Reliability of the time trade-off technique of utility assessment in patients with retinal disease

Hussein Hollands,*† MSc; Miu Lam,† PhD;
Joe Pater,† MD, MSc; Dave Albiani, BSc;
Gary C. Brown,§ MD, MBA; Melissa Brown,§ MD, MBA;
Alan F. Cruess,‡ MD; Sanjay Sharma,*†‡ MD, MSc

ABSTRACT • RÉSUMÉ

Background: Studies in medical fields other than ophthalmology have given conflicting results regarding the reliability of the time trade-off technique of utility assessment. We performed a study to determine the test–retest reliability of the time trade-off technique for assessing utilities in patients with ocular diseases of the retina and to investigate possible factors associated with differences in utility over time.

Methods: Patients referred to the retina service of a tertiary care hospital in eastern Canada were eligible for the initial interview if they had best corrected vision of 20/30 or worse in at least one eye and were deemed competent to answer the required questions. Patients were interviewed prospectively between December 1999 and March 2000 during a normal 30-minute period needed for pharmacologic mydriasis to occur. Demographic, clinical (including Snellen visual acuity) and time trade-off utility information was collected through chart review and standardized interview. Patients who completed the interview successfully were called back 28 days later for follow-up.

Results: Of the 138 eligible patients 112 (81.2%) completed the initial interview. Of the 112, 96 (85.7%) completed the second interview. Half of the respondents were women, and all but one respondent were white. The mean age was 65.3 years. The primary reasons for visual loss included diabetic retinopathy (59 patients [61.4%]) and age-related macular degeneration (14 patients [14.6%]). The intraclass correlation coefficient between the initial and follow-up visual utilities was 0.7634 (95% confidence interval 0.6655–0.8355).

Interpretation: Our results show excellent reliability of the time trade-off technique of utility assessment in patients with ocular diseases of the retina.

Contexte: Les études des autres champs de la médecine que l'ophtalmologie ont

From *the Cost-Effective Ocular Health Policy Unit, Department of Ophthalmology, Queen's University, Hotel Dieu Hospital, Kingston, Ont., the Departments of †Community Health and Epidemiology and ‡Ophthalmology, Queen's University, Kingston, Ont., and §the Center for Evidence-based Health Care Economics, Philadelphia, Pa. Mr. Albiani is a third-year medical student at Queen's University, Kingston, Ont.

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Reprint requests to: Dr. Sanjay Sharma, Cost-Effective Ocular Health Policy Unit, Brock II-224B, Hotel Dieu Hospital, 166 Brock St., Kingston ON K7L 5G2; sanjay_sharma60@hotmail.com

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donné des résultats contradictoires quant à la fiabilité de la technique de l'échange de temps (*time trade-off*) pour mesurer l'utilité. Nous avons effectué une étude pour établir la fiabilité de la technique de l'échange de temps pour mesurer l'utilité chez les patients qui ont une maladie oculaire de la rétine et étudier les facteurs qui seraient éventuellement associés aux écarts entre les indices d'utilité.

Méthodes : Les patients confiés à un service de la rétine dans un hôpital de soins tertiaires de l'est du Canada étaient admissibles à l'entrevue initiale s'ils avaient une vision corrigée de 20/30 ou pire dans au moins un œil et qu'ils avaient la capacité de répondre aux questions requises. Les patients ont été soumis, entre les mois de décembre 1999 et mars 2000, à une entrevue prospective durant 30 minutes, le temps normalement requis pour la manifestation de la mydriase médicamenteuse. Les données démographiques, cliniques (y compris l'acuité visuelle de Snellen) et utilitaires par la technique de l'échange de temps ont été recueillies par l'étude des dossiers et les entrevues normalisées. Les patients qui avaient réussi l'entrevue furent rappelés au bout de 28 jours pour le suivi.

Résultats : Des 138 patients admissibles, 112 (81,2 %) ont terminé l'entrevue initiale. Parmi ces derniers, 96 (85,7 %) ont terminé la seconde entrevue. La moitié des répondants était des femmes, et tous, sauf un, étaient blancs. La moyenne d'âge était de 65,3 ans. Les causes premières de la perte de la vue étaient la rétinopathie diabétique (59 patients [61,4 %]) et la dégénérescence maculaire associée à l'âge (14 patients [14,6 %]). Le coefficient de corrélation dans la même catégorie entre l'indice utilitaire du début et celui du suivi était de 0,7634 (intervalle de confiance à 95 % : 0,6655 à 0,8355).

