

Office of the West Bengal Clinical Establishment Regulatory Commission

1st Floor, 32 B.B.D Bag, West Bengal, Kolkata – 700001.

Phone:- (033) 2262-8447 , Email: wbcerc@wb.gov.in Website: www.wbcerc.gov.in

Case Reference: ID- INT/KOL/2023/057

Present: Justice Ashim Kumar Banerjee (Retired), Chairman

Dr. Sukumar Mukherjee,

Dr. Makhan Lal Saha

Dr. Maitrayee Banerjee,

Sri. S. K. Thade, IAS (Retd)

Smt. Madhabi Das.

Mr. Utsab SenComplainant

- Versus-

Medica SuperSpeciality HospitalRespondent

Heard on: May 3, 2023

Judgment on: June 19 , 2023.

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BACKDROP

Uttam Sen aged about 66 years was admitted at Medica with the complaint of severe S and TAVI under Dr. Dilip Kumar, Senior consultant cardiologist, Director interventional cardiology. Dr. Kumar examined him at OPD on February 7, 2022. The patient had a loud Ejection systolic murmur over the aortic area. He was advised for an ECG, Echo and blood tests. The Echo report was reconfirmed twice and found a peak / mean transaortic valve gradient of 150/90 mm. Dr. Kumar advised him to go for TAVI procedure. Mr. Sen was admitted on March 9, 2023 as advised, on Dr. Kumar to go for the planned surgical procedure under the care of Dr. Kumar in presence of Dr. Rajneesh Kapoor who had wide experience for 26 years. On March 9, 2023 Mr. Sen got himself admitted at Medica for TAVI surgery to be done on the next day at 7 am. According to the complainant, the son of Mr. Sen, just prior to the surgery he was informed, Dr. Kapoor would not be available and Dr. Prashant Dwivedi was engaged to act as proctor. The Medica team insisted, Dr. Dwivedi had the required expertise and assured adequate care at the time of surgery. On such insistence, the complainant gave consent. The admission was under a medi-claim policy. TPA sanctioned Rs. 7,00,000/- out of total package of Rs. 15,00,000/-. Prior to the surgery, the nurse came and asked the complainant to sign the prescribed format giving due consent for surgery and related issue. Being perplexed, he wanted to click picture of the form. The nurse prohibited him to do so. On her dictate, the complainant had to sign it urgently to

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expedite the process of surgery. In the morning of March 10, 2023 the patient was quite fit. He had the ability to walk into the operation theatre. Dr. Kumar reassured the patient family that the patient would be physically fit and healthy in no time. OT began at 7 am and doctor assured, it would be over by 30-45 minutes.

It was almost two hours when they did not get any input from the OT. The relatives asked the nurse about the development. They were reluctant to give any response. When they saw Dr. Dwivedi changing his OT dress and preparing to leave, the complainant rushed to him and asked him for update. The proctor said that the patient condition was critical and there were very remote chance of survival. He further added, when the valve was being replaced the surrounding sedimentations were pressurized which led to bursting of vein and fluids flowing in from other parts of the body.

At 10 am Dr. Kumar came outside the OT and informed that the patient condition was very critical and he was kept in ICU. At about 10.50 am they declared him dead giving no plausible explanation as to the cause of his death. When the complainant got the death certificate he did not find any observation that Dr. Dwivedi had stated after the OT.

COMPLAINT

The complainant had a grievance, the patient died due to a failed procedure and the surgical team was responsible for the same.

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Being aggrieved the complainant filed a complaint before us on March 25, 2023 against Medica.

RESPONSE

We asked for response from Medica. Medica gave a detailed response on March 28, 2023. The relevant paragraphs are quoted below:-

" On the day of the procedure, patient relatives were explained with the high-risk nature of the procedure and the possibilities of stroke, hematoma, annular rupture, pacemaker implantation, cardiogenic shock, ventricular arrhythmia, etc and only after understanding they gave the consent for the procedure (consent form signed by the relatives attached BHT). The procedure was going well and 23 mm valve with 1 cc less volume was deployed. The angiogram shot just after the valve replacement showed proper valve deployment with mild but acceptable PVL. However, as the procedure was about to finish the patient developed episodes of ventricular arrhythmia, with an in-between rhythm dependent on a temporary pacemaker.

