Assessment of a patient-completed questionnaire for keratoconjunctivitis sicca

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ABSTRACT A patient-completed questionnaire has been shown to be equivalent to an observer-administered format in discriminating between subjects with and without keratoconjunctivitis sicca. As well as saving time it can screen patients for the presence of keratoconjunctivitis sicca without the need for more specialized and/or invasive techniques.

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In 1972 Anderson et al. validated the feasibility of utilizing a simple questionnaire to assist in the diagnosis of keratoconjunctivitis sicca.[1] Each of the responses to the 10 questions had a weighted score, and a simple formula was used to derive the total score which, by logistic discrimination, separated those persons with keratoconjunctivitis sicca (score, less than -2.0) from those persons without keratoconjunctivitis sicca (score, greater than $+2.0$). (Those persons with scores between -2.0 and $+2.0$ were designated as having equivocal results.) The questionnaire was physician-administered and both it and the score calculation were quite straight-

forward. As the score was derived from a linear function, the method also could be used to compare different groups of patients for the presence of keratoconjunctivitis sicca. Its major advantage was that, to a large degree, it obviated the need to refer patients to an ophthalmologist for slit-lamp biomicroscopy in order to reach a diagnosis of keratoconjunctivitis sicca.

To the best of our knowledge, this validated diagnostic aid for keratoconjunctivitis sicca has been used only in one other study.[2] During an evaluation of the parameters that are utilized to assess Sjögren's syndrome with a cohort of 465 patients and 650 control subjects at our unit, the subjects returned a self-completed single-page questionnaire that covered 40 points, before their formal assessment.[3] However, this patient-completed questionnaire was not entirely satisfactory as some modification was necessary to the format of the 10 keratoconjunctivitis-sicca-symptom questions, and because it sought a three-option response of "often/occasionally/never" without directions to guide the subjects' choice. In addition, this altered format of, and new responses to, the 10 keratoconjunctivitis-sicca-symptom questions had not been evaluated against those of and to the original physician-administered questions.

Therefore, it was decided to recast the original 10-point keratoconjunctivitis-sicca questionnaire into an uncluttered, single-page format where each question occupied a single line and was couched in the form that was found to be the most appropriate to elicit the symptom that was being sought. This form was headed with an explanatory statement and with directions for the completion of the questionnaire, which included four graded responses that were defined clearly and that we considered would afford a reasonably clear separation between the positive and the negative experience of the 10 symptoms of keratoconjunctivitis sicca.

It was obviously necessary to assess the validity or otherwise of this newly-designed patient-completed questionnaire against the originally used observer-administered questionnaire. The present exercise was designed to do just this, and was not in any way an attempt to assess its usefulness in the clinical situation.

Materials and methods

Sixty-six subjects were all interviewed separately by each of two observers (M.L. and C.S.). Of these subjects, 38 were patients who were attending the Rheumatology Department and the remainder were employees at The Royal North Shore Hospital of Sydney. In order to minimize bias, half the subjects were first interviewed by an observer (M.L.) and the observer-administered questionnaire B was completed. A Schirmer-I tear test was then performed and the subject was given the patient-completed questionnaire A which was collected later. Another observer (C.S.) first saw the other half of the subjects, leaving them to complete questionnaire A for 30 minutes. The completed forms were then collected, questionnaire B was administered and a Schirmer-I tear test was carried out. Each observer then also evaluated those subjects who were interviewed first by the other observer. Thus, all subjects completed both questionnaires twice and underwent two Schirmer-I tear tests.

The two questionnaire forms are shown in Figure 1. Questionnaire B duplicated that of Anderson et al. and sought a "yes/no" response from the observer.[1] The graded responses that were offered for the patient's choice in questionnaire A were selected in the expectation that the "always" (equals four or more days each week) and "often" (equals one or two days most weeks) options would prove the equivalents to a "yes" response as evaluated by the observer on questionnaire B.

The weighted keratoconjunctivitis-sicca scores were calculated according to the formula that was derived by Anderson et al. as follows:

$$S = 4.7 - 5.2Q1 - 3.0Q2 - 1.3Q3 - 5.4Q4 - 4.0Q5 + 1.1Q6 + 0.8Q7 - 1.9Q8 + 2.1Q9 - 2.0Q10$$

where $Q1$–$Q10$ are the numbered questions, and $Qn = 1$ for a "yes" response and $Qn = 0$ for a "no" response. Thus, the observer-administered data from questionnaire B generated keratoconjunctivitis-sicca scores (SB) as described originally. A keratoconjunctivitis-sicca score of less than -2.0 was classified as abnormal; a keratoconjunctivitis-sicca score of greater than $+2.0$ was classified as normal; and a keratoconjunctivitis-sicca score of between -2.0 and $+2.0$ was classified as equivocal. With the use of the patient-completed data from questionnaire A, the keratoconjunctivitis-sicca scores were calculated to find an $SA1$ ($Qn = 1$ for "always"), an $SA2$ ("always" or "often") and an $SA3$ ("always", "often" or "occasionally").

The standard Schirmer-I tear test was carried out by means of commercially-available filter paper strips that were manufactured specifically for this purpose (SMP International Inc.). The result was regarded as: normal, when in five minutes, greater than 15-mm wetting of both strips occurred; equivocal, when one or both strips were wet from 5 mm to 15 mm; and abnormal, when one or both strips were wet for less than 5 mm. Student's t-test and the χ^2 statistic were used to evaluate the results.

Results

The interobserver concordance for the two observers (M.L. and C.S.), which was calculated from questionnaire B, was very high at 94% for all 10 symptoms and ranged from 84.8% to 100% for individual symptoms, as is listed below.

Symptom number	*Interobserver (questionnaire-B) concordance*
1	98.5%
2	97.0%
3	84.8%
4	100%
5	93.9%
6	87.9%
7	90.9%
8	97.0%
9	98.5%
10	87.9%
All symptoms	94.0%

The intrasubject concordance for questionnaire A was also at a high level of 83.5% for all 10 symptoms and ranged from 72.7% to 90.9% for individual symptoms, as is listed below.

Symptom number	*Intrasubject (questionnaire-A) concordance*
1	81.8%
2	90.9%
3	77.3%
4	81.8%
5	83.3%
6	84.8%
7	72.7%
8	87.9%
9	78.8%
10	84.8%
All symptoms	83.5%

Concordance was also examined between the "yes" and the "no" responses that were obtained from the observer's questions in questionnaire B, and the various patient-chosen options from questionnaire A, as is listed below.

	Answers to questionnaire B	
Answers to questionnaire A	*"Yes"*	*"No"*
Always	40.4%	0.9%
Always/often	77.0%	—
Always/often/occasionally	97.0%	—
Never	2.5%	73.3%
Never/occasionally	—	96.0%
Never/occasionally/often	—	99.0%

It can be seen that good agreement occurred between the "yes" and "always/often" (77%) responses, as well as between the "no" and "occasionally/never" (96%) responses.

The weighted keratoconjunctivitis-sicca scores are listed below.

	Mean keratoconjunctivitis-sicca scores ± SD	
	Observer M.L.	*Observer C.S.*
SB	2.1 ± 4.7	2.5 ± 4.4
SA1	3.5 ± 3.0	3.3 ± 3.7
	($t = -3.81$; $P = <0.001$)	($t = -3.47$; $P = <0.05$)
SA2	2.4 ± 4.5	2.3 ± 4.3
	($t = -1.11$; NS)	($t = 0.66$; NS)
SA3	-2.0 ± 6.0	-2.3 ± 6.2
	($t = 7.21$; $P = <0.001$)	($t = 8.35$; $P = <0.001$)

SB = score from questionnaire B; *SA1* = score from questionnaire A for "always"; *SA2* = score from questionnaire A for "always" or "often"; *SA3* = score from questionnaire A for "always", "often" or "occasionally". NS = not significant.

Questionnaire A for Sjögren's syndrome

Date:..... Name:..... Unit number:.....

Age:..... Sex:.....

Rheumatic diagnosis: .....

