied by this LUTS TCA. Surgery causes lots of different and specific constraints as self-perception after surgery, physical modification, and surgery complication. Thus, LUTS TCA is only interesting for medical treatment of LUTS.

LUTS TCA, composed of 22 independent items, evaluates a wide sample of constraints due to urinary treatment (Appendix). Thus social, psychological, environmental, and financial constraints, but also beliefs', doubts', and patients' feeling (with the proposed treatment) are necessary to be taken into account in the discussion of the proposition, the pursuit, and obviously, in the evaluation of the treatment. Thereby, such an evaluation of the different domains of constraints allows a full analysis of patient's satisfaction. This objective evaluation is important to adjust treatment and help to choose other therapeutic strategies when needed. We can easily imagine changing an antimuscarinics treatment if constraints are to important even if satisfaction with treatment is good. LUTS TCA could allow to compare two

classes of antimuscarinics and finally choose the best one for each patient. Moreover, this specific evaluation, which takes into account the global patient discomfort as well as the global improvement, allows to correct the dose or the type of treatment and thus enhances compliance and adherence. LUTS TCA could be used in consultation to perform patients' follow-up and detect patients with lots of constraints who are susceptible to stop their treatment. It could help to reduce risk of treatment discontinuation and finally increase quality of life and treatment satisfaction.

LUTS-TCA is the first validated questionnaire designed to evaluate constraints due to urinary treatment for neurogenic LUTS. This tool has very good psychometric parameters with an excellent internal consistency reliability and an excellent reproducibility.

This questionnaire can be used in clinical practice to better choose and follow-up urinary treatments but also in clinical research particularly to take in to account not only the classical side effects but also all the different domains of global constraints induced by the different treatments.

It could be interesting to validate this questionnaire in non-neurogenic population especially idiopathic overactive bladder.

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Compliance with ethical standards

Conflict of interest No conflict of interest.

Appendix: LUTS TCA questionnaire

This questionnaire aimed to evaluate constraints due to urinary treatments (clean intermittent catheterization, tablets, intra-detrusor injection of botulinum toxin A, and posterior tibial nerve stimulation).

Be careful, this questionnaire does not address constraints due to your urinary symptoms or your disease, but those secondary to the treatment prescribed for your urinary disorders.

Please answer the following questions by surrounding a single answer among four proposals.

1. To take a daily treatment for my urinary disorders is constraining:
   A: not at all
   B: a little
   C: a lot
   D: greatly

2. To take/realize a treatment for my urinary disorders outside of my home is constraining:
   A: not at all
   B: a little
   C: a lot
   D: greatly

3. To follow specific instructions (dosage regimen, rhythm...) to take/realize the treatment of my urinary disorders is constraining:
   A: not at all
   B: a little
   C: a lot
   D: greatly

4. To take a long-term treatment for my urinary disorders beside those took for my other disease is constraining:
   A: not at all
   B: a little
   C: a lot
   D: greatly

5. To be dependent of the treatment of my urinary disorders is constraining:
   A: not at all
   B: a little
   C: a lot
   D: greatly

6. To take a long-term treatment for my urinary disorders is difficult to accept:
   A: not at all
   B: a little
   C: a lot
   D: greatly

7. To take a treatment which improves my urinary disorders without curing them necessarily is a problem:
   A: not at all
   B: a little
   C: a lot
   D: greatly

8. To take a treatment for my urinary disorders has a negative impact on my humor:
   A: not at all
   B: a little
   C: a lot
   D: greatly

9. To take a treatment for my urinary disorders is constraining for my social or professional life:
   A: not at all
   B: a little
   C: a lot
   D: greatly

10. To take a treatment for my urinary disorders is constraining in my family life:
   A: not at all
   B: a little
   C: a lot
   D: greatly

11. To take a treatment for y urinary disorders is constraining for my hobbies (sport, outdoor activities, movies, trips, reading…):
   A: not at all
   B: a little
   C: a lot
   D: greatly

12. To take a treatment for my urinary disorders is constraining in my daily life activities (dress, dressing, food):

A: not at all
B: a little
C: a lot
D: greatly

13. To take a treatment for my urinary disorders is constraining for my intimate relationships:

A: not at all
B: a little
C: a lot
D: greatly

14. To provide the treatment of my urinary disorders is constraining:

A: not at all
B: a little
C: a lot
D: greatly

15. Financial cost due to the treatment of my urinary disorders is constraining:

A: not at all
B: a little
C: a lot
D: greatly

16. Medical follow-up (consultations, prescription refill) due to the treatment of my urinary disorders is constraining:

A: not at all
B: a little
C: a lot
D: greatly

17. To realize specific exams (due to the treatment of my urinary disorders) is constraining:

A: not at all
B: a little
C: a lot
D: greatly

18. To take/realize the treatment of my urinary disorders is constrainingbecause of the other people's look:

A: not at all
B: a little
C: a lot
D: greatly

19.Side effects due to the treatment of my urinary disorders are constraining:

A: not at all
B: a little
C: a lot
D: greatly

20. To continue the treatment of my urinary disorders is difficult because of side effects:

A: not at all
B: a little
C: a lot
D: greatly

21. Organizing myself to take/realize the treatment of my urinary disorders is constraining:

A: not at all
B: a little
C: a lot
D: greatly

22. To take/realize the treatment of my urinary disorders becomes more and more constraining in time:

A: not at all
B: a little
C: a lot
D: greatly

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