

## **Commentary: Increasing cases of litigations against ophthalmologists: How can we minimize litigations during ophthalmic practice?**

The medical profession is considered to be one of the noblest professions in the world. The practice of medicine is capable of rendering noble service to humanity provided with due care, sincerity, efficiency, and professional skill is observed by the health professionals. India is rapidly becoming one of the main destinations for medical tourism. With highly advanced medical setups, healthcare centers equipped with the latest medical technology and internationally trained medical professionals, India is making a name in the global health care industry. Offering reasonable, less expensive and efficient alternatives to complex medical procedures, patients from different countries prefer to have their treatment and surgeries in India.<sup>[1]</sup>

While we are making tremendous progress on the global map, on the contrary, doctor–patient relationship is deteriorating, our internal medical setup is facing extensive problems with medical litigation being the most serious of all issues. Many doctors are charged for their lack of diligence, leading to litigations in the consumer courts and civil or criminal courts.

Ophthalmology, in this respect, is no different from other medical sectors. Being one of the most complex and high-tech specialties, even the slightest error from the ophthalmologists' end can lead to severe consequences including lifetime blindness and visual impairment of the patient.

Several cases have been reported against ophthalmologists and decisions have been taken by the National Consumer Disputes Redressal Commission (NCDRC). It is reported that 942 cases of medical negligence were decided by the NCDRC from 2002 to 2018 and, out of these cases, 30 were related to ophthalmology. A total of 73.3% of the alleged cases of medical

negligence in ophthalmology were proved, and compensation for the cases ranged between Rs. 200,000 and Rs. 10 million.<sup>[2]</sup>

Such deplorable numbers compel the fraternity to indulge in evaluating the reasons behind the prevalence of such practice and efforts should be done to educate and sensitize ophthalmologists to minimize such cases. There are several cases taking place frequently which continue to raise questions against the quality of practice being led by the ophthalmologists in the country.

In some instances, the judgment was given against the ophthalmologist even for complication well reported in the published literature. For example, an ophthalmologist in Gujarat was asked by the consumer court to pay Rs. 100,000 compensation to a patient for vitreous hemorrhage following an anti-VEGF (Avastin) injection in the patient's eye, leading to temporary blindness.<sup>[3]</sup> Vitreous and retinal hemorrhage have been reported as complications of intravitreal injection in the published ophthalmic literature; however, as per court judgment, this case was clearly one of negligence and deficiency in service.

In another case reported from Punjab (2017), the State Consumer Disputes Redressal Commission passed a judgment against the hospital and the ophthalmologists for their medical negligence in the treatment of the patient and failure to produce the pertaining medical records.<sup>[4]</sup> The complainant was suffering from diabetes for 13 years and was on antidiabetic drugs. According to the court, the medical professionals did not produce any medical record showing that the required measures were taken to control the blood sugar and blood pressure before conducting the surgery. Also, the hospital team did not take valid consent from the complainant before conducting the laser treatment and did not disclose any risk or complication involved in the process. The decision was passed against the hospital and a compensation of Rs. 2, 00,000 was awarded to the complainant's heirs.<sup>[5]</sup>

In light of the above-mentioned cases, it is evident why there are a rising number of legal cases against ophthalmologists. It is extremely important for all ophthalmic colleagues to follow the checklist, take informed consent, explain the pros and cons of treatment and document it in medical records, and an overall due diligence carried out in this specialty. It is recognized that human error is the root cause of such breaches in patient safety — either preoperatively or intraoperatively — and at least some are preventable. Major risk factors for mistakes related to high-volume ophthalmic surgery include a breakdown in communication between the surgeon and the patient and team, the lack of verification procedures (e.g. incorrect IOL power), inadequate validation of site marking procedures (e.g. surgery in the wrong eye), inadequate preoperative checklists, incomplete patient assessment, staff distractions, limited or compromised information available in the operating room, and cultural or language barriers that may not be uncommon during high-volume eye surgery.