Interprétation : Le résultat démontre l'excellente fiabilité de la technique de l'échange de temps pour mesurer l'utilité chez les patients qui ont une maladie oculaire de la rétine.

Utilities were first introduced by Von Neumann and Morgenstern[1] in economics and game theory and have since become widely used in the health sciences field. A utility can be defined as the strength of preference for a particular outcome[2] and in a health care setting can be thought of as a measure of the quality of a person's life.[3] By convention, a utility is a value between two extreme end points, 1 (perfect health) and 0 (death). Consequently, utility valuation allows for quantification of a person's functional impairment with respect to activities of daily life.[4]

Utilities can be used simply as a descriptive measure of a patient's health-related quality of life or can be applied in specific disciplines, including medical decision analysis and randomized controlled trials.[5] In ophthalmology, utilities calculated with the time trade-off method have been shown to be highly correlated with visual acuity in the better-seeing eye.[4,6,7] In addition, group utilities can be incorporated with treatment costs and efficacy data to perform cost–utility analyses. Utilities calculated with the time trade-off method have been used as the backbone of cost–utility analyses in order to quantify the cost-effectiveness of various known treatments for retinopathy of prematurity,[8] subfoveal choroidal neovascularization,[9,10] diabetic retinopathy,[11] severe vitreous hemorrhage[12] and age-related macular degeneration.[13]

Although there is no accepted "gold standard" in utility assessment, qualities that are necessary of a good utility assessment tool have been described.[14] It is imperative that a utility assessment tool be reliable, easy to administer, valid and responsive, and that the results be interpretable.[14]

A MEDLINE search using the key words "time trade-off" and "reliability" failed to identify literature investigating the reliability of the time trade-off method in ophthalmology. However, we found several studies that gave different results regarding the reliability of this method of utility assessment in other medical fields.[15–18] Three studies showed good reliability,[16–18] and one study showed poor reliability.[15] We performed a study to determine the test–retest reliability of the time trade-off technique for assessing utilities in patients with ocular diseases of the retina and to investigate possible factors associated with differences in utility over time.

METHODS

Design and study population

The base population for the study consisted of patients who had been referred to two of us (S.S. and A.F.C.) at the retina service of the Hotel Dieu Hospital, Kingston, Ont. Referrals are made by general ophthalmologists, optometrists and family physicians. Most patients who present have diabetic retinopathy or age-related macular degeneration.

Patients were eligible for the initial interview if they had best corrected vision of 20/30 or worse in at least one eye and were deemed competent to answer the required questions. Patients were excluded from the study if they had language or other communication barriers, a developmental disability or a psychiatric illness. A test–retest design was used in which patients were eligible to be called back for the follow-up interview if they completed the initial interview. The study was approved by the Human Research Ethics Board of Queen's University, Kingston, Ont.

Initial interview

Consecutive patients were interviewed prospectively between December 1999 and March 2000 during a normal 30-minute period needed for pharmacologic mydriasis to occur (patients are given eyedrops and must wait about 30 minutes before being seen by the ophthalmologist). All patients were interviewed by an experienced researcher (H.H.) who had formal training in utility evaluation interviews.

We used a standardized interview and chart review to collect background clinical and time trade-off utility information. Visual information was obtained from the patients' charts after an ocular examination was performed, including determination of Snellen visual acuity and improvements with a pinhole. Visual acuity in the affected eye was defined as the Snellen visual acuity in the eye with the worse vision, and vision in the unaffected eye was defined as the Snellen visual acuity in the better-seeing eye.

During the interview demographic information, including age, sex, ethnicity, occupation and education level, was recorded. Patients were asked about coexisting diseases, specifically diabetes mellitus, high blood pressure, arthritis, heart conditions and stroke. Finally, patients were asked how long they had experienced their visual problems.

We determined visual utility values from the patients' responses to two hypothetical questions. First, patients were asked to take a best guess as to their life expectancy. Next, they were told to consider a hypothetical situation in which there existed a technology that could permanently return their vision to normal, would always work, but would decrease their survival. Patients were then asked to state the maximum number of years, if any, out of their estimated life expectancy they would be willing to trade in return for normal vision. The visual utility value was calculated as the number of remaining years of life minus the number of years the patient was willing to trade for perfect vision, divided by the number of remaining years of life. For example, if a patient expected to live 16 years and was willing to give up 4 years for perfect vision, the visual utility would be $(16 - 4)/16 = 0.75$. The visual utility is a value between 0 (defined as willingness to trade all remaining life for perfect vision) and 1 (defined as not willing to trade any years).

Follow-up interview

We asked patients who completed the initial interview successfully whether we could call them back in 4 weeks' time to complete the study. Patients were not prompted with the fact that similar or identical questions would be asked at the second interview. Patients who agreed were telephoned 28 days after their initial interview. The follow-up period was used to reduce recall bias and to decrease the chance that changes in visual acuity or disease status had occurred since the initial interview. If patients could not be reached, they were called seven times over the next 2 weeks at various times of the day. The same interviewer performed the initial interview and the follow-up interview in order to minimize differences between interviewers. The interviewer was masked as to the utilities calculated at the initial interview.

At the beginning of the follow-up interview patients were asked whether they had noticed any slight or significant changes in their eyesight or their ocular disease state. This was asked to assess possible visual changes since the initial interview that could potentially influence visual utility responses. Next, patients were again asked how many years of life they would be willing to trade in return for perfect vision.

Data management and analysis

Initially, we calculated descriptive statistics of clinical characteristics, visual acuity and visual utilities for the sample. Next, we compared the descriptive

statistics of the sample with those of the sample of eligible patients who completed the initial interview but not the call-back portion of the study (nonrespondents). This was done to investigate potential selection bias between the respondents and the nonrespondents. Bivariate analyses (χ^2 test and Student's *t*-test) were used when appropriate.

We performed a cross-tabulation of initial and follow-up visual utilities. To determine the test–retest reliability, the mean change in time trade-off utility is reported along with appropriate 95% confidence intervals (CIs). In addition, we calculated the intraclass correlation coefficient (ICC) together with 95% CIs.[19,20] An ICC is used to measure the association between two replicates of the same sample (in this case, two time trade-off utility values from the same patient).[21] The ICC is different from the more frequently used Pearson correlation coefficient, which measures the association between two distinct variables.

We performed a sample size calculation a priori, which showed that 85 to 96 participants were needed to detect a lower CI limit of the ICC of 0.4, given that the true ICC was 0.6 (assuming type I error = 0.05 and that the study had a power of 80% to correctly reject the null hypothesis).[22]

Patients with different utilities at the initial interview and at follow-up may have different sociodemographic or clinical characteristics than patients with the same utilities at both interviews. We performed bivariate analyses to determine which variables were independently associated with utility consistency (same utility in the two interviews). To investigate these factors simultaneously and to relate them to the utility consistency outcome, we used a backward logistic regression model (cutoff $p = 0.10$ for staying in the model).

Potential variables used to predict utility consistency were sex, education, marital status, number of coexisting diseases, vision in the affected eye, vision in the unaffected eye, years expected to live, primary reason for visual loss and whether the patient noticed differences in vision between the two interviews. Two-way interactions were entered into the model as potential covariates, one interaction term at a time. When categoric variables with more than two groups were entered into the model and one of the dummy variables was found to be significant, all dummy variables were forced into the model.

Results

A total of 138 patients were eligible for the initial interview, of whom 112 (81.2%) completed the initial interview. Of the 26 patients who did not complete the initial interview, 22 were unable or unwilling to answer the time trade-off utility questions, and 4 refused to be interviewed. Of the 112 patients who completed the initial interview, 96 successfully completed the call-back interview, for a participation rate of 85.7%. Of the 16 patients who did not complete the call-back phase of the study, 7 could not be reached, 5 refused initially or did not have a telephone, 3 refused when they were contacted by telephone, and 1 had become ill and was unable to be interviewed.

