Patient Reported Outcome Measuring Tools in Cataract Surgery – Clinical Comparison in a Tertiary Hospital.

Short title
Comparison of Patient Reported Outcome Measuring Tools in Cataract Surgery.

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Abstract

Purpose

To assess the performance of Patient Reported Outcome Measure (PROM) questionnaires and determine their appropriateness for routine use in cataract patients.

Setting

Moorfields Eye Hospital, London, United Kingdom.

Design

Prospective cohort study.

Method

Patients undergoing cataract surgery between February and March 2013 were recruited. Four questionnaires, including Catquest-9SF, EQ-5D and its visual analog scale (VAS), NEI-SES and VF-8R were given to patients to complete before surgery, 3 weeks post-surgery and 3 months post-surgery. Rasch-analyzed data, when possible, was used to compare questionnaires’ performances. Statistical significance was calculated with paired student’s t-test. Pearson’s correlation coefficients were determined between PROMs’ scores and visual acuity.
Results

Among the 123 patients recruited, 67.62% and 61.8% completed 3 weeks and 3 months follow-up respectively. Changes in mean scores for Catquest-9SF, EQ-5D, EQ-VAS, NEI-SES and VF-8R at 3 weeks were 44.01, 20.88% (p<0.0001), 1.61, 0.62% (p=0.61977), 3.37, 0.62% (p=0.098), 16.12, 5.8% respectively. At 3 months, these were 16.29, 57.42% (p<0.0001), 4.54, 2.4% (p=0.164), 4.84, 0.9%, 54.63, 49.13% (p<0.0001) and 876.55, 3.37% (p<0.0001), respectively. Weak correlations were found between Catquest-9SF, NEI-SES and pre-operative visual acuity. While all PROM questionnaires correlated to post-operative visual acuity measures, the correlations were variable and weak at best.

Conclusion

It is feasible to assess patient reported outcome in cataract surgery as routine practice. Improvements in visual function could be detected as early as 3 weeks post-surgery by Catquest-9SF and VF-8R, while cataract surgery may exert a delayed effect on patient’s socioemotional construct. Visual acuity measures do not fully reflect patients’ reported visual function and lack of correlations between PROMs and visual acuity clinicians should consider assessment of raised the importance of assessing patient reported visual function prior to cataract surgery in order to facilitate surgical decision-making.
Introduction

Cataract surgery is the commonest procedure performed in the public healthcare system, the National Health Service (NHS), in the United Kingdom, with around 330 000 cases performed in England. Although there is clear evidence of objective visual improvements from modern cataract surgery, based on visual acuity measurement, this fails to accurately evaluate patient perceived benefits of the procedure.

Patient-reported outcome measures (PROMs) examining health related quality of life, functional status and symptom scores have increasingly been recognized as important tools in patient centered care and in measuring the value of health interventions. A Generic PROM, measured by EQ-5D, has been a mandatory requirement for four types of high volume elective surgeries performed in NHS England, namely hip and knee replacements, groin hernia repair, and varicose vein surgery since 2009. Despite the volume of cases, cataract surgery is currently not included due to uncertainties of validity and responsiveness of EQ-5D in these patients.

The 51-item National Eye Institute Visual Function Questionnaire (NEI-VFQ) is considered the ‘gold-standard’ for assessing visual function. A shortened version of NEI-VFQ with 25 items (NEI-VFQ-25) has also been introduced in the assessment of vision-related quality of life of patients with ocular diseases in cross-sectional studies. This has remained largely a research setting tool, as they are lengthy and time-consuming both for patients to complete and for clinicians to analyze, making them difficult to implement therefore not practical in routine
clinical practice settings, and therefore has remained largely a research tool.

NEI-VFQ was also found to contain several design issues that reduces its validity, namely multidimensionality (more than 1 construct in 1 score), questions that did not fit the construct, suboptimum targeting of item difficulty to person ability, and dysfunctional subscales.\(^1\)

A shortened version of NEI-VFQ with 25 items (NEI-VFQ-25) has been used more widely in the assessment of vision-related quality of life of patients with ocular diseases in cross-sectional studies.\(^6\)\(^-\)\(^8\) More recently, shorter validated questionnaires for cataract patients have been developed. These include VF-8R and Catquest-9SF,\(^12\)\(^-\)\(^13\) the latter of which has been successfully adopted in Sweden since 1998 as part of the Swedish National Cataract Register and is promoted by the International Consortium for Health Outcomes Measurement for international use.\(^11\)\(^-\)\(^14\) In the UK, however, so far there is no consensus in the UK on a PROM for cataract surgery patients so far.

The aim of this study is to evaluate the feasibility of using PROMs in routine NHS service for cataract patients in the United Kingdom, and to compare the responsiveness of different tools in order to identify the best PROM for this purpose. To our knowledge, this is the first clinical study comparing PROMs for cataract patients in the United Kingdom.
Method

Study cohort

This was a prospective longitudinal study of consecutive patients scheduled for cataract surgery at Moorfields Eye Hospital, London between February and March 2013. Patients were recruited during their pre-operative assessment. Eligible patients had cataracts in one or both eyes, were ≥40 years of age, were scheduled to have phacoemulsification and intraocular lens implant insertion, were able to read and interpret English without translation, and could give valid consent. We excluded patients with significant visual impairment from ocular comorbidities in the eye that was to be operated upon (e.g., advanced age related macular degeneration, advanced glaucoma, uncontrolled diabetic retinopathy and maculopathy, and other conditions that carried a guarded visual prognosis after cataract surgery), and patients with psychiatric or cognitive diseases. Those with stable ocular comorbidities not causing significant visual impairment were included in this study (Table 1).

The study complied with the Declaration of Helsinki and was approved as a part of service evaluation. Informed consent was obtained from all participants in this study.
Data collection

A study pack with four questionnaires, consisted of Catquest-9SF, EQ-5D, NEI-SES and VF-8R was given to patients to complete. Clarifications and support were given by nursing staff if patients were unable to understand the questionnaire. In accordance with the design of all the questionnaires used, patients were instructed to consider their situation during the 2 weeks prior to the assessment only. Data from one operated eye was recorded. In second eye patients, no questionnaires were given within 2 weeks of completion of the first eye surgery.

The same pack was subsequently mailed to the patients at 3 weeks and at 3 months post-surgery. Questionnaire response rates were enhanced by telephone call reminders at 3 weeks and 3 months post-surgery.

Clinical data for the subjects was retrieved from medical records. Data collected included past medical history, pre- and post-operative corrected distance visual acuity (CDVA) and refraction, slit-lamp biomicroscopy findings, operation report, and any intra- and post-operative complications.

Patient-reported outcome measuring tool selection

Four preference-based patient-reported outcome instruments were selected for this study. The 4 questionnaires were selected in order to cover 3 different areas: generic health status, disease-specific health status, and socioemotional status.
EQ-5D was used as the tool for generic health status measurement. National Institute of Clinical Excellence (NICE) and the UK Department of Health have recommended the use of this questionnaire as part of a wider comparative health-care economic analysis in other common procedures in England. It consists of 5 questions concerning subject’s self-reported health, and a visual analogue scale (EQ-VAS) that allow subjects to report their perceived overall status of general health. EQ-5D has not been recommended specifically for cataract patients, but some recent studies have shown that it is responsive in patients with visual impairments, although none of them were based in primarily English-speaking patient population.

For disease-specific measuring tool, Catquest-9SF and VF-8R were selected. Both questionnaires were specifically designed to capture visual function data in cataract patients, and have previously been vigorously validated in English-speaking populations. Furthermore, a head-to-head study has shown that Catquest-9SF to be superior to other questionnaires in cataract patients. We decided to include VF-8R because its predecessor (VF-14) was recommended for UK cataract patients. However, we did not use VF-14 as it has not been Rasch-validated and is less responsive in detecting longitudinal changes in visual function.

NEI-SES was chosen to assess the socioemotional changes brought about by cataract surgeries. This questionnaire was based on the 39-item National Eye Institute Visual Function Questionnaire (NEI-VFQ). After validation and the removal of redundancies by Pesudovs et al., NEI-SES was developed to capture data measuring socioemotional construct.
Statistical analysis

Sociodemographic and clinical characteristics were analysed by descriptive statistics. Subgroup analyses on patients undergoing cataract surgery for the first time and for the second time were also performed.

To assist data analysis, EQ-5D health states were converted to index values as reported previously. \(^{19-22}\) Raw value of EQ-VAS was used, as no index score conversion was available. For Catquest-9SF, VF-8R and NEI-SES, Rasch adjusted scoring systems were preferred over summative (Likert) scoring system. The advantages of using Rasch scoring include validated scoring weighting, better precision in detecting change over time, \(^{12,13}\) and the possibility of using parametric statistical techniques, allowing direct comparison of the performances of the questionnaires. Rasch measuring scale is linear and uses a unit known as logit, or log-odds unit, which is the logarithm of odds ratio of the probability a person will endorse a particular rating scale step over 1- the same probability, with persons of higher ability achieving a negative score. \(^{14,15}\) In other words, negative logit scores represent better health states. The conversion was based on previously published articles for each questionnaire. \(^{9,10,18,19,20,13}\)

Visual acuity was assessed by Snellen-converted ETDRS. Corrected distance visual acuity data were analyzed with ipsilateral eye undergoing surgery (CDVA), better-seeing eye (BEVA), worse-seeing eye (WEVA) and weighted average of both eyes (WVA) as separate variables of interest. The WVA was
based on 75% contribution by BEVA and 25% contribution by WEVA. Data analysis was performed with Microsoft Excel for Mac 2011 (Microsoft Corp, 2010). Association between continuous variables were examined using the Pearson’s correlation coefficient. Coefficients were considered strong (>0.5), moderate (>0.35 – 0.50), weak (>0.20 – 0.35), and no correlation (≤0.2). Statistical significance (P<0.05) was assessed using two-tailed paired student’s t-test after non-respondents were excluded from longitudinal data analysis.
Results

One hundred and twenty-three patients were recruited for the study. Sixty-five patients (52.9%) were male. Mean age of all subjects (± S.D.) was 70.7 ± 10.60 years. Sixty-eight patients (54.5%) were undergoing cataract surgery for the first time. Forty-nine patients (48.4%) were White British and Forty-one (33.6%) were Indian. Mean pre-operative CDVA, BEVA, WEVA and WVA were 0.63±0.489, 0.267±0.2730, 0.654±0.501 and 0.367±0.2730 LogMAR, respectively. Post-operative mean CDVA, BEVA, WEVA and WVA were 0.204±0.2630, 0.146±0.205, 0.357±0.358 and 0.204±0.216 LogMAR, respectively. Peri-operative complications include 1 case of contained anterior radial capsular tear as well as 1 case of cystoid macular oedema, 1 case of raised intraocular pressure and 1 case of post-operative uveitis, all of which settled after a short course of medical treatment. Table 1 summarises the sociodemographic and clinical data.

Of the 123 patient recruited, 824 (67.25±9%) patients responded at 3 weeks after surgery, while 76 (61.8%) patients responded at 3 months after surgery. Non-respondents at each point of follow-up were excluded from further statistical analyses. Table 2 showed the median age, gender and ethnicity distribution between respondents and non-respondents at 3 weeks and at 3 months. Age and gender distributions were similar between the two groups at both time points, although the ethnic groups were slightly different between respondents and non-respondents at both time points.
Patient responses at pre-operative assessment, at 3 weeks post-surgery and at 3 months post-surgery are summarized in Table 3. All questionnaires reported improvement in patient reported outcomes in relation to post-operative CDVA improvement. Catquest-9SF reported the largest and statistically significant changes at both 3 weeks and 3 months post-surgery (120.86±10.8%, \( P_p<0.0001 \) and 162.42±7.3%, \( P_p<0.0001 \), respectively). VF-8R was also statistically significant at both time points (61.76%, \( P<0.0001 \) and 87.55, \( P<0.0001 \) respectively). Both VF-8R and NEI-SES reported statistically significant changes at 3 months post-surgery (86.3±54.63%, \( P_p<0.0001 \) and 49.1%, \( P=0.0006 \) respectively). Neither EQ-5D health states nor the EQ VAS showed change that achieved statistical significance at any time point.

Figure 1 illustrates the responses from patients at both 3 weeks and at 3 months post-surgery. Catquest-9SF and VF-8R showed changes that were statistically significant results at all time points. NEI-SES did not show statistically significant change in either of the patients subgroups until 3 months post-operatively. Neither EQ-5D nor EQ VAS showed change that was statistically significant results at any time point.

We further investigated the patients who responded to PROMs at both 3-week and 3-month post-operatively. (Table 4) Sixty-four patients responded at both time points. The changes in response to the different questionnaires were similar to those observed when all patients were considered. Significant improvements versus pre-operative responses were recorded by Catquest-9SF and VF-8R at 3-weeks post-operatively. These two questionnaires and NEI-SES also registered significant improvements from pre-operative
responses at 3-months post-operatively. However, unlike Catquest-9SF and NEI-SES whose scores significantly improved between the two follow-ups, VF-8R did not register further significant improvement during this period. EQ-5D and EQ-VAS did not yield noticeable changes at either time points.

Subgroup analyses into the effect of first and second eye cataract surgery were performed and shown in Table 5. Catquest-9SF and VF-8R both was the only measuring tool that demonstrated statistically significant changes in both groups of patients at 3 weeks; whereas VF-8R demonstrated statistically significant change only in second eye patients at 3 weeks. Subgroup analysis of NEI-SES and EQ-5D performance in both sets of patients were similar to the overall results shown in Figure 1.

Although considerable changes were recorded by VF-8R, these changes did not achieve statistical significance. EQ-5D and EQ-VAS did not yield noticeable changes.

Table 6 illustrates the Pearson’s correlation coefficients between visual function and clinical variables. Pre-operatively, only Catquest-9SF showed weak correlation to one of the four visual function variables (WEVA, r=0.22, P<0.05). All other PROM tools did not show any correction to visual function. At 3-weeks post-surgery, Catquest-9SF, VF-8R, NEI-SES and EQ-5D were found to be weakly correlated to CDVA, BEVA and WEVA. In addition, NEI-SES and EQ-5D were also weakly correlated to WVA. At 3-months post-surgery, CDVA, BEVA and WVA were weakly correlated with VF-8R and NEI-SES.
SES, while WEVA was correlated to Catquest-9SF, VF-8R, NEI-SES and EQ-VAS.

We found no association between Catquest-9SF and either pre-operative CDVA or BEVA, and weak correlation to WEVA and WVA (Pearson’s correlation coefficients 0.18, 0.14, 0.25 and 0.22, respectively). Similarly, we found no association between NEI-SES and pre-operative CDVA and BEVA, but weak correlation to WEVA and WVA (Pearson’s correlation coefficients 0.11, 0.12, 0.17 and 0.14, respectively). VF-8R, EQ-5D and EQ-VAS did not appear associated with pre-operative visual function.

Post-operatively, Catquest-9SF was weakly correlated to all four parameters of visual function at 3 weeks (Pearson’s correlation coefficients 0.28, 0.32, 0.37 and 0.32 for CDVA, BEVA, WEVA and WVA, respectively). However, it only remained correlated to WEVA at 3 months. VF-8R was only correlated to WEVA at 3 weeks, but showed weak correlations with WEVA as well as BEVA and WVA at 3 months. NEI-SES has a similar pattern of correlation to visual function, showing weak correlations at 3 weeks to BEVA, WEVA and WVA and correlation to WEVA only at 3 months post-surgery. In contrast, EQ-5D only showed weak correlation to WEVA at 3 weeks and no correlation to other parameters at any other time points. We found no evidence of association between EQ-VAS and any visual function parameters at any time point.
Discussion

Routine use of patient reported outcome measures could help patients and clinicians make better decisions, facilitate comparisons and stimulate improvements in the provision of healthcare.\textsuperscript{22,23} To our knowledge, this is the first clinical study evaluating different PROM tools in the same cohort of patients as part of routine cataract surgery in the UK NHS. This study showed that cataract surgery has a positive impact on visual function and is best measured by Catquest-9SF as early as 3 weeks after surgery. We also showed possible delayed improvements in the socioemotional construct in patients undergoing cataract surgery, and poor correlations between PROMs results (i.e. visual function) and clinical parameters (i.e. visual acuity) in cataract patients.

