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ORIGINAL ARTICLE

Impact of Cataract Surgery on Quality of Life in Patients with Early Age-Related Macular Degeneration

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ABSTRACT

Purpose. To investigate if cataract surgery improves overall and specific areas of quality of life (QoL) in patients with early age-related macular degeneration (AMD) using the impact of vision impairment (IVI) questionnaire.

Methods. Patients with visually significant cataract and early AMD, who were being considered for cataract surgery in the study eye, were recruited. Eligible patients were randomized to either "early surgery" or "standard surgery" (standard cataract surgery waiting time of 6 months) groups. The IVI, sociodemographic, and clinical data were collected. Rasch analysis was used to estimate QoL person measures at baseline and follow-up. The data were analyzed using repeated measures ANOVA. Effect sizes were calculated using Cohen's d coefficient.

Results. Fifty six patients (mean age = 78.5 years and visual acuity = 6/15) had one eye randomly allocated to either the early surgery (n = 29) or standard surgery (n = 27) groups. At follow-up, significant interaction effects were found for the overall IVI score [$F(1,54) = 17.7$; $p < 0.001$], the emotional well-being [$F(1,54) = 13.4$; $p = 0.001$], mobility and independence [$F(1,54) = 13.4$; $p = 0.001$], and reading and accessing information subscales [$F(1,54) = 13.1$; $p = 0.001$]. The standard surgery group systematically recorded worse scores at 6 months on all QoL measures whereas the early surgery group recorded significant gains ($p < 0.001$; Cohen's d = 0.66 to 0.91) on all of them. Visual acuity in the study eye significantly improved in the early surgery group only (Cohen's d = 1.1; $p < 0.05$) and improvement in log MAR lines read was identified as the single independent predictor of enhanced QoL explaining between 26 and 34% of the variance in the IVI scores.

Conclusions. Cataract surgery is justified in patients with early AMD. It brings significant improvements in visual acuity, aspects of daily living, and overall QoL.

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Key Words: cataract surgery, age-related macular degeneration, quality of life, Rasch analysis, visual acuity

Age-related macular degeneration (AMD) is currently the major cause of severe vision loss in people aged 65 years or over in the developed world.[1,2] The prevalence of AMD has been estimated to be about 10% between 65 and 75 years and increases threefold in those over 75 years.[3] AMD-related vision impairment has been associated with depression, poor mental health and reduced quality of life (QoL).[4–6] Cataract is the other age-related disease that is often responsible for vision impairment in an aging population.[7,8] However, the possible benefits or risks of cataract surgery in AMD patients have not been adequately determined. Some studies have suggested that cataract surgery may hasten the progression of AMD, but these are mainly assessing life time risk of AMD after cataract surgery.[9–11] There is some suggestion that cataract surgery may increase the risk of choroidal neovascularization (CNV) complications of AMD in people at high risk of this complication but this hypothesis has not been adequately tested. However, because of this concern, some ophthalmologists are hesitant to recommend cataract surgery in this group of patients and therefore deny them the possible benefits of surgery. There are several published results where cataract surgery has been beneficial in improving visual acuity.[12–14] However, measures

such as visual acuity do not comprehensively capture all aspects of vision functioning from a patient's perspective. Rather, patient-centered QoL questionnaires have been used and recent reviews have described over 30 vision-related QoL instruments.[15–18]

There is, however, limited information in the literature about the impact of cataract surgery on QoL in patients with early AMD.[14,19,20] For example, Armbrecht et al. found that there were significant improvements in QoL and visual function measures in patients with mild and moderate levels of AMD.[14,20] However, the authors used a summed "total" score to evaluate the effectiveness of cataract surgery on QoL. Summary scoring assumes erroneously the value of each item represents equal difficulty, and scores them equally. Furthermore, the response scale used for each item assumes categories are equidistant for that item.[21] Alternatively, item response theory should be used to maximize the validity and accuracy of the outcome data from a QoL scale. Rasch analysis, a special case of item response theory, is based on a probabilistic measurement model that identifies a unidimensional construct, measures its validity, and provides estimates of item and person measures on an interval scale.[22] Rasch analysis makes the scoring process more accurate and removes noise from the measurement.[23,24] This is an important consideration when determining the effectiveness of intervention programs. Recently, the impact of visual impairment (IVI), a vision-specific QoL questionnaire, has been revalidated using Rasch analysis and shown to be a valid scale to measure self-reported restriction of participation in daily living activities and QoL.[25] This study of patients with AMD aimed to determine if cataract surgery increased the risk of CNV, in people at high risk, within 6 months of the operation being performed. These results will be published elsewhere. However, in this article, using the IVI and Rasch analysis techniques, we investigated if cataract surgery improves not only overall QoL, but also specific areas of daily functioning namely; reading and accessing information, mobility and independence, and emotional well-being in patients with early AMD.