The demographic characteristics of the 96 respondents are presented in Table 1. The mean age was 65.3 (standard deviation [SD] 12.54) years, and the median age was 68.0 years. Half of the respondents were

Table 1—Demographic characteristics of 96 patients with retinal disease

Characteristic	No. (and %) of patients
Age, yr	
21–50	13 (13.5)
51–60	16 (16.7)
61–70	24 (25.0)
71–80	36 (37.5)
> 80	7 (7.3)
Female sex	48 (50.0)
Race	
White	95 (99.0)
Asian	1 (1.0)
Education	
Less than high school	38 (39.6)
High school	27 (28.1)
Beyond high school	31 (32.3)
Employment status	
Retired	56 (58.3)
Employed	16 (16.7)
Never worked	20 (20.8)
Disabled or looking for work	4 (4.2)
Marital status	
Married/common-law	62 (64.6)
Single	11 (11.4)
Widowed	16 (16.7)
Divorced/separated	7 (7.3)
No. of coexisting diseases	
0	16 (16.7)
1	22 (22.9)
2	29 (30.2)
≥ 3	29 (30.2)

women, and all but one respondent were white. Table 2 shows the clinical characteristics of the respondents. Over 40% had a visual acuity in the affected eye of 6/60 or worse. In most patients (61.4%) diabetic retinopathy was the primary reason for visual loss. In just under 15% age-related macular degeneration was the primary reason for visual loss, and the remaining 24% had other diseases of the retina, including retinal detachment, macular hole, choroidal neovascular membrane, central retinal vein occlusion and branch retinal vein occlusion. The duration of visual loss (self-reported) ranged from 1 month to 44 years (average 5.2 [SD 6.2] years, median 3.0 years).

On average, patients expected to live a further 15.9 (SD 10.5) years (median 15 years). The time trade-off utility values are shown in Table 3. The average visual utility was 0.82 (SD 0.22).

Table 2—Clinical characteristics of the sample

Characteristic	No. (and %) of patients
Visual acuity in affected eye	
6/9–6/15	26 (27.1)
6/18–6/30	31 (32.3)
6/60–6/120	19 (19.8)
Counting fingers to no light perception	20 (20.8)
Visual acuity in unaffected eye	
6/7.5 or better	34 (35.4)
6/9–6/15	42 (43.8)
6/18–6/30	15 (15.6)
6/60–6/120	5 (5.2)
Primary reason for visual loss	
Diabetic retinopathy	59 (61.4)
Age-related macular degeneration	14 (14.6)
Other ocular disease of retina	23 (24.0)
Duration of visual loss, yr	
0–1	22 (22.9)
1.01–5	47 (49.0)
5.01–10	16 (16.7)
> 10	11 (11.4)

Respondents versus nonrespondents

No significant difference was found between the respondents and the 16 nonrespondents in age, sex, visual acuity in the affected eye or initial visual utility.

Reliability of time trade-off technique

The mean difference in visual utility, defined as the initial utility minus the utility at callback, was –0.0186 (95% CI –0.05, 0.01). This represented, on average, less than 2.5% of a patient's initial utility score. A cross-tabulation of initial and follow-up visual utilities is given in Table 4. Of the 96 respondents 68 (70.8%) reported identical utilities in the two interviews. At follow-up 79 patients (82.3%) reported that their vision remained unchanged since the initial interview, 10 (10.4%) reported that their vision was slightly better, and 7 (7.3%) reported that their vision was slightly worse. No patient reported that their vision was significantly better or significantly worse at follow-up than at the initial interview. The ICC for visual utility at the initial and follow-up interviews was 0.7634 (95% CI 0.6655–0.8355). This coefficient was significantly different from 0 ($p < 0.005$).

Predictors of reliability

Initially, bivariate analyses were performed to determine which variables were independently associated with unreliability of the time trade-off technique, as defined by a patient's having different utilities initially and at follow-up. Twenty-eight patients (29.2%) responded differently in the two interviews, and their results were therefore unreliable. None of the clinical or demographic variables investigated showed a statistically significant independent relation with reliability of utility response (all p values were greater than 0.1) (results not shown).

