

**THE WEST BENGAL CLINICAL ESTABLISHMENT
REGULATORY COMMISSION.**

Present: Justice Ashim Kumar Roy, Chairperson.

Smt. Sanghamitra Ghosh, IAS, Vice-Chairperson.

Dr. Sukumar Mukherjee, Member.

Dr. Makhan Lal Saha, Member.

COMPLAINT ID: KOL/2018/000340.

Mr. Sandip Sen.....Complainant.

-versus-

B.M. Birla Heart Research CenterRespondents.

Date of judgment: 26th December, 2018.

J U D G M E N T.

It is the case of the complainant, as it emerges from his letter of complaint together with the complaint filed in the form of affidavit, are as follows,

His mother, Smt. Bandana Sen, aged about 76 years (at the time of occurrence), had in the year 2001 having left sided carcinoma breast was operated upon and received post operation three cycles chemotherapy. After long treatment, she was completely cured. In the year 2016, she had been suffering from gait abnormalities with vertigo followed by repeated syncopl attacks and carotid artery dopler shows atherosclerotic changes Holter monitoring however showed normal.

On 02/09/2017 his mother was admitted at Kasturi Medical Hospital with fever and was diagnosed that she was suffering from klebsiella urosepsis with hyponatremia. On the day of her discharge from the said hospital, she had suffered syncope followed by three more similar events at home and was unable to move.

On 02/10/2017, she was again admitted at AMRI Dhakuria and diagnosed SICK SINUS syndrome with klebsiella urosepsis with hyponatremia. On examination, it was found she had a severe bradycardia and on routine examination of urine, it was found she was having 10/12 pus cells, cultures negative treated with oral fosfomycin and was advised for permanent pacemaker.

On 07/10/2017 took DAMA from AMRI with Hemodynamically stable condition, tolerating oral feed.

Thereafter, on 07/10/2017 she was shifted to B.M. Birla and consequentially had a temporary pacing done.

Even though his mother was a CGHS entitled patient, however, without obtaining permission from CGHS, Dr. Saroj Mondal gave instructions to CCU1 of B.M. Birla to make the patient ready for PPI. However, the same could not be proceeded on that day. As a result of this, patient was kept on fasting for two successive days which obviously was not healthy for an aged person. However, Dr. Saroj Mondal confessed at board meeting on 02/11/2017 that he was neither aware of this incident nor about the misplacement of the temporary pacemaker.

On 10/10/2017 PPI was finally done by Dr. Saroj Mondal at around 7 pm and left for OPD at B.M. Birla. Surprisingly, when his mother came out from the Cath-Lad immediately after the PPI, junior doctors informed him that they were not getting the pulse of the patient. Dr. Saswati of CCU1 furthermore informed the complainant that she was administering life support drug to his mother. The complainant repeatedly reported this to Dr Saroj Mondal in his OPD at B.M. Birla but he vehemently denied nor did he clarify the situation clearly since he was busy with his OPD. In the mean time, the condition of the mother of the patient was very critical over the night and accordingly, in the early morning, she was put on ventilation.

The complainant became astonished as to why immediately after pacing his mother's condition being very critical, she had to be put on ventilation Since then,

she had spent 103 days at B.M. Birla Heart Research Center with prolonged period of ventilation and on 18/01/2018, she took her last breath at B.M. Birla Heart Research Center.

On 27/12/2017 Dr. Saroj Mondal gave a clinical note to medical superintendent at B.M. Birla Heart Research Center informing that his mother's cardiac condition was stable. However, within 2 weeks of the said information his mother expired due to cardiac arrest.

On the aforesaid allegation, the complainant prayed before the Commission for a proper investigation regarding the cause of death of his mother.

2. On receipt of the aforesaid complaint, the Commission directed the Clinical Establishment to furnish their reply in the form of affidavit. However, the allegation essentially one of medical negligence and was directed against the treating doctor, Dr. Saroj Mandal, the reply in the form of affidavit was filed by Dr. Mandal.

