EBO technical review of the validity of Recommendation #14 of the Clinical Practice Guidelines for the Management of Cataract among Adults

ABSTRACT

Purpose
To assess the current validity of Recommendation #14, which states that both phacoemulsification and extracapsular cataract extraction (ECCE) are acceptable techniques among patients undergoing cataract surgery.

Methods
Updating the guideline recommendation was done in two stages: (1) identifying significant new evidence by conducting a systematic review of the literature, and (2) assessing whether the new evidence warrants updating or withdrawal by using the delphi method in soliciting the opinion of experts from the original panel that developed the guidelines. We reran the search for primary studies comparing ECCE to phacoemulsification from January 2001 to May 2005. Trials were identified from the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Group Trials Register) on The Cochrane Library and Medline. Based on the results of the identified evidence, Recommendation #14 was classified as "Retain, append new evidence." The proposed revision was sent to all members of the original panel for approval.

Results
Two new metaanalyses and one prospective randomized controlled trial were identified, retrieved, and appraised. Two trials comparing the costs and benefits of ECCE with those of manual small-incision cataract surgery were included to introduce the latter technique as an additional option in addressing the cataract backlog in the Philippines. Among the 21 members of the original panel that developed the guidelines, 15 (71%) responded. All agreed to retain and update Recommendation #14 by appending new evidence. The remaining six (29%) were not able to submit their responses in time for this update.

Conclusion
Recommendation #14 of the Clinical Practice Guidelines for the Management of Cataract among Adults should be retained but relevant new information for clinicians needs to be appended.

Keywords: Guidelines, Cataract, Phacoemulsification, Extracapsular cataract extraction
PRACTICE variations and the emerging changes in our health-care system have engendered the need for clinical guidelines in medical practice. In response to these changes, the Philippine Academy of Ophthalmology developed and released its first Evidence-Based Clinical Practice Guidelines for the Management of Cataract in March 2001. In the same year, the guidelines became the first in Asia to be included in the National Guideline Clearinghouse, an on-line database of evidence-based clinical practice guidelines put up by the Agency for Healthcare Research and Quality of the United States Department of Health and Human Services.

It has been 4 years since the cataract guidelines were developed. In a rapidly evolving field like ophthalmology, some of the recommendations formulated then may no longer represent the most appropriate in local clinical practice.

The process of updating the entire set of guidelines can be very costly and time-consuming. Thus, the committee on Evidence Based Ophthalmology plans to approach this task by evaluating the document in sections, prioritizing recommendations that are deemed outdated in reference to changes in the evidence, available resources, and values placed on outcomes.

In recent years, a growing number of local ophthalmologists have shifted from extracapsular cataract extraction to phacoemulsification because of the immediate visual rehabilitation and superior visual outcomes seen in the latter. However, in a country burdened with a huge cataract backlog and limited resources, cost-effective methods of delivering eye care may have to be employed.

It is against this background that the committee gave priority to the review of Recommendation #14, which states that both phacoemulsification and extracapsular cataract extraction (ECCE) are acceptable techniques among patients undergoing cataract surgery.

**OBJECTIVE**

To assess the current validity of Recommendation #14, which states that both phacoemulsification and extracapsular cataract extraction (ECCE) are acceptable techniques among patients undergoing cataract surgery.

**METHODOLOGY**

Using the conceptual model developed by the US Agency for Healthcare Research and Quality, the group evaluated Recommendation #14 to determine whether it should be updated or withdrawn. Accordingly, an update was warranted under any of the following circumstances:

1. New preventive, diagnostic, or treatment interventions may have emerged to complement or supersede other interventions.
2. New evidence may require updating of the estimates of benefits and harm for existing interventions.
3. New evidence may identify as important outcomes that were previously unappreciated or wholly unrecognized.
4. Evidence that current practice is optimal may change.
5. The values that individuals or society place on different outcomes may change over time.
6. The resources available for health care may change significantly.

Updating the guideline recommendation was done in 2 stages: (1) identifying significant new evidence by conducting a systematic review of the literature, and (2) assessing whether the new evidence warrants updating or withdrawal by using the delphi method in soliciting the opinion of experts from the original panel that developed the guidelines.

**Search strategy**

We reran the search for primary studies comparing ECCE to phacoemulsification from January 2001 to May 2005. Trials were identified from the Cochrane Controlled Trials Register–CENTRAL/CCTR (which contains the Cochrane Eyes and Vision Group trials register) on the Cochrane Library and MEDLINE.

The following strategy was used to search CENTRAL Issue 2 2004:

- #1 Cataract-Extraction*1:ME
- #2 Lens-Implantation-Intraocular*1:ME
- #3 #1 or #2
- #4 Cataract near Extract*
- #5 ((Lens next Opacit*) and Extract*)
- #6 Extracapsular or Phaco or Phako
- #7 Extracapsular or Manual-Small-Incision

The following strategy was used to search MEDLINE to August 2005:

- #1 EXPLODE “CATARACT-EXTRACTION”/all subheadings
- #2 “LENS-IMPLANTATION,-INTRAOCULAR”/all subheadings
- #3 #1 or #2
- #4 Lens near Opacit*
- #5 (Cataract or #4) near Extract*
- #6 Extra?Capsular or Pha?O or
- #7 Extra?Capsular or Manual- Small - Incision
- #8 (Intraocular next Lens*) near Implant*)
- #9 Sutureless near Cataract
- #10 #4 or #5 or #6 or #8 or #9
- #11 #5 or #10

The following strategy was used to search MEDLINE to August 2005:

- #1 EXPLODE “CATARACT-EXTRACTION”/all subheadings
- #2 “LENS-IMPLANTATION,-INTRAOCULAR”/all subheadings
- #3 #1 or #2
- #4 Lens near Opacit*
- #5 (Cataract or #4) near Extract*
- #6 Extra?Capsular or Pha?O or
- #7 Extra?Capsular or Manual- Small - Incision
- #8 Intraocular next Lens*
- #9 #7 near Implant*
To identify randomized controlled trials, this search was combined with the following:
1. "RANDOMIZED-CONTROLLED-TRIAL"/all subheadings
2. "RANDOMIZATION"/all subheadings
3. "CONTROLLED-STUDY"/all subheadings
4. "MULTICENTER-STUDY"/all subheadings
5. "PHASE-3-CLINICAL-TRIAL"/all subheadings
6. "PHASE-4-CLINICAL-TRIAL"/all subheadings
7. "DOUBLE-BLIND-PROCEDURE"/all subheadings
8. "SINGLE-BLIND-PROCEDURE"/all subheadings
9. #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
10. RANDOM* or CROSSOVER* or FACTORIAL* or PLACEBO* or VOLUNTEER* in TLAB
11. (SINGL* or DOUBL* or TREBL* or TRIPL*) near (BLIND* or MASK*) in TLAB
12. #9 or #10 or #11
13. HUMAN in DER
14. #12 and #13
15. #13 not #14
16. #11 not #15

Data Collection and Analysis

Identified evidence was used to assess the current validity of Recommendation #14. These results were used to classify the recommendation into one of the following categories:
1. Withdraw. New evidence called into question 1 or more key therapeutic recommendations, or new evidence suggested the need for new key therapeutic guideline recommendations.
2. Retain, append new evidence. Key therapeutic recommendations were still valid, but new evidence supported changes to other recommendations, or supported greater refinement of existing recommendations.
3. Retain. The guideline continued to represent good clinical care.

Based on the results of the identified evidence, Recommendation #14 was thus classified as Retain, append new evidence. The proposed revision was sent to all members of the original guideline developer group for approval.

RESULTS

Two new metaanalyses6,7 and 1 prospective randomized controlled trial8 were identified, retrieved, and appraised. Two trials comparing the cost and benefits of ECCE with those of manual small-incision cataract surgery9,10 were included to introduce the latter technique as an additional option in addressing the cataract backlog in the Philippines. (See Appendix for details.)

Among the 21 members of the original panel that developed the guidelines, 15 (71%) responded. All 15 agreed to retain and update Recommendation #14 by appending new evidence. However, 3 out of the 15 (20%) did not accept all the proposed changes. One remarked that the outcomes should have been expressed in odds ratio or relative risk for the strength of the recommendation to be better appraised. The other 2 suggested that phacoemulsification be singled out as the preferred procedure. The remaining 6 (29%) of the 21 members of the panel were not able to review and submit their responses in time for this update.