## Medical Negligence

### How to minimize error(s) by following the "checklist" and "protocols"?

When it comes to medical negligence, it is an accepted fact that the ophthalmologists operate in spheres where the success and failure of a case depend on various factors that may or may not

be in the control of the professional (for example contaminated irrigating solution). However, negligence is not something that can be overlooked. If the legal definition of the term is looked up to, it is the standard of conduct that is to be observed under all likely circumstances.<sup>[6]</sup> Train your staff members and OT team to follow the checklist and protocols to minimize any error(s). Double check the consent signed by the patient, site of operation, and medical records etc. before taking the patient in the OT, check the IOL type and its power, carefully inspect the irrigating solution for any floating particles, always cross check date of expiry of drugs and devices. Always follow the practice to minimize postoperative endophthalmitis such as application of adhesive drapes, preoperative cleaning of eye and periocular area with 5% povidone iodine solution and instillation of one drop of povidone iodine solution after completion of intraocular surgery.

Exercising utmost care while performing eye surgery or giving intravitreal injections is important as patient is actively listening all conversation and may (wrongly) correlate negligence in case of lack of desired results. Most of the eye surgeries are done under topical or local anesthesia with the doctor speaking to their staff or anesthetists and the patient hearing everything.

The main factor behind increased penalties against ophthalmologists concerning medical negligence is greater consumer awareness as well as information about diseases and treatment available on Internet ("Dr. Google"). The patients are now more aware of their consumer rights and are provided forums and legal means to pursue their claims against the doctors.<sup>[7]</sup> This awareness has led many ophthalmologists to unnecessary legal charges, and the decision against doctors are published by the media houses prominently encouraging other patients to follow the same route. Never criticize or disapprove treatment or surgery done by your professional colleague in front of patients or relatives as it can provoke them to file malpractice lawsuits.

The increased cost of service delivery has ultimately led the consumers to have higher expectations from the medical providers. Combined with the increased awareness and the availability of means to vocalize their grievances, patients can highlight cases of negligence even for the smallest deficiency in the service.

### Poor record keeping and poor preoperative and postoperative communications

The perceived loss of vision is the second-highest probability after death. This increases the chances of litigations carried out against ophthalmologists. With higher treatment cost and more possibility of damage as compared to other specialties, ophthalmologists are more inclined towards getting complaints registered against them.

According to a study, there are 31.25% proved cases of medical negligence.<sup>[8]</sup> An analysis of the ophthalmology-related cases carried out by Yadav, Bansal, and Garg (2018) states that 14 cases out of 30 were reported to have a deficiency of service present at the postoperative stage and one case at the preoperative stage.<sup>[2]</sup>

The preoperative stage entails taking valid informed consent (video consent in all high risk cases) of the patient for executing the proposed treatment, taking and recording the history of the patient, carrying out a proper examination,

diagnosis and investigations, preanesthetic check-up, detailed counseling, complete systemic and ophthalmic investigations and then treatment.

The operative stage includes the complications encountered during the operation, accidents, and mishaps experienced while operating, (for example implanting wrong IOL), death during operation, and other similar incidents. Always take help of anesthesiologist for monitoring vital parameters after taking patients in the operation theater.

Under the postoperative stage, operative notes, discharge, follow-up advice, detailed instructions about using the medications/eye drops, and communication about the postoperation complications are included. With 11 out of 30 cases having a deficiency of service at the postoperative stage shows that ophthalmologists are not as vigilant in maintaining good communication with the patients or taking enough time to go through the postoperative measures to ensure a healthy recovery. As a result, the chances of infections and complications increase, leading to alleged medical negligence cases.

There is a dire need of maintaining a practice of good interpersonal skills with the right approach taken to follow the checklists (at each and every step) and maintain proper documentation. This will not only ensure better service delivery but will curtail the chances of legal suits carried against the doctors and hospitals.<sup>[9]</sup>

#### Deficiency at service and free eye camps

The complications in the ophthalmic procedures can lead to severe consequences including complete or partial blindness and visual impairment. With a higher risk of complications, the practitioners must show diligence not just during the operation but in the pre and postoperative stages as well. Any information overlooked or prior medical condition deliberately undermined can lead to severe consequences for the patient and subsequently, legal problems for the ophthalmologist, too.