This questionnaire is about any eye symptoms you may have. Please answer all questions by writing, in the box provided, your own assessment of your experience of the symptom or complaint by means of the following scoring system:

3 = Always = four or more days each week
2 = Often = one or two days most weeks
1 = Sometimes = one or two days each month
0 = Never = less than one day each month

		Department use only Calculation
1. Do your eyes feel as though there is something in them?	[ ]	−5.2
2. Do your eyes have a burning sensation?	[ ]	−3.0
3. Are your eyes tired and/or difficult to keep open?	[ ]	−1.3
4. Do your eyes feel dry?	[ ]	−5.4
5. Do your eyes get red a lot?	[ ]	−4.0
6. Do your eyes feel blurry, like a film over them?	[ ]	+1.1
7. Do your eyes feel itchy, gritty or sandy?	[ ]	+0.8
8. Do your eyes ache a lot?	[ ]	−1.9
9. Are your eyes often sore or painful?	[ ]	+2.1
10. Does bright sunlight irritate your eyes?	[ ]	−2.0
		=
		ADD +4.7
		SA3 + 2 =

Thank you for your help

Schirmer-I tear test	R	L
(mm)		
(max = 5 min) (min)		

Questionnaire B for Sjögren's syndrome

Date:..... Name:..... Unit number:.....

Age:..... Sex:.....

Rheumatic diagnosis: .....

Place [Y] = Yes or [N] = No in each box		Calculation
1. Foreign body sensation?	[ ]	−5.2
2. Burning?	[ ]	−3.0
3. Tiredness with or without difficulty opening eyes?	[ ]	−1.3
4. Dry feeling with or without poor response to physical or chemical irritants and emotions?	[ ]	−5.4
5. Redness?	[ ]	−4.0
6. Difficulty in seeing?	[ ]	+1.1
7. Itchiness?	[ ]	+0.8
8. Aching?	[ ]	−1.9
9. Soreness or pain?	[ ]	+2.1
10. Photosensitivity and excess secretion which may be watery, ropey, or like a film over eyes?	[ ]	−2.0
		=
		ADD +4.7
		SB =

Schirmer-I tear test	R	L
(mm)		
(max = 5 min) (min)		

FIGURE 1: Format of the two questionnaires that were used in the present study.

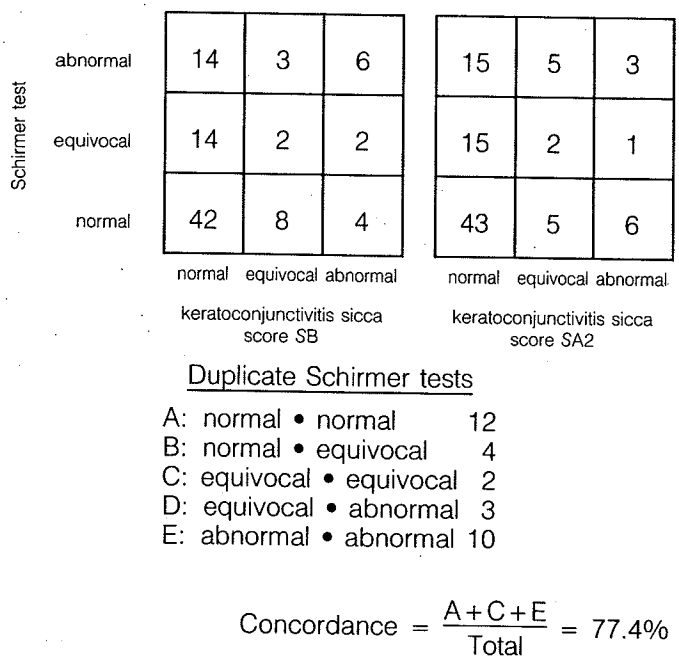

FIGURE 2: The Schirmer-I tear test-results compared with the keratoconjunctivitis sicca scores SB and SA2 and the concordance between the duplicated Schirmer tests.

