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Psychometric Evaluation of a New Questionnaire Measuring Treatment Satisfaction in Hypothyroidism: The ThyTSQ

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ABSTRACT

Objectives: There is a clinical impression of dissatisfaction with treatment for hypothyroidism among some patients. Psychometric properties of the new ThyTSQ questionnaire are evaluated. The questionnaire, measuring patients' satisfaction with their treatment for hypothyroidism, has two parts: the seven-item ThyTSQ-Present and four-item ThyTSQ-Past, measuring satisfaction with present and past treatment, respectively, on scales from 6 (very satisfied) to 0 (very dissatisfied).

Methods: The questionnaire was completed once by 103 adults with hypothyroidism, age (mean [SD]) 55.2 [14.4], range 23–84 years (all treated with thyroxine).

Results: Completion rates were very high. Internal consistency reliability was excellent for both ThyTSQ-Present and ThyTSQ-Past (Cronbach's alpha = 0.91 and 0.90, respectively [N = 102 and 103]). Principal components analyses indicated that the seven items of the ThyTSQ-Present and the

four items of the ThyTSQ-Past could be summed into separate Present Satisfaction and Past Satisfaction total scores. Mean Present Satisfaction was 32.5 (7.8), maximum range 0–42, and mean Past Satisfaction was 17.5 (6.1), maximum range 0–24, indicating considerable room for improvement. Patients were least satisfied with their present understanding of their condition, mean 4.2 (1.7) (maximum range 0–6), and with information provided about hypothyroidism around the time of diagnosis, mean 3.9 (1.8) (maximum range 0–6). Conclusions: The ThyTSQ is highly acceptable to patients with hypothyroidism (excellent completion rates), and has established internal consistency reliability. It will assist health professionals in considering psychological outcomes when treating people with hypothyroidism, and is suitable for clinical trials and routine clinical monitoring.

Keywords: hypothyroidism, questionnaire, thyroxine, treatment satisfaction, validation.

Introduction

Hypothyroidism is a common chronic endocrine disorder [1,2] with physical symptoms associated with slowing of the metabolism, such as weight gain or cold intolerance, and also psychological symptoms, including reduced cognitive functioning [3]. The standard treatment is thyroxine (T4) replacement therapy which is converted to the more metabolically active triiodothyronine (T3) in the peripheral tissues [4]. This treatment returns patients to a biochemical euthyroid state, with normal levels of thyroid stimulating hormone (TSH) concentration and serum Free T4 (FT4). Nevertheless, some patients continue to report persistent symptoms despite their TSH and FT4 levels being within the reference ranges indicating that their T4 replacement is adequate [5]. For example, one study found that the number of individuals with significant

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impairment in psychological well-being was 21% higher in thyroxine-treated patients than euthyroid controls of similar age and sex, even though patients' TSH levels were within the normal laboratory reference range [6]. Some patients report increased well-being only with slightly elevated FT4 and low or undetectable TSH [7]. There is much controversy about the interpretation of TSH levels and appropriate T4 dosage to alleviate persistent symptoms but avoiding possible long-term effects of excessive T4 replacement (osteoporosis and heart disease) [8], and whether to treat those with subclinical hypothyroidism or not [9,10] or add T3 to the standard T4 therapy [11].

Patients may express their dissatisfaction with treatment in patients' newsletters (e.g., British Thyroid Foundation) and there are anecdotal reports from clinicians of continuing dissatisfaction in some of their patients [12]. Poor adherence to treatment by patients is not uncommon [13], perhaps reflecting dissatisfaction with the treatment. Walsh defined dissatisfaction with thyroxine therapy as "persistence or recurrence of symptoms of hypothyroidism despite apparently adequate thyroxine replacement" and remarked that

