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Techniques in Thyroidology

Design of New Questionnaires to Measure Quality of Life and Treatment Satisfaction in Hypothyroidism

C.V. McMillan,¹ C. Bradley,¹ A. Woodcock,¹ S. Razvi,² and J.U. Weaver³

Introduction: This paper reports work undertaken to design two new condition-specific questionnaires for use in hypothyroidism: the Underactive Thyroid-Dependent Quality of Life Questionnaire (ThyDQoL) and the Underactive Thyroid Treatment Satisfaction Questionnaire (ThyTSQ). *Methods:* Semistructured interviews exploring quality of life (QoL) and experiences of treatment were conducted with 30 women and 8 men with hypothyroidism, (mean age, 51.9; range, 29–79 years), 37 of 38 treated with thyroxine, recruited from hospital clinics and primary care. *Results:* Despite thyroxine treatment, most interviewees reported negative impact of hypothyroidism on QoL, particularly on energy, physical capabilities, motivation, physical appearance, and weight. The newly designed ThyDQoL has 18 domains covering these and other aspects of life affected by hypothyroidism. It is an individualized measure of patients' perceived impact of hypothyroidism on their QoL, which takes into account the importance of personally applicable life domains to the patient. A 7-item measure of satisfaction with current treatment was designed (ThyTSQ-Present) but interviews also indicated the need for a separate 4-item section measuring satisfaction with past treatment around the time of diagnosis (ThyTSQ-Past). *Conclusions:* The ThyDQoL and ThyTSQ questionnaires have good face validity and content validity for adults with hypothyroidism. They are now ready for use in clinical research and psychometric evaluation.

Introduction

HYPOTHYROIDISM is a lifelong chronic disease with multiple aversive symptoms, both physiological and psychological, that can have a considerable negative impact on quality of life (QoL). Although there has been much interest in clinical aspects of hypothyroidism and its treatment over the past 20 years, psychosocial aspects have received less attention. Sonino and Fava (1) have pointed out the need for multidimensional assessments of the effects of treatment in thyroid disorders, including psychosocial aspects. However, there is no published self-completion measure of QoL in hypothyroidism. A literature search found two measures, neither of which fulfils the requirements for a condition-specific measure of QoL: the Canadian disease-specific Chronic Thyroid questionnaire, comprising questions relating to symptoms of hypothyroidism (2), is for completion by health professionals during interviews with patients; the QoL-Thyroid Scale evaluates the impact of thyroid hormone withdrawal on aspects of QoL of patients with thyroid cancer undergo-

ing scanning procedures (3), and is not suitable for the majority of people with hypothyroidism.

The simple tablet treatment regimen for hypothyroidism is unlikely to be a major cause of dissatisfaction to patients compared to, for example, injecting growth hormone to treat growth hormone deficiency. However, some patients with hypothyroidism may not be satisfied with thyroxine treatment because they do not feel as well as they did before the onset of the thyroid disorder. Many complain of persistent symptoms while taking thyroxine (4). Patients on thyroxine replacement can have significant impairment in psychological well-being compared to controls of similar age and sex (and who had not had thyroid disease), even though their TSH levels are within the normal laboratory reference range (5). Such patients are likely to be dissatisfied with their current treatment. There is some evidence of poor adherence to treatment by patients, perhaps signifying some dissatisfaction with treatment. Ladenson (6) quoted unpublished data from one American clinical laboratory that indicated the possibility that patients do not fully adhere to two thirds of thyrox-

¹Health Psychology Research, Department of Psychology, Royal Holloway, University of London, United Kingdom.

²Department of Diabetes and Endocrinology, Queen Elizabeth Hospital, Gateshead, United Kingdom.

³University of Newcastle upon Tyne, School of Clinical Medical Sciences, Queen Elizabeth Hospital, Gateshead, United Kingdom.

ine prescriptions dispensed. Toft and Beckett (7) reported that "some patients achieve a sense of well-being only if free T_4 is slightly elevated and TSH low or undetectable." There is also research and increasing discussion in the literature about the benefits of combined treatment with thyroxine and triiodothyronine (8–10). A sensitive measure of treatment satisfaction is needed for clinical trials of any new treatments or treatment combinations in the future. No such measures of treatment satisfaction are known to exist at present.

This study aimed to design two new condition-specific questionnaires based on the views and experiences of people with hypothyroidism: the Underactive Thyroid-Dependent Quality of Life Questionnaire (ThyDQoL) and the Underactive Thyroid Treatment Satisfaction Questionnaire (ThyTSQ).

Materials and Methods

ThyDQoL questionnaire

The first draft of the ThyDQoL for use in early interviews was informed by a review of the literature on hypothyroidism and discussions with clinicians. Design of the ThyDQoL was based on the Audit of Diabetes-Dependent Quality of Life (ADDQoL) (11,12), which in turn was influenced by the generic interview method known as the SEIQoL (Schedule for the Evaluation of Individual Quality of Life [13]). Adaptations of the ADDQoL for people with renal disease (RDQoL [14]), macular disease (MacDQoL [15]), diabetic retinopathy (RetDQoL [16]) and growth hormone deficiency (HDQoL [17]) were also considered when designing the ThyDQoL, and relevant items adapted for inclusion. All these questionnaires define QoL as "how good or bad you feel your life to be," on the basis that QoL is "what the patient says it is" (18).

The first section of the ThyDQoL has two items providing an overview of the respondent's QoL. Question I (QI-present QoL) asks people to rate their present QoL on a 7-point scale from *excellent* to *extremely bad* (scored +3 to -3). Question II (QII-impact on QoL) asks people to rate what their QoL would be if they did not have underactive thyroid, on a 5-point scale from *very much better* to *worse* (scored -3 to +1), providing a global measure of perceived impact of underactive thyroid on QoL. The first draft of the ThyDQoL then had 40 life domain items that covered relationships, work and leisure, physical aspects including symptoms, cognitive aspects including memory, psychological aspects including depression, and managing everyday activities. Many of these items were derived from the ADDQoL and versions for other disorders (11, 14–17). Domains are introduced by a hypothetical statement with five response options, e.g., If I did *not* have underactive thyroid, my working life would be . . . *very much better*, *much better*, *a little better*, *the same*, *worse* (the impact rating: scored from -3 to +1). Respondents then rate how important that domain is to their QoL on a four-point Likert scale from *very important* to *not at all important* (the importance rating: scored from 3 to 0) (Fig. 1). A weighted domain impact score is obtained by multiplying the domain's impact rating by the corresponding importance rating. Weighted domain scores range from -9 to +3 (maximum negative to maximum positive impact of hypothyroidism on the domain). Similar to the ADDQoL, the ThyDQoL is individualized. It takes into account the relevance

13 (a)	If I did <i>not</i> have underactive thyroid, my physical appearance would be:				
	-3	-2	-1	0	1
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	very much better	much better	a little better	the same	worse
(b)	My physical appearance is:				
	3	2	1	0	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	very important	important	somewhat important	not at all important	

FIG. 1. Example of an Underactive Thyroid-Dependent Quality of Life Questionnaire (ThyDQoL) domain item with scoring (scores are not shown on the questionnaire itself).

for the individual of each aspect of life covered in the questionnaire, by giving respondents the opportunity to indicate whether a particular domain, (e.g., *work* or *sex life*), is not applicable. In a "free comments" section at the end of the questionnaire, patients may describe any other ways in which underactive thyroid, and any treatment affect their QoL, allowing for the addition of further domains to the questionnaire in the future, as part of its continuing development.

ThyTSQ questionnaire^a

The first draft of the ThyTSQ was prepared after a review of the literature and discussions with clinicians. Its design was based on the widely used Diabetes Treatment Satisfaction Questionnaire (DTSQ [19–21]) and related questionnaires for people with renal disease (RTSQ [22]), human immunodeficiency virus (HIVTSQ [23]), and diabetic retinopathy (RetTSQ [24]). Instructions ask patients to consider their experience of treatment for underactive thyroid over the previous few weeks. The first draft of the ThyTSQ comprised 10 questions including items concerning satisfaction with current treatment, convenience, and understanding of treatment, 6 of which were derived from the DTSQ questionnaire for people with diabetes. Patients respond to each item by circling a number on a scale from 6 to 0, indicating their degree of satisfaction with that aspect of treatment (e.g., from *very satisfied* to *very dissatisfied*) as in the following example:

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

very satisfied 6 5 4 3 2 1 0 very dissatisfied

Patient recruitment criteria

Patients were recruited at three U.K. centers: Queen Elizabeth Hospital, Gateshead, Royal Surrey County Hospital, Guildford, and St. Thomas' Hospital, London, with some patients also being identified and recruited at primary care clinics local to the Gateshead and London hospitals. Recruitment took place by telephone or in person during clinics. The patients were to be representative of the age range and typical female:male ratio found in hypothyroidism (approximately

^aFor access to and permission to use the ThyDQoL and ThyTSQ questionnaires, contact the copyright holder, Clare Bradley, Ph.D., Professor of Health Psychology, Health Psychology Research, Royal Holloway, University of London, Egham, Surrey, TW20 0EX: c.bradley@rhul.ac.uk.

roidism and hyperthyroidism. On the other hand, the term "underactive thyroid" was used spontaneously by 21 patients, and understood by 15 more patients. One patient did not understand the term, and one patient was unsure of the difference between underactive and overactive thyroid. Because the term underactive thyroid was understood by the great majority of patients, it was used to refer to the hypothyroid condition throughout both the ThyDQoL and ThyTSQ questionnaires, after the first few interviews had been conducted. The instructions on the finalized questionnaire make it clear to patients that they should consider their QoL from the point of view of the treated condition, if applicable, as follows:

The following questions are about how underactive thyroid has affected different aspects of your life in recent weeks. If you are currently being treated for underactive thyroid, please consider the effects of the treated condition.

The 25 patients (those not participating in a reversed interview) who were asked how their QoL would be affected if they no longer had underactive thyroid, mentioned 18 areas of life specifically at this point. The key areas of life affected were: energy, weight, physical appearance, bodily discomfort (e.g., cold intolerance, aches and pains), and physical capabilities (see spontaneous mentions in Table 2).

Responses to the two overview items (QI and QII) showed that present QoL was between *good* and *excellent* for the great majority (81%), and from *bad* to *extremely bad* for only two patients (6%). Despite this, 62% perceived the overall impact of hypothyroidism on QoL as negative (i.e., that their QoL would be better if they did not have underactive thyroid). However, 38% reported that the disorder had no impact on their QoL. The selection of 18 domains was arrived at through the iterative interview process, taking particular account of the life domains that received spontaneous mentions, patients' marked responses, and comments while completing the ThyDQoL. Nine of the 18 domains have "not applicable" response options (Table 2). Hypothyroidism was perceived as having a negative impact on applicable domains by 39% to 81% of patients, and the domains were important to most people. Table 2 shows the numbers reporting negative impact (score -3, -2, -1), no impact (0), or positive impact (+1), the wide range of responses selected indicating that the questionnaire is likely to be responsive to different subgroups of patients with the disorder. The most severely impacted domains were: *energy*, *physical capabilities*, *motivation*, *physical appearance*, and *weight*. However, for all 18 domains there were some patients who perceived hypothyroidism as having no impact on the domain, particularly for domains *social life*, *future*, and *getting out and about*. In the majority of domains there were no reports of any positive impact of hypothyroidism, as expected, but there was one woman who reported the positive impact of having the condition diagnosed and successfully treated, after some years of experiencing tiredness and other symptoms. Another patient reported a positive impact in that she had become more understanding of people with health problems or disabilities. Although some domains received few spontaneous mentions, (*sex life*, *relationship*, *future*), they were included in the final version of the ThyDQoL because they re-

ceived reports of negative impact on QoL when patients were completing the questionnaires, and were usually important when applicable. Item means are shown in Table 3 for the 18 patients in the later interviews (by which stage mostly finer adjustments to items were being made but underlying concepts remained the same). These show the greatest negative weighted impact of hypothyroidism was perceived to be for *bodily discomfort* (-4.6 ± 3.95), *energy* (-4.17 ± 3.09) and *motivation* (-3.57 ± 3.03).

Twelve of the final 18 domains on the ThyDQoL were derived from or are similar to domains on the ADDQoL (for diabetes). Additional domains not found on the ADDQoL were derived from other questionnaires: 2 from the HDQoL (for growth hormone deficiency) and 2 from the MacDQoL (for macular degeneration). *Weight* and *depression* are important further domains (not used in previous DQoL measures), because excessive weight gain and depression following onset of hypothyroidism were frequently mentioned as being particularly distressing. Of the 40 domains in the first draft ThyDQoL, 18 items were dropped over the course of interviews, for the reason that they were, for the majority of patients, not applicable or not important, and/or not negatively impacted by hypothyroidism, and/or there were no spontaneous mentions of the domain before the questionnaire item was presented. Items dropped were: feelings about fertility, physical stamina, bodily pain, local or long distance journeys, self-confidence, way people in general react to me, financial situation, depend on others, depend on medication, sleep, lose things, tolerance of stress, handle my personal affairs, shopping, do things for others, living conditions, spiritual/religious life, and people fuss or worry about me. In addition four items relating to specific symptoms of hypothyroidism (problems with memory, concentration, voice/speech, and appetite) were also dropped from the earlier drafts of the ThyDQoL because the majority of patients reported they were not applicable. They have been included, together with other more common symptoms mentioned by the patients, in a new short, 15-item Underactive Thyroid Symptom Checklist, suitable for self-completion, the development of which will be reported elsewhere.

ThyTSQ design. One aim of the study was to design a measure of patients' satisfaction with their current treatment for hypothyroidism. However, half the patients in the first sets of 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' experiences 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/mistreatment. A separate section was therefore drawn up, after half the interviews had been conducted, with questions covering satisfaction with past treatment, the ThyTSQ-Past. It is an extension of the main questionnaire, which was renamed the ThyTSQ-Present.

Following the iterative process, the final version of the ThyTSQ-Present has seven items including questions about satisfaction with current treatment, control of symptoms of underactive thyroid, convenience, and patient understand-

TABLE 3. THYDQoL ITEM MEANS AND STANDARD DEVIATIONS FROM THE FINAL EIGHTEEN INTERVIEWS

No.	Abbreviation	Mean \pm SD	n ^a
(I)	Present QOL	1.29 \pm 0.99	17
(II)	Hypothyroid-dependent QOL	-1.11 \pm 0.96	18
1	Spare time	-1.39 \pm 2.12	18
2	Working life	-2.56 \pm 2.60	9
3	Holidays	-2.40 \pm 3.00	15
4	Family life	-3.00 \pm 3.43	18
5	Social life	-1.35 \pm 2.47	17
6	Relationship	-2.25 \pm 2.93	12
7	Sex life	-0.58 \pm 1.24	12
8	Physical capabilities	-3.56 \pm 3.37	18
9	Energy	-4.17 \pm 3.09	18
10	Speed	-3.06 \pm 3.65	18
11	Getting out and about	-2.83 \pm 3.24	18
12	Household tasks	-2.78 \pm 3.04	18
13	Physical appearance	-1.94 \pm 2.41	17
14	Weight	-3.43 \pm 3.16	14
15	Bodily discomfort	-4.60 \pm 3.95	10
16	Depressed	-1.60 \pm 1.67	5
17	Motivation	-3.57 \pm 3.03	14
18	Future	-1.89 \pm 3.09	18

^aData from final 18 interviews only, by which time questionnaire items were approaching finalization.

ThyDQoL, Underactive Thyroid-Dependent Quality of Life Questionnaire; SD, standard deviation.

ing of treatment (Table 4). Three items were dropped from the early draft ThyTSQ-Present concerning side effects, flexibility and safety of treatment, as these were not perceived to be relevant issues by the patients interviewed. Least satisfaction was found for patients' understanding of their condition (mean 4.58) and for how well the treatment was working (mean 4.97), but there were high means (> 5.0) for the other five items on satisfaction with present treatment.

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. Sixteen patients spontaneously mentioned some dissatisfaction with past treatment before they saw the draft ThyTSQ. When draft questions about past treatment were being tested in later interviews, 8 of 18 patients expressed some degree of dissatisfaction with aspects of early treatment. Least satisfaction with past treatment was reported for information provided by doctors about the condition and about the treatment (both means less than 4.0) (Table 4). The wide range of responses selected for the majority of items in both treatment satisfaction measures is indicative of the likely responsiveness of these measures to different treatments.

Discussion

This paper has reported the design of two new questionnaires for use with adults with hypothyroidism. The ThyDQoL is an individualized patient-centered measure of the impact of hypothyroidism on QoL and the ThyTSQ measures satisfaction with treatment for this disorder. The ThyDQoL

has two overview items to assess current QoL and overall impact of hypothyroidism on QoL, and 18 items covering specific domains of life that may be impacted by hypothyroidism, domains that were important to the great majority of interviewees. The ThyTSQ was divided into two separate and independent sections: the 7-item ThyTSQ-Present, which measures satisfaction with current treatment for hypothyroidism, and the 4-item ThyTSQ-Past measuring past satisfaction with treatment around the time of diagnosis. Our experience was that use of the ThyTSQ-Past allowed interviewees to express their often strongly held views about past treatment and enabled them to focus on current treatment when completing the ThyTSQ-Present. If the ThyTSQ-Past were not used it is likely that ThyTSQ-Present scores would be distorted by dissatisfaction with earlier treatment. It appears that perceived misdiagnosis and mistreatment is a common experience for people with hypothyroidism. Interviews were conducted with 38 people with a range of diagnoses of hypothyroidism and sociodemographic characteristics. As the interviews progressed and patients' comments on items and wording were incorporated into instructions and items, the questionnaires were found to be both acceptable to patients (one indication of good face validity), and easily understood. No new domains appeared in the later interviews, and thus it can also be concluded that the questionnaires have good content validity. Over the course of the iterative interview process, many draft items were dropped from the early versions of the questionnaires, and new items inserted, or different forms of wording used. This has shown the importance of developing condition-specific questionnaires rather than using generic measures, or making superficial modifications to questionnaires designed for other conditions.

There is considerable support for the domains selected for inclusion in the ThyDQoL. All but 2 of the final 18 domains were spontaneously mentioned by patients who were asked what effect there would be on their QoL if they did not have underactive thyroid. The exceptions were *holidays* and *depression*, but these were often mentioned in other parts of the interviews. Despite treatment with thyroxine, hypothyroidism was found to have a negative impact on QoL, particularly for the domains of *bodily discomfort*, *energy*, *motivation*, *physical capabilities*, *weight* and *physical appearance*. This confirms the reports of continuing symptoms and effects of hypothyroidism on QoL that appear in newsletters produced by thyroid patient organisations (e.g., British Thyroid Foundation) and also recent discussion in the medical literature (4). In the interviews, patients expressed some dissatisfaction with the efficacy of thyroxine treatment in controlling symptoms, and in wider aspects of treatment such as their understanding of their hypothyroid condition, and particularly dissatisfaction with insufficient or misleading information provided about the treatment and the condition around the time of diagnosis. If such dissatisfaction were confirmed in a larger study, this would point to the need for improvements in relation to effective education about the condition and its treatment.

A problem for a measure of QoL in hypothyroidism is that patients may have treated comorbidities such as pernicious anemia or diabetes, which often have diffuse symptoms that are indistinguishable from those caused by hypothyroidism. The advantage of the ThyDQoL, however, is that each item

No.	Abbreviation	Wording	Response options	Spontaneous ^a	Mean \pm SD [range]	n ^b
ThyTSQ-Past						
<i>How satisfied were you? . . .</i>						
1	Past satisfaction	with the way doctors dealt with your underactive thyroid around the time it was first diagnosed?	very satisfied-very dissatisfied	10	4.20 \pm 2.35 [0-6]	10
2	Information-condition	with the information provided by doctors about underactive thyroid?	very satisfied-very dissatisfied	3	3.36 \pm 2.06 [0-6]	14
3	Information-treatment	with the information provided by doctors about the treatment for underactive thyroid?	very satisfied-very dissatisfied	5	3.43 \pm 2.47 [0-6]	14
4	Taken seriously	that doctors took you and your underactive thyroid seriously?	very satisfied-very dissatisfied	3	4.85 \pm 1.77 [1-6]	13
	Final open question	Are there any other features of your early experiences of treatment for underactive thyroid, causing either satisfaction or dissatisfaction, that have <i>not</i> been covered by the questionnaire? (Yes/No). If <i>yes</i> , please describe in the box provided.	(box in which to write responses)	1 patient offered suggestions that were incorporated into subsequent version		

^aAll centers.

^bThyTSQ-Present: *n* = 36 completed questionnaires (i.e., excludes accompanying sibling and one untreated patient). Lower *n* (present and past versions) indicates those items tested in later interviews only, with varying numbers of patients.

ThyTSQ, Underactive Thyroid Treatment Satisfaction Questionnaire.

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Address reprint requests to:
C.V. McMillan, Ph.D.
Health Psychology Research
Department of Psychology
Royal Holloway
University of London
Egham
Surrey TW20 0EX
United Kingdom

E-mail: c.mcmillan@rhul.ac.uk