Taiwan Journal of Ophthalmology xxx (2016) 1–5

Contents lists available at ScienceDirect

Taiwan Journal of Ophthalmology

journal homepage: www.e-tjo.com

Review article

Evidence-based medicine in glaucoma surgery

Yoshiaki Kiuchi*

Department of Ophthalmology and Visual Sciences, Graduate School of Biomedical Sciences, Hiroshima University, Hiroshima, Japan

A R T I C L E I N F O

Article history:
Received 12 January 2016
Received in revised form
8 May 2016
Accepted 16 May 2016
Available online xxx

Keywords:
evidence-based medicine
glaucoma
trabeculectomy
tube surgery

A B S T R A C T

Evidence-based medicine (EBM) is a tool and guide for performing effective medical treatment. Here, as an example, EBM was applied to determine which between trabeculectomy and Baerveldt implant surgery would be more effective in a patient with a history of open-angle glaucoma. First, the author asked answerable clinical questions. Second, evidence using general search engines, such as the Cochrane Library or MEDLINE database, was collected. It was found that the Tube Versus Trabeculectomy (TVT) Study was a landmark study in determining optimum glaucoma surgical procedure. Third, the study's level of evidence was carefully examined. As the TVT Study was a prospective, randomized multicenter control study, its level of evidence was high. Fourth, the evidence to actual clinical decisions was applied, calculating the magnitude of the treatment effect using the results of the TVT Study. The event (surgical failure) rate in the control (trabeculectomy) and experimental (tube implant) groups (control event rate and experimental event rate, respectively) was obtained and the absolute risk reduction (ARR) was calculated by subtracting the experimental event rate from the control event rate. The inverse of ARR is the number needed to treat (NNT), which is the number of patients who must be treated to prevent a bad outcome. Using this method, it is possible to calculate the absolute risk (adverse event) increase (ARI) and the number needed to harm one more patient (NNH = 1/ARI). The balance of NNT and NNH is called the "likelihood of being helped and harmed." The practice of EBM integrates clinical expertise of individuals with the best available external clinical evidence from systematic research.

1. Introduction

Evidence-based medicine (EBM) is the conscientious, explicit, and judicious use of the optimal, current evidence to make decisions about the care of individual patients. The practice of EBM integrates individual clinical expertise with the optimal available external clinical evidence from systematic research.[1,2] EBM is a tool and guide for achieving effective treatment outcomes. To perform EBM studies, doctors are required to constantly gather new information. EBM is connected to lifelong learning and enhancing the performance of doctors. EBM was initially proposed more than 20 years before by Gordon Guyatt and is a well-recognized term in the medical field.[3–6] However, it is unclear how well doctors truly understand the concept of EBM. In this study, EBM is applied to a glaucoma patient and the specific steps used are discussed.

2. Case scenario

2.1. Patient and her medical history

The patient studied was an 82-year-old woman with a history of open-angle glaucoma for > 10 years. Her ophthalmologist gradually increased the dosage of eye drops due to deterioration in her visual function. She was currently using eye drops of a prostaglandin analogue, beta-blocker, carbonic anhydrase inhibitor, and alpha-2 stimulator in both eyes. Because of severe ocular surface damage, the patient also took hyaluronic acid to treat superficial keratopathy. She had a mildly high blood pressure level and required only one medication to maintain her blood pressure level within the normal range. She had no other systemic diseases, such as diabetes mellitus, heart disease, lung disease, or a malignant tumor. Her corrected visual acuity was 0.3 in the right eye and 0.5 in the left eye; intraocular pressure (IOP) was 22 mmHg and 28 mmHg in the

Conflicts of interest: The author has no proprietary or commercial interest in any of the materials discussed in this article.

* Corresponding author. Department of Ophthalmology and Visual Sciences, Graduate School of Biomedical Sciences, Hiroshima University, 1-2-3 Kasumi Minami-ku, Hiroshima 734-8551, Japan.
E-mail address: ykiuchi@hiroshima-u.ac.jp.

http://dx.doi.org/10.1016/j.tjo.2016.05.003

right and left eyes, respectively. The mean deviation values according to the 30-2 program of the Humphrey visual field analyzer were −18.7 dB in the right eye and −25.0 dB in the left eye.

Superficial keratopathy was graded as A2D3 in both eyes (Figure 1).[7] She underwent cataract surgeries in both eyes by temporal clear corneal incision. Multiple antiglaucoma agents were suggested to be the possible cause of her ocular surface disease.

EBM consists of five parts, and these are detailed with respect to this patient in the following sections.

3. Step 1. Collecting answerable clinical questions.[1,5,6]

The clinical questions comprise the following four essential components: "P," patients or population; "I," intervention of exposure, test or other agents; "C," comparison of interventions; and "O," outcome(s) of clinical importance.