Table 3—Time trade-off utility responses at the initial interview

Variable	No. (and %) of patients
No. of yr expected to live	
0–5	21 (21.9)
5.01–10	20 (20.8)
10.01–20	32 (33.3)
> 20	23 (24.0)
Visual utility	
0–0.5	15 (15.6)
0.501–0.75	23 (24.0)
0.751–0.999	8 (8.3)
1.0	50 (52.1)

Table 4—Initial and follow-up visual utilities

Follow-up utility	Initial utility; no. (and %) of patients				
	0–0.5	0.501–0.75	0.751–0.999	1.0	Total
0–0.5	10 (10.4)	2 (2.1)	0 (0.0)	1 (1.0)	13 (13.5)
0.501–0.75	3 (3.1)	11 (11.4)	0 (0.0)	3 (3.1)	17 (17.7)
0.751–0.999	0 (0.0)	6 (6.2)	6 (6.2)	3 (3.1)	15 (15.6)
1.0	2 (2.1)	4 (4.2)	2 (2.1)	43 (44.8)	51 (53.1)
Total	15 (15.6)	23 (24.0)	8 (8.3)	50 (52.1)	96 (100.0)

The factors that were associated in multivariate analysis with unreliability of the time trade-off technique of utility assessment are shown in Table 5. Women were more likely than men to have different utilities (odds ratio 3.23, $p = 0.0348$). People who had never worked were less likely than retired people to have different utilities (odds ratio 0.24); the difference approached but did not reach statistical significance ($p = 0.057$).

Interpretation

Considering the amount of novel research being performed with the time trade-off technique of utility assessment in ophthalmology, it is important that this technique meet the qualities that have been suggested of a good utility instrument, including reliability. Rosner[21] has classified an ICC less than 0.4 as indicating poor reproducibility, an ICC between 0.4 and 0.75 as indicating fair to good reproducibility, and an ICC of 0.75 or greater as indicating excellent reproducibility. The ICC of 0.7634 (95% CI 0.6655–0.8355) observed in our study shows that the time trade-off technique of utility assessment in patients with retinal disease demonstrates excellent reliability. These results are similar to those of other studies, which demonstrated good reliability of the time trade-off technique in various medical fields.[16–18] However, poor reliability of this technique has also been reported.[15]

Since 29% of our patients gave different responses at the second interview than at the first interview, we were able to investigate possible factors associated with inconsistency. When other covariates were controlled for, women were more likely than men to give different responses. It is not clear why this occurred but may have been due to some confounding factor, such as mode of decision making, time spent thinking about the response or personal interest in the issue.

People who had never worked were more likely than retired people to give different responses. However, the difference between the two groups was not significant at the $p = 0.05$ level. Given our knowledge of the participants, this result does not follow any particular hypothesis. Participants who were employed

Table 5—Predictors of unreliable responses to time trade-off technique of utility assessment in multivariate logistic regression model

Predictor variable	Odds ratio (and 95% confidence interval)	*p* value
Employment status		
Retired	1.0	
Employed*	0.927 (0.183, 4.699)	0.927
Never worked	0.244 (0.057, 1.043)	0.057
Disabled or looking for work*	< 0.000 (< 0.000, 5.9×10^{21})	0.767
Sex		
Male	1.0	
Female	3.23 (1.081, 9.624)	0.035

*Term forced into model because it is a dummy variable of a characteristic for which other dummy variables were significant.

and participants receiving disability benefits were not significantly more likely than retired people to give different responses at the two interviews.

Seventeen patients reported a "slight" improvement or deterioration in their eyesight between the initial interview and the callback interview. This variable was not a significant predictor of reliability of the time trade-off technique. However, no participants noted significant changes in their vision between the two interviews. Perhaps a slight change in perceived visual state was not enough to cause a change in utility response.

Despite this analysis, there are many reasons why a patient could potentially respond differently between the initial interview and the follow-up interview that we were not able to control. For instance, some patients mentioned that they thought about the questions considerably during the follow-up interval and within that period decided on a different answer to the visual trade-off questions.

We studied a very specific group of older patients with ocular diseases of the retina. Therefore, the generalizability of our results to other groups is not known. Another limitation of our study is that we used a face-to-face interview for the initial interview and a telephone interview for follow-up. This was done for logistical reasons, but the effects with respect to potential bias are not clear. However, it has been reported that utilities assessed by telephone and by face-to-face interview are similar.[23]

In conclusion, our results show excellent reproducibility of the time trade-off technique of utility assessment in ophthalmology. Furthermore, it is possible to determine clinical and demographic characteristics that seem to be associated with good reliability between initial and follow-up utility assessment. Our findings suggest that the time trade-off technique is an appropriate instrument for assessing health-related quality of life in this population.

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