

Date: 28-04- 2016

## Final Report

To

The Commissioner & Chairman, AMC MET

Respected Madam,

An Independent inquiry committee has been constituted on 13<sup>th</sup> January, 2016 by the Municipal Commissioner & Chairman, AMC MET comprising of Dr. Shashank Patel, Dr. Bharat Ghodadra and Dr. Beena Desai to investigate the incident in detail and submit findings including suggestions about the incident happened at the C.H. Nagri Eye Hospital after giving intravitreal Avastin to the patients [18 patients] having retinal vascular disorders due to various reasons like Diabetes, senile, age related macular degeneration, Hypertension etc. on 12<sup>th</sup> January, 2016 between 11.30 am to 1.00 pm. After examining the facts/records submitted by the hospital authority and review of clinical condition of the patients, we submitted our preliminary report on 18 January, 2016 for your perusal.

In our intrem investigation report we submitted as under:

A) the treatment of the patient diagnose with retinal vascular disorders due to various reasons like Diabetes, ARMD, Hypertension etc. has been done with standard protocol and care.

B) All patients who had developed hyperinflammatory response in form of sterile endophthalmitis; had been diagnosed immediately on the basis of their complaints and treated immediately for the same as per the standard protocol of care.

C) Emergency primary vitrectomy were done in all needed patients in time by expert vitreo retinal surgeon team as per standard protocol of care.

D) On examining the data and the record submitted by Micro Biology Department of Smt. NHL Municipal Medical College, it can be concluded that all patients' vitreous tap did not show any growth of micro organism. Therefore they all seems to have developed sterile endophthalmitis.

S.H. Patel

Bharat Ghodadra

Beena Desai



E) On prima facie we do not find any short fall or lacunae in any procedures of standard protocol of care by treating medical and paramedical staff members. We also do not find any medical negligence in treatment of those patients as per standard protocol of care.

The hospital authority has submitted samples of the inj. Avastin 100mg from similar Batch No: B7031B10 to Food and Drug Control Department, Sola Civil Hospital. Upon receiving the report from the Food and Drug control when received shall be submitted to this committee for further evaluation and conclusion.

We have received the report of Food and Drug Control Administration, Ahmedabad-II dated 23/2/2016 including test report No: Q-1/578/2016 dated 9/2/2016 of Food and Drug Laboratory , Vadodara. In which we have found that Food and Drug control administration has reported the sample of Avastin 100mg/4 ml Batch No: B7031B10 manufactured by Roche Products (India) Pvt. Ltd. (Which was used by Nagri Hospital) to be of No Opinion. Further they have mentioned that the sample complies with the test for description, bacterial endotoxin test and sterility test.

The test report of Food and Drug control also complies with our preliminary report observation which also suggests

- a. The used drug sample found to have no microorganisms.
- b. The intraocular fluid sample of each patient did not show presence of micro organisms.
- c. The clinical presentation of those patients was hyper inflammatory reaction after use of Inj. Avastin.

Conclusion:

We are of the opinion that there is not any short fall or lacunae in any procedures of standard protocol of care by treating medical and paramedical staff members of the C. H. Nagri Municipal Eye hospital Further the response of the hospital after reporting of the incidence was very quick and no medical negligence in treatment of those patients found.

We are also submitting the recent guideline for further use of the drug ( Inj. Avastin) at the eye hospital in future issued by All India Ophthalmology Society and Vitreo-retina Society of India upon request by Director General of India for your perusal.

S.M. Patel

B. Shinde

B. Shinde

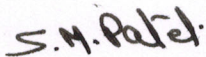


**Suggestions:**

At present H&FW dept. of GOI is in the process of making the detail guideline for the ophthalmic use Inj. Avastin. The regional Ophthalmic Institute i.e M & J western Regional Institute of Ophthalmology will start the use Inj. Avastin for ophthalmic purpose only after the availability of guidelines from GOI. The C.H. Nagri Hospital and other ophthalmic departments shall also follow the same norms and guideline.

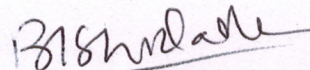
We also suggest to have a rapid and modern sterilization system to be placed separately for Ophthalmic OT in their own OT.

We sincerely thank Municipal Commissioner & Chairman of AMC MET 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.

  
(DR. SHASHANK PATEL)

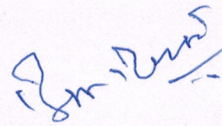
Director

M & J institute of  
Ophthalmology Western  
Regional Institute

  
(DR. BHARAT GHODADRA)

Medical Superintendent

GCS Medical College

  
(DR. BEENA DESAI)

Professor & Head of Dept of  
Ophthalmology

AMC MET Medical College