Published in : Neurourology and Urodynamics (2009)
Status: Postprint (Author's version)

The Impact of Detailed Explanatory Leaflets on Patient Satisfaction with Urodynamic Consultation: A Double-Blind Randomized Controlled Trial

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Aims: To develop and validate a scale that is applicable in Belgium to investigate the aspects of female patients' satisfaction with urodynamic consultation, and to use it to measure the impact of a detailed explanatory leaflet on their satisfaction. **Materials and Methods:** Question items were obtained from a group consensus (Delphi process). Each item was scored on a five-point Likert scale. The satisfaction scale was administered to two groups of patients attending the clinics for urodynamics. One hundred twenty-nine patients were included in the study and randomized in two groups. One group (n = 60) received a detailed explanatory leaflet about urodynamic consultation and the other did not (n = 69). Responses were subjected to a reliability and principal component analysis (PCA) to achieve data reduction and analysis, and to assess the reliability of the new scale. Relevant items were retained to compare both interventions using regression analysis. **Results:** A 15-item scale was derived from the Delphi process. Exploratory factor analysis suggested a single factor solution with 11 meaningful items. No significant difference was noted in global scores of satisfaction between the two groups ($P = 0.051$). **Conclusions:** A short-form patient satisfaction scale with acceptable validity and reliability was developed and used to measure patient satisfaction with urodynamic consultation in this population of Belgian women. This study did not provide support for the effectiveness of explanatory leaflets in improving satisfaction.

Keywords : explanatory leaflet ; satisfaction ; satisfaction scale ; urodynamics

INTRODUCTION

Urodynamic consultation can be useful for the evaluation of incontinence. However, urodynamics is an invasive medical procedure and is potentially distressing and embarrassing for the patient owing to fear of the unknown, the intimate nature of the procedure, lack of privacy, anxiety, embarrassment, and fear of pain.[1-3] This might impact on patients' satisfaction.[1] In general practice, different interventions have been suggested to alleviate negative feelings with medical consultations such as improvement of interpersonal and communication skills.[4] Introduction of Patient Information Leaflets (PIL) has been recommended to ameliorate this problem and has become a standard practice in the United Kingdom and elsewhere.[5-7]

Consumer feedback on health services is important to increase the quality of care provided. Questionnaires are commonly used to measure patient satisfaction in medical settings. However, there are very few studies in the literature on patient satisfaction following urodynamic investiga-tions,[1-3,8,9] with none from Belgium, and no questionnaire that measures satisfaction with urodynamic consultation has been reported so far. Furthermore, measurement scales are specific to the country, the discipline, and the cultural environment.[10-12] The objective of the current study was to develop and validate a scale that is applicable to our population of Belgian female patients to investigate their satisfaction with urodynamic consultation, and to measure with it the impact of a detailed explanatory leaflet.

It is commonly accepted that standard methods for the stepwise development and testing of measuring instruments (questionnaire or scale) designed to assess subjective states must be used.[13,14] Instrument development involves the generation of items (questions) that represent theoretic constructs. In general, the items are generated through groups of patients with the disease and then reviewed by clinicians and nurses who routinely manage those patients. Alternatively, a Delphi process can be used.[15] This is a group facilitation technique that is interactive and multistage, designed to transform the opinion of a group of people (patients, gynecologists, physiotherapists, and nurses in this study) into consensus. Each person is asked to rank their agreement with each item in a first round. Their answers are summarized and this results in a new version of the

questionnaire. This process is repeated in different rounds till an agreement is reached. Once items are generated, factor analysis can be used to investigate which aspects of satisfaction may be represented by the questions that are asked (i.e., factors or components) and to reduce the number of items by eliminating those which are not correlated to others. Some questions may not be relevant when tested on a real population and in that case the score of people for those questions is not correlated to their global score of satisfaction.

Then, the instrument is subjected to validity and reliability testing.[13,14,16] It must be established that the data-gathering instrument will target the characteristic it is designed to measure (patient's satisfaction), which is defined as the validity of the instrument. In addition, the instrument must measure the characteristic it is designed to measure in a consistent manner. The pattern of consistency is referred to as reliability. Once the adequacy of the instrument has been demonstrated, it can be used to measure the impact of an intervention, such as, in the current study, the use of detailed explanatory leaflets.