The patient was given antiarrhythmic medication and multiple DC cardioversions but the unstable ventricular rhythm kept reappearing after a few seconds of cardioversion. The patient developed cardiogenic shock because of the multiple shocks and unstable heart rhythm. The possible reason for this incessant electrical instability was possibly the stretching of LVOT and calcium pushing and injuring

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the conduction system and the nearby myocardial structure or could be because of the calcium embolization to coronary arteries. In spite of all possible care and best of efforts, the patient expired on 10/03/2023.

Dr. Dilip Kumar and Dr. Prashant Dwvedi conveyed to the relatives, explaining that the possible stretching and calcium-induced injury led to abnormal rhythm, pulmonary edema (fluid accommodation in lungs), and backwards requiring mechanical ventilation and cardiogenic shock. The same team, alongwith has successfully performed TAVR at Medica on much sicker patients. Dr. Prashant who proctored the case and has done more than 300 TAVR procedures, which in itself is a testimony of his skills and expertise in this field. "

HEARING

We heard the parties at length on May 3, 2023 the complainant was represented by Mr. Koustab Mukherjee, Learned Advocate whereas Mr. Komal Dashora represented the CE.

We initially intended to wait till a final decision would come from the West Bengal Medical Council on the treatment procedure. Mr. Mukherjee, however, insisted that we should consider the hospital negligence on four issues that according to him, could be effectively gone into without a medical decision from the West Bengal Medical Council.

On his insistence, we permitted the parties to deliberate on the issue.



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FOUR ISSUES

Mr. Mukherjee raised four issues on hospital negligence:-

- I) Medica published an advertisement that inter-alia assured the patient that they were having adequate infrastructure and expertise for TAVI procedure.
- II) During OPD visit Dr. Kumar suggested few tests including Echo cardiography. When the patient went back to him with the report he was not satisfied with the Echo report and asked for a repeat Echo and made certain comment on a chit of paper by hand. Such paper was not given to him when Dr. Kapoor checked the report he suspected the result was up to the mark and called the lab supervisor to re-examine the patient. The patient was taken back for retest and lab assistant wrote a few testing values on a piece of paper and shared it with the doctor. On the basis of such hand written chit Dr. Kumar suggested for TAVI as according to him, the patient had several blockage in his valve and recommended for valve replacement that chit was never given back to the patient and / or to the patient relatives.
- III) The surgery was planned keeping Dr. Rajneesh Kapoor as proctor. At the last moment the proctor was changed for the reasons best known to Medica. When Dr. Kapoor was recommended the family got inputs from outside and verified his credibility and gave consent for TAVI. The



hospital brought Dr. Dwivedi at the last moment and family could not verify his credibility and had to give consent considering the gravity of the situation, particularly the condition of the patient.

- IV) Soon after the surgery, Dr. Dwivedi categorically informed, while doing the surgery the vein ruptured and the patient's blood pressure sought up abnormally and there had been bleeding. Those inputs that Dr. Dwivedi gave soon after the surgery, were conspicuously absent in the death certificate.

PER CONTRA

Mr. Komal Dashora, representing Medica would contend, the advertisement was to get prospective patients. There was no mis-statement made in the advertisement. According to him, no guarantee could be given by any one as to the medical procedure and the advertisement in fact did not give any positive assurance. With regard to lab reports, Mr. Dashora would contend, since Dr. Kapoor was not happy with the Echo cardiography report he suggested for retest that was done. All medical records have already been given to the patient family. Nothing has been concealed.

On the proctor issue Mr. Dashora, would contend, Dr. Kapoor was pre-occupied hence, Dr. Dwivedi was engaged. Dr. Dwivedi was equally good for the job. In any event, the patient family gave consent to his appointment before the surgical procedure.



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On the death certificate issue, Mr. Dashora would contend, it was completely the job of the doctor and would require technical expertise. In this case the treating doctor issued the death certificate. The CE had nothing to do with the same. In case complainant had any issue with regard to death certificate he may approach the appropriate authority questioning such certificate. The Commission is not empowered to go into such question.

We have concluded the hearing and kept the judgment reserved. We permitted parties to disclose further documents.

The complainant vide mail dated May 4, 2023 sent eight folders containing documents in support of his case. Mr. Dashora also disclosed the BHT on May 4, 2023.