3. In reply, Dr. Saroj Mandal filed his affidavit-in-reply before the Commission.

The patient Mrs. Bandana Sen has got admitted in B.M. Birla Heart Research Centre on 07.10.2017 with history of 3 episodes of syncope and recurrent episodes of dizziness since 02.10.2017. She was admitted at AMRI hospital 7 days prior to this with Urosepsis and Hyponatremia and syncope where she was advised Pacemaker implantation. She took DAMA from AMRI Hospital. Even prior to that she had admitted at Kasturi Medical Center Hospital on 20.09.2017 with fever. They found to have klebsiella urosepsis with hyponatremia, and on the day of discharge she had syncope. She was a known case of hypertension, Bronchial Asthma, Left sided Carcinoma Breast (for which she got chemotherapy and radiotherapy), in 2001 and she also had history of Pulmonary Tuberculosis in 2013.

On admission she was detected with symptomatic Sick Sinus Syndrome and had temporary pacing. Implantation of Permanent pacemaker was done on

10.10.2017. Procedure was uneventful. Post procedure, she developed vomiting and hypotension. Around 7 pm after she was shifted to ward from OT, her pulse was not felt. Immediate Echocardiography and Chest X-ray PA was done and that revealed no pericardial or pleural collection or pneumothorax. Immediately on being informed, the deponent personally visited the patient and gave the necessary medical advice and the patient party was apprised of the situation and counseled. At 9.50pm the deponent again visited the patient which was documented in the clinical notes, and he advised Inj Pipzo, substituted by Inj Meronem and Inj. Targocid. However she developed persistent hypoxia and was incubated on 11.10.2017 early morning. On 11.10.17 Procacitonin came and was 21.96. She was started on inj. Meropenem and inj. Teicoplanin, which were subsequently changed based on culture reports and in consultations with Infectious Disease specialist Dr D Gupta. Dr Pawan Agarwal Pulmonologist visited and gave his opinion; he opined that likelihood of MDR pathogen in view of recent hospitalization & use of antibiotics for Urosepsis. Gradually as her condition improved she was extubated and ionotopes withdrawn. Urine C/S showed positive for XDR Klebsiella which was corroborative with previous infection (at AMRI Hospital). After extubation she was put on CPAP. She developed pneumothorax for which she had to be put in intercostals drainage and re-intubated on 16.10.2017. Packed cell was transfused as she was anemic. Antibiotics escalated to Colistin and Fosfomycin after consulting Infectious Disease specialist, Physician and Nephrologist. On 28.10.2017 Intercostal drainage was removed and the patient was extubated. But she again developed CO2 retention and had to be intubated again on 31.10.2017.

On multiple occasions weaning from ventilator was attempted but failed and she was ventilator dependent. But throughout the course of hospital she was conscious and very much alert. On 14.10.17 she developed cyanosis of the left tip of thumb followed by dry gangrene, in spite of the fact she was on Inj Heparin and Tablet Aspirin (anticoagulation and antiplatelet medication). Dr Anupam Golas,

consultant Plastic Surgeon, was consulted and his advice was followed. Medical board was formed on two separate occasions (02.11.2017 and 28.11.2017) with concerned doctors of multiple specialties and their opinion was complied. As prolonged ventilation patient needed tracheostomy and it was done by ENT Surgeon Dr S Chakrabarty and it was regularly checked by ENT Surgeon. Tracheostomy tube was changed on several occasions by ENT Surgeon DR S Charabarty. Each and every occasion condition and prognosis explained to patients relatives.

Throughout her course of treatment she was under consultation and regularly followed up by Dr Pawan Agarwal (Pulmonologist), Dr Anirban Karmakar (Critical Care Specialist), Dr Deb Kishore Gupta (Infectious Disease Specialist), Dr Biswajit Ghosh Dastidar, Dr S Chakrabarty (ENT specialist), Dr Anupam GOVT. OGolas(Plastic Surgeon) and Prof (DR.) Manotosh Panja and all of them are eminent doctors of the city.

