Validity of the time trade-off and standard gamble methods of utility assessment in retinal patients

S Sharma, G C Brown, M M Brown, H Hollands, R Robins, G K Shah

Aim: To assess the validity of the time trade-off (TTO) and standard reference gamble (SRG) techniques of utility assessment in patients with retinal disease. A cross section of eligible patients was studied and validity was determined through their relation with two logical constructs, visual acuity and scores from the Visual Function 14 (VF-14) index.

Methods: The study consisted of eligible patients presenting to a tertiary retinal facility who completed an interview. All patients had best corrected vision of 20/40 or worse in at least one eye. TTO and SRG utilities, as well as a VF-14 questionnaire, were administered through a standardised interview. Demographic and clinical (including Snellen visual acuity) information was also collected.

Results: 323 patients met these study criteria. Significant predictors of TTO utilities in the multivariate analysis were vision in the better seeing eye (p<0.01) and VF-14 scores (p<0.01). Significant predictors of standard gamble utilities were also vision in the better seeing eye (p<0.01) and VF-14 scores (p<0.05).

Conclusion: Both the standard gamble and TTO methods demonstrate strong validity when evaluated against visual acuity in the better seeing eye and the VF-14 score.
information are used to determine the utility value for the patient as follows:

utility value = (No of years expected life − No of years trade-off)/No of years expected life

For example, if a patient expects to live 16 years and would be willing to give up 4 years for perfect vision, then the visual utility is calculated as (16 years − 4 years)/16 years = 0.75. The visual utility is a value between 0 (defined as willingness to trade off all remaining life for perfect vision), and 1 (defined as not willing to trade off any years).

**Standard reference gamble utilities**

SRG utilities were ascertained through answers to a similar question about a hypothetical technology. Patients were asked to consider a scenario where a new technology for their eye problem exists. When this technology works, they would receive perfect vision in both eyes for the rest of their lives. However, when the procedure fails, they would not survive. Patient were asked to estimate the largest percentage risk of death they would be willing to accept to be relieved of their ocular disease. The SRG utility is simply this percentage. Consequently, if a patient perceives an 80% chance of having a successful treatment (that is, returning eyesight to normal) and a 20% chance of death as being equivalent to maintaining their current visual state, then his or her SRG visual utility is 0.8.

**Data management and analysis**

Data were entered, managed, and analysed using srs 10.0 for Windows. Demographic characteristics, clinical characteristics, visual utility values (using both the SRG and TTO methods), and VF-14 scores were displayed for the sample. The main outcome variable of interest was visual utility scores (using TTO and SRG techniques). Bivariate analyses were performed to determine the association between visual utility and the variables of interest (demographic characteristics, clinical characteristics, and VF-14 scores). Pearson correlation coefficients and analysis of variance (ANOVA) were used with appropriate significance tests. Also, a cross tabulation between visual acuity in the better seeing eye with VF-14 scores, TTO, and SRG utility scores was displayed.

In order to investigate the construct validity of the two utility assessment techniques, backward multiple linear regression, with an exclusion of p=0.05, was employed. Two regression analyses were performed, one using TTO utility scores as the outcome variable in order to assess the validity of the TTO, and the other using SRG utility scores as the outcome variable, in order to assess the validity of the SRG. All available independent variables (visual acuities, VF-14 scores, demographic variables, and clinical variables) were used as potential predicting variables.

**RESULTS**

**Description of sample**

Three hundred and twenty three eligible patients completed the entire survey. Demographic characteristics of the sample are shown in Table 1. The mean age of the sample was 67.5 years (SD 11.9 years), 63.5% were female, and over 96% were over 70 years old.
white. Over 40% of the sample had some formal post-secondary education, and over 50% of the sample was retired while just under 40% were employed.

The clinical characteristics of the sample are shown in Table 2. Over 60% of the sample had visual loss in the affected eye of 6/60 or worse. The median Snellen acuity in the unaffected eye was 6/12; whereas, the median acuity in the affected eye was 6/90. Patients suffered from their ocular condition for an average of 2.9 years (SD 5.03 years). One hundred and seven patients (33.1%) suffered from age related macular degeneration, 105 (32.5%) suffered from diabetic retinopathy, and 111 (34.4%) suffered from other ocular diseases including cataract, glaucoma, retinal detachment, non-diabetic oedema, amblyopia, vascular obstruction, and corneal disease.

Visual utility and VF-14 responses are shown in Table 3. Patients expected to live, on average, 15.3 years (SD, 9.4 years) from their present age. The mean TTO visual utility was 0.770 (SD 0.21). The mean VF-14 score, out of 100, was 68.46 (SD 28.43).

