Evidence-based medicine in eye care-Relevant research to inform practice!

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Evidence-based medicine aims to help clinicians and practitioners with information on how to care for their patients by making use of the best evidence available.[1],[2]This evidence invariably derived from deliberations at conferences, meetings, or unpublished and published scientific literature. " Hunches" or "gut feelings" or "expert opinions" have had an informal burial with the birth of the more formal evidence-based medicine, which now influences clinical decision-making and practice.

There have been rapid advances relating to technology and clinical management in the practice of ophthalmology. Knowledge regarding such advances has had the opportunity to percolate down to the practitioner through various media of dissemination. However, it is ultimately the discretion of the treating practitioner, in our case the ophthalmologist, to decide *(1) What the results are? (2) Are they valid? and (3) Are they applicable to the patients I treat?* Epidemiology and Statistics shed light on questions 1 and 2 above but only set a direction for question 3. The third question must be answered using scientific methods.Evidence-based medicine allows the physician to answer such questions as: the representativeness (external validity) of the subjects (Are the study subjects similar to the patients I see?); adequacy of the numbers studied to produce valid results (was the sample size adequate?); the benefits and costs of treatment and the numbers needed to treat (NNT) or harm (NNH). The NNT,[3],[4] a current buzzword in evidence-based practice, is a reflection of the number of patients that need to be treated to prevent a negative outcome in one patient. The smaller the NNT, the more efficacious the treatment. The treatment decision also takes into account affordability of the treatment, and the natural history of the disease.

Ocular melanomas can be fatal if not treated appropriately due to the potential for widespread dissemination and metastasis to other vital organs. The fatal nature of the disease has prompted much research into various treatment options for this disease. However, large scale randomized

controlled trials for different interventions have been limited by the rarity of the disease. Limitations also include enrollment of a sufficient number of subjects to make valid conclusions, and the potentially long follow-up required to ensure there is no recurrence or effect of the tumour. The COMS study involving 43 centres across the United States and Canada, in progress since 1985 illustrates these difficulties.[5]

Another pressing issue that informs practice is " clinical relevance of study outcomes". Considering the COMS study[5], what implications do these results have for clinicians in India? The first issue is the generalizability of the results to an Indian population. Are these results in the Caucasian population valid for patients in India? It is not clear if the natural history of the disease is different for patients in the Indian subcontinent. Currently there are no studies to either refute or support such a hypotheses. However, other issues need to be considered while looking at representativeness. One would be the relative rarity of ocular melanoma. It might take another 15 years to prospectively get a large enough sample size of patients to either prove or disprove similarities in the disease course between Caucasian and Asian Indian populations. It may be possible to get this information through a retrospective review of case records. However, it is more likely that there will be a lot of missing detail in retrospective analysis to make any valid conclusions. Secondly, the almost fatal nature of the disease requires initiating treatment at an early stage, which the reviewed study[5] has suggested. Considering these factors it does not appear that representativeness of the populations should be a major issue to consider initiating treatment. It is, however, a moot point; if modalities of treatment and resolution of disease differ based on ethnicity of the population. Were these patients representative of a North American population? Although only close to 50% of those eligible enrolled in the study, the characteristics of those who enrolled, and those who did not, were well balanced to suggest representativeness. Additionally, the study subjects probably comprised 34-45% of incident cases expected during the 11.5 years of COMS patient accrual suggesting a certain degree of representativeness.

The next issue is the sample size of subjects studied. The COMS trial studied an adequate number of subjects, and also followed them up for a reasonably long period of time. The large sample size for a relatively rare condition like ocular melanomas and the large number of subjects followed at the 5-year interval (81%) suggest that the results may be considered valid. The results suggest that 5-year all-cause mortality was not significantly different between those enucleated and those treated with brachytherapy. There was no statistical difference for 5-year mortality among subjects with medium-sized melanomas who were either treated or not treated; however, this may due to the smaller number of subjects without treatment studied at 5 years. The visual impairment rates after brachytherapy may appear to fall alarmingly. But it may be presumed that this is definitely better compared to the "no vision status" after enucleation or among those not treated **.** Again vision loss is surrogate to the near fatal consequences in conditions like ocular melanoma!

In terms of the NNT, through a very rough calculation, if 5-year mortality rates following treatment is 18% as compared to the mortality among those eligible but not treated (30%), then the NNT is about 8. The implication is that just more than 8 patients of medium sized ocular choroidal melanoma are to be subjected to treatment to prevent one less death from occurring at the end 5-years compared to no treatment at all. This does not tell us how many other complications may arise from brachytherapy compared to no treatment alone. Are the costs that are tangible and benefits that are both tangible and intangible worthwhile? Taking into consideration that the sample size in the natural history group is very small to attempt any valid judgement about whether to treat or not, we may at this point be open to the vagaries of probability!

So what then, does this trial imply for the ophthalmologist? They *are*

1) There is no conclusive evidence that any particular modality of treatment is better than the other for

treatment of medium-sized melanomas

2)There is no conclusive evidence that current treatment modalities offer benefits compared to no

treatment for medium-sized melanomas.

3) Early diagnosis and treatment of melanoma is important.

How does one translate these conclusions into clinical practice? 1) Have a higher index of suspicion for ocular melanomas for early diagnosis, 2) Make a balanced judgment regarding the cost-benefits of the treatment- does the chance for vision impairment after brachytherapy still provide a better quality of life to the patient compared to the "no vision" status after enucleation? Fortunately, choroidal ocular melanomas are most of the time unilateral and unifocal. Such a judgment will have to consider the needs of individual patients, including affordability of treatment. The absence or negligible quality of low vision or rehabilitation services in India will make such decisions somewhat easier: in our case, enucleation.

It is apt to conclude that scientific knowledge and literature is growing exponentially, but at the same time it is imperative that practicing physicians summarize and assimilate information into useful entities, some of which are described above, to inform our decisions.

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