

DEFINITION OF SUCCESS WITH SEAPI-QMM QUALITY OF LIFE INDEX AFTER TENSION FREE VAGINAL TAPE PROCEDURE: DOES VALIDATION OF SCORE SHEET IN PATIENT'S OWN LANGUAGE EFFECT THE OUTCOME?

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ABSTRACT

Introduction: We evaluate the importance of the validation of the SEAPI-QMM quality of life index in patient's own language to determine the outcome of tension-free vaginal tape operation (TVT®) for stress urinary incontinence.

Materials and Methods: SEAPI-QMM quality of life index was translated into Turkish. Patients with stress urinary incontinence and healthy controls were asked to fill out the Turkish version of SEAPI-QMM quality of life index scoring form. Group I consisted of 50 controls Turkish speaking women who were referred consecutively to the clinic for evaluation of diagnoses unrelated to incontinence. The mean age of those patients was 27 (range 22-55). Group II consisted of 48 Turkish speaking women with urodynamic stress urinary incontinence who were planned to undergo TVT® operation with a mean age of 54.8 (range 35-79). Receiver Operating Characteristics (ROC) plots were used to define the detecting cut off or threshold score and Youden's index was used to detect the best reflecting optimal sensitivity and specificity. After the scoring system was validated and the cut-off values were detected according to the results, Group II patients were reevaluated 1 and 6 months after surgery with the same questionnaire and pad testing.

Results: The total score of SEAPI-QMM quality of life index was determined to range from zero to 45. The mean scores were 0.34 (range 0-3) and 23.5 (range 7- 43) in groups I and II, respectively. A patient with a score of four or greater had a disrupted quality of life leading to treatment seeking behavior, with 100% sensitivity and 100% specificity in our patient population. The difference between cut-off values of 4 and 6 of Turkish or original version, respectively, would not change the interpretation of success in patients who underwent tension-free vaginal tape operation (TVT®). To note is that four of 14 patients (28%) who reported dry after the operation also reported a score of more than the cut-off values.

Conclusion: Although there is minimal difference between cut-off values of English and Turkish version of SEAPI-QMM quality of life index, it would not effect the interpretation of success after the tension-free vaginal tape operation. Small number of patients may report inconsistent results between the SEAPI-QMM quality of life index score and incontinence episodes; this might effect the interpretation of success after surgery.

Key words: Bladder, Urinary incontinence, Outcome assessment (health care), Questionnaire

INTRODUCTION

Female stress urinary incontinence (SUI) is common and currently available treatment options are quite successful for most patients¹. Quality of Life (QoL) assessment is considered essential in evaluating the outcome of any intervention for urinary incontinence².

Although pathophysiology and presentation of SUI are well described, there is not yet a generally accepted validated method of quantitative and standard evaluation of success of treatment options in respect to impact on QoL³⁻⁷. SEAPI-QMM quality of life index is an acronym for stress-related

leak (S), emptying ability (E), anatomy (female) (A), protection (P), inhibition (I), quality of life (Q), mobility (M), and mental status (M) introduced by Raz⁶. QoL related to incontinence is measured with an index consisting of a 15-item questionnaire that looks at a broad variety of aspects of a patient's life domains. The domains include social interactions, personal strain, global health and quality of life, satisfaction and financial impact. Each item is graded from 0-3, with 0 representing no impact and 3 representing the worst impact, for a maximum score of 45⁸.

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Although the original English version of SEAPI-QMM quality of life index has been validated and used for the evaluation of stress incontinence most of the urology clinics, those urologists have used the direct translation of validated English versions without any validation for their own speaking language. Our institution has also been using direct translation without validation of SEAPI-QMM quality of life index since 1998.

In this study, we validate SEAPI-QMM quality of life index in our own language and compare the incontinence episodes which were determined by objective tests and SEAPI-QMM quality of life index scores for the interpretation of outcome after TVT® operation.

MATERIALS and METHODS

Translation and Validation Process of Turkish version of SEAPI-QMM quality of life index

SEAPI-QMM quality of life index was translated into Turkish by one native speaking English and one Turkish medical doctor. After then Turkish version of scoring chart was translated into English again. There was no important difference between the original and translated English versions of SEAPI-QMM quality of life index scoring system. The pilot study was done on 20 subjects in order to understand reliability of Turkish version of SEAPI-QMM quality of life index. We did not determine any difficulty during filling phase of charts. After the institutional review board approval was obtained, patients from different geographical areas of Turkey with SUI and healthy controls were asked to fill out the Turkish version of SEAPI-QMM quality of life index in the appropriate spaces of our outpatient clinic. Patients were selected randomly from our urology clinic. Randomization method was determined as every day selecting the first 5 female patients who carried the inclusion criteria until reaching the sample size. Sample size was calculated with Instat® computer package program. The assumptions of the calculations were estimated standard deviation of each population as 1.5; minimum difference wish to detect as significance as 1; the power of the study was as 0.90 and α error as 0.05. Under these assumptions sample size needed was calculated as 48. Group I consisted of 50 controls Turkish speaking women who were mother and other women family members of medical students with free of

symptoms. The mean age of patients in Group I was 27 (range 22-55). Group II consisted of 48 Turkish speaking female patients with mean age of 54.8 (range 35-79) who underwent TVT® operation for urodynamic SUI. All subjects of Group II were preoperatively evaluated with a complete history, physical examination including pelvic examination, urinalysis, voiding diary, pad test and urodynamics in our Female Urology sub-specialty clinic. Urinary incontinence was objectively confirmed by stress test, pad testing with standard lady pad and urodynamic studies in all Group II patients.

Pad Test

Pad testing according to ICS guidelines was used to quantify urine loss in our patients with SUI⁹. Pad testing lasted for 24 hours and was performed in our hospital. Pad weight gain measured as grams for 24 hours pad test.

Voiding Diary

Additionally, a 3-day bladder diary was completed by each patient including the timing of voids, the volumes voided, incontinence episodes, pad usage, fluid intake and urgency⁹.

Statistics

Symptoms scores were evaluated using a spreadsheet program with statistical functional capabilities. According to the answers of both groups, Receiver Operating Characteristics (ROC) plots were used to define the detecting cut off or threshold score and Youden's index was used to detect the best reflecting optimal sensitivity and specificity¹⁰.

Comparison of SEAPI-QMM quality of life index and incontinence rates

Every patient who underwent TVT® surgery as a result of merely stress or mixed incontinence completed the SEAPI-QMM quality of life index and performed a retest after 1 and 6 months after TVT® surgery in respect to cut-off values. All subjects of Group II who reported incontinence postoperatively evaluated with pad test and voiding diary in our Female Urology sub-specialty clinic by the same surgeon.

RESULTS

The total score was found to range from 0 to 45. Among 50 controls in Group I, the mean score was 0.34 (Range 0-3). Among the 48 patients in

Group II, the mean score was 23.5 (Range 7- 43). Mean scores of SEAPI-QMM 15-item quality of life index of both groups were significantly different ($p=0.001$). Statistical analysis revealed that within a confidence interval of 95%, the patient with a score of four or greater had a disrupted quality of life, with 100% sensitivity and 100% specificity. Statistical analysis also revealed that within a confidence interval of 95%, the patient with a score of six or greater had a disrupted quality of life, with 98% sensitivity and 100% specificity as Stothers study⁸. Mean scores of SEAPI-QMM 15-item quality of life index before, four weeks and six months after treatment with TVT® were also significantly different in Group II 21.6 (Range 7-43) and 6.125 (Range 0-45) and 5.39 (Range 0-37) respectively ($p<0, 05$) (Table I).

As shown on figure I, the dramatic response in respect to decrease in scores of domains after operation was seen in social interactions domain, global health and quality of life domain, and personal strains domain, respectively.

Twenty-eight subjects who reported no sexual activity because of any reason have been reevaluated and there were no statistically significant differences between sexually active and inactive patients in our study group in respect to the cut off value.

Thirty-nine patients in the control group scored a total of "0." Eleven patients in the control group reported a total score different than "0." Two questions in the quality of life domain namely questions number 13 "overall quality of life" and number 14 "impact on quality of life if there was no incontinence" were reported different than "0." None of the control patients had a total score of four or greater.

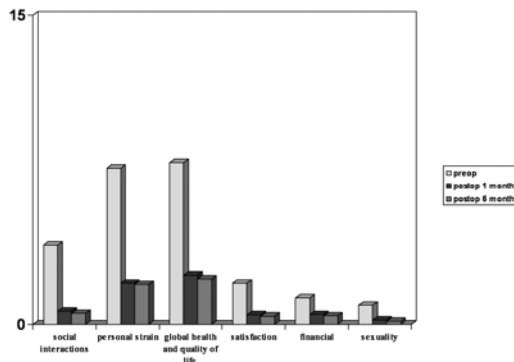
Preoperative total SEAPI-QMM score was five or greater in all patients. Postoperative total SEAPI score was in 34 patients three or lower and in 14 patients was 6 or greater at postoperative 1 and 6 months. Of those fourteen patients, four patients who reported no incontinence after the operation also reported a score of 6 or more. Six of those 14 patients who reported only one pad leakage/

Table I: Answers of subjects before and after TVT®

	Preoperative		Postoperative 4th week		Postoperative 6th month	
Question	Mean	Median	Mean	Median	Mean	Median
1	1,6875	0	0,395833	0	0,541667	0
2	2	0	0,520833	0	0,416667	0
3	1,833333	2	0,520833	0	0,458333	0
4	1,416667	1	0,270833	0	0,25	0
5	1	0	0,145833	0	0,104167	0
6	0,9375	0	0,208333	0	0,166667	0
7	1,416667	1	0,229167	0	0,1875	0
8	1,291667	1	0,479167	0	0,416667	0
9	1,166667	1	0,3125	0	0,229167	0
10	2,041667	2	0,541667	0	0,5	0
11	1,729167	2	0,416667	0	0,395833	0
12	1,395833	1	0,333333	0	0,3125	0
13	1,770833	2	0,5625	0	0,5	0
14	1,8125	2	0,729167	0	0,729167	0
15	1,979167	2	0,458333	0	0,395833	0
TOTAL	21.6	20	6.125	0	5,395833	0

Table II: Result of Pad tests and abnormal SEAPI-QMM quality of index of patients

Patient No	Preoperative evaluation			Postoperative 6 th month visit		
	incontinence pad/day	Total pad weight	SEAPI total score	incontinence pad/day	Total pad weight	SEAPI total score
1	1	23	28	0	0	6
2	3	83	33	1	13	14
3	2	41	21	0	0	8
4	3	43	17	3	48	33
5	2	27	22	1	7	6
6	3	37	15	1	16	16
7	2	91	38	1	13	10
8	3	68	21	1	17	21
9	4	83	28	3	43	17
10	2	73	32	0	0	6
11	3	68	36	2	71	37
12	4	113	37	3	91	22
13	3	97	39	1	17	20
14	2	39	19	0	0	20

**Figure I:** Response of patients in respect to decrease in scores of domain after operation

day after operation also reported a score 6 or more. The rest of the four patients who reported more than one pad/day also reported a score of 6 or more than 6. Scores of those remaining four cases (more than 1 pad/day) were 17, 22, 33 and 37 respectively. The calculated results of pad weight were also correlated with scores (Table II).

DISCUSSION

Although the international literature describes questionnaires and specific scales for incontinent patients, adequate Turkish-language instruments

are scarce¹¹⁻¹². The SEAPI-QMM Incontinence Classification System was developed by Raz and Erickson in the early 1990s as a system that could quantify urinary incontinence and its impact without special equipment or time-consuming procedures⁶.

