

DATE: 18-3-16

To,
The Municipal Commissioner
Ahmedabad Municipal Corporation.

Respected Madam,

A team of three of us, has been appointed to investigate the incidence in detailed and submit findings including suggestions about the incident happened at the L.G. Hospital i.e 4 patients acquiring infection in their operated eye after operating for PHACO surgery.

We have reviewed all the aspects including theatre asepsis, sterilization details, patient status, laboratory reports in details and other relevant factors. We are hereby submitting the report.

Sincerely yours,

S. M. Patel
(DR. SHASHANK PATEL)

Director

M & J institute of
Ophthalmology Western
Regional Institute

Bharat Ghodadra
(DR. BHARAT GHODADRA)

Medical Superintendent

GCS Medical College

M. M. Mansuri
(DR. Mariam Mansuri)

Professor of Dept of
Ophthalmology

Civil Hospital,

Ahmedabad

M. M. Mansuri
19/3/16

Date: 18th March, 2016

Report

To,
The Municipal Commissioner, Ahmedabad

Respected Madam,

An Independent inquiry committee has been constituted on 14th March, 2016 by the Municipal Commissioner & Chairman, AMC MET comprising of Dr. Shashank Patel, Dr. Bharat Ghodadra and Dr. Mariam Mansuri to investigate the incident in detail and submit findings including suggestions about the incident happened at the L.G. Hospital i.e. 4 patients acquiring infection after cataract surgery by PHACO technique on 11th March, 2016.

We have visited the L.G. General Hospital first on 15th March, 2016 subsequent to 18th March, 2016.

During our visit, we have inspected Eye OT, CSSD and Ward of LG General Hospital. We have also examined affected patients admitted at L.G. General Hospital at bed side. We inquired about patients' complaints. We have also verified records pertaining to CSSD, OT, Sterilisation and fumigation and microbiology reports.

We also had a detailed interaction with the hospital authority including Medical Superintendent, RMO, Treating doctors, Resident doctors, Para Medical and technical Staff and support staff about the Procedure and Protocol for cataract surgery OT protocol, sterilization of surgical instruments including Phaco probe / tubings (Phaco Set) and fumigation of operating room protocol.

We have also checked Fumigation and sterilization records (ANNEXURE-1), microbiological report of operating room (ANNEXURE-2),

1. Patient Profile

There were 4 patients were operated for cataract surgery by phaco technique on 11/3/2016 at L.G. General hospital by Dr. Beena Desai (Professor) and Dr. Gazala Mansuri (Senior Resident) & were assisted by Dr. Anupama Mahant (Associate Professor) as per operation theatre record (Annexure-3) patients were discharged on the same day after surgery as they were having no complains.

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On Day 12/3/2016, all 4 cases were examined for follow up and found to have inflammatory response on slit lamp. They were advised to start broad spectrum topical antibiotic and prednisolone drops and cycloplegic medications.

On 13/3/2016, patient named Mrs. Dhanvantari Thadani reported at L.G. Hospital at 9.30 Am with complain of pain, redness and diminision of vision in the operated eye. Patient was examined by Dr. Gazala Mansuri and found to have corneal ring abscess with severe anterior chamber inflammation and loss of fundal glow. Patient was referred to C. H. Nagri Hospital for further investigation and management. Ocular ultrasound confirmed severe intraocular vitreous inflammation suggestive of endophthalmitis. Patient was subjected to intravitreal injection of antibiotic immediately and fortified drops of broadspectrum antibiotic with after two hours.

Patient named Mrs. Kulsumben was telephonically contacted and requested to report to C. H. Nagri Hospital for eye checkup. She had similar ocular complaints and on examination found to have post operative endophthalmitis hence admitted for further treatment. She was also given above mentioned intravitreal injection and topical treatment. Vitreous tap was collected during intravitreal procedure and sent for culture sensitivity. Other two patients could not be contacted because of lack of information pertaining to their contact nos.