its prevalence among thyroxine-treated patients was not known and that further research in this "neglected area" should be encouraged [12]. A questionnaire measuring patients' satisfaction with treatment for hypothyroidism has been designed recently: the Underactive Thyroid Treatment Satisfaction Questionnaire (ThyTSQ) [14], the first known measure of its kind for patients with hypothyroidism. During the qualitative design stage of the ThyTSQ design work, semistructured interviews were conducted with 38 patients, interviews in which patients talked about their experiences of treatment and completed and commented on the draft questionnaire. Possible changes were discussed and new or modified items piloted with subsequent patients. Weak draft items were eliminated at this stage and checks made that instructions and questions were understood and responded to easily. Although the aim was to design a measure of patients' satisfaction with their current treatment for hypothyroidism, half the patients in the early interviews (10/20) spontaneously reported negative experiences of treatment around the time of diagnosis. These negative experiences related to delays in diagnosis, and/or in prescribing thyroxine treatment, and/or lack of information provided about the condition or the treatment. Even though patients' experience of current treatment might be positive, in some cases these past negative experiences interfered with completion of questions about current treatment, because patients wanted to express their dissatisfaction with earlier treatment/perceived mistreatment. A separate section was therefore drawn up, after half the interviews had been conducted, with questions covering satisfaction with past treatment around the time of diagnosis, the ThyTSQ-Past. It is an extension of the main questionnaire, the ThyTSQ-Present, which measures satisfaction with current treatment. The design of the ThyTSQ is based on the widely used Diabetes Treatment Satisfaction Questionnaire (DTSQ) [15-17] and related questionnaires for people with renal disease (RTSQ) [18], Human Immunodeficiency Virus (HIVTSQ) [19], and diabetic retinopathy (RetTSQ) [20], but hypothyroidism is the first disorder for which it has been found necessary, at the design stage, to produce a separate section on past satisfaction with early treatment around the time of diagnosis.

The psychometric properties of the ThyTSQ (factor structure, and aspects of reliability and validity) need to be evaluated so that the new measure may be used to identify patients dissatisfied with their current treatment regimen and in clinical trials of any new treatments or treatment combinations in the future. This was undertaken in a cross-sectional survey of patients in Gateshead, UK. The Gateshead Local Research Ethics Committee gave approval for the study and patients provided their informed consent.

Methods

The ThyTSQ

The ThyTSQ-Present has seven items including questions about satisfaction with current treatment, and control of symptoms of underactive thyroid (Table 1). Instructions ask patients to consider their experience of treatment for underactive thyroid over the previous few weeks. Patients respond to each item by circling a number on a scale from 6 to 0 (where 3 is considered a neutral option), indicating their degree of satisfaction with that aspect of treatment, for example, from very satisfied to very dissatisfied, as in the following example (item 1 of the ThyTSQ-Present):

How satisfied are you with the current treatment for your underactive thyroid?

very satisfied 6 5 4 3 2 1 0 very dissatisfied

The ThyTSQ-Past has four items concerning satisfaction with the way doctors dealt with the patient or the thyroid condition around the time of diagnosis, and satisfaction with information provided about the condition and its treatment (Table 1). Instructions inform respondents that the items are concerned with their early experiences both before and after they were told they had underactive thyroid. At the end of each part there is a "free comments" section in which respondents are asked if there are any other features of their treatment (i.e., recent treatment [ThyTSQ-Present], or early treatment [ThyTSQ-Past]) causing either satisfaction or dissatisfaction, that have not been covered by the questionnaire. These open sections allow for the addition of further domains to the questionnaire in the future, if necessary, for its continuing development.

Recruitment

Study participants were recruited from the Diabetes and Endocrinology Clinic at the Queen Elizabeth Hospital Gateshead, UK and three local Primary Care Practices. Inclusion criteria: age 18+ years (no upper limit); a diagnosis of hypothyroidism on the basis of two blood tests taken at least three months apart, that is, no patient had transient hypothyroidism. People with mental health problems that would render them incapable of understanding and completing the questionnaire were excluded from the study.

Statistical Analyses

Normality of distributions was determined through investigation of histograms and z (skew) scores, where z (skew) scores within ± 2.58 are indicative of normality [21]. Cronbach's alpha coefficient of internal consistency reliability was determined [22]. An alpha of 0.8 was taken as the minimum acceptable [23], but 0.9 was preferable because it is considered by some to be

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Table I ThyTSQ items and their response options, with item means

