IN THE DELHI STATE CONSUMER DISPUTES REDRESSAL COMMISSION

Date of Institution: 15.12.2017
Date of hearing: 29.03.2023
Date of Decision: 11.09.2023

COMPLAINT CASE NO.-2022/2017

IN THE MATTER OF

MR. MOGES ALEMU
C/O SRIVASTAVA & ASSOCIATES
17, CENTRAL LANE BENGALI MARKET
NEW DELHI -110001
(Through: Mr Vinayak Srivastava, Advocate)

…Complainant

VERSUS

1. **INDRAPRASTHA APOLLO HOSPITALS**
   SARITA VIHAR, DELHI MATHURA ROAD
   NEW DELHI- 110076
   (Through: Mr. Lakshay Luthra,, Advocate)

2. **MEDICAL DEVICES INