

VALUE BASED OPHTHALMOLOGY

Utilities associated with diabetic retinopathy: results from a Canadian sample

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22 August 2002**Background/aims:** To report patient based utilities, using the time trade-off technique, associated with visual loss secondary to diabetic retinopathy in a sample of Canadian patients. In addition, to compare these utility values with a sample collected in a similar manner in a tertiary care practice in the United States.**Methods:** A cross sectional study of eligible patients with diabetic retinopathy presenting to a tertiary facility was performed. Demographic and clinical variables (including Snellen visual acuity), and utilities were collected both through chart review and standardised interviews with diabetic patients.**Results:** 221 patients with diabetic retinopathy were eligible for this study and completed the interview. The mean age was 63.5 (SD 12.5) years, and 48.4% were female. Over 35% of the sample had visual acuity in the affected eye of 6/60 or worse. The mean utility for the sample was 0.79 (SD 0.23). The mean utility from this sample did not differ significantly from that obtained from a series of patients with diabetic retinopathy who were referred to a tertiary facility in the United States (mean 0.77, SD 0.21, $p=0.313$). Our cross border comparison had a power of 95% to detect a difference in utility of 0.1 between the two groups.**Conclusion:** On average, Canadian patients with diabetic retinopathy were willing to trade off over 20% of their remaining lifespan in order to eliminate their ocular disease. The mean utility obtained from our sample of Canadian patients with diabetic retinopathy was not statistically different from that obtained from a similar sample of American patients.

Utility measure represents a preference based measure of health related quality of life (QOL). From this evaluation, a specific numerical value can be obtained that encompasses a subject's desirability to exist in a particular health state.¹ A utility is a value between two extreme end points, 0 and 1, where 1 signifies perfect health and 0 signifies the worst possible health outcome, usually death.² Utility valuation allows for the objective measurement of the preference of a disease state according to a patient's own perception of their life.³ There are many ways of assessing utilities including the standard reference gamble, time trade-off technique (TTO), willingness to pay method, and the visual analogue technique.

Utilities have been used in ophthalmology, especially in the area of retinal disease, in order to quantify patients' quality of life associated with their particular ocular conditions. Using the TTO method, researchers have shown that utility in ophthalmic patients is most strongly related to visual acuity in the better seeing eye.³⁻⁵ In addition, utilities collected through interviews with retinal patients have been used as a backbone for a number of cost effectiveness studies. These include studies investigating the cost effectiveness of various known treatments for retinopathy of prematurity,⁶ subfoveal choroidal neovascularisation,⁷⁻⁸ and diabetic retinopathy.⁹ Consequently, it is important that investigators understand factors that are related to utilities, and understand whether they can be collected consistently and reliably in different medical centres.

After a review of the English literature using Medline, we were unable to find any studies that compared utilities obtained from ophthalmic patients collected from different countries or medical centres. The present study was performed to evaluate the utilities associated with diabetic retinopathy obtained from a large sample of Canadian patients with diabetes.

In addition, we investigated the consistency of utility valuation among patients with diabetic retinopathy through a

comparison of two samples, one from a tertiary facility in Canada and the other from a previously published sample obtained from a tertiary facility in the United States.

METHODS

Design and study population

This cross sectional study, which was approved by Queen's University's human research ethics board, was conducted between 22 May 2000, and 28 February 2001. Patients were eligible for the study if they had visual loss secondary to diabetic retinopathy (20/30 or worse in at least one eye) and were deemed competent to undergo the interview process. Patients were excluded from the study because of language or other communication barriers, developmental disability, or psychiatric illness.

The study sample was obtained from a consecutive series of patients with diabetic retinopathy who were referred to an attending retinal specialist at a university affiliated tertiary facility (SS).