Cataract surgery positively impacts visual function and therefore quality of life as determined by all the instruments in this UK population, and similar to findings from previous studies have been reported by Desai and colleagues.\textsuperscript{25} Both Catquest-9SF and VF-8R were highly sensitive to this change, with the logit scores improved significantly by 162.5\% and 86.8\% at 3 months, respectively. It has been shown previously that Catquest-9SF was the most responsive questionnaire of 16 instruments in a head-to-head study, including VF-8R in a Swedish patient cohort,\textsuperscript{16} but the authors advised caution in the extrapolation of its superiority over other questionnaires to other populations. Nevertheless, our study lends support to the idea that Catquest-9SF is a highly responsive tool and may be the most appropriate questionnaire of...
choice for the measurement of patient reported outcomes in cataract surgery in UK.

Previous PROM studies have reported outcomes between 3 to 6 months after cataract surgery.\textsuperscript{9,10,11} We purposefully chose a much earlier timeframe of 3 weeks after surgery as the first point of data collection, in order to assess the feasibility of using PROMs as part of patients' routine post-operative care, since UK patients most commonly return for their final post-operative review at 2-6 weeks either in the hospital or at their community optometrist.\textsuperscript{c} By integrating PROMs with routine post-operative review, patient-reported outcomes could be collected without further patient visits or the difficulties of obtaining post-discharge questionnaire return, thereby improving patient participation rates while minimizing administrative and resource costs.

At 3 weeks post-surgery, Catquest-9SF detected statistically significant improvements in visual function in patients who underwent their first cataract surgery as well as those for the second time. In contrast, at 3-weeks post-surgery status, VF-8R similarly produced statistically significant responses in both groups of patients but to a much smaller effect, especially in first eye patients at 3 weeks only in patients who underwent second eye cataract surgery. Furthermore, we showed (Table 4) that although VF-8R responded to early improvements in patient reported visual function, it was less sensitive in capturing changes between early and later follow-up, suggesting a plateau effect of its responsiveness. These findings suggest that Catquest-9SF performance is superior to that of VF-8R, as previously shown in a head-to-head comparison study.\textsuperscript{18} Our results also showed that, while improvements
in PROM could be recorded as early as 3-week post-surgery, further significant improvement could be recorded up until 3-month post-surgery. Further longer-term longitudinal study with Catquest-9SF may help demonstrate the sustainability of the PROM changes after cataract surgery. A previous study suggested that visual function improvement in patients receiving unilateral cataract surgery was dependent on whether the fellow eye has significant visual impairment (defined as CDVA ≤0.20). However, this is an unlikely explanation for our failure to detect an effect with VF-8R, since the majority of our first eye patients had CDVA < 0.20 in the fellow eye (42 of 63, 66.7%). Visual function improvements in the first eye subgroup were statistically significant when measured by VF-8R at 3 months status-post. We therefore interpret our findings as providing evidence that Catquest-9SF captures changes of visual function at an earlier time after cataract surgery than VF-8R.

A study by Shekhawat and colleagues has shown that cataract surgeries could improve patients’ socioemotional status. Changes in socioemotional status have also been reported in cross-sectional studies involving patients undergoing other procedures, such as corneal transplants. However, to the best of our knowledge, longitudinal socioemotional changes have not been previously reported in cataract patients. In our study, changes in NEI-SES were delayed and only became statistically significant at 3 months after cataract surgery. These results suggest that improvement in socioemotional status occurred after improvement of visual function, and this phenomenon may not be fully assessable until at least 3 months.
months post-operatively. Socio-emotional changes brought about by medical interventions are currently poorly understood. We speculate that neuroplasticity could account for the delayed changes in socioemotional status. Neuroplasticity is the ability of the brain to reorganise its structure and function in response to changes in the environment, and there is now a growing body of evidence that neuroplasticity occurs in adult patients with amblyopia and those after refractive surgery. Patients with multifocal lens also seem to display neuroplasticity or "neuroadaptation" after surgery to counteract the associated side effects, such as glare, halos and loss of contrast sensitivity, and this process can take several months. While studies of neuroplasticity in ophthalmology have focused on the visual cortex, we hypothesise that changes in other areas of the brain, including ones controlling social interactions and emotional status, also occur after cataract surgery. Since changes in socioemotional construct appeared to take longer than visual function to materialise, future research in this area should take into account the timing of data collection.

In our study, EQ-5D and EQ-VAS did not respond were poorly responsive well to cataract surgery. There have been conflicting reports of validity and sensitivity of EQ-5D in patients with visual or ophthalmic related conditions. Although there are some studies showing good performances of EQ-5D in cataract patients, many of these reports consist involve of patient cohorts with very different ethnic compositions compared with to our this study. Our current results do not support the use of EQ-5D in routine assessment of patient reported visual function improvement after cataract surgery.
All the questionnaires, at best, showed weak correlation with visual acuity status. Only WEVA was consistently weakly associated with Catquest-9SF and NEI-SES at all time points. Similar findings have been reported noted in patients who underwent cataract surgery and in those with age-related macular degeneration. Our study therefore adds weight to their findings and suggests that the severity of visual acuity impairment measured in clinical settings may not fully reflect patient’s visual function or their perception of the severity of their health problems. We believe, and supports the view that pre-operative assessment of patient-reported visual function and severity of deterioration could be an important tool to help assist decision-making by both patients and clinicians.

Limitations in this study are that it has a near 30% non-respondent rate, despite multiple telephone reminders during the study period, and raises concerns on the feasibility of routine use of PROMs. Non-respondent rates of around 50% are commonly reported in studies based on mail surveys. The use of PROMs at routine post-operative visits for cataract patients would help resolve this issue. Although age and gender distribution was similar between respondents and non-respondents, there were differences in the ethnic distributions. Further work is needed to investigate any potential differences in the responses by different ethnic groups in the questionnaires we used. Furthermore, this study was based in a tertiary centre in a metropolitan area; therefore the findings may not generalize across the UK. We did not include other generic health status measuring tools due to concerns of inducing interviewee fatigue, although further studies with
different generic PROMs, such as the Health-utilities index 3 (HUI-3) may yield results that are more suitable for cost-utility analyses.

In conclusion, this study demonstrated the feasibility of collecting patient-reported outcomes in cataract surgery in routine clinical practice. Improvements in patient-reported visual function could be detected as early as 3 weeks post-operatively, with Catquest-9SF being the most responsive measuring tool. Results from NEI-SES suggest that cataract surgery could exert a delayed effect on patient's socioemotional construct and further research in this area should be mindful of the possible bias induced by timing of data collection. Generic PROMs produce insufficient response to cataract surgery and should not be used in these patients. Visual acuity measurements correlates poorly with patient-reported visual function, and the incorporation of PROMs into routine practice could assist clinical decision-making and in assessing the value of ophthalmic interventions.
What was known

- Patient Reported Outcome Measures (PROMs) are important in assessing outcomes in patients undergoing medical interventions.
- Previous reports have demonstrated the robustness of various PROMs in cataract surgery.

What this paper adds

- Catquest-9SF was shown to be the most responsive PROM tool in a British cohort at an earlier follow-up time than previously reported.
- Delayed response in NEI-SES suggests a possible late effect of cataract surgery in socio-emotional construct.


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Figure legends

Figure 1. Box-plots of patient responses to (a) Catquest-9SF, VF-8R and NEI-SES, and; (b) EQ-5D and EQ-VAS pre-operatively, at 3 week post-surgery and at 3 months post-surgery. For easier comparison, logit scores were inverted to show improvement in health states captured by Catquest-9SF, VF-8R and NEI-SES. For EQ-5D, index scores were used. For EQ-VAS, percentages (in decimal) were used. Pre-operative – white; 3 weeks post-surgery: dotted; 3 months post-surgery: diagonals.