METHODS

Participants

All participants needed to be 50 years or older. Patients with visually significant cataract and either bilateral early AMD fulfilling the AREDS criteria for category 3 or one eye with advanced AMD and the other (study eye) with AREDS category 2 features or 3 AMD changes[26] were involved in the study. Patients under category 2 had mild AMD with multiple small drusen, single, or nonextensive intermediate drusen (62 to 124 μm), pigment abnormalities, or any combination of these in one or both eyes. Patients under category 3 had no advanced AMD in both eyes and one eye with VA ≥20/32 with at least one large druse (125 μm).[26] Cataract status in these patients needed to be such that adequate clinical and angiographic documentation of the fundus could be achieved. Referred patients were excluded if they had end-stage AMD in the study eye or were allergic to fluorescein. Other significant ocular conditions which excluded participants from the study were high myopia (>8 D sphere), diabetic retinopathy, an intermediate or posterior intraocular inflammatory disease, previous laser treatment for any retinal pathology, or the presence of diseases associated with CNV other than AMD.

Patients were prospectively recruited from the ophthalmology clinics of the Royal Victorian Eye and Ear Hospital (Melbourne, Australia). All patients were being considered for cataract surgery at the time of recruitment. Potential participants were examined by a retinal specialist and underwent a fundus fluorescein angiogram to exclude the presence of advanced AMD in the study eye and to determine eligibility. Participants who agreed to participate signed a consent form, which allowed access to their medical records. Once eligibility was determined, each participant's eye was then randomized to either an "early surgery" or "standard surgery" group (a 6-month delayed surgery period coincided with the mean waiting time for cataract surgery at the Royal Victorian Eye and Ear Hospital). Those with bilateral early AMD and visually significant cataracts had both eyes recruited into the study, where one eye underwent immediate surgery whereas the other was observed. Those with advanced AMD in one eye could only have the fellow eye recruited into the study. Ethical approval was obtained from the Royal Victorian Eye and Ear Hospital's Human Research and Ethics Committee. This research adhered to the tenets of the Declaration of Helsinki.

Measures

The IVI, sociodemographic, and clinical data were collected at baseline and 6 months preoperatively for the "standard surgery" and 6 months postoperatively for the "early surgery" groups. All questionnaires were interviewer-administered. Partners or relatives were instructed not to contribute or comment to avoid biasing responses to the perception of another person's opinion of the participant's ability. Interpreters or family members were only used in cases where the participant's grasp of English was not sufficient. All examiners were masked to the randomization of the two groups.

Details about family history of AMD, hypertension, diabetes, atherosclerosis and smoking were also collected. Distance visual acuity (using a 4-m log MAR chart and the ETDRS protocol) and lens photography were also performed. Distance VA was measured monocularly. An orthoptist refracted each patient and the best corrected visual acuity was used. The ETDRS protocol was followed for luminance and type of chart. The presence of nuclear, cortical, and posterior subcapsular cataract in each eye was documented by Schiempflug and retro illumination lens photography utilizing the Nidek EAS-1000 system (Nidek Co. Ltd., Japan). Clinical lens grading using the slit lamp and the Wilmer classification of semiquantitative lens grading were also performed.