No.	Abbreviation	ThyTSQ-Present item wording	Response options	Mean (SD)	Median	Ν
I	Present satisfaction	How satisfied are you with the current treatment for your underactive thyroid?	Very satisfied-very dissatisfied	4.89 (1.27)	5	103
2	How well working	How well do you feel the treatment is working?	Very well-very badly	4.22 (1.47)	4	102
3	Convenient	How convenient have you found your treatment to be recently (e.g., remembering to take the medication, getting prescriptions)?	Very convenient-very inconvenient	5.24 (1.18)	6	103
4	Understanding of condition	How satisfied are you with your understanding of your underactive thyroid?	Very satisfied-very dissatisfied	4.19 (1.73)	5	103
5	Encourage	Would you encourage someone else with underactive thyroid to have your kind of treatment?	Yes, I would definitely encourage them-no, I would definitely not encourage them	5.10 (1.26)	6	103
6	Controlling symptoms	How well do you feel that the treatment is controlling symptoms of underactive thyroid?	Very well-very badly	4.36 (1.27)	4	103
7	Continue	How satisfied would you be to continue with your present treatment and dose? ThyTSQ-Past item wording	Very satisfied-very dissatisfied	4.52 (1.43)	5	103
		How satisfied were you				
I	Past satisfaction	with the way doctors dealt with your underactive thyroid around the time it was first diagnosed?	Very satisfied-very dissatisfied	4.72 (1.68)	5	103
2	Information- condition	with the information provided by doctors about underactive thyroid?	Very satisfied-very dissatisfied	3.94 (1.80)	4	103
3	Information- treatment	with the information provided by doctors about the treatment for underactive thyroid?	Very satisfied-very dissatisfied	4.20 (1.72)	4	103
4	Taken seriously	that doctors took you and your underactive thyroid seriously?	Very satisfied-very dissatisfied	4.59 (1.78)	5	103

ThyTSQ-Present © Prof Clare Bradley: 22.7.03.

ThyTSQ-Past © Prof Clare Bradley: 22.7.03.

The ThyTSQ scores range from 6 (very satisfied) to 0 (very dissatisfied).

For access to questionnaire see ThyTSQ Copyright section.

the minimum for making decisions about individuals [24]. Acceptable item–total correlations were those ≥0.2 [25]. Factor structure was explored using principal components analysis. Salient loadings were taken as ≥0.4. This is higher than the recommended minimum 0.3 [26], erring on the side of caution in an effort to reduce the risk of spurious loadings that owed their origin to any non-normality of item distributions, and also to avoid double loadings. A minimum of five respondents per questionnaire item is required for factor analysis [27], and the obtained sample size (103) was more than sufficient to factor analyze the two parts of the ThyTSQ (containing seven and four items separately or 11 combined together) [26].

Exploratory correlations were undertaken between ThyTSQ variables and age, and with biomedical variables: body mass index (BMI), duration of hypothyroidism, and the most recent available TSH measurement obtained from biochemical thyroid function tests. Insufficient data were obtained on FT4 measurements (see Results) and these were not included in correlational analysis. Correlations were investigated using Pearson's r for normally distributed, and Spearman's rho for skewed data. Subgroup analyses explored differences in sex, and cause of hypothyroidism (autoimmune vs. iatrogenic), using t-test or Mann-Whitney test for normally distributed and skewed data, respectively, and differences in TSH level (within the reference range, above or below this range) using Univariate Analysis of Variance (ANOVA).

Because this was an exploratory study, the Bonferroni correction for "familywise" error in multiple tests was not performed. Means are reported as mean (SD). Two-tailed significance applied. Analyses were conducted using SPSS for Windows Version 9 (SPSS Inc, Chicago, IL, U.S.A.).

Results

Recruitment

Of the 130 patients invited to complete the ThyTSQ, 103 accepted and returned completed questionnaires (an acceptance rate of 79%): Queen Elizabeth Hospital (40 patients), and three local primary care practices (A, B, and C) (providing 9, 6, and 48 patients, respectively). There were four methods of recruitment: faceto-face (20%), letter (48%), telephone (1%), and combined letter plus telephone (31%).

Questionnaire Completion Rates

Completion rates for the ThyTSQ were >99.8% whether at the hospital, where health-care professionals prompted respondents to complete any missed items on the questionnaires, or at the three primary care clinics (where patients were not prompted to complete missing data). The Flesch Reading Ease statistic [28] was calculated to be 54.1 (ThyTSQ-Present) and 57.2 (ThyTSQ-Past). These are slightly less than the optimal 60–70 (in a possible score range of 0–100, where a higher score indicates greater reading ease).