The case of one of the eye hospitals from Trichy (Tamil Nadu) before the Madurai Bench of Madras High Court on 10 September 2018 is one of the primary examples of how perceived deficiency at service during ophthalmic procedures can cause substantial legal charges against doctors.<sup>[10]</sup>

The case was filed against three senior executives, two medical officers, and an ophthalmic technician of one of the eye Hospital in Trichy for deficiency of service causing 61 patients to lose their vision of the operated eye, and 5 patients partially losing the vision of their operated eye. The allegations against the hospital included:

- Running the hospital without taking legal consent from Tamil Nadu Pollution Control Board.
- Improper design and maintenance of operation room.
- No separate room available for sterilization and storage of medicines.
- No appointment of anesthetist to assist the cataract operation but ophthalmic technicians were utilized for the purpose.
- No pharmacist was appointed to Eye Hospital.
- Hospital was allowed to function without a laboratory or laboratory technician to conduct a blood, urine test.
- No measures taken to check for illnesses such as diabetes, chronic pulmonary conditions, cardiovascular conditions, and renal condition.

- No trained staff for sterilization available at the time of operation in the operation theater.
- The mass postoperative infection was not reported to the District Medical authorities by the accused.
- Families of the victims were not informed about the incident.
- Ophthalmic technician utilized for the service was not qualified as an anesthetist.

Three of the seven members of the hospital team were sentenced to one-year imprisonment for complications related to the cataract surgeries because of the clinical negligence carried out before, during, and after the cataract surgeries. The hospital was ordered to pay Rs. 0.22 to Rs. 0.57 million as compensation to the victims.

At important point to note here is that these surgeries were carried out at an eye camp in Perambalur (Tamil Nadu). The services were offered at a lower cost and in a charitable camp. Complications are more likely in such situations.

In the above-mentioned case, the patients suffered mass infection (endophthalmitis) because there was no proper operation theater setup or any proper team aligned to carry out the cataract surgeries. Because eye camps are organized with limited funds and limited resources, it is impossible to lace them with the required technology and staff.

This raises the question that if the eye camp setups should be prohibited and the rural population should be compelled to travel to bigger cities and pay hefty costs for the surgeries. The answer is no. Eye camps should not be closed off. Instead, the the hospitals and eye camp in-charge should carefully follow proper checklists, preoperative systemic and ocular investigations, taking detailed consent, and taking all necessary precautions related to Operation Theaters for such camps to minimize the complications. Offering services at a lower (or free of) cost should not mean comprising the nobility of the profession and putting the patients at risks knowingly.

In such circumstances, the blame should not be put on the doctors completely as they are pressurized by various factors like extending services to rural areas that lack proper medical setup, limited funds provided to organize these camps, and the shortage of trained staff. To minimize litigations in such situations, it is mandatory to take all possible measures for caution, and guidelines are to be followed. This will ultimately protect the doctor in case any allegation is being carried out against a doctor.

#### Role of ophthalmic societies

Ophthalmic societies (such as All India Ophthalmic Society, AIOS) must include more sessions in the annual conferences to sensitize its members about how to avoid litigation during clinical practice. Every effort must be made to extend the legal support for the members whenever they are in trouble. The society should handle the print and electronic media to publish the news in a balanced way.

#### Conclusion

The number of cases against eye care professionals for malpractice is increasing because of the increased awareness among the patients. While some cases are legitimate and based on clinical negligence exercised by the doctors, most doctors are wrongfully accused because of the lack of public understanding. The eye care professionals must emphasize diligent service

delivery and also maintain proper records about the patient history, consent, and treatment. This practice will bring down the incidents of malpractice, and will protect the doctors from allegations and fake lawsuits.

Doctors need to have a clear understanding of how the legal system works and what consequences they might face in what circumstances. Alongside, establishing good communication with the patients is important before, during, and after the operative procedures. This is necessary for understanding the exact health condition and history of the patient. A good doctor-patient relationship is the foundation of efficient service delivery, as effective communications help both the doctor and the patient to understand each other's perspective. This ultimately minimizes the chances of mishaps leading to legal suits.

For the ophthalmologists in India, it is imperative to take substantial measures to ensure due diligence while performing surgical procedures, and follow the provided guideline and take all necessary measures before performing any surgery in the hospital or in remote areas during eye camps. Following surgical checklists, protocols, proper documentation (maintaining medical records), taking informed consent, communication about the outcome of the procedure or treatment, timely referral of the patient (in case of any complication) and obtaining adequate professional liability insurance are few important tips to minimize risk of litigation against ophthalmologists.

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