There were no significant differences between the two observers for any of the keratoconjunctivitis-sicca scores. Also, there was no significant difference between the observer questionnaire-B scores *S*B and the patient-derived questionnaire-A scores *S*A2 for both observers. This would indicate that the subjects who are experiencing these symptoms with the graded frequencies of "always" or "often" would have been regarded as having the symptoms as assessed by the observers.

The Schirmer-I tear test-results are shown in Figure 2. All but two subjects underwent one test and 31 subjects underwent a second test (those who refused the second test did so because the initial test was irritating to their eyes). There was reasonably good concordance between the duplicate measurements of wetting of the filter paper strips (77.4%). However, there was no significant association between the weighted keratoconjunctivitis-sicca scores and the tear test-results (for *S*B: $\chi^2 = 5.31$, df = 4, not significant; and for *S*A2: $\chi^2 = 3.20$, df = 4, not significant).

Discussion

In their original description of the use of weighted keratoconjunctivitis-sicca scores as a statistical aid to the diagnosis of Sjögren's syndrome, Anderson et al. were concerned with the reproducibility among different observers and the validity of the method in the clinical situation.[1] They ascertained this by utilizing their ophthalmological observer's keratoconjunctivitis-sicca scores as the "gold standard" in patients who were verified by him as having or not having keratoconjunctivitis sicca. In the present study, we were concerned with the validation of a patient-completed questionnaire against the observer-administered questionnaire that was developed by Anderson et al., and the reproducibility of both questionnaires.

The high (94%) concordance between our two observers reassures us that the keratoconjunctivitis-sicca questionnaire that was devised in Glasgow can be utilized by other clinicians at other centres. The 83.5% level of concordance for the patient-completed questionnaire, when administered twice, seems sufficiently good for its continued use in this way to assess whether a patient has significant keratoconjunctivitis-sicca symptoms. The absence of any significant difference between the observer-obtained "yes" keratoconjunctivitis-sicca score, *S*B, and the patient-selected "always/often" keratoconjunctivitis-sicca score, *S*A2, indicates that the graded responses that are utilized presently enable the distinction to be made between those with and those without symptomatic keratoconjunctivitis sicca, as based on the patients' returned questionnaires.

The reasons why the Anderson et al. questionnaire[1] has not been utilized more widely as a diagnostic aid to keratoconjunctivitis sicca are speculative. It may be that workers have greater confidence in the more directly-measurable parameters that are expected to be altered in patients with Sjögren's syndrome (Schirmer tear test-result, slit-lamp biomicroscopy, salivary flow, sialography, salivary-gland scintiscans, salivary-gland histopathology), in order to document clearly its presence and to satisfy the proposed Copenhagen criteria.[4] However, we found the keratoconjunctivitis-sicca questionnaire scores proved a better discriminant than did any of these other measured parameters,[3] and that there was a lack of correlation not only between the keratoconjunctivitis-sicca questionnaire scores and these other parameters but also among the parameters themselves, in patients with Sjögren's syndrome.

It has become evident to us that the observer-administered questionnaire with its "yes/no" response relied upon the acquired but unmeasurable judgement of the observer as to what constituted a significant positive (or negative) response to the question. Indeed, most rheumatologists would consider that the manner of the questions has an important bearing on the eliciting (and the interpretation) of the responses that are appropriate to the questions. The previous patient-completed questionnaire was time-saving,[3] yet it fell short by not defining the response options that were offered, by altering the format of the questions, and by not having been validated against the original observer-administered questionnaire. We consider that the present study has dealt satisfactorily with these points.

The lack of correlation between Schirmer-I tear test-results and weighted keratoconjunctivitis-sicca scores is similar to previous observations in 465 patients.[3] The reason for this was not evident and is not able to be explained from the present observations. In both studies it is possibly due, in some degree, to a failure to proceed with a forced lacrimation Schirmer-II tear test when the Schirmer-I test gave equivocal results.

We believe that the patient-completed questionnaire that was used in this study is able to screen patients for the presence of keratoconjunctivitis sicca effectively, and thus obviates the need for specialized ophthalmological manoeuvres or other more invasive diagnostic procedures.

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