Data regarding patient utilities and other necessary background information were obtained via standardised interview and chart review. Visual information was obtained from charts after an ocular examination was performed which included both Snellen and pinhole acuities. In those instances when vision was improved with a pinhole, the pinhole value was used as the best corrected visual acuity since it is believed that this is a more accurate representation of visual potential in a real life setting.³

All patients underwent standardised interviews performed by trained interviewers. The interview process took 20 minutes, on average, and took place during pharmacological mydriasis. In the interview patients were asked demographic questions including age, occupation, and highest level of education. Sex and ethnicity were also recorded. Patients were asked about co-morbidities, specifically, if they suffered from

diabetes, high blood pressure, arthritis, heart conditions, stroke, or other medical conditions, in addition to the length of their visual dysfunction. Furthermore, patients were asked questions regarding their visual problems in order to obtain a utility through the time trade-off technique. Although the technique that we use has been described elsewhere,³ briefly, utility valuation is based on a patient's response to two hypothetical questions: how long they expect to live and how much time they would be willing to trade off in return for normal vision? These two pieces of information are used to determine a patient's utility as follows:

utility value = 1 - (expected duration of life - amount of time willing to trade off/expected duration of life)

Data management and analysis

All data were entered into, managed, and analysed using SPSS 10.0 for Windows.¹⁰ Participation rates were calculated, as were differences between those who did and did not complete the utility portion of the interview (χ^2 tests and Student's *t* tests were used as appropriate). Descriptive statistics of demographic variables, clinical characteristics, visual acuity, and visual utilities were also calculated. In addition, overall mean utility, as well as mean utility stratified by visual acuity in the better seeing eye were reported.

In order to conduct a cross border comparison of utility values, utilities derived from our sample were compared to those published by Brown *et al*,³ which sampled 95 American patients with diabetic retinopathy. A two tailed independent Student's *t* test was used for comparison. This was performed for the overall utility values, and for the utility values associated with different visual acuity levels in the better seeing eye. Power calculations were also performed to determine the power with which we had to detect clinically relevant differences in utilities between the two samples (assuming an α of 0.05).

RESULTS

Participation

Two hundred and twenty one patients were eligible for the study and completed the interview. Eighty eight per cent of patients who met our inclusion criteria completed the study. There were no significant differences with respect to those who completed the entire interview process and those who did not with respect to age, sex, race, highest level of education, marital status, visual acuity in the affected and unaffected eye, and self reported duration of visual loss ($p > 0.05$). However, employment status between the groups was significantly different ($p = 0.02$). Those not completing the utility interview were less likely to be on disability benefit or to be retired but more likely to have never worked.

Description of the respondents

Sociodemographic and clinical data were available for 221 respondents and are shown in Tables 1 and 2. The mean age was 63.5 (SD 12.5) years, and the median age was 67.0 years. Just under half of the sample was female, and over 35% of the sample had visual acuity in the affected eye of 6/60 or worse. The self reported duration of visual loss ranged from 1 month to 60 years, with an average of 5.7 (SD 6.75) and a median of 3.5 years. The average length a patient expected to live was 15.3 years (SD 10.8) and the median expected lifespan was 10 years.

Canadian utilities

The average visual utility for patients in the study was 0.79 (SD 0.23). Utilities, stratified for visual acuity in the better seeing eye, ranged from 0.881 from the group of patients with vision of equal to or better than 6/7.5 vision, to 0.478 from the group of patients with counting fingers to no light perception vision (Table 3).

Table 1 Frequencies of demographic characteristics

Descriptive characteristics	No
Age (years)	
0-50	32 (14.5%)
51-60	47 (21.3%)
61-70	66 (29.9%)
71-80	68 (30.8%)
>80	8 (3.6%)
Sex	
Female	107 (48.4%)
Male	114 (51.6%)
Race	
White	217 (98.2%)
Other	4 (1.8%)
Highest education level	
Less than high school	112 (50.7%)
High school	60 (27.1%)
Beyond high school	49 (22.2%)
Employment status	
Retired	128 (57.9%)
Employed	36 (16.3%)
Never worked	45 (20.4%)
Disability/looking for work	12 (5.4%)
Marital status	
Married or common law	158 (71.5%)
Single	20 (9.0%)
Widowed	29 (13.1%)
Divorced/separated	14 (6.3%)

