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Design and Validation of the Marmara Post-prostatectomy Incontinence Symptom Score

Marmara Post-prostatektomi İdrar Kaçırma Semptom Skoru Oluşturulması ve Validasyonu

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What's known on the subject? and What does the study add?

Incontinence developing after post-prostatectomy is a very disturbing problem. There are many questionnaires for evaluating incontinence in the field of urology. There is however no dedicated form which evaluates incontinence that develops particularly after prostatectomy. The present study explores a valid and reliable questionnaire in analysis of post-prostatectomy incontinence.

Abstract

Objective: This study aims to validate the "Marmara post-prostatectomy incontinence symptom score (M-PPISS)" designed for the assessment of post-prostatectomy incontinence (PPI).

Materials and Methods: The questionnaire consists of 3 sections including 8 questions (4 questions examining the type and degree of PPI, 3 questions examining the effect of PPI on quality of life (QoL) and 1 question examining bladder emptying) and an analogue scale to assess the impact of PPI on the QoL. The questionnaire was completed by 106 patients, who underwent radical prostatectomy (RP) in our clinic between 2007 and 2015, at the end of the first week, first month and at 3-month intervals up to one year after RP.

Results: The mean score of 106 patients at the end of the first week after the operation was 6.57 (minimum: 0, maximum: 24). The internal consistency coefficient measured for our questionnaire was found to be higher (Cronbach's alpha: 0.887). When an item was deleted, Cronbach's alpha was not lower than 0.85 for any value. According to the 27% rule, p value was calculated as 0.0001. In the numerical evaluation of total score and the analogue scale considering QoL (satisfaction and dissatisfaction); patients with a total score of 0-4 were accepted as "satisfied with QoL", while patients with a total score of ≥5 were included in the dissatisfied group (cut-off value: 5).

Conclusion: The M-PPISS was found to be a reliable and valid instrument in the evaluation of urinary incontinence after RP.

Keywords: Prostatectomy, incontinence, questionnaire, validation

Öz

Amaç: Çalışmamızda prostatektomi sonrası idrar kaçırma (PSİK) değerlendirilmesi için oluşturduğumuz "Marmara post-prostatektomi idrar kaçırma semptom skoru (M-PPİKSS)" validasyonu amaçlandı.

Gereç ve Yöntem: Sorgulama formu 3 bölümden oluşmakta ve idrar kaçırma şeklini ve miktarını sorgulayan 4 soru, idrar kaçırmanın yaşam kalitesi üzerine olan etkilerini sorgulayan 3 soru ve mesane boşaltımını sorgulayan 1 soru olmak üzere toplam 8 soru bulunmaktadır. Bu sorgulama formu kliniğimizde 2007-2015 yılları arasında radikal prostatektomi (RP) operasyonu uygulanan hastalardan 106 tanesine operasyon sonrası 1. hafta, 1. ay ve 3 aylık kontrolleri sırasında doldurduldu ve sonuçları sorgulama formunun validasyonu açısından değerlendirildi.

Bulgular: Ameliyat sonrası 1. haftada toplam 106 hastanın ortalama skorları 6,57 (minimum: 0, maksimum: 24) olarak bulundu. Sorgulama formu için hesaplanan iç tutarlılık katsayısı yüksek tespit edildi (Cronbach's alfa: 0,887). Öğe silindiğinde Cronbach's alfanın hiçbir değer için 0,85'in altına düşmediği izlendi. %27 kuralına göre ise p değeri 0,0001 olarak hesaplandı. Toplam skor ile analog skala arasında yaşam kalitesi düşünülerek

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(memnuniyet ve memnuniyetsizlik) yapılan sayısal değerlendirmede ise, toplam skoru 0-4 aralığında olanlar yaşam kalitesi için memnun olarak kabul edilirken, toplam skoru ≥5 olanlar ise memnun olmayanlar grubuna dahil edildi (eşik değeri: 5).
Sonuç: M-PPİKSS, RP sonrası idrar kaçırma değerlendirilmesinde geçerli ve güvenilir bir araç olduğu saptandı.
Anahtar Kelimeler: Prostatektomi, idrar kaçırma, sorgulama formu, validasyon

Introduction

Incontinence, which develops after surgical interventions for prostatic diseases such as prostate cancer (PC) and benign prostatic hyperplasia, is a disturbing problem and affects a significant group of patients with varying intensity (1). Radical prostatectomy (RP) remains the most common treatment option for the treatment of localized PC (2). However, in spite of the advances in the techniques and technology, post-RP incontinence affects 4 to 50% of patients mildly and 0 to 15.4% of patients severely (3,4,5).