The Symptom and Quality of Life Assessment Committee of the international continence society performed a detailed review of the literature related to urinary incontinence in an effort to describe the impact on QOL and the methods by which this is measured in clinical practice and research. They extended these systematic reviews to 2004 with a review of the literature and provide new recommendations for the use of questionnaires developed to assess urinary and anal incontinence in clinical practice and research. They graded SEAPI-QMM as grade A^{new} (Highly recommended, which is the grade given to newly developed measures with published reports of acceptable validity, reliability and responsiveness indicated with rigor in at least 1 study)¹³.

Although the SEAPI-QMM quality of life index has been validated and used for evaluation of stress incontinence, our clinic has been using direct translation of validated English versions without

any validation study since 1998. Such an objective evaluation of impact of symptoms on QoL not only would allow proper decision making for invasive treatment modalities for treatment of SUI, but also would make monitoring the response to treatment more objective¹⁰. Therefore, suitable instruments are needed to be developed or adapted for the patient's own speaking language.

Stothers determined the reliability to further validate the SEAPI-QMM quality of life index⁸. She reported that of the 213 females, 113 underwent an anterior vaginal wall sling for stress incontinence, 13 had urgency incontinence, three had a vesicovaginal fistula, 10 had overflow incontinence, and 62 had mixed stress and urgency incontinence. She evaluated the patients before and six months after the operation. According to her results, 106 women who reported no incontinence after treatment had a median score of 1 with 1.1 standard deviation (range 0 - 5). Five women who reported less than one incontinence episode had a median score of 8 with 5.1 standard deviation (range 2-16) and two women who reported more than one incontinence episode had a median score of 18 with 7 standard deviation (range 13-23) after operation⁸.

In our study, postoperative total SEAPI-QMM quality of life index was found to be 3 or lower in 34 patients and 4 or greater in 14 patients assessed at 1 and 6 months after operation.

According to our study there were some inconsistent results between scores and pad tests. Four of 14 patients who reported no incontinence after operation also reported scores of 6, 6, 8 and 20 respectively (Table II). The detailed analyses of scores of those four patients did not show any specific accumulation in respect to domains of index. Mean scores for the rest of our 10 patients who reported one or more than one pad leakage/day after operation was 16.8 (range 6-37). Stothers also reported the same inconsistent results. In the latter study, patients who reported incontinence episodes after the operation also had a score of less than 6 (minimum 3 - maximum 30)⁸. These findings reflect that QoL is difficult to measure because it is a collection of indicators such as emotional well-being and overall satisfaction, rather than a physical entity. In addition, the reduction of incontinence does not always correlate well with patients' per-

ception of "success" in terms of health related quality of life⁸. Furthermore, cultural differences may lead to different cut off values for the same index, as shown in our study. However, it is to note that although the cut-off values reported were less than six in the study of Stothers, the additional 2% sensitivity would not affect the result in our patient population, according to statistics.

After reevaluation of 28 subjects who reported no sexual activity because of any reason, we found no statistically significant differences between sexually active and inactive patients in our study group in respect to cut-off value. Stothers also reported that men with incontinence regardless of age, reported that urinary incontinence had the greatest impact on the quality of life in the area of sexual relations, compared to women, where the greatest impact was in the social domain⁸. In our patient population, the dramatic response in respect to decrease in scores of domains after operation was seen in social interactions domain, global health and quality of life domain, and personal strains domain, respectively.

The index was filled easily within almost same time consuming period as IPSS (International Prostate Symptom Score) system. Although adding further items would be beneficial for discriminate patients and controls, it would increase the length of time to require completing the index.

CONCLUSIONS

This study showed that the Turkish translation of the SEAPI-QMM quality of life index is able to differentiate pre and post-treatment changes in frequency of incontinence episodes measured using a 3-day voiding diary and pad test. However, it is to note that there still may be some patients who report relatively high SEAPI-QMM quality of life index scores after a successful anti-incontinence procedure. Therefore, we believe that SEAPI-QMM quality of life index scoring system should be validated before using in different languages and cultures.

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