EXPERT OPINION

Dr. Sukumar Mukherjee, perused the medical records and has given his opinion that is quoted below:-

"History:

Shortness of breath on exertion (duration not mentioned) Attended Dr. Dilip Kumar, MD, DM, FRCP consultant interventional cardiologist and Electro physiologist. On 7 February 2023 as per hospital recommendation the patient was diagnosed to have severe Aortic Valve Stenosis with Bicuspid valve with moderate calcification, Hypertension and Dyslipidemia. Dr. Kumar counselled the

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patient regarding the option for aortic valve replacement. The patient was operated TAVR (Trans Aortic Valve Replacement) on 10 March 2023. Unfortunately the patient expired post operatively on same day i.e 10 March, 2023 few hours after.

Observation:

1. Echocardiogram done preoperatively showed
 - a) Thickened aortic cusp with areas of dense calcification deranging the morphology of cusp.
 - b) Systolic pressure gradient 150 mm (peak) and 90 mm (mean).
 - c) Mild Aortic regurgitation ; EF 60 % and IV II diastolic dysfunction with enlarged LA.
2. ECG shows gross left ventricular hypertrophy with IVCD and ST-T changes.
3. CT aortogram : Bicuspid aortic valve with valve leaflet calcification. Aortic annulus 27 mm.
4. It appears that the patient has severe bicuspid aortic valve calcific stenosis with gross left ventricular hypertrophy and co morbidities like systemic hypertension and dyslipidemias.
5. No comparative risk benefit ratio of TAVR and SAVR (surgical aortic valve replacement) has ever been discussed in BHT as per updated 2017 ESC (EACTS) guideline in this index patient of 66 years with co morbidities.

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The scope of SAVR in this patient is not at all discussed as per records. Comparative safety options between the two methods are not found in BHT.

- 6. On the other hand in the "informed consent" (page 28) the commonly encountered risks involving the above procedure (Transcatheter Aortic Valve Replacement- TAVR) have been mentioned with signatures of both Dr. Dilip Kumar Cardiologist and Mr. Utsab Sen (son).*
- 7. The stretching of LVOT and dislodged calcium related electrical instability of myocardium leading to cardiogenic shock have been postulated to be the likely cause of postoperative fatality in this index case. Has it ever been anticipated prior to TAVR? Was there any way to prevent it? No answer.*
- 8. It is observed Mr. Utsab Sen, son of the index patient had to sign some blank papers before the operation. Is it the norm?*

Comment:

We have no access to scientific scrutiny as per regulation of therapeutic options in severe calcific aortic stenosis with co-morbidities but safety of his patient is of supreme priority while considering management issues related to TAVR and SAVR."

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OUR VIEW

FOLDERS

Let us first deal with the folders disclosed by the complainant on May 4, 2023.

Folder No 2, 4 and 8 would relate to bill and estimate given by Medica that was never questioned before us. Moreover, we find, out of the total sum of Rs. 14,00,000/-, Rs. 13,00,000/- had already been sanctioned by TPA and the patient had to pay Rs. 1,00,000/-. We do not find any scope to interfere on that count.

Folder no 1 would relate to papers to be signed by the complainant on behalf of the patient for admission. Folder no 3 would relate to test reports.

Folder no 6 and 7 are respectively the CV of Dr. Prashant Dwivedi and Dr. Rajneesh Kapoor. We have perused the same. Both of them are having wide experience to act as faculty and working in the field of TAVR. Who is better than whom, is a question that we cannot decide. In any event, that cannot be a concern for the Commission.

Folder no 5 is the prescription of Dr. Kumar dated February 7, 2023 and the controversial hand chit that is signed by Dr. Kumar on February 7, 2023.

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The complainant raised four issues as elaborately discussed above. Let us now express our views on each of the issues, one after the other.

- I) **ADVERTISEMENT** : The complainant would contend, they were inspired by the advertisement given by Medica inviting patients for TAVI procedure. The complainant would further contend, rather gave an impression to us, they understood the advertisement that such procedure would be successful and Medica had all infrastructure for doing the same. Medica admitted, they gave advertisement for TAVI however, made it clear, no guarantee was given for success in the procedure. We have not got any opportunity to examine the advertisement to understand the true purport thereof. Neither of the parties disclosed such advertisement before us. Hence, it would be difficult for us to hold one way or the other on the issue.
- II) **PROCTOR**: The complainant would contend, Dr. Kumar examined the patient, advised for TAVI procedure and engaged Dr. Rajneesh Kapoor as proctor. The complainant verified the credentials of Dr. Kapoor and being satisfied, gave their consent. At the last moment, Medica brought Dr. Prashant Dwivedi in place of Dr Kapoor as Dr Kapoor was not available. The complainant did not get any opportunity to verify the

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details of Dr. Dwivedi and had to sign the consent being compelled by the criticality of the situation.