### Table 4

<table>
<thead>
<tr>
<th>Visual characteristic</th>
<th>No</th>
<th>TTO utility (95% CI)</th>
<th>SRG utility (95% CI)</th>
<th>VF-14 score (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vision in better seeing eye</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6/7.5 or better</td>
<td>75</td>
<td>0.908 (0.875 to 0.942)</td>
<td>0.948 (0.924 to 0.972)</td>
<td>90.70 (88.29 to 93.12)</td>
</tr>
<tr>
<td>6/9 to 6/15</td>
<td>136</td>
<td>0.797 (0.762 to 0.833)</td>
<td>0.897 (0.869 to 0.925)</td>
<td>79.28 (76.14 to 82.41)</td>
</tr>
<tr>
<td>6/18 to 6/30</td>
<td>58</td>
<td>0.708 (0.653 to 0.764)</td>
<td>0.769 (0.696 to 0.842)</td>
<td>51.01 (45.55 to 56.48)</td>
</tr>
<tr>
<td>7/360 to 6/120</td>
<td>58</td>
<td>0.621 (0.555 to 0.687)</td>
<td>0.742 (0.672 to 0.812)</td>
<td>34.03 (27.44 to 40.62)</td>
</tr>
<tr>
<td>CF to NLP</td>
<td>17</td>
<td>0.473 (0.323 to 0.624)</td>
<td>0.603 (0.451 to 0.754)</td>
<td>18.25 (5.49 to 31.02)</td>
</tr>
<tr>
<td>Total</td>
<td>323</td>
<td>0.770 (0.745 to 0.795)</td>
<td>0.853 (0.829 to 0.876)</td>
<td>68.46 (63.33 to 71.57)</td>
</tr>
</tbody>
</table>

### Table 5

<table>
<thead>
<tr>
<th>Predictor variable</th>
<th>Beta coefficient (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>0.497 (0.442 to 0.553)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Vision in better seeing eye (logMAR scale between 0 and 1)</td>
<td>0.176 (0.065 to 0.288)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>VF-14 score (score out of 100)</td>
<td>0.0027 (0.003 to 0.004)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

*Backward linear regression with p=0.05 cut-off for exclusion was used.

### Table 6

<table>
<thead>
<tr>
<th>Predictor variable</th>
<th>Beta coefficient (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>0.638 (0.602 to 0.713)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Vision in better seeing eye (logMAR scale between 0 and 1)</td>
<td>0.193 (0.082 to 0.304)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>VF-14 score (score out of 100)</td>
<td>0.0015 (&lt;0.0005 to 0.003)</td>
<td>0.011</td>
</tr>
</tbody>
</table>

*Backward linear regression with p=0.05 cut-off for exclusion was used.

Bivariate analyses

Bivariate analyses were performed in order to determine which variables were independently associated with visual utility scores. TTO utility scores were not significantly associated with any of the demographic variables including age, sex, ethnicity, years of formal education, or employment status at the 5% level. In addition, TTO utility scores were not significantly associated with duration of visual loss at the 5% level. However, TTO utility scores were significantly associated with visual acuity in the affected (p<0.01) and unaffected (p<0.01) eye, reason for visual loss (p<0.01), and number of co-morbid diseases (r = −0.152, p=0.006). Better visual acuity in the affected and unaffected eye was both independently associated with higher utility scores (p<0.01).

Bivariate associations between SRG visual utilities and the variables of interest were similar to the associations with TTO utilities. SRG utilities were not significantly associated with any of the demographic characteristics available at the 5% level. Better visual acuity in both the affected (p<0.01) and unaffected (p<0.01) eye was independently associated with higher utility scores.

### Multivariate analyses

Separate multivariate analyses were performed for both TTO utilities and SRG utilities as dependent variables, respectively, and are shown in Tables 5 and 6. Visual acuity in the better seeing eye (p<0.01), and VF-14 scores (p<0.01) were the only variables that significantly predicted TTO utilities. The model was highly significant (F=61.9, p<0.01).

The results of the backward regression analysis using SRG visual utilities, as the dependent variable, were very similar to the results for TTO utilities. Again, visual acuity in the better seeing eye (p<0.01), and VF-14 scores (p<0.05) were the only variables that significantly predicted SRG utility scores. This model was also highly significant (F=36.1, p<0.01).

### DISCUSSION

Utilities are currently being used in cost utility analyses that investigate the cost effectiveness of various treatments for ocular diseases. It is important that the techniques being employed have significant construct validity. This is the first study, to our knowledge, to examine the relation between utilities and both visual acuity and VF-14 scores, as well as other potential covariates, simultaneously. By examining this relation we can assess the construct validity of the SRG and TTO utility methods using visual acuity and VF-14 scores as the logical constructs.

Our results demonstrate that both the SRG and TTO techniques show good construct validity, as they are highly...
associated with both visual acuity in the better seeing eye and scores on the VF-14 questionnaire simultaneously. In addition, none of the other demographic or clinical variables was significantly associated with the utility values when visual acuity and VF-14 scores were accounted for.

Two limitations with this study must be noted. Firstly, the study used a very specific group of older patients with ocular diseases of the retina. Therefore, the generalisability of these results to other groups of patients is not known. Secondly, we have only used a visual specific HRQL questionnaire and did not employ a general HRQL questionnaire such as the SF-36. Therefore, perhaps a general HRQL questionnaire would allow us to explain more of the variation in utility values, which was observed. We are currently performing a study that will allow us to evaluate the validity of utility valuation as measured against the construct of the SF-36 score.

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