

Ophthalmic Research in India: Are We on the Right Track?

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Abstract: Research plays an important role in the present era of evidence based medicine. The article deals with the present scenario in the field of research in India in terms of opportunities and challenges. India has been projected as one of the attractive destinations for conducting United States of America's FDA regulated clinical trials. The large patient base, well equipped and state-of-the-art health care bodies, English speaking properly trained physicians, accredited laboratories and good information technology network are some of the reasons helpful in conducting trials in India. However, challenges which a researcher has to face in India are : Low priority to research over clinical practice, lack of conducive environment to perform high quality research in India, pursuing vigorous research here is considered as "professional suicide", ignorance of ethical concern, lack of training in basic clinical research, and inadequate infrastructure for research in many medical colleges. The picture may look gloomy but as a silver lining, various Governmental organizations are always ready to finance the appropriate projects and many courses are being conducted on regular basis to train researchers in various aspects of research. In conclusion, the opportunities are tremendous for conducting research in India.

In today's era of evidence-based medicine, research plays an integral part in the development of any science including the medical field. It is seen that proper infrastructure and sufficient funds are the basic needs for any research, but are not given priority by either the Government or any Institution in our country. Understandably, the basic health care gets top priority by the Government. The progress of Indian economy has improved ophthalmic care and research in India, which is evident by a steady increase in the publications by Indian authors.

The path of research is not rosy. Research needs commitment, honesty and time. Wong et al.¹ have beautifully enumerated certain challenges in the development of research, particularly, for the Asian countries. To begin with, departmental heads and institutions give more recognition and weightage to high volume clinical work instead of "high priority" to research activities. People are yet to realize that quality research needs time and cannot be done as a part time hobby. However, the concept is changing slowly and publications in indexed journals are taken into consideration for individual job promotion and institutional recognition. Secondly, there is lack of conducive environment to perform high quality research by clinician scientists in India. There is no dearth of researchers, as indicated by the fact that many Indians are involved in quality research abroad. When they come back to India, they are well recognized initially. However it has been noticed that most of them do not pursue vigorous research here as many consider it "Professional suicide". One also has to contend with the fact that research ethics are ill understood in India and not followed to the core.

It has been estimated that upto 65% of FDA regulated trials will be outsourced from US. India and China have been projected as the most attractive destinations for these clinical trials². Various reasons for this have been nicely enumerated by Thatte et al.² India has a large population of treatment naïve patients. The large population of our country is supported by well equipped and state-of-the-art healthcare bodies which have trained English speaking physicians, which make it easy for undertaking trials, which need large hospitals with a big patient load. All of this is supported by good communication and information technology capabilities. Also, accredited labs with good network help in high enrollments of subjects who are compliant and can be retained for the entire study. Data entry, management, analysis and ultimately report writing are now easy to manage due to the advancement in infrastructure. Since the patients are well informed

by the physicians about the trials there is no negative perception in their minds which goes a long way in making the research a success and building up a strong patient base. Clinical research organizers (CROs) find it quite economical in conducting researches in India, hence they can save a large amount of expenditure.

There are many limitations that investigators encounter while conducting research in India². Lack of adequate infrastructure and well trained staff and their high turnover at some institutions is usually made up by the sponsors of the study. The doctor patient ratio is deficient in India hence doctors are put to the most essential work of basic health care. Doctors also need to be trained in basic clinical research, ethical issues regulatory requirement and Good Clinical Practice (GCP) guidelines. There is a lack of opportunity for developing skills required for conducting these clinical trials such as counseling research participants, documentation and performing pharmacovigilance. The basic characteristics of good investigators are integrity, enthusiasm and experience. India is a vast country and there is quite a bit of variability in standard of care, infrastructure and attitude. Usually, the participating centers in the trials do not participate in study planning and protocol writing. Most of the investigators participate due to the financial interest as the payments made towards the study are considered high for Indian standards. The conflict of interest creeps in due to "payment for performance" strategy.

There is lack of infrastructure for basic post graduate training in many medical schools of India³⁻⁶, hence, to expect research facility in these institutions will be far from reality. Though conducting research and writing thesis is included in the curriculum of all post-graduate training programs, majority are conducted without any proper planning. To a large extent it is due to poor understanding of the total process of research activity.

Though the picture looks gloomy, it is *changing* for better. This is because of the increasing number of publications by Indian authors. A Pubmed search of publications by Indian authors and institutions in 2008 yielded 16290 results whereas it was 11307 in 2005. Also, institutions like Indian Council of Medical Research (ICMR), Department of Science and Technology (DST), Department of Biotechnology (DBT) and others are very active and always ready to grant funds for appropriate research. ICMR has identified new areas of research in ophthalmology and designated coordinators for the specific areas. We should not be ecstatic about the fact that India

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is fast becoming a new destination for conducting the multi-centric trials. I would like to put a word of caution here that we should not consider this as another avenue for revenue, but should be treated as an opportunity to participate in research^{7,8}, while signing the clinical research agreement (CRA).