It is true, Dr. Rajneesh Kapoor was engaged to act as Proctor. Medica contended, since Dr. Kapoor was not available they got Dr. Prashant Dwivedi who had the expertise in case of TAVI. We, the Commission, are not empowered to examine the treatment protocol. Dr. Kapoor and Dr. Dwivedi both, were medical experts. Who was better than the other, cannot be decided by us. There is nothing on record to prove, Dr. Dwivedi did not have appropriate expertise to act as proctor. We also do not find any evidence to the effect that procedure failed due to his negligence hence, this issue does not inspire our confidence to have an affirmative answer.

III) **HAND CHIT:** The complainant would contend, Dr. Kumar was not satisfied with the ECHO report and used a hand chit where something was written by him in hand which he handed over to the lab technician to do the retest. Such hand chit was not given to the complainant at the appropriate time. Medica asserted before us, all medical records were given to the complainant. Complainant did not categorically deny such assertion. On the contrary, the complainant wanted to disclose the said hand chit by filling the same with us. We kept our judgment reserved to

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enable the complainant to disclose further evidence including the so called hand chit. The complainant made such disclosure after the hearing.

We find, it was mainly a time schedule fixed for medication and the last one was probably a test that Dr. Kumar had suggested. Now that the complainant is having the chit he would be at liberty to use it before the appropriate authority where he would questioning treatment protocol pursuant to have being granted to him by us by the forgoing judgment. Neither we do not find any scope to interfere on this score nor do we have such competence.

IV) **DEATH CERTIFICATE** : The complainant contended, Dr. Dwivedi informed the complainant, while valve was being replaced the sedimentation was pressurized that caused rupture of the vein causing bleeding that could not be controlled. This part of the post surgical complication did not find place in the death certificate.

We have considered the issue. In our view, death certificate is not issued by any CE. It is prepared and signed by a doctor. The contents of the death certificate particularly, cause of the death as written in the death certificate, is determined by the doctor himself. Questioning the same, would amount to questioning treatment issue that would require medical expertise to decide. Neither the Commission is authorized to do so nor it

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has got such competence. Hence, this issue is also left for the appropriate authority to decide, if, approached.

CONCLUSION

Valve replacement procedure would have two methods, SAVR and TAVR. Considering the condition of the patient, whether TAVR was the right method, is a question to be decided by the doctor himself. Dr. Mukherjee, in his opinion, clearly observed, no comparative risk benefit of those two methods, were discussed in the BHT. Hence, it would be difficult for us to say, whether TAVI was the right procedure for this particular patient as decided by Dr. Kumar. Dr. Dwivedi acted as proctor. While participating in the surgery, he must have considered the condition of the patient and agreed to participate in TAVI procedure. Both Dr. Kumar and Dr. Dwivedi were involved in the process of TAVI. Even if it is held, there was no negligence of any of their part, unless and until a proper comparative discussion is had between two procedures qua the condition of the patient and the same is considered by an expert body. It would be difficult for us to blame the CE for the failed procedure.

We feel, interest of justice would be sub-served, if we wait for a decision of the West Bengal Medical Council, if approached.

We grant liberty to the complainant to approach the West Bengal Medical Council questioning the treatment protocol, the efficacy as well as the participation of Dr.

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Dwivedi in place of Dr. Kapoor. Let the complainant come back to us afresh in case he is successful before the West Bengal Medical Council.

The complaint is disposed of accordingly.

Sd/-

(**ASHIM KUMAR BANERJEE**)

We agree,

Sd/-

Dr. Sukumar Mukherjee,

Sd/-

Dr. Makhan Lal Saha

Sd/-

Dr. Maitrayee Banerjee,

Sd/-

Sri. S. K. Thade, IAS (Retd)

Sd/-

Smt. Madhabi Das

Authenticated
S. P. Das
21/06/2023.
Secretary
West Bengal Clinical Establishment
Regulatory Commission

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