Table 2 Frequencies of clinical and utility characteristics

Characteristic	No (n=186)
Vision in affected eye	
6/9 to 6/15	72 (32.6%)
6/18 to 6/30	67 (30.3%)
6/60 to 6/120	39 (17.6%)
CF to NLP	43 (19.5%)
Vision in unaffected eye	
6/7.5 or better	68 (30.8%)
6/9 to 6/15	99 (44.8%)
6/18 to 6/30	33 (14.9%)
6/60 to 6/120	18 (8.1%)
CF to NLP	3 (1.4%)
Duration of visual loss	
0 to 1 year	49 (22.2%)
1.01 to 5 years	100 (45.2%)
5.01 to 10 years	40 (18.1%)
More than 10 years	32 (14.5%)
Years expected to live	
0 to 5 years	48 (21.7%)
5.01 to 10 years	60 (27.1%)
10.01 to 20 years	64 (29.0%)
More than 20 years	49 (22.2%)
Comorbid diseases (no)	
0	57 (25.8%)
1	74 (33.5%)
2	54 (24.4%)
3 or more	36 (16.3%)

Comparison of Canadian and American utilities

Our data were compared with those of Brown *et al*,³ obtained from 95 American patients with diabetic retinopathy (Table 3). There was no difference in mean utilities of the Canadian and American samples ($p = 0.465$). This particular analysis had a power of 80% to detect a difference in utility of 0.08 between the two groups assuming an α level of 0.05. Alternatively, the study had a power of 95% power utility difference of 0.10 between the groups. There were no cross border differences noted in utilities when stratified by categorical visual acuity groupings. However, owing to limited sample size, there was

Table 3 Comparison of our sample to a similar sample taken in the United States

Visual characteristic	Present sample (n=221)	Brown <i>et al</i> (n=95)*	p Value
Overall visual utility	0.79 (SD 0.23)	0.77 (SD 0.21)	0.313
Visual utility (stratified by vision in the better seeing eye)			
6/7.5 or better	0.881 (SD 0.19)	0.85 (SD 0.19)	0.568
6/9 to 6/15	0.786 (SD 0.22)	0.78 (SD 0.20)	0.873
6/18 to 6/30	0.728 (SD 0.26)	0.78 (SD 0.19)	0.423
6/60 to 6/120	0.730 (SD 0.22)	0.64 (SD 0.15)	0.281
CF to NLP	0.478 (SD 0.47)	0.59 (SD 0.37)	0.741

*Data taken directly as reported by Brown *et al*.³†Last two categories were compacted in order to perform a valid χ^2 test.

insufficient power to detect clinically relevant differences between some of these strata.

DISCUSSION

Our study reveals that the average patient in our Canadian sample was willing to trade off 20% of their remaining life to eliminate their visual dysfunction from diabetic retinopathy. Those whose vision was profoundly affected by this disease were willing to trade off only 50% of their remaining life.

To our knowledge, this is the first study that compares utilities collected from ophthalmic patients in Canada with those collected in the United States. The results of this investigation indicate that utilities associated with visual loss secondary to diabetic retinopathy can be consistently collected in different medical centres across the Canada/US border. In addition, the analysis on our Canadian sample supports previous research indicating that visual acuity in the better seeing eye is a strong predictor of utility.

In recent years, time trade-off utilities have been used as the backbone of a number of cost effective analyses in ophthalmology,¹¹⁻¹⁴ which have the potential to contribute important information regarding the allocation of limited resources in Canada, the United States, and other countries. Consequently, it is critically important that the patient based utilities, upon which these analyses are based, are valid, reliable, and can be collected consistently across different medical settings. It has previously been demonstrated that the time trade-off method of utility assessment in ocular patients is highly reliable as measured by test-retest reliability,^{15,16} and this methodology has also been demonstrated to be valid.¹⁶

In this study we have demonstrated that utilities from patients suffering from diabetic retinopathy are very similar between two samples of diabetic patients. We believe that this finding increases the validity of the time trade-off technique for utility valuation.

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