Well formulated programs by dedicated teams appear like silver lining. Here I would like to make a mention of the regular programmes conducted by Indian Journal of Ophthalmology in association with P.D.Hinduja National Hospital and Medical Research Centre on Research Methodology and Scientific Writing. We have noticed a steady increase in the demand and popularity of this course and the feedback from the attendees has been very encouraging and we keep receiving plenty of appreciation letters. Developing interest in research is also evident by the popularity of the short term studentship (STS) programme of ICMR⁹. It is only natural to acknowledge that some ophthalmic institutions in India have set up good research facilities. It would be inappropriate not to make a mention of five institutions in this regard : Dr. Rajendra Prasad Centre for Ophthalmic Sciences, New Delhi; L.V. Prasad Eye Institute, Hyderabad; Post Graduate Institute, Chandigarh; Sankara Nethralaya, Chennai and Aravind Eye Hospital, Madurai.

To conclude, the research scenario in India was not very good some

time back, but things are changing, opportunities are being created and support system, as well as, infrastructure is improving. Above all, the mind set is changing and approach towards research is becoming positive. I am quite optimistic and can say it with confidence that we are on the right path.

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LITERATURE REVIEW

Clinical Features of confirmed versus suspected Urogenital Tuberculosis. Zarrabi AD, Heyns CF, Urology. 2009 May 8.

This study compared the characteristics of confirmed vs suspected cases of urogenital tuberculosis (UGTB) in a geographic region with an extremely high prevalence of pulmonary tuberculosis. UGTB is notoriously difficult to diagnose. A retrospective clinical record review was performed of 68 patients treated from March 1989 to July 2007. Group 1 has UGTB confirmed by microbiologic or histologic examination. Group 2 had a high suspicion of UGTB because of the clinical features, but no microbiologic or histologic confirmation. This data were collected and statistically analyzed using Student's t-test for parametric data and Fisher's exact test for contingency tables ($P < 0.05$ was accepted as statistically significant, except for flank pain (14% vs 43%), renal cavitation (14% vs 44%), urolithiasis (0% vs 25%), and ureteral stricture formation (7% vs 39%) in groups 1 and 2, respectively. Anti TB medication was given to patients (30%) in group 2 despite the lack of a confirmed diagnosis. The outcome in terms of complications and renal function loss was not significantly different between the 2 groups. Flank pain, renal cavitation, urolithiasis, and ureteral stricture formation were significantly more common in the group with suspected UGTB than in those with confirmed UGTB. However, other clinical characteristics did not differ significantly between the 2 groups. In patients with clinical features highly suspicious of UGTB, it appears reasonable to institute anti-TB treatment, despite the lack of a confirmed diagnosis.

Erectile dysfunction after prostatectomy: An evaluation of the risk factors. Soleimani M, Hosseini SY, Aliasgari M, Dadkhah F, Lashay A, Amini E. Scand J Urol Nephrol 2009 April 29:1-5

The occurrence of erectile dysfunction (ED) in patients who have undergone prostatectomy has been assessed in the previous studies; however, its rate and risk factors vary in different studies. This study was conducted to assess the possible risk factors for ED after prostatectomy. **MATERIAL AND METHODS:** In total, 246 men with benign prostatic hyperplasia (BPH) who were candidates for either open prostatectomy or transurethral resection of the prostate (TURP) were admitted in this study during a period of 3 years between December 2000 and December 2003. Cardiac risk index was assessed before the operation using American Heart Association guidelines and erectile function was assessed both preoperatively and 6 months after surgery. Patients with moderate to severe ED according to the five-item version of the International Index of Erectile Function were considered as ED afflicted. In this study, the prevalence of preoperative ED, the incidence of postoperative ED, and those conditions that could lead to an increase in the incidence of postoperative ED in either procedure were determined. **RESULTS:** The mean age of the patients was 63.7±9.7 years. The prevalence rates of preoperative ED were 24.6% and 25.9% in TURP and open prostatectomy groups, respectively. Among patients with no or mild ED preoperatively, 12.5% showed moderate to severe ED postoperatively (13.4% in TURP group vs 11.25% in open prostatectomy group). **CONCLUSIONS:** The incidence rate of postoperative ED after prostatectomy was 12.5%. Risk factors for its appearance included hypertension, diabetes mellitus, higher transfusion rates, higher cardiac risk index and an older age.