The deterioration of clinical condition of the patient was never related to pacemaker implantation procedure and can from the very beginning her pacemaker wound site was healthy and pacemaker was functioning well.

Her ill health and ventilator dependency and multiple infection episodes were related to her frail health condition and multiple pre-existing co-morbid, & immune-compromised conditions (like Post Carcinoma Breast, Post Chemotherapy, Post Pulmonary Tuberculosis, and Obstructive Airway Disease).

As far as medical protocol, the service recipient, Bandana Sen received necessary medical treatment and there was no negligence or mismanagement. The patient parties were continuously updated about her waxing and waning clinical conditions and each step was done after careful consideration of her medical needs and after proper explanation and obtaining consent of patient parties.

Even when the transfer of the patient was initiated from cardiology point of view her son expressed that they were happy with B M Birla Hospitals medical management. Patient remained ventilated for a long period but gradually her overall condition improved was tolerating T piece and even she was planned for a discharge but unfortunately after a prolonged stay on 18.01.2018 she had cardio-respiratory arrest and she became unresponsive and she expired.

Her death was due to multiple co-morbid conditions of the patient and it had no connection with pacemaker implantation procedure.

4. Heard the parties at length. Considered their respective submissions. Perused the medical records and the affidavits filed by the parties.

5. On the face of the allegations, made by the complainant we find this is one of the case of medical negligence by a medical professional and adjudication of the same is beyond our purview as provided under the First proviso to sub-Section (iii) of Section 38 of the West Bengal Clinical Establishment (Registration, Regulation and Transparency) Act, 2017. The complainant was well apprised about such position.

6. However, before parting with we must record what is apparent from the medical papers.

- a. Patient had multiple co-morbidities since long.
- b. Patient had three times hospitalization prior to pacing i.e. on 2nd September, 2017, again on 2nd October, 2017 and on 7th October, 2017.
- c. Recurrent syncope and recurrent infections were the major issues in a high risk patient requiring permanent pacing.
- d. With three times hospitalization, patient was already infected requiring varieties of multiple Antibiotics. Evening during third hospitalization, permanent pacemaker was put on 10/10/2017 and Pro-calcitonin-a biomarker

for sepsis was moderately positive on 11/10/2017 indicating already evident infection on 10/10/2017.

- e. Post pacemaker implantation, the patient had a vomiting and hypo-tension with shock without bleeding or volume deficit or acute cardiac event.
- f. It is quite reasonable to think ongoing infections and bradycardia are the principal issues, it appears pacemaker implantation has been done in an already infected patient from repeated hospitalisation.
- g. Antibiotics received during the stay in B. M. Birla, are considered a major step which accompanied multiple intervention-related complications like femoral vein thrombosis, left thumb gangrene (despite being on anticoagulants and antiplatelets) and right Pneumothorax requiring intercostal drainage.
- h. Finally, patient's stay in the hospital was more than 100 days and she could not be weaned off the ventilation on repeated attempts and the patient after prolonged therapy expired on 18/01/2018.

Thus, the service recipient, an elderly lady, aged about 76 years was quite critical suffering from various ailments and after more than 100 days of stay in different hospitals, she finally died.

7. Having regards to above and in the light of the provisions of West Bengal Clinical Establishment (Registration, Regulation and Transparency) Act, 2017, we find no case is made out for our intervention.

Accordingly, this case stands closed and disposed off.

Sd/-

Justice Ashim Kumar Roy
Chairperson.

Sd/-

Smt. Sanghamitra Ghosh, IAS, Vice-Chairperson.

Sd/-

Dr. Sukumar Mukherjee, Member.

Sd/-

Dr. Makhan Lal Saha, Member.

Authenticated
[Signature]
ARSHAD HASAN WARSI
Secretary
W. B. C. E. R. C.