3.1. Patient

In 2013, the average life expectancy of a Japanese woman was 86.61 years.[8] Will this 82-year old-female patient die 4 years later? However, elderly people are anticipated to live a long, healthy life. An 82-year-old Japanese woman could live an additional 10.12 years.[8] The patient had mild blood hypertension, but no other severe diseases. Therefore, she might live an additional 10 years and possible up to 100 years. The patient's old age cannot be an excuse to ignore the therapeutic strategy.

Elderly patients with vision loss can readily develop cognitive damage. Nursing a man with dementia and vision loss is challenging for the caregiver and society. Therefore, maintaining good IOP and visual function in elderly people throughout their entire lifespan is a primary concern of ophthalmologists.

3.2. Intervention

The patient's visual field in both eyes indicated end-stage glaucoma. Antiglaucoma eye drops could not sufficiently control IOP and caused ocular surface damage. Although additional laser therapy might decrease her IOP, IOP reduction alone would be insufficient to protect her visual function.[9,10] Therefore, glaucoma surgery appeared to be necessary to achieve low IOP levels.[11]

3.3. Comparison

It is common to perform trabeculectomy in patients with uncontrollable primary open-angle glaucoma. Recently, the results of the Tube Versus Trabeculectomy (TVT) Study were published. The study demonstrated the superiority of Baerveldt implantation over trabeculectomy with mitomycin C (MMC) in controlling IOP.

3.4. Outcome

Which is better for this patient: Baerveldt implantation or trabeculectomy with MMC?

4. Step 2. The next step in EBM is "Collecting the necessary information."

First, the guidelines for glaucoma were reviewed.

The European Glaucoma Society published the *Terminology and Guidelines for Glaucoma* in 2014.[12] The use of long-tube devices, such as those described by Molteno, Krupin, Baerveldt, Ahmed, or Schocket, are generally reserved for patients with risk factors for a poor outcome following trabeculectomy with antimetabolites (weak recommendation, very low evidence), although recent trials have established their efficacy and safety in primary surgical procedures (weak recommendation, moderate evidence[12]). Factors that decrease the chance of successful trabeculectomy and make tube surgery attractive include previous failed filtering surgery with antimetabolites, excessive conjunctival scarring due to previous ocular surgery with severe conjunctival or surface disease, active neovascular disease, pediatric aphakia, or cases where filtration surgery will be technically difficult (weak recommendation, very low evidence).

The guidelines proposed by the Japan Glaucoma Society[13] also presented a similar standard for tube surgeries. Both recommendations were graded as weak recommendation, very low evidence.

Information from medical search engines and textbooks were once recommended as informative sources. However, many believe that textbooks should be avoided for EBM, as the information in textbooks may be outdated due to long durations before publication.[1] Nonetheless, textbooks remain useful to obtain standard background information.

The PubMed/MEDLINE and The Cochrane Library databases must be continually checked. For this work, when "tube versus trabeculectomy" was entered as a search term in the PubMed database, 29 manuscripts, published until the end of October 2015, were identified. The TVT Study was a landmark study for determining the glaucoma surgical procedure.[14,15] When the search term "Baerveldt glaucoma implant" was entered in the Cochrane Library database, similar results were obtained.

The TVT Study found that tube shunt surgery had a higher success rate than trabeculectomy with MMC during a 5-year

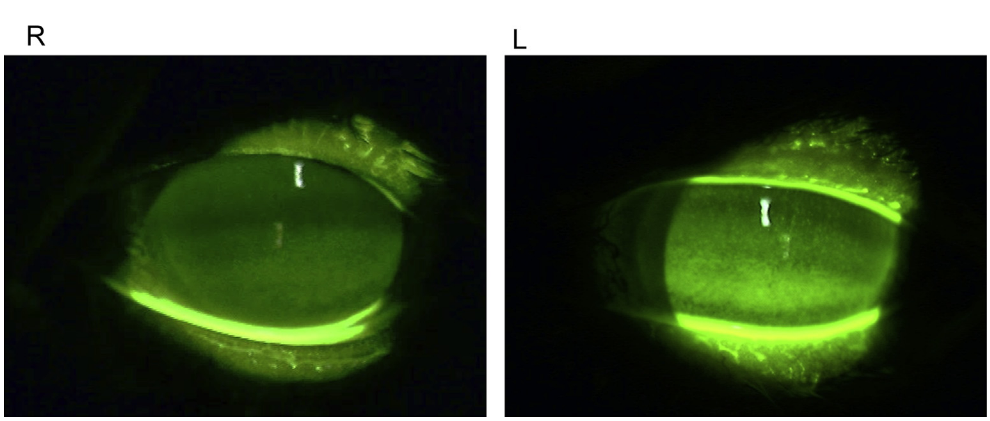

Figure 1. Fluorescein staining in the cornea. L = left; R = right.

Please cite this article in press as: Kiuchi Y, Evidence-based medicine in glaucoma surgery, Taiwan Journal of Ophthalmology (2016), http://dx.doi.org/10.1016/j.tjo.2016.05.003