Besides routine urological evaluation for post-RP incontinence, using a questionnaire can be helpful for the assessment of the nature and quantity of the incontinence and its effect on the quality of life (QoL). There are a number of questionnaires for evaluating incontinence in the field of urology. Those forms are important for the purpose of standardizing the information received from the patients and eliminating subjectivity and, such questionnaires are recommended to be used in daily practice (6). There are 4 questionnaires, which are validated, investigating incontinence and impotence after RP (7,8,9,10). However, the need for a brief and dedicated questionnaire still exists for the evaluation of incontinence developing particularly after RP.

In this study, we aimed to introduce and validate the "Marmara post-prostatectomy incontinence symptom score (M-PPISS)" form for the evaluation of post-prostatectomy incontinence.

Materials and Methods

The M-PPISS questionnaire consists of 3 sections with a total of 8 questions (Annex 1). In the first section, there are 4 questions regarding the type and severity of incontinence where five different answers can be given from (0) never to permanently/ frequently (4). In the second section, there are 3 questions, questioning the effects of incontinence on the QoL, where four different answers can be given from (0) never to very much (3). And in the last section, there is 1 question questioning bladder emptying, where four different answers can be given from (0) (I urinate comfortably) to 3 (I cannot urinate at all).

Total scores vary between 0 and 28. Furthermore, there is an analog scale which helps to evaluate the overall QoL related to micturition status at the end of the questionnaire. Such analog scale is in the range I am happy (0) - I feel miserable (6).

For the validation of the questionnaire, a total of 106 patients, who underwent RP operation in our clinic between 2007 and 2015, completed the M-PPISS at the 1st week, 1st month and 3 months controls after the RP.

Statistical Analysis

Validity and reliability analyses were performed using SPSS 17.0 software. A p value of less than 0.05 was considered statistically significant.

Results

The average age of the 106 patients, who completed the M-PPISS questionnaire, was 63.9±6.4 years. The average M-PPISS scores of the patients are presented in Table 1, where continuous decreases were observed with longer follow-up periods (Table 1).

After test-retest analysis carried out by means of comparing 1st week, 1st month and 3 monthly M-PPISS during follow-up, where significant differences were observed in the answers given by the patients to each question, in total score and in averages ($p<0.05$).

The internal consistency coefficient calculated for the questionnaire was high (Cronbach's alpha: 0.887) and when an element was deleted for each question within the M-PPISS questionnaire, Cronbach's alpha value did not drop below 0.85 for any value (Table 2).

The correlation analysis of the M-PPISS total score and analog scale is given in Table 3, where the "27% rule" applied for the M-PPISS questionnaire form has been found to be significant at an advanced level ($p=0.0001$).

A total score between 0 and 4 was considered satisfactory with regard to QoL, while a total score of ≥5 was interpreted as unsatisfied (threshold: 5) (Figure 1). Numerical evaluation was performed between total score and analog scale (satisfaction and dissatisfaction) and the sensitivity was calculated as 91.1 and specificity as 85.2.

Discussion

Although the international literature describes questionnaires and specific scales for incontinent patients, instruments specific for post-RP incontinence are scarce. The M-PPISS shows excellent internal consistency and reliability. Furthermore, the test-retest correlation, which is another

measurement of reliability, has also been found to be high. The threshold value we offer for the total score is 5 and as evident in the receiver operating characteristic curve, beyond such threshold is the value with highest sensitivity (91%) and specificity (85%).

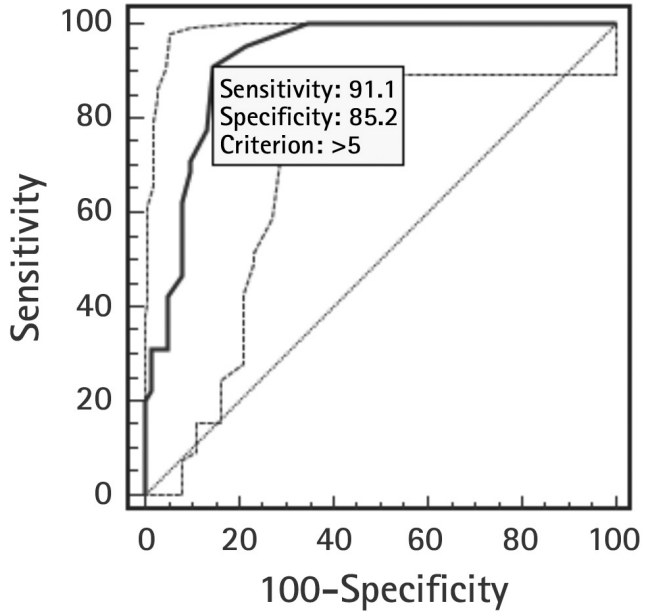

Figure 1. The receiver operating characteristic analysis formed between total score and analog scale, considering the quality of life

