The effect of a visual aid on the understanding of informed consent for cataract surgery in a rural, indigent South Indian population

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Disclosure

• Approval was granted by:
  • Yale University Human Subjects Committee
  • The Vision Foundation- Chennai, India

• No authors have any financial conflicts
Background

• Cataract surgery involves
  • An incision
  • Removal of the native lens
  • Placement of artificial lens
  • Risks and side effects
  • Benefits
Effects of presentation method on the understanding of informed consent.

Informed consent in vulnerable populations

• Barriers to informed consent include:
  ➢ Illiteracy
  ➢ Poor comprehension/education
  ➢ Unfamiliarity with basic scientific and medical principles
  ➢ Physical barriers - blindness, hearing impairment, organic brain disease…

➢ Physicians
Overview

Villages → Uma Eye Clinic → Hande Surgical Hospital
60 Patients Randomized

Group A
30
- Quiz
- Verbal Consent
- Surgery
- Quiz
- One day after surgery

Group B
30
- Quiz
- Verbal and Poster
- Surgery
- Quiz
cloudy lens
Before Informed Consent

Group A 30

Group B 30

After Informed Consent

Group A 30

Group B 30

1 Day Post-op

Group A 23

Group B 17

Verbal Consent

Verbal Consent and Poster
Verbal Quiz

• Most patients were unable to read, due to education or visual impairment, so the quiz was administered verbally.

• Pilot testing with Multiple Choice & Open Ended Format
  • Too difficult for patients to remember answer options
  • Patients not familiar with this testing format

• Protocol switched to an 11 Question Verbal Quiz
  • True
  • False
  • I don’t know
1. A cataract is the clouding of the lens.
2. Lack of certain vitamins, exposure to sunlight, and old age can all cause cataracts.
3. Wearing strong glasses can remove a cataract.
4. If you do not remove a mature cataract, you will suffer irreversible blindness.
5. During cataract surgery, the surgeon makes an incision in the eye with a special blade.
6. The way the surgeon removes the cataract is by breaking apart and removing the lens and placing a new, artificial lens in the eye.
7. Everyone will have improved vision after cataract surgery.
8. There are no risks involved with cataract surgery.
9. Benefits of cataract surgery include never needing glasses again.
10. The normal post-operative course is typically that vision will be perfect the next day.
11. Post-operative drops are used to prevent infection and inflammation.

Verbal Quiz

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2. Lack of certain vitamins, exposure to sunlight, and old age can all cause cataracts.
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## Results

Average Correct Responses (out of 11)

<table>
<thead>
<tr>
<th>Group</th>
<th>Before Informed Consent Mean (SD)</th>
<th>p-value for difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without poster</td>
<td>5.867 (2.161)</td>
<td></td>
</tr>
<tr>
<td>With Poster</td>
<td>4.767 (1.455)</td>
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<td></td>
<td><strong>0.02483</strong></td>
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p-value for difference between groups: 0.02483 | 0.4212
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<th>1 Day Post-op Mean (SD)</th>
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<tr>
<td>Without poster</td>
<td>5.867 (2.161)</td>
<td>7.900 (1.493)</td>
<td>7.391 (1.305)</td>
</tr>
<tr>
<td>With poster</td>
<td>4.767 (1.455)</td>
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| p-value for difference between groups | 0.02483 | 0.4212 | 0.0049 |
Mean Scores

# Correct

Without Poster | With Poster

Pre IC | Post IC | 1 Day Post Op

0 | 0 | 0
1 | 1 | 1
2 | 2 | 2
3 | 3 | 3
4 | 4 | 4
5 | 5 | 5
6 | 6 | 6
7 | 7 | 7
8 | 8 | 8
9 | 9 | 9
10 | 10 | 10
### Table 2: Change in Number of Correct Responses

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<th>Post-Informed Consent to Post-Operative Mean (SD)</th>
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<td>Without poster</td>
<td>2.033 (2.385)</td>
<td>-0.7391 (2.261)</td>
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<td>0.3244</td>
<td>0.04188</td>
<td>0.001909</td>
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Change in Scores between Testing Sessions

Change in Scores

-0.5
-1
Without Poster
With Poster

- Before Consent to Post-Op
- Immediately After Consent
- After Consent to Post-Op

Before Consent to
Immediately After Consent
After Consent to Post-Op

Without Poster
With Poster
Influence of Covariates

Was the change in scores dependent on any of the following?

Linear regression models → change in scores the dependent variable

- Group membership
- Age
- Gender
- Highest education level
- Literacy
- Previous eye surgery
- Prior knowledge of the surgery
- Visual acuity (best of the two eyes)

Only Pre-IC to Post-Op showed Group Membership to override other factors
Limitations of the study

- Difficulty in standardization due to a verbally administered quiz with translator
- Patient comprehension
- Small sample size
- Limited number of questions

- The experimental variable was based on a visual stimulus
  - Note: Analysis of covariates did not show visual acuity to be linked with any significant change in scores
Conclusions

• Informed consent improves patient comprehension of the cataract surgery.

• A visual aid improves comprehension and retention of information better than a verbal consent alone for rural, indigent South Indian cataract patients.

• A visual aid during informed consent makes patients not want to take a quiz on post-op day one.
Impact

• The poster has been adapted in several Unite for Sight locations as part of patient education prior to surgery
A sincere thank you to our patients and to the staff and faculty at the Uma Eye Clinic and Hande Hospital, especially to Dr. Tamilarasan Senthil and Dr. Arulmozhi Varman, as well as Sasi, Thanraj, and Kumar.