The IVI was developed to assess the restriction of participation in daily activities and QoL in people with low vision. The 32-item IVI has been described previously.[25,27–30] Responses to the IVI items rated as "not at all" (0), "rarely" (1), "a little" (2), "a fair amount" (3), "a lot" (4), "can't do because of eyesight" (5). The IVI was further validated using Rasch analysis to examine its response scale and internal consistency as well as to provide the true linear scoring benefits of Rasch analysis.[25] Recently, the dimensionality of the 28-item IVI was assessed and a 3-subscale structure possessing interval level measurement characteristics was confirmed.[27] The three subscales were "mobility and independence"(11 items),

"emotional well-being"(8 items), and "reading and accessing information" (9 items).[27]

Rasch Analysis

Rasch analysis was used to estimate subscale and overall person measures at baseline and follow-up using the RUMM2020.[31] The partial credit approach[32] (which allows each item to have its own threshold parameters) was used because the likelihood-ratio test in RUMM2020 was statistically significant ($p < 0.001$) indicating that the rating scale model (which requires equivalent thresholds across all items) was not appropriate.

Initially, the 28-item IVI questionnaire with a four-category response scale for 26 items and a three-category response scale for two items were fitted to the Rasch model. There was evidence of disordered threshold for two items (visiting family and friends and feeling embarrassed because of eye sight) which necessitated the four categories to be collapsed to three categories. This procedure resulted in ordered thresholds for all 28 items. The questionnaire demonstrated fit to the Rasch model as illustrated by the following statistics: item-trait interaction χ^2 (df) = 65.9, (56) p = 0.17 (where a nonsignificant p value indicates no substantial deviation of the IVI data from the model); mean ± SD person fit residual values = −0.17 ± 1.14; mean ± SD item fit residual values = 0.03 ± 1.03 (where if the items and persons fit the Rasch model, mean and standard deviation values about 0 and 1, respectively) and person separation reliability = 0.96. All three subscales also fitted the Rasch model: the emotional well-being [χ^2 (df) = 13.7, (16) p = 0.0.62], mobility and independence [χ^2 (df) = 14.5, (22) p = 0.88], and reading and accessing information (χ^2 (df) = 23.8, (18) p = 0.16).

If the item and scale calibrations demonstrate stability over time (i.e., they are invariant), then differences between the persons measures at baseline and follow-up are valid indicators of changes in the person over time.[33] Consequently, the baseline and follow-up data sets were stacked and the absence of differential item functioning (DIF) in RUMM was used to establish invariance over time. DIF occurs when groups of scores within the sample (e.g., baseline and follow-up), despite equal levels of the underlying characteristic being measured, respond in a different manner to an individual item. The statistical test used for detecting DIF is an ANOVA of the person item deviation residuals with person factors (e.g., time) and class intervals (e.g., group along the trait) as factors. We found no evidence of DIF for time (baseline-follow-up) for the IVI and its three subscales. The Rasch-transformed interval scores were exported to SPSS for further analyses.

Statistical Analysis

Descriptive statistical analyses were performed to characterize the sociodemographic, clinical and IVI data of the participants. A one-way ANOVA was used to determine differences between the two groups at baseline on the dependent measures. Treatment effects were assessed using repeated measures ANOVA to determine between group (early surgery and control surgery) and time (baseline and follow-up) effects and group-by-time interactions. Time effects were investigated with paired t-test. Effect sizes for the both groups were calculated using Cohen's d coefficient.[34] An effect size >0.8 was considered large, around 0.5 moderate, and <0.2 small.[34] Linear regression analysis models were used to determine the independent factors associated with change in the overall and subscale IVI scores at follow-up. Variables found to be univariately associated ($p < 0.05$) with the changes in the four IVI scores were entered in the regression models. The standard multiple regression method was selected. Potential confounders such as age, gender, and baseline level of VA (study and fellow eyes), if not found to be significantly associated with changes in IVI scores, were also included in the regression models. Data were analyzed using the SPSS statistical software (Version 14.0, SPSS Science, Chicago, IL). An α level of $p < 0.05$ was chosen as the criterion for significance.