Based on the review, 2 studies11,12 previously cited were also excluded from the Summary of Evidence.

CONCLUSION

Based on these data, Recommendation #14 of the Clinical Practice Guidelines for the Management of Cataract among adults should be retained but relevant new information for clinicians needs to be appended.

References
Appendix
Clinical Practice Guidelines for the Management of Cataract among Adults

Updated Recommendation #14

Among patients undergoing cataract surgery, small-incision surgery (either by phacoemulsification or manual phacofragmentation) and extracapsular cataract extraction (ECCE) are acceptable techniques. (Grade A Recommendation)

SUMMARY OF EVIDENCE

Currently, the two most common cataract-extraction procedures being done in the Philippines are phacoemulsification and extracapsular cataract extraction (ECCE).

ECCE by phacoemulsification uses an ultrasonic device that emulsifies the hard nucleus, enabling the surgeon to remove the lens material by a suction device. This method allows smaller incisions. In ECCE by nuclear expression, the hard nucleus is removed from the capsular bag in one piece, and the residual cortex is removed by irrigation and aspiration. This procedure requires a larger incision and several sutures to close the wound.

A metaanalysis by Powe et al. (1994), which involved 90 studies published between 1979 and 1990, reviewed the effectiveness and risks of modern cataract surgery. The study showed that complications of IOL malposition or dislocation and retinal detachment were no different for phacoemulsification vs. ECCE (pooled OR of 1.1; 95% CI: 0.5-2.4 and pooled OR 1.1; 95% CI: 0.4-2.8). However, the proportion of eyes with vitreous loss was lower following phacoemulsification than ECCE (pooled OR 0.14; CI 95% 0.05-0.41).

In terms of intraoperative and perioperative adverse events, numerous studies comparing the aforementioned procedures have been done. A one-year prospective study by Oshika et al. (1992) assessed the time course of change in intraocular inflammation after three cataract surgery procedures. It demonstrated that immediate postoperative inflammation was significantly greater in the larger-incision-surgery groups.

Schein (1994) concluded that phacoemulsification was a better procedure than ECCE in terms of immediate postoperative complications (RR of 0.79 and 0.85, respectively). However, four months after the surgery, the two techniques were comparable in terms of adverse-events rate (RR 1.15).

Another study by Montan et al. (1998) revealed that a higher percent of endophthalmitis occurred in patients who had ECCE (0.27%) compared with those who underwent phacoemulsification (0.20%). However, a systematic review by Taban et al. (2005) indicated an increasing incidence of endophthalmitis associated with the development of sutureless clear corneal incisions over the last decade.

The strongest evidence to date is a metaanalysis by Snellingen et al. published in The Cochrane Library, Issue 2, 2004. This review included 6 randomized controlled trials evaluating surgical treatment for 7,828 people with age-related cataract. Phacoemulsification gave a better visual outcome than extracapsular surgery. In addition, the costs per procedure were not markedly different between the two techniques. Extrapolation of these results to other parts of the world where cataract surgery is very different must, however, be made with caution.

Another metaanalysis by Wei Li You (2004) likewise showed results in favor of phacoemulsification in providing excellent and immediate visual rehabilitation.

Phacoemulsification is considered the standard of care for cataract surgery in developed countries. But in developing countries, the cost of equipment, training, consumables, and maintenance should be considered. There is evidence pointing to manual phacofragmentation, also known as manual small-incision cataract surgery (MSICS), as an acceptable and cost-effective procedure in addressing the cataract backlog in developing countries.

In the single-masked, randomized controlled trial by Gogate et al., MSICS, done through a scleral tunnel that does not need to be sutured, showed better short-term visual results than standard ECCE, particularly before correction, with fewer complications or adverse outcomes and marginally lower cost.

Nonetheless, more local data are needed to compare the value and applicability of these different techniques in the Philippines where cataract is still the leading cause of blindness. Ultimately, the choice of surgical technique depends on the type of cataract, the surgeon’s skills, and available resources.

References

Appendix References