Table 1. Average scores of the patients in Marmara post-prostatectomy incontinence symptom score

	n	Average	Standard error
1st week	106	6.57	0.60
1st month	106	5.44	0.63
3rd month	104	4.12	0.56
6th month	103	3.75	0.53
9th month	97	3.38	0.54
12th month	91	2.89	0.54

Table 2. Cronbach's alpha value when an element was deleted for each question within the Marmara post-prostatectomy incontinence symptom score questionnaire (n=106)

Question number	Cronbach's alpha value when an element was deleted
1	0.875
2	0.874
3	0.857
4	0.873
5	0.861
6	0.862
7	0.877
8	0.894

Incontinence is a significant QoL issue after RP and post-prostatectomy incontinence has been reported at various levels and rates (3,4,5). With the advancing techniques for preservation of the neurovascular bundle, provision the length of the remaining urethra at a maximum level and creation of vesico-uretral anastomoses, post-RP urine control rates are maintained at a higher level (11). The first detailed study on the influence of post-RP problems was carried out by Fowler et al. (12) in 1995 using "Medicare database" and 89% of the patients stated that they would prefer surgery to other treatment options as it provided better cancer control in spite of post-RP incontinence and impotence complaints. Fortunately, the urinary control increases as the time advances after the operation. In a study carried out by Lepor and Kaci (13), in a two-year post-RP follow-up, 71%, 87%, 92% and 98.5% of patients achieved continence, which was defined as the use of no pad or a single protective pad in a 24-hour period, in 3rd, 6th, 12th and 24th months, respectively.

Post-RP incontinence is known to affect the QoL significantly (14). There are questionnaires assessing the complaints of incontinence and analyzing the effect of incontinence on the QoL. The subjective data received from the patient will be standardized from clinical and practical points of view using these questionnaires (6). For this purpose, The International Continence Society (ICS) recommends many questionnaires aimed at assessing male incontinence. The most important one among those is the ICSmaleSF questionnaire, which questions urinary symptoms and their influence on QoL in benign prostate hyperplasia (15). However, that form has been used in patients suffering from incontinence due to benign lesions of the prostate, and does not cover incontinence in patients who underwent RP for PC.

The validated forms, which have been used frequently for the assessment of post-RP incontinence, are summarized in Table 4 (16). The University of California-Los Angeles Prostate Cancer Index (UCLA-PCI) contains 20 questions related to post-RP incontinence, impotence and intestinal problems of patients (7). The Expanded Prostate Index Composite (EPIC) is a long and comprehensive questionnaire consisting of 50 questions

Table 3. The Marmara post-prostatectomy incontinence symptom score total score and correlation of the analog scale

Correlation coefficient	r	p
1st week	0.72	p=0.0001
1st month	0.82	p=0.0001
3rd month	0.70	p=0.0001
6th month	0.87	p=0.0001
9th month	0.79	p=0.0001
12th month	0.78	p=0.0001

Table 4. The most frequently employed post-radical prostatectomy questionnaires

1. The UCLA Prostate Cancer Index (PCI):
The questionnaire consisting of 20 questions specific to prostate.
2. The Expanded Prostate Cancer Index-Composite:
Extended version of the UCLA PCI questionnaire including 30 additional questions regarding prostate cancer treatment.
3. The European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire with its prostate cancer-specific module:
25 additional questions specific to prostate regarding incontinence, sexual life and intestinal functioning, questioning the cancer treatment-related quality of life.
4. The Functional Assessment of Cancer Therapy-Prostate:
The questionnaire consisting of 38 questions particularly aimed at assessing the quality of life of males with metastatic disorder, of which 26 are general, 12 are specific to the disease.

UCLA: The University of California-Los Angeles

asking incontinence, impotence and intestinal problems in patients who underwent RP, radiotherapy or brachytherapy for PC (8). This form was shortened as EPIC 26 and EPIC-CP and, re-validations were performed (17,18). UCLA-PCI and EPIC have been shown to be valuable and correlated with each other with regard to their questioning of incontinence and impotence as for QoL (19). The European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire with its PC-specific module (EORTC QLQ-C30-PR25) has 25 additional prostate-specific questions related to incontinence, sexual life and intestinal functioning, questioning cancer treatment-related QoL (9). And the Functional Assessment of Cancer Therapy-Prostate (FACT-P) consists of 38 questions particularly aimed at assessing QoL of males with metastatic disorder, of which 26 are general, 12 are specific to the disease (10). These questionnaires do not specifically question incontinence, but assess negative post-prostatectomy effects in general while the M-PPISS questionnaire specifically questions incontinence and analyses its effect on the QoL of the patient. The M-PPISS is a short and dedicated questionnaire for the evaluation of incontinence after RP with an internal consistency and reliability.