RESULTS

Baseline Measures

The sociodemographic, clinical, and QoL data for the whole, early surgery, and control surgery groups at baseline are shown in Table 1. Fifty-six patients (37 women) participated in this study. Their mean (±SD) age was 78.9 years (±5.7) and the majority was white (n = 50; 89%). The mean (±SD) distance VA in the study eye was 0.39 (±0.24) log MAR (6/15 Snellen) and the duration of vision impairment was 3.9 years (±11.4). The mean (±SD) distance VA in the fellow eye was −0.25 (±0.27) log MAR (6/4 Snellen). Clinical lens grading, using the slit lamp and the Wilmer classification of semiquantitative lens grading, found that nuclear sclerosis ranged from 1.4 to 4.5 (0 to 4.9 scale), posterior subcapsular lens opacities ranged from 1 to 3 mm^2, and cortical opacities ranged from 0 to 1 (0 to 4 scale).

Fifty patients had bilateral drusen (AREDS category 3) and eight had CNV in the nonstudy eye. Five patients (18.5%) from the control surgery group and 11 patients (38%) from early surgery group, respectively, had cataract surgery in the fellow eye before being involved in the study (χ^2; p = 0.14). There was no significant difference between patients who had one or two cataract operations on any of the variable at baseline ($p > 0.05$). Fifty-six patients had one eye randomly allocated to either the early surgery (n = 29) or control surgery (n = 27) groups. No significant differences ($p > 0.05$) between the two groups on any of the variable at baseline, except for the emotional well-being subscale, where the early surgery group had a significantly worse score than the control group (0.9 vs. 2.3, respectively; ANOVA, p = 0.01). The mean (±SD) IVI scores were 2.2 (±1.9), 1.6 (±2.1), 2.5 (±2.2), and 2.5 (±2.1) for the overall, emotional well-being, mobility and independence, and reading and accessing information domains, respectively (Table 1).

Overall, the three most difficult items for our AMD patients with cataract were "reading ordinary-sized print?," "worried about your eyesight getting worse?" and "reading labels or instructions on medicines?" which recorded logit values of 2.1, 1.9, and 1.1, respectively. Conversely, the three least difficult items were "generally looking after your appearance?," "opening packaging?" and "operating household appliances and the telephone?" with logit scores of −1.9, −1.4, and −1.3, respectively.

TABLE 1.
The sociodemographic, clinical, and IVI quality of life values (logits) of the standard and early surgery groups at baseline

	Standard surgery (n = 27)	Early surgery (n = 29)	Sample (n = 56)
Age (yr)	79.0 (±5.2)	79.5 (±6.1)	78.9 (±5.7)
Gender (female)	18 (67.0%)	18 (62.0%)	37 (64.0%)
Mean duration of impairment (yr)	6.0 (±16.0)	1.9 (±2.8)	3.9 (±11.4)
Never smoked (n)	22 (81.5%)	23 (79.3%)	45 (80%)
Family history of AMD (n)	5 (18.5%)	2 (6.9%)	7 (13%)
Diabetes (n)	4 (14.8%)	3 (10.3%)	7 (13%)
Atherosclerosis (n)	6 (22.2%)	9 (31.0%)	15 (27%)
Hypertension (n)	14 (51.9%)	17 (58.6%)	31 (55%)
Race (white)	24 (88.9%)	26 (89.7%)	50 (89%)
Visual acuity-study eye (log MAR)	0.37 (±0.23)	0.41 (±0.26)	0.39 (±0.24)
Visual acuity-fellow eye (log MAR)	−0.22 (±0.25)	−0.29 (±0.30)	−0.25 (±0.27)
IVI-overall score	2.7 (±1.7)	1.6 (±1.7)	2.2 (±1.9)
IVI-emotional well-being subscale	2.3 (±1.9)	0.9 (±1.9)	1.6 (±2.1)
IVI-mobility and independence subscale	3.1 (±2.1)	2.1 (±2.2)	2.5 (±2.2)
IVI-reading and accessing information subscale	2.9 (±2.4)	2.1 (±1.8)	2.5 (±2.1)

TABLE 2.
The impact of vision impairment (IVI) scores (logits) and visual acuity results (log MAR) at baseline and follow-up for the standard surgery and early surgery groups

	Standard surgery (n = 27)			Early surgery (n = 29)			Interaction
	Baseline	Follow-up	Effect size	Baseline	Follow-up	Effect size	p value
Overall score	2.7 (±1.7)	1.8 (±1.5)[a]	−0.56	1.6 (±1.7)	3.4 (±2.2)[b]	0.91	<0.001
Emotional well-being	2.3 (±1.9)	1.8 (±1.7)	−0.28	0.9 (±1.9)	2.6 (±2.0)[b]	0.87	0.001
Mobility and independence	3.1 (±2.1)	2.3 (±1.7)[a]	−0.42	2.1 (±2.2)	3.5 (±2.1)[b]	0.66	0.001
Reading and accessing information	2.9 (±2.4)	2.5 (±1.9)	−0.18	2.1 (±1.8)	4.0 (±2.5)[b]	0.87	0.001
Visual acuity-study eye	0.37 (±0.23)	0.28 (±0.23)	0.39	0.41 (±0.26)	0.13 (±0.27)[b]	1.10	0.027

[a]Denotes a significant deterioration at follow-up ($p < 0.05$).
[b]Denotes a significant improvement at follow-up ($p < 0.05$).

Follow-Up

IVI. All patients were reassessed 6 months after baseline measurement. Repeated measures ANOVA showed that there were significant group by time interaction effects for the overall IVI [$F(1,54) = 17.7$; $p < 0.001$], the emotional well-being [$F(1,54) = 13.4$; $p = 0.001$], mobility and independence [$F(1,54) = 13.4$; $p = 0.001$], and reading and accessing information subscales [$F(1,54) = 13.1$; $p = 0.001$] at follow-up (Table 2). In the four IVI measures, the control surgery group systematically recorded worse scores at follow-up although the worsening in QoL scores was statistically significant only for "overall" and "mobility and independence" scores.

On the other hand, the early surgery group systematically improved on all the IVI measures at follow-up. The cataract surgery-induced IVI gains were substantial for the "emotional well being," "mobility and independence," "reading and accessing information," and "overall" scores, respectively ($p < 0.001$ for all). The magnitude of the cataract surgery on the four IVI scores ranged from moderate to large (Cohen's d coefficient values ranging from 0.66 to 0.91, Table 2).

Visual Acuity (VA). There was a significant interaction effect on visual acuity at follow-up in the study eye [$F(1,54) = 5.15$; $p = 0.027$], where the control surgery group recorded no significant change in VA whereas the early surgery group significantly improved after cataract surgery (Table 2). The magnitude of the change in VA in the early surgery group was considered to be substantially large (Cohen's d coefficient = 1.1). The improvement in VA in the early surgery group resulted in an improvement of almost three lines of LogMAR letters at follow-up (2.8 lines) when compared with the control surgery group (1.0 line, $p = 0.056$).

Independent Predictor of Cataract-Induced Improvement in IVI Scores. Univariate analyses showed that only improvement in VA and log MAR lines read at follow-up in the study eye were associated with an enhanced scores in the four IVI scores ($p < 0.001$, respectively). When these two variables were entered into linear regression models (after controlling for age, gender, and baseline VA), only an improvement in log MAR lines was identified as the single significant predictor of improved IVI scores (Table 3). Improvement in log MAR lines explained between 26 and 34% of the variance in the four IVI scores suggesting that enhanced QoL measures is independently associated with an improvement in the number of letters read after cataract surgery.

DISCUSSION

This is the first study to have used a Rasch-analyzed QoL instrument to determine the impact of cataract surgery on QoL in pa-

TABLE 3.
The impact of vision impairment (IVI) linear regression model summary including standardized β-coefficients, R^2, and adjusted R^2 after controlling for age, gender, and baseline level of visual acuity for the independent predictor "change in log MAR letters read at follow-up"

Independent predictor	Dependent variable-change in IVI scores at follow-up	Standardized β (95% confidence interval)	R^2	Adjusted R^2
Change in log MAR letters read at follow-up	Overall	0.51[a] (0.11–0.67)	0.31	0.23
	Emotional-well being	0.45[a] (0.12–0.61)	0.34	0.28
	Reading and accessing information	0.52[a] (0.11–0.68)	0.26	0.19
	Mobility and independence	0.51[a] (0.16–0.67)	0.26	0.16

[a]$p < 0.05$.

tients with early AMD using a randomized controlled trial design. Our findings indicate cataract surgery in AMD patients significantly improves overall QoL and three specific aspects of daily living namely; emotional well-being; mobility and independence, and reading and accessing information. The average gain in QoL was almost twofold at follow-up in the early surgery group and argues strongly that cataract surgery should not be withheld from patients with early AMD. Improvement in QoL scores were significantly associated with improved visual acuity and log MAR lines read after cataract surgery, emphasizing the critical relationship between vision impairment and restriction of participation in daily living.[4,25,27–30] Increased log MAR lines read at postcataract surgery, which is a surrogate measure of improved visual acuity, was the single independent predictor of gains in QoL measures indicating unequivocally that the improvement in visual acuity is one of the mechanisms underpinning the positive changes in QoL measures.

Our main finding of the effectiveness of cataract surgery in AMD patients is similar to Armbrecht et al. investigation that used the VF-14 questionnaire to determine whether AMD patients benefit from cataract surgery in terms of visual function and QoL measures.[14] The authors also found significant gains in the overall QoL and vision function after cataract surgery although the magnitude of these gains were substantially smaller than those found in this study. For example, the change in visual acuity for early surgery group was considered to be substantially large (Cohen's d = 1.1) compared to only a small effect size (Cohen's d = 0.09) reported in Armbrecht et al. study. Similarly, the absolute improvement in the IVI overall score was considerable when compared with a rather modest gain in the VF-14. Our patients had early AMD in the study eye and the cataract was likely to be the main cause of vision impairment rather than from AMD. This argument appears to be justified as the early treatment group mean visual acuity improved to 0.13 log MAR (6/7.5 Snellen) after cataract surgery. In Armbrecht et al. study, the mean distance visual acuity was still <6/12 after cataract surgery. It appears therefore that although cataract surgery is effective in improving restriction of participation in daily life, it appears to be more beneficial if performed early in AMD patients before the macular degeneration has caused significant loss of acuity.

Another critical finding of this study is the impact of 6 months of "nontreatment" of the cataract on overall and specific QoL in our control surgery group. The deterioration was systematic and almost of the same magnitude in all aspects of QoL at follow-up. Considering there was no significant change in visual acuity in the control surgery group at follow-up, it is possible that the worsening in QoL was related to other aspects of vision function namely, near vision, contrast sensitivity, glare, and stereoacuity which were not assessed in this study. In contrast, Armbrecht et al.,[14] found no significant change in the overall score and individual items of the VF-14 in the control surgery group at follow-up. The discrepancy between these two studies could be related to a longer follow-up period in the current study.

One of the aims of this study was to evaluate the effectiveness of cataract surgery, not only in overall QoL, but also in specific areas of restriction of participation. It was reassuring to note that substantial improvements were recorded across the three subscales, confirming that patients with AMD do benefit from cataract surgery across areas of emotional well-being, reading, and mobility. The greatest absolute gain was, however, recorded in emotional well-being subscale when compared with the "mobility and independence" and "reading and accessing information" subscales. Considering that no psychological intervention was prescribed, this finding is important as it holds considerable promise in reducing the psychological consequences of vision impairment in this population awaiting cataract surgery.

The preoperative visual acuity data for the standard treatment group improved by one line at follow-up. This improvement was not expected for a group of patients having no intervention and is particularly unusual in this type of trial. However, our sample size was small and the improvement in visual acuity was not statistically significant suggesting that it may have been just a random event. Considering the examiner who undertook the visual acuity assessment was masked to the randomization of the groups, there is no other explanation for this improvement except that the patients and examiner may have tried harder at the second visit when compared with the first.

In conclusion, cataract surgery is justified and warranted in patients with early AMD. It brings significant improvements in vision function, several areas of daily living, and overall QoL. Conversely, delaying cataract surgery can impact negatively on overall QoL and is not recommended. All too often there is a delay in offering cataract surgery to people at high risk of neovascular complications of AMD because of a, so far hypothetical, concern of aggravating this risk. Although there is still no solid data on what that increased risk might or might not be, it is clear that in those whom remain free of CNV, there are great benefits to be gained with cataract surgery. Until there is more information on the risks of provoking CNV with cataract surgery in pa-

tients with high risk early AMD, all attempts to exclude the presence of CNV should be made before embarking on cataract surgery. Thereafter, these patients should be considered for cataract surgery like other potential cataract patients.

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