MATERIALS AND METHODS

Study Population

Recruitment took place from January 2007 to October 2007 at the Centre Hospitalier Regional de la Citadelle (University of Liège) in the Department of Gynaecology. The local Human Research Review Board approved the study protocol. Female patients attending for urodynamics during the study period were considered for potential study eligibility. Three designated nurses were trained as site liaisons by the research team for female patient recruitment. An information letter was distributed before the consultation, which invited patients to participate and provided them with study information. Eligible volunteers who agreed to participate gave informed consent. Patients who were unable to read the document, unwilling to spend the time requested to fill it out, or did not give their consent were excluded. We also excluded women who could not receive a full investigation for medical reasons (infection of the urinary tract, psychiatric pathology except depression and anxiety).

Study Design

This study combined a Delphi process, factor analysis, and assessment of reliability to design a questionnaire that was used in a double-blind randomized controlled trial to compare a "leaflet" intervention to a "no-leaflet" intervention. Assignment to one of the two study groups was performed by a computer-generated randomization with a block size of 4. Instructions and questionnaires were placed in opaque sealed envelopes, and patients who gave consent to participate in the study before the consultation received one envelope with their appointment. Allocation was concealed from both the investigators and the examiner. As the purpose of the study was to assess the impact of the explanatory folders, patients were not informed that they had been randomly allocated to a group "receiving leaflet" or "not receiving leaflet," and that the outcome measure was the difference in satisfaction between the two groups. This might have biased the whole study. This aspect of the protocol was also explicitly accepted by the Ethical Committee. The urodynamic consultation leaflet designed by the "Groupe d'information et d'éducation du patient" of the CHR La Citadelle (Ref:GT/ Agiep-/Gyneco-Urodynamique/Fevrier 04) was used. This leaflet was a two-page document in simple wording that explained: (1) what is urodynamic investigation; (2) what is the usefulness of urodynamics; (3) what are the different steps of urodynamic investigation (uroflowmetry, filling cystometry, static urethral pressure profilometry, and voiding cystometry) and how they are performed. Patients were also informed in that document that: (1) the investigations were about half an hour long; (2) the equipment was either sterile or single use; (3) no injection would be performed; (4) slight pain might be noted during urination in the following days; (5) rarely a urinary infection might develop and for that reason antibiotics would be prescribed at the end of the consultation.

Development and Administration of the Satisfaction Scale

Eight persons including two gynecologists, a clinical urogy-necology physiotherapist, three nurses, and two patients were asked to suggest 12 question items that assess patient satisfaction. Relevant literature and guidelines were also revised by the first author to generate potential items. [1-3,8,9] A series of questions, positively or negatively worded, were selected for the development of the scale. A Delphi process was used to gain consensus among the eight persons.[15] A draft questionnaire was subsequently submitted to two patients for pre-test and revised for wording and understanding. Emphasis was placed on using simple and unambiguous wording of items and responses.

A five-point Lickert-type scale was used for the answers to the question items.[17] These were labeled "strongly agree," "agree," "uncertain," "disagree," and "strongly disagree." One, two, three, four, and five were assigned to these responses if the questions were positively worded, and the reverse order if negatively worded. Each of the items received equal weight when summed to arrive at a global (total) score. A low global score was therefore a representative of high satisfaction, whereas a high score indicated low satisfaction. A text field allowed participants to write in additional comments. Basic demographic information including age, height, weight, and number of infants (parity) was obtained at the beginning of the consultation. The patient completed her questionnaire after the consultation and the discussion of results and treatment plan.

Data Analysis

To further understand and identify the attributes of patient satisfaction and reduce the number of items, an exploratory factor analysis was conducted. Factor analysis was carried out by principal component analysis (PCA) and parallel analysis was used to identify important underlying factors. Pattern loadings near 0.40 or greater (in absolute value) were used to interpret the results. Reliability was analyzed using Cronbach's alpha. Cronbach's alpha reliability coefficient was computed to measure internal consistency. A minimum alpha of 0.8 was considered satisfactory. The scores for the retained items were used to determine the differences in satisfaction between the two groups of patients using regression analysis. Data were collected in a Microsoft Access Database. Statistical analysis was performed using SPSS package (SPSS 12.0, Chicago, IL). Parallel analysis was run using the Monte Carlo PA software.[18]

RESULTS

The Urodynamic Consultation and Study Population

Patients seen for urodynamics in the Department of Gynaecology at the "CHR La Citadelle" between January 2007 and October 2007 were referred by gynecologists or general practitioners for further investigation of incontinence or prolapse. On the day of appointment, patients undertook a full clinical examination including history and urogenital assessment. Urodynamic investigations were carried out immediately afterwards. These included uroflowmetry, filling cystometry, static urethral pressure profilometry, and voiding cystometry. Ultrasonography was also performed in specific cases. The results were subsequently discussed with the patient and the treatment was advised and explained. No local anesthesia was used prior to urethral catheter insertion.

In the study period, there were 150 patients who visited this outpatient clinic and were referred for urodynamic investigations. The flow of participants through each stage of the randomized trial is shown in Figure 1. Table I presents the demographic characteristics of patients. Randomization succeeded in balancing the two study groups on age, weight, and parity.

Fig. 1. *The flow of participants through each stage of the trial (Consort statement[28])*

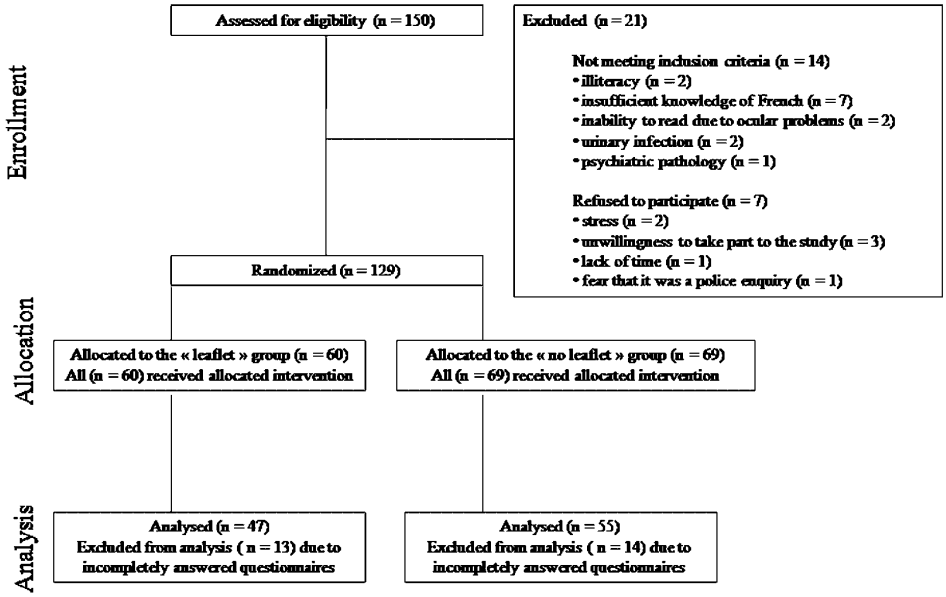

TABLE I. *Baseline Characteristics of Patients Included in This Study*

Characteristic (mean, SD)	Group 1 (n = 47)	Group 2 (n = 55)	*P*-values
Age	56.12 (13.96)	55.63 (13.28)	0.856
Weight (kg)	69.72 (13.42)	70.61 (13.47)	0.738
Height (cm)	164.82 (5.97)	157.85 (23.03)	0.046*
Parity	2.21 (1.46)	1.95 (1.31)	0.332

*Significant at $P < 0.05$.

Development and Validation of the Satisfaction Scale

A series of 19 questions were elaborated in the first phase of the development of the questionnaire. The Delphi process removed four questions. This resulted in a 15-item scale (Table II).

Inspection of the correlation matrix revealed a fairly good correlation between the items. Items Q4, Q5, and Q11 were discarded as they were minimally correlated with the rest of the data. PCA revealed three components with eigenvalues exceeding 1 with a cumulative variance of 55.3%. The components 1, 2, and 3 explained, respectively, 36.4%, 10.5%, and 8.5% of the variance. Inspection of the scree plot revealed a stark break after the first component suggesting that only the first factor should be retained (Figure 2).[16] The decision to retain a single component was also supported by the fact that only the first component was able to exceed the corresponding criterion values of a randomly generated data matrix of the same size (12 variables and 102 respondents) from parallel analysis. The 12 items had a loading near or above 0.4.

A reliability analysis was run using Cronbach's alpha. Initially alpha was 0.78 and removal of the item 012 improved it to 0.80. The analysis on the remaining 11 items was stable and all the conclusions from the initial analyses held true. Table III shows the communality and component matrix after extraction.

Fig. 2. *Scree plot showing the amount of variance accounted for by each factor.*

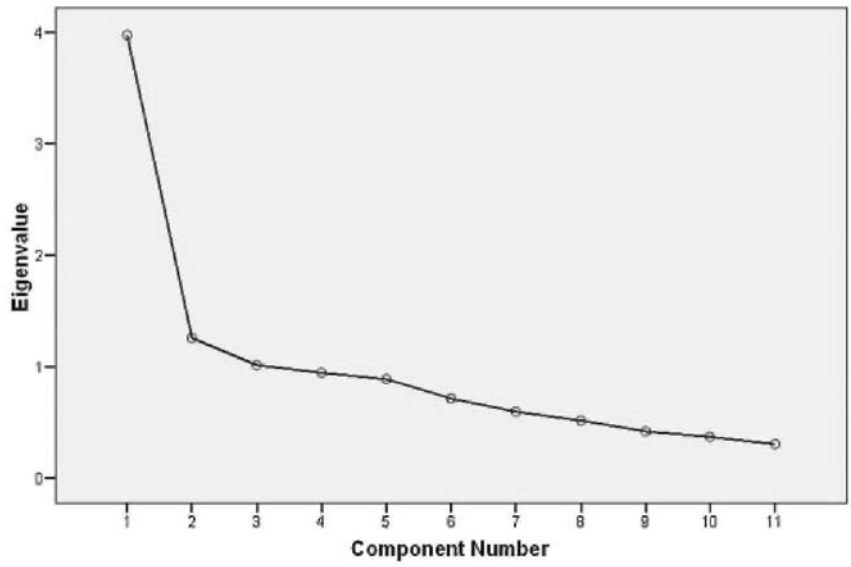

TABLE II. *Descriptive Statistics for Individual Items*

Items	Mean ± SD
Q1: The room for consultation was adequate (big enough, warm, comfortable)	1,4 (0.7)
Q2: The discussion and the taking of history before the investigations made me confident	1.2 (0.5)
Q3: I could explain my complaints clearly	1.2 (0.4)
Q4: I could urinate when asked to do so	1.8 (1.0)
Q5: I was embarrassed to make noise when I urinated in the uroflowmeter	2.8 (1.5)
Q6: I was able to demonstrate my symptoms during the test	2.0 (1.0)
Q7: I was reassured by the clinicians during the consultation	1.1 (0.3)
Q8: The explanations that were given along the consultation were clear	1.2 (0.5)
Q9: This consultation has answered to my questions and has identified my problem	1.3 (0.6)
Q10: My intimacy was respected	1.2 (0.4)
Q11: The procedure was painful	2.5 (1.4)
Q12:I am ready to undergo other investigations if I am advised to do so	1.4 (0.6)
Q13: I am reassured by hygiene measures during consultation	1.3 (0.5)
Q14: I am ready to take the treatment that has been recommended	1.3 (0.6)
Q15: I wish I'd consulted earlier	1.9 (1.0)

Items 4, 5, 11, and 12 were not retained after principal component analysis.

TABLE III. *Component Matrix and Communalities Extracted From the Final PCA Analysis of Component One*

Items	Communality	Component matrix
Q1	0.671	0.577
Q2	0.566	0.584
Q3	0.453	0.561
Q6	0.556	0.373
Q7	0.512	0.697
Q8	0.587	0.716
Q9	0.780	0.606
Q10	0.498	0.658
Q13	0.498	0.686
Q14	0.581	0.521
Q15	0.569	0.554

The communality column indicates the amount of common variance measured by a variable. Common variance is considered important since it shows that a variable (a question or item) is measuring a similar underlying concept (satisfaction) with the rest of the variables (items). The higher this value the better. A value or a loading below 0.35-0.4 is not considered optimal. Component matrices further refine the real contribution of a variable to the underlying concept. A variable with a smaller communality can have a higher component matrix if it contributes well toward measuring the underlying concept (i.e., even though it has a relatively smaller communality that is closer to 0.4 compared to the rest of the variables).

Answers to the Questionnaire

The above 11 relevant questions were retained to calculate the global score of satisfaction. The mean score of the sample was 15.15 (SD ± 3.97). This corresponds to a high level of satisfaction (the highest level of satisfaction with this scale would be 11 and the worst 55) .The results for the individual items are reported in Table II. The scores of the responses to the questions had a relatively minimal dispersion, and the mean scores had not achieved normal distribution. The regression model was significant ($P = 0.017$, $R^2 = 12.8\%$). There were no significant interactions. Comparing women who received the leaflet to those who did not, no significant difference was noted regarding the global score of satisfaction ($P = 0.051$). The global score was 14.4 (SD 3.3) for the leaflet group and 15.7 (SD 4.4) for the no-leaflet group. The parity was significantly associated with a lower satisfaction ($P = 0.004$, B 0.84) and the age did not influence satisfaction ($P = 0.23$), independently of the intervention. Age and parity did not have a significant correlation ($r = 0.15$, $P = 0.06$).

There were 33 patients who left short comments. A group of comments (n = 16) concerned compliments and thanks about the course of the investigations, the respect shown to the patient, and the explanations that were given. One patient (n = 1) who was in the "no-leaflet group" wished that she could receive explanations before instead of during the procedure. Two patients (n = 2) expressed their stress before and during urodynamics. Comments about the room were given in two cases (n = 2). Thirteen patients commented on their experience of pain. They reported that it was less painful than expected (n = 5), or they described it more as an unpleasant sensation than as real pain (n = 3), or they localized it in the lower abdomen (n = 3), or they reported a pricking sensation (n = 2).

DISCUSSION

This article reports the development of a questionnaire whose items are tailored to the consultation for urodynamics in the Department of Gynaecology at the CHR La Citadelle. The advantage of such a patient satisfaction scale is that the factor structure and reliability have been established. Qualitative methods like the Delphi method were used to evaluate content validity. The Delphi process was also a useful method for generating the items and was an interesting and easy alternative to focus groups' interviews. Concurrent validity was not assessed as no gold standard or applicable scales have been validated and published so far in the field of urodynamics. The test-retest reliability was not assessed as our Belgian patients are not used for surveys, studies, and questionnaires and are generally not willing to fill out the same scale again a few days or weeks after finishing the first one.

In this study, the factor analysis revealed one component. The decision to retain one underlying factor is fair since there is no theoretical basis on which we could base extraction of more than one factor against the statistical evidence. In the current study, four items were removed. One item (Q4) concerned the patient's ability to urinate when instructed to do so, which may appear as clinicians' concern more than patient's concern. Two other items (Q5 and Q11) referred to the embarrassment caused by the noise generated by urination in the uroflowmeter and to pain. These items may not be correlated to others because patients have learned from previous medical consultations that medical examination may be painful and embarrassing. Therefore, pain may not represent a dimension of satisfaction for patients, even if it may be a concern, as expressed in free comments left by 13 patients. Furthermore, the final scale included a limited number of items (11), which may enhance the patient response and make it easier for the patient. This is important with a population of patients not used to questionnaires after consultations. In 28 of the 121 questionnaires (23%), the last page including four questions was not answered. This was due to a missing page for six patients but in others this may be linked to weariness in filling in the answers. This also highlights the importance of factor analysis to identify unnecessary questions and reduce the number of items.

However, this study has several weaknesses. Interestingly, they reveal some of the pitfalls that should be taken into account when undertaking a study of satisfaction. First, the sample of patients included in the study may not reflect the patients who will undertake urodynamic investigations elsewhere in Belgium or the general population seen for urodynamics at the CHR La Citadelle. Seven out of 150 (7%) patients were not included in the study because of illiteracy (1.3%), insufficient knowledge of French (4.5%), and ocular problems (2.2%). In addition, reduced ability to understand or fill in the questionnaire because of lower education may also have played a role in incomplete answers to the questionnaires. To respect privacy, no enquiry was planned in the design of the study and undertaken at baseline to assess patients' socio-economic status and educational level. Qualitative research and interviews might be more appropriate to investigate satisfaction in those patients who could not answer accurately or were not included at baseline. Second, other variables that were not investigated in this study could have also influenced our results such as prior pelvic surgery, type of urinary incontinence by history, history of prior urodynamic evaluation, presence or absence of pelvic organ prolapse requiring reduction during urodynamics. We might also have strengthened our investigation by including a validated questionnaire on general quality of life (e.g., SF-36). Third, the responses had not achieved normal distribution as the satisfaction of patients was generally high; this limits the conclusion to the sample under study.

As reported by others[2,3,8,9] urodynamic investigations seemed well tolerated in this study (mean total score = 15.15). . Our data have not shown a statistically significant difference in satisfaction according to age ($P = 0.23$). However, lower satisfaction was associated with higher number of infants. It is difficult to explain that observation as we might expect that mothers used to the burden of a busy family would be easier to please. On the other hand, it is possible that parity influences the degree of incontinence and complaint, and therefore the level of expectations. Zhang et al.[19] have reported that less healthy persons have higher expectations.

This prospective randomized study showed that satisfaction with urodynamics was not significantly different in the group of women who received the leaflet compared to the group who did not receive it. Positive results have been reported about the impact of providing women with written educational material on their satisfaction with the use of health services in postpartum contraceptive decisions[20,21] and in genetic testing for breast cancer diagnosis.[22] Another study in anesthesiology, on the contrary, concluded that, when satisfaction was measured by a valid and reliable questionnaire, the introduction of leaflets did not improve patient satisfaction and that the evidence for better patient outcomes after patient education interventions was not convincing.[23] A study about colposcopy indicated that informative leaflets might increase the knowledge and so be useful in obtaining clinical consent to the procedure.[24] However, evidence-based leaflets were not effective in promoting informed choice in women using maternity services.[25] In the current study, the three patients who refused to undertake urodynamic investigations did so after reading the leaflet and one patient who did not receive a leaflet regretted the information regarding the procedure was not given before. In pediatrics, the quality of leaflets was reported to influence some outcomes, for example, understanding and reassuring the written information provided.[6] It would also be interesting to measure the impact of explanatory leaflets on postprocedure pain perception in female patients. Greenstein et al.[26] concluded that pain from urodynamics was more resented in men than in women, especially when they had experienced similar procedures before, and female patients who underwent urodynamic testing anticipated higher degrees of discomfort than they experienced during the procedure.[27] Therefore, further research should evaluate the impact of different leaflet contents about urodynamics. The mode of information delivery might also make a difference in satisfaction and other ways of delivering information should be investigated such as video or a 5-10 min presentation by the nurse.

Designing and validating a scale that is specific for the discipline and the setting are essential to analyze the effects of different interventions on patient satisfaction and to contribute to further improvement of health care. Although this experimentation does not provide support for the effectiveness of explanatory leaflets in the population under study, further research is required to determine the best methods for optimizing the effectiveness of leaflets provided before urodynamic consultations and their impact on other outcomes. Interviews might be considered to complement satisfaction enquiry when written format is not applicable.

Qualitative research should be considered to identify other dimensions of satisfaction in our Belgian women patients and improve our measurement scales.

ACKNOWLEDGMENTS

We thank Dr. Alison Peattie for her help in reviewing the manuscript. We express our thanks to Professor Michele Nisolle and Dr. Patricia Nervo for their precious help in the design of the questionnaire. We are grateful for the expertise of our nurses: Pierina Cicirello, Marie-Grace Schenato, and Patricia Ubialli. We also thank the clinical site clerks: Magal Spletincx and Barbara Deneumostier.

REFERENCES

1. Shaw C, Williams K, Assassa PR, et al. Patient satisfaction with urodynamics: A qualitative study. J Adv Nurs 2000;32:1356-63.

2. Ku JH, Kim SW, Kim HH, et al. Patient experience with a urodynamic study: A prospective study in 208 patients. J Urol 2004;171:2307-10.

3. Scarpero HM, Padmanabhan P, Xue X, et al. Patient perception of videourodynamic testing: A questionnaire based study. J Urol 2005;173: 555-9.

4. Aharony L, Strasser S. Patient satisfaction: What we know about and what we still need to explore. Med Care Rev 1993;50:49-79.

5. Capuzzo M, Gilli G, Paparella L, et al. Factors predictive of patient satisfaction with anesthesia. Anesth Analg 2007;105:435-42.

6. Paul F, Jones MC, Hendry C, et al. The quality of written information for parents regarding the management of a febrile convulsion: A randomized controlled trial. J Clin Nurs 2007;16:2308-22.

7. Shrestha BM. Patient information leaflets in surgical practice: A contemporary review J Nepal Med Assoc 2007;46:84-9.

8. Gorton E, Stanton S. Women's attitudes to urodynamics: A questionnaire survey. Br J Obstet Gynaecol 1999;106:851-6.

9. Oh SJ, Son H, Jeong JY, et al. Patients' experience with ambulatory urodynamics. A prospective study. Scand J Urol Nephrol 2006;40:391-6.

10. Zaghloul AA. Validation of a patient satisfaction scale for primary care settings. J Egypt Public Health Assoc 2001;76:411-29.

11. Meakin R, Weinman J. The 'Medical Interview Satisfaction Scale' (MISS-21) adapted for British general practice. Fam Pract 2002;19:257-63.

12. Takemura Y, Liv J, Atsumi R, et al. Development of a questionnaire to evaluate patient satisfaction with medical encounters. Tohoku J Exp Med 2006;210:373-81.

13. McDowell I, Newell C. Pain measurements. In: Measuring health: A guide to rating scales and questionnaires, 2nd edn. New York: Oxford University Press; 1996. pp. 470-519.

14. Streiner DL, Norman GR. Health measurement scales, 3rd edn. Oxford: Oxford University Press; 2007. pp. 15-161.

15. Jones J, Hunter D. Consensus methods for medical and services research. Br Med J 1995;311:376-80.

16. Cattell RB. A guide to statistical techniques. In: The scientific use of factor analysis in behavioral and life sciences. Caltell (Ed). New York: Plenum Press; 1978. pp. 17-32.

17. Lickert R. A technique for the measurement of attitudes. Arch Psychol 1932;140:44-53.

18. Watkins MW. Monte Carlo parallel analysis (PA). 2008. http://www. personal.psu.edu/mwwlO/Watkins3.html. Accessed January 9, 2008.

19. Zhang Y, Rohrer J, Borders T, et al. Patient satisfaction, self-rated health status, and health confidence: An assessment of the utility of

single-item questions. Am J Med Qual 2007;22:42-9.

20. Johnson LK, Edelman A, Jensen J. Patient satisfaction and the impact of written material about postpartum contraceptive decisions. Am J Obstet Gynecol 2003;188:1202-4.

21. Kabakian-Khasholian T, Campbell OM. Impact of written information on women's use of postpartum services: A randomised controlled trial. Acta Obstet Gynecol Scand 2007;86:793-8.

22. Mancini J, Noguès C, Adenis C, et al. Impact of an information booklet on satisfaction and decision-making about BRCA genetic testing. Eur J Cancer 2006;42:871-81.

23. Lee A, Gin T. Educating patients about anaesthesia: Effect of various modes on patients' knowledge, anxiety and satisfaction. Curr Opin Anaesthesiol 2005;18:205-8.

24. Galaal KA, Deane K, Sangal S, et al. Interventions for reducing anxiety in women undergoing colposcopy. Cochrane Database Syst Rev 2007;18: CD006013.

25. O'Cathain A, Walters SJ, Nicholl JP, et al. Use of evidence based leaflets to promote informed choice in maternity care: Randomised controlled trial in everyday practice. Br Med J 2002; 16; 324:643.

26. Greenstein A, Bar-Yosef Y, Chen J, et al. Does information provided to men before a urodynamic study affect their expectation of pain? BJU Int 2005; 96:1307-9.

27. Ellerkmann RM, McBride AW, Dunn JS, et al. A comparison of anticipatory and postprocedure pain perception in patients who undergo urodynamic procedures. Am J Obstet Gynecol 2004;190:1034-8.

28. Rennie D. How to report randomized controlled trials. The CONSORT statement. J Am Med Assoc 1996;276:649.