Study Limitations

In the study design, test-retest validity and reliability assessed by 1st week, 1st month and every 3 months forms. However, the patient's symptoms might relieve after RP and the patient's score may change according to convalescence. Performing test-retest reliability in a stable health condition rather than the patient population is lacking.

Conclusion

The M-PPISS was found to be a reliable and valid instrument in the evaluation of urinary incontinence after RP. The M-PPISS is specifically questioning incontinence and its effect on the QoL and is a brief and easy-to-administer questionnaire for post-RP incontinence.

Ethics

Ethics Committee Approval: Retrospective study, Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: Tufan Tarcan, Levent Türkeri, İlker Tinay, Murat Akgül, Design: Tufan Tarcan, Levent Türkeri, İlker Tinay, Murat Akgül, Data Collection or Processing: Murat Akgül, Muhammed Sulukaya, Ahmet Şahan, Analysis or Interpretation: Nural Bekiroğlu, Literature Search: Murat Akgül, Tufan Tarcan, İlker Tinay, Writing: Murat Akgül, Muhammed Sulukaya.

Conflict of Interest: No conflict of interest was declared by the authors.

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Ek 1: M-PPİKSS sorgulama formu

1. Bir günde kaç ara bezi değiştiriyorsunuz?

Hiç (0)	(1)	(2)	(3)	4 ve daha çok

2. Kullandığınız pet büyüklüğü nedir?

(0)	Pet kullanmıyorum
(1)	Küçük pet (Avuç içi büyüklüğünde)
(2)	Çocuk bezi
(3)	Büyük hasta bezi
(4)	Prezervatif sonda kullanıyorum

3. Değiştirdiğiniz pet ne kadar ıslanıyor?

(0)	Hiç ıslanmıyor
(1)	Çok az ıslaklık oluyor
(2)	Yarısından azı ıslanıyor
(3)	Yarısından fazlası ıslanıyor
(4)	Tümüyle sırılsıklam oluyor

4. Ne zaman idrar kaçırıyorsunuz?

(0)	Hiçbir zaman
(1)	Ayağa kalkarken, yürürken
(2)	Gülmekle, ıkınmakla, öksürmekle
(3)	En ufak bir hareketle
(4)	Sürekli

5. İdrar kaçırmanız günlük işlerinizi ne derecede etkiliyor?

(0)	Hiç etkilemiyor, günlük işlerimi yapabiliyorum
(1)	Az miktarda etkiliyor, günlük işlerimi çoğunlukla yapabiliyorum
(2)	Orta derecede etkiliyor, günlük işlerimin bazılarını yapabiliyorum
(3)	Ciddi derecede etkiliyor, günlük işlerimin çoğunu yapamıyorum

6. İdrar kaçırmanız arkadaşlarınızla olan ilişkileriniz ne derecede etkiliyor?

(0)	Hiç etkilemiyor, ilişkilerimde değişiklik yok
(1)	Az miktarda etkiliyor
(2)	Orta derecede etkiliyor
(3)	Ciddi derecede etkiliyor

7. İdrar kaçırmanız psikolojik durmunuzu etkiliyor mu?

(0)	Hiç etkilemiyor
(1)	Az miktarda etkiliyor, hafif derecede sinirli ve gergin olmaktayım
(2)	Orta derecede etkiliyor ve gergin oluyorum
(3)	Ciddi derecede sinirli ve gergin oluyorum

8. İdrarınızı nasıl yapıyorsunuz?

(0)	Rahat idrar yapmaktayım
(1)	İdrar yapmada biraz zorlanıyorum
(2)	İdrar yaparken çok zorlanıyorum ve kesik kesik idrar yapıyorum
(3)	Hiç idrar yapamıyorum

Toplam Skor : _____

Hayatınızın bundan sonraki bölümünde idrar durumunuz aynen devam ederse nasıl hissederdiniz ?	**Mutlu olurum**	**Memnun olurum**	**İyi**	**Bazen iyi bazen kötü**	**Çoğunlukla kötü**	**Mutsuz**	**Berbat**
	0	1	2	3	4	5	6