However these two patients named Mrs. Hasumatiben Bhagat and Mr. Rameshbhai Makawana reported to L.G. General Hospital on 14/3/2016 at 10.00am in the OPD with similar complaints. They were examined by Dr. Beena Desai and found to have corneal abscess with thinning and loss of fundal glow suggestive of acute bacterial post operative endophthalmitis. They were advised to get admitted for further treatment. They were given intravitreal injection and topical drops of broad spectrum antibiotics. Case papers and patient details are attached here with as Annexure -4.

2. **Standard Protocol for cataract surgery procedure**

The standard protocol for cataract surgery procedure is attached herewith as **ANNEXURE-5**. Upon investigation, observation and interaction with Medical / Para Medical Staff we found that, the hospital authority has followed all protocols. The procedure for **cataract surgery** has been performed by qualified ophthalmic surgeon and there are no lacunae or negligence found on that part.

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3. Sterilisation and Fumigation Protocol:

The standard protocol for sterilisation of operating instrument including Phaco set and fumigation of operating theatre is attached herewith as **ANNEXURE- 6**. We have seen past 3 microbiology report (8TH march, 29TH February & 22ND February) for fumigation validity having no growth of micro organism culture from Ophthalmic OT (ANNEXURE -2). Upon investigation, observation and interaction with Medical / Para Medical Staff we found that, the hospital authority has followed all protocol and there is no lacunae or negligence found on that part.

It was observed that, the standard care for post operative endophthalmitis has been observed and standard care has been provided in time as per protocol.

Review of literature reveals that the incidence of post operative endophthalmitis or severe intraocular inflammation are noted following any type of cataract surgery and reported incidence of post operative endophthalmitis in cataract surgery less than 1% worldwide. However in sporadic incidences this has been reported as high as 1.5 % in different hospitals.

Sheth L. G. Municipal General hospital has catered this treatment to the poor and needy citizens from 2009 onwards. Since 2009 approximately more than 90,000 patients were treated on OPD basis while around 2,500 cases were operated for different ocular conditions including phaco surgery as per hospital data record. (**ANNEXURE-7**). So far incidence of endophthalmitis is not noted.

On examining the records and other evidences, preliminary we can conclude that prima facie,

A) Qualified ophthalmic surgeons performed cataract surgery as per standard protocol and observed necessary care.

B) patients who reported with severe ocular complain and found post operative endophthalmitis had been diagnosed immediately and treated immediately as per the standard protocol of care. At the same time considering the possibility of infection after cataract surgery in other cases operated on the same day they were tried to be contacted by the Professor & Head Dr. Beena Desai for early diagnosis and even management.

C) On examining the data and the record of fumigation & sterilisation submitted by hospital authority, we found that sterilisation of operating instruments ,fumigation of operation theatre and its micro Biology tests have been done as per standard protocol.

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D) On prima facie we do not find any short fall or lacunae in any procedures of standard protocol of cataract surgery by treating medical and paramedical staff members. However considering the serious complication of post operative bacterial endophthalmitis, there is an urge to find out the source of infection. The post operative in cataract surgery is multi factorial. This includes standard sterilization protocols, standard aseptic and antiseptic precautions in operating room and during surgery. It also includes the immunity activity in patients. We can only reduce the bacterial load in the operating environment and in operative procedure. However to reduce it completely is beyond the possibility and capability.

Upon your request, herewith we submit this interim report for your perusal.

It has been reported that the culture of vitreous fluid of 1) Mr. Rameshbhai and 2) Mrs. Kulsumben are found positive with pseudomonas bacterial growth. The culture of conjunctiva as well as vitreous fluid of Hasumatiben did not show any organism growth. Mrs. Dhanvantriben Thadani had a dry tape so culture could not be found. (Annexure-8)

To investigate multi factorial aspects of infection in this incidence happened at the L.G. Hospital i.e. 4 patients acquiring infection after cataract surgery by PHACO technique on 11th March, 2016, we required more time to come to the possibility of conclusion.

We sincerely thank Municipal Commissioner for keeping faith in us and appoint us as team of expert. We sincerely thank the patients and their relative for their co operation for our investigation in spite of their stressful conditions. We also thank the hospital staff and other concerned authority for their kind co operation during our investigation and observation.

S.M. Patel.