Table 2 Characteristics of ThyTSQ respondents (N = 103)

	Mean (SD) [range]	N
Mean age (years)	55.2 (14.4) [23–84]	103
Mean duration of hypothyroidism (years)	8.7 (9.1) [0.25–57]	96
Age at leaving full-time education (years)	16.2 (2.5) [14–27]	87
BMI (kg/m²)	28.6 (6.2) [18–48.8]	92
TSH (mU/L)	3.8 (5.2) [0.02–28.7]	88
FT4 (pmol/L)	18.0 (4.4) [8.9–28.4]	43
Ratio women to men		85:18
Ratio white to nonwhite		102:1
Hypothyroidism		
Autoimmune		87
Secondary to treatment for thyroid cancer or hyperthyroidism		9
Secondary to lithium treatment		1
Secondary to amiodarone treatment		2
Subclinical (autoimmune)*		4

Comorbid conditions occurring in two or more patients: ischemic heart disease (9), osteoarthritis (9), Type 2 diabetes (8), asthma (7), Type 1 diabetes (6), rheumatic disorder (6), cancer (4), pregnancy (4), Addison's disease (3), depression (3), pernicious anemia (3), celiac disease (2).

*Subclinical hypothyroidism defined as: TSH level >4 mU/L and FT4 level in normal range (9–25 pmol/L) [33].

BMI, body mass index; FT4, free thyroxine; TSH, thyroid stimulating hormone

The Flesch statistic takes into account the average number of syllables per word and words such as "underactive" and "dissatisfied," having four syllables, detract from the score although are not found to be difficult words. The high completion rates, however, indicated that the questionnaire was readily understood by this sample of respondents.

The Study Sample Characteristics

The average age of the sample was 55.2 (SD 14.4) years, with a mean duration of hypothyroidism of 8.7 (9.1) years. The great majority of patients had autoimmune hypothyroidism (88%) of whom four patients had subclinical hypothyroidism. All patients were receiving thyroxine replacement. The ratio of women to men was 85:18, similar to the sex ratio of thyroid disease found in the general US population in a recent study [2]. Recent measurements of TSH levels were available for 88 patients but, in the case of FT4 levels, only 43 patients (42%) as FT4 levels are only measured if the TSH levels are outside the reference range. See Table 2 for full details of the sample characteristics. Details are available for 18 of the 27 people who did not respond to the invitation to complete the questionnaire. They were all white women, with a mean age of 53.4 (11.5) years (not significantly different from the age of the participants, P = 0.63).

Analyses, using methods adopted elsewhere [29], showed that there were no systematic differences in the data from the four recruitment sources, and that these data could be treated as one for the purposes of reliability and factor analysis, where larger N is desirable (full results not reported).

Reliability and Factor Analyses

The seven-item ThyTSQ-Present had very high internal consistency reliability (Cronbach's alpha = 0.907,

standardized item alpha = 0.914 [N = 102]). All corrected item–total correlations were satisfactory, the lowest being 0.504 (item 4: *understanding of condition*), which was also the only item to increase overall scale alpha if deleted (alpha if item deleted was 0.925) and therefore detract slightly from the scale reliability while broadening the content. The four-item ThyTSQ-Past had high internal consistency reliability (Cronbach's alpha = 0.896, standardized item alpha = 0.896 [N = 103]). All corrected item–total correlations were satisfactory, the lowest being 0.692 (item 1: *past satisfaction*). No item detracted from the ThyTSQ-Past scale alpha.

An unforced principal components analysis, conducted on the 11 items (transformed to near normality), of the two questionnaires combined, produced two clean factors: Component 1 had all ThyTSO-Present items loading >0.65; Component 2 had all four ThyTSQ-Past items loading >0.82 (Table 3). Separate unforced principal components analyses of both ThyTSQ-Present and ThyTSQ-Past variables produced single components with an eigenvalue >1, accounting for 63.8% (ThyTSQ-Present) and 77.2% (ThyTSQ-Past) of the variance (Table 3). This indicated that all seven ThyTSQ-Present items could be summed into a ThyTSQ-Present Satisfaction score (range 0-42) and all four ThyTSQ-Past items could be summed into a separate ThyTSQ-Past Satisfaction score (range 0–24). A lower score indicates greater dissatisfaction with treatment, and a higher score indicates greater satisfaction with treatment. We do not recommend summing the Present and Past Satisfaction scores into an overall Treatment Satisfaction score for the two sections combined. The correlation between the Past and Present Satisfaction scores was rho = 0.649, P < 0.001, N = 102, an indication that the two scales are not measuring the same construct, as a correlation < 0.7

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Table 3 Unforced factor loadings of the ThyTSQ-Present and ThyTSQ-Past

	$\frac{\text{Separate analyses*}}{\text{Component}}$	Combined analyses [†]	
ThyTSQ-Present		Component I	Component 2
1: present satisfaction	0.822	0.823	0.019
2: how well working	0.871	0.866	-0.093
3: convenient	0.653	0.656	0.049
4: understanding of condition	0.661	0.655	-0.131
5: encourage	0.813	0.815	-0.014
6: controlling symptoms	0.874	0.868	-0.139
7: continue	0.863	0.867	0.043
ThyTSQ-Past			
1: past satisfaction	0.822	-0.028	0.824
2: information—condition	0.914	-0.107	0.908
3: information—treatment	0.914	-0.055	0.908
4: taken seriously	0.861	0.032	0.858

^{*}Principal components analyses with Varimax rotation conducted on each section (Past and Present) separately and †on the 11 items of the Past and Present sections combined. Satisfactory loadings (≥0.4).

falls short of the convention indicating adequate convergence of scales [30]. Further reliability analyses were conducted using a method reported previously [31] that showed calculation of overall ThyTSQ-Present Satisfaction score was reliable at alpha = 0.9 with no items of missing data and reliable at alpha = 0.8 with up to two items of missing data, and ThyTSQ-Past Satisfaction score was reliable at alpha = 0.8 with no more than one item of missing data.

Descriptive Statistics

Non-normality (negative skew toward high satisfaction with treatment) was found in most ThyTSQ items and was dealt with successfully by conducting reflect and log transformations, leaving two items with a small degree of non-normality (z [skew] = 4.2). ThyTSQ-Present item means (Fig. 1, Table 1) indicate that overall patients were satisfied with all aspects of

their treatment. Patients were most satisfied with convenience of treatment (item 3, mean 5.24), and least satisfied with their understanding of their condition (item 4, mean 4.19). Mean Present Satisfaction was 32.5 (7.8) (maximum possible range 0-42). Of the six patients (5.9%) who had Present Satisfaction scores of <21 (expressing dissatisfaction with current treatment) five had available TSH measurements: mean 1.64, range 0.12-3.53, that is, were being treated so that their TSH levels were within the laboratory reference range of 0.4-4.0 mU/L. Patients were more satisfied than dissatisfied with all four aspects measured by the ThyTSQ-Past (Fig. 1, Table 1), but had least satisfaction with information provided about the condition or its treatment at time of diagnosis. Mean Past Satisfaction was 17.5 (6.1) (maximum possible range 0-24). Nineteen patients (18.4%) had Past Satisfaction scores <12 indicating overall dissatisfaction with past treatment.

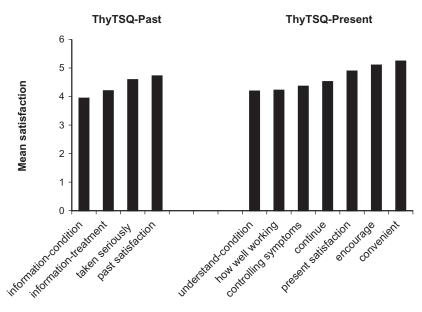


Figure I ThyTSQ item mean satisfaction ratings.

Correlations

ThyTSQ-Present item 7: continue correlated negatively with BMI (rho = -0.23, P = 0.03, N = 92), 3: convenient correlated with TSH levels (rho = -0.22, P = 0.04, N = 88) indicating that those with high BMI were more dissatisfied to continue their present treatment, and those with high TSH levels were more dissatisfied with convenience of treatment. Variables 1: present satisfaction, 2: how well working, 6: controlling symptoms and 7: continue all correlated positively with age (rho values ranged from 0.32 to 0.40, $P \le 0.001$, N ranging 102–103). ThyTSQ-Past items 1: past satisfaction and 2: information—condition also correlated with age (rho = 0.23 and 0.21, respectively, P < 0.05) indicating improved satisfaction with increasing age. There were no significant correlations between the Satisfaction scores and the number of comorbid conditions that patients had or duration of hypothyroidism.

Subgroup Differences in ThyTSQ Variables

The only significant subgroup difference found was a sex difference: women had higher satisfaction with the control of their hypothyroid symptoms, median 5, compared with men, median 4 (U = 528.5, P = 0.034). There were no significant differences in ThyTSQ-Present or Past Satisfaction scores, between respondents whose TSH levels were within the reference range of 0.4-4.0 mU/L (N = 46), and those below (N = 12), and above this range (N = 29) (P = 0.092), nor between those who had autoimmune hypothyroidism (N = 91) and those with hypothyroidism caused by treatment (N = 12).

Free Comments Sections

The free comments sections were used by 12 patients (ThyTSQ-Present) and 19 patients (ThyTSQ-Past), all of whom expressed dissatisfaction with treatment. Comments were carefully considered, but analysis showed that these areas of dissatisfaction were either already covered in the questionnaires or insufficient numbers of patients (≤ 2) mentioned them to justify the addition of new items. Comments (one respondent in each case) on the ThyTSO-Present included: problems with forgetting to take daily medication (covered by item 3: convenient, which specifically mentions remembering to take the medication), concerns about treatment dose (lack of stable dose, incorrect dose), desire for alternative therapies, including more holistic approaches (all could be covered by 1: present satisfaction and/or 7: continue). Nine patients (8.7%) reported dissatisfaction about aspects of the way doctors had dealt with their underactive thyroid around the time it was first diagnosed, including the time taken to diagnose their thyroid problem or prescribe treatment (six patients), especially if they were "borderline" between overt and subclinical hypothyroidism

(covered by 1: past satisfaction). Other comments (one respondent in each case) on the ThyTSQ-Past included: aspects of patients' understanding of their condition or its treatment, for example, the length of time to reach a satisfactory dosage (covered by 2: information—condition and 3: information—treatment); or being told that their symptoms were "in the mind" (covered by 4: taken seriously).

Discussion

We report the psychometric evaluation of the recently designed ThyTSQ measure of patient satisfaction with treatment for hypothyroidism. The ThyTSQ-Present measures satisfaction with present treatment and the ThyTSQ-Past measures satisfaction with treatment around the time of diagnosis, but past treatment in the broader sense of the term, to include medical care and interactions with health-care professionals. Use of the ThyTSQ-Past is recommended to avoid any negative experiences of past treatment interfering with completion of questions about current treatment, although if it were used in a clinical trial it might only be completed once, at baseline (in the present study they were used together). Use of the ThyTSQ-Present alone without the ThyTSQ-Past would need further psychometric evaluation. The measure is short and quick to complete, with minimal respondent burden, and the very high completion rates indicated good acceptability to respondents. The factor structure was clear. When the 11 items of both sections were combined in one unforced factor analysis, two clean factors emerged, with Past and Present items loading on separate factors. Unforced analyses performed on each separate section produced one factor each, with very high factor loadings, which lent support for summing the individual item scores into Present and Past Satisfaction scores. The internal consistency reliability of each section was also excellent. The moderate correlation between the total scores of the two parts is an indication that they are measuring different but related constructs.

When the free comments were analyzed, they showed that the areas of dissatisfaction mentioned were, for the most part, already covered by the items of the questionnaire, suggesting that respondents were emphasizing or explaining dissatisfaction already reflected in existing items. Insufficient numbers of patients specified particular issues to justify the addition of new items, hence the measure would appear to have good content validity; however, the measure is still at a relatively early stage of development, and new items may be added in the future when more data become available. Construct validity was not assessed in this exploratory study because no prior hypotheses were formulated. The only significant subgroup difference found was that women had higher satisfaction

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than men with the control of their hypothyroid symptoms. Satisfaction improved with increasing age for both Past and Present scores, perhaps because people expect to have more health problems as they grow older and, with lower expectations of treatment, are more likely to be satisfied with treatment.

Generally high satisfaction rates were found, but a small proportion of patients were dissatisfied, giving support to anecdotal reports from clinicians. More patients expressed dissatisfaction with their present understanding of the condition and with information provided about the condition in the past than any other item on the ThyTSQ-Present and Past, respectively. Although dissatisfaction with thyroxine therapy has been defined in relation to persistence of symptoms [12], it is clear, not only from interviews conducted when developing this questionnaire [14] but also from the analyses presented here, that symptoms are not the only aspect causing dissatisfaction. This study has found support for having the section on satisfaction with past treatment, and some patients clearly welcomed the opportunity to report their dissatisfaction as evidenced by the larger number of patients using the free comments section of the ThyTSQ-Past than the ThyTSQ-Present.

This study has shown that more consideration needs to be given to the interaction between patient and doctor at the time of diagnosis. More consultation time may be required at the point when a patient is first told that they have a condition that requires life-long treatment. Patients may be too distressed, at the time they are first told they have hypothyroidism, to absorb much of the information they are given, especially as cognitive functioning of people with untreated hypothyroidism is reduced in some cases [32]. They may welcome information leaflets that they can take home and study in their own time. Although the daily tablet regimen in itself is not complicated, some patients may not understand why their dosage must be increased slowly until equilibrium is reached between hypo and hyperthyroidism. Others may be despondent if treatment does not return them to their previous state before onset, and not fully adhere to the tablet treatment regimen. Thus, it is possible that increased adherence to treatment would result if patients understood their treatment better. Use of the ThyTSQ questionnaire will pinpoint lack of understanding in individual patients, who can then receive more help from health-care professionals.

Although further studies will be needed in the future to assess test–retest reliability, sensitivity to change (ThyTSQ-Present only), and construct validity, the questionnaire is now ready to be used in clinical trials of treatments for hypothyroidism. It can be used also with individual patients, completed questionnaires forming the basis for discussion between patients and health-care professionals.

Conclusions

The ThyTSQ is a new self-completion measure of satisfaction with treatment in hypothyroidism with sections measuring present satisfaction with treatment, and past satisfaction with treatment around the time of diagnosis. The questionnaire is performing well: it has good acceptability to respondents, and excellent internal consistency reliability. A Satisfaction score is calculated for each section, ThyTSQ-Present and ThyTSQ-Past, or individual items can be analyzed separately if required. The ThyTSQ appears to be a valuable tool for use in clinical trials or to use in routine care of individual patients. Its test–retest reliability and sensitivity to change now need to be evaluated in clinical trials.

ThyTSQ Copyright

For access to and license to use the ThyTSQ, contact the copyright holder, Clare Bradley PhD, Professor of Health Psychology, Health Psychology Research, Royal Holloway, University of London, Egham, Surrey, TW20 0EX. Website: http://www.hpr-international.com

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References

- 1 Tunbridge WM, Evered DC, Hall R, et al. The spectrum of thyroid disease in the community: the Whickham Survey. Clin Endocrinol (Oxf) 1977;7:481–93.
- 2 Hollowell JG, Staehling NW, Flanders WD, et al. Serum TSH, T (4), and thyroid antibodies in the United States population (1988 to 1994): National Health and Nutrition Examination Survey (NHANES III). J Clin Endocrinol Metab 2002;87:489–99.
- 3 Wiersinga WM. Adult Hypothyroidism. In: Thyroid Disease Manager, 2002. Available from: http://www.thyroidmanager.org. [Accessed November 5, 2005].
- 4 Hendrick V, Altshuler L, Whybrow P. Psychoneuroendocrinology of mood disorders. The hypothalamic-pituitary-thyroid axis. Psychiatr Clin North Am 1998;21:277–92.
- 5 Kaplan MM, Sarne DH, Schneider AB. In search of the impossible dream? Thyroid hormone replacement therapy that treats all symptoms in all hypothyroid patients. J Clin Endocrinol Metab 2003;88:4540–42.

- 6 Saravanan P, Chau WF, Roberts N, et al. Psychological well-being in patients on 'adequate' doses of 1-thyroxine: results of a large, controlled community-based questionnaire study. Clin Endocrinol (Oxf) 2002;57:577–85.
- 7 Toft AD, Beckett GJ. Thyroid function tests and hypothyroidism. Br Med J 2003;326:295–6.
- 8 Walsh JP, Shiels L, Lim EM, et al. Combined thyroxine/liothyronine treatment does not improve well-being, quality of life, or cognitive function compared to thyroxine alone: a randomized controlled trial in patients with primary hypothyroidism. J Clin Endocrinol Metab 2003;88:4543–50.
- 9 Owen PJ, Lazarus JH. Subclinical hypothyroidism: the case for treatment. Trends Endocrinol Metab 2003;14:257–61.
- 10 Vanderpump M. Subclinical hypothyroidism: the case against treatment. Trends Endocrinol Metab 2003; 14:262–6.
- 11 Cooper DS. Combined T4 and T3 therapy—back to the drawing board. JAMA 2003;290:3002–4.
- 12 Walsh JP. Dissatisfaction with thyroxine therapy—could the patients be right? Curr Opin Pharmacol 2002;2:717–22.
- 13 Ladenson PW. Psychological wellbeing in patients. Clin Endocrinol (Oxf) 2002;57:575–6.
- 14 McMillan CV, Bradley C, Woodcock A, et al. Design of new questionnaires to measure quality of life and treatment satisfaction in hypothyroidism. Thyroid 2004;14:916–25.
- 15 Bradley C, Lewis KS. Measures of psychological wellbeing and treatment satisfaction developed from the responses of people with tablet-treated diabetes. Diabet Med 1990;7:445–51.
- 16 Bradley C. The Diabetes Treatment Satisfaction Questionnaire: (DTSQ). In: Bradley C, ed., Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice. Chur: Harwood Academic Publishers, 1994; 111–32.
- 17 Howorka K, Pumprla J, Schlusche C, et al. Dealing with ceiling baseline treatment satisfaction level in patients with diabetes under flexible, functional insulin treatment: assessment of improvements in treatment satisfaction with a new insulin analogue. Qual Life Res 2001;9:915–30.
- 18 Barendse SM, Speight J, Bradley C. The Renal Treatment Satisfaction Questionnaire (RTSQ): a measure

- of satisfaction with treatment for chronic kidney failure. Am J Kidney Dis 2005;45:572–9.
- 19 Woodcock A, Bradley C. Validation of the HIV Treatment Satisfaction Questionnaire. Qual Life Res 2001;10:517–31.
- 20 Woodcock A, Bradley C, Plowright R, et al. Patient experiences of treatment for diabetic retinopathy: development of a retinopathy-specific treatment satisfaction questionnaire. Diabet Med 2003;19(Suppl. 2):S10.
- 21 Tabachnik BG, Fidell LS. Using Multivariate Statistics. New York: Harper & Row, 1983.
- 22 Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika 1951;16:297–334.
- 23 Todd C, Bradley C. Evaluating the design and development of psychological scales. In: Bradley C, ed., Handbook of Psychology and Diabetes: A Guide to Psychological Measurement in Diabetes Research and Practice. Chur: Harwood Academic Publishers, 1994.
- 24 Nunnally JC, Bernstein IH. Psychometric Theory. New York: McGraw-Hill, Inc., 1994.
- 25 Kline P. A Handbook of Test Construction. London: Routledge, 1993.
- 26 Kline P. An Easy Guide to Factor Analysis. London: Routledge, 1994.
- 27 Tabachnik BG, Fidell LS. Using Multivariate Statistics (2nd ed.). New York: HarperCollins, 1989.
- 28 Flesch RF. A new readability yardstick. J Appl Psychol 1948;32:221–33.
- 29 Bradley C, Todd C, Gorton T, et al. The development of an individualized questionnaire measure of perceived impact of diabetes on quality of life: the ADDQoL. Qual Life Res 1999;8:79–91.
- 30 Bech P. Methodological issues in individual quality of life assessment. In: Joyce CR, O'Boyle CA, McGee H, eds., Individual Quality of Life: Approaches to Conceptualisation and Assessment. Amsterdam: Harwood Academic Publishers, 1999.
- 31 Mitchell J, Bradley C. Psychometric evaluation of the 12-item Well-being Questionnaire for use with people with macular disease. Qual Life Res 2001;10:465–73.
- 32 del Series Quijano T, Delgado C, Martinez Espinosa S, et al. Cognitive deficiency in mild hypothyroidism. Neurologia 2000;15:193–8.
- 33 Helfand M, Redfern CC. Screening for thyroid disease: an update. Ann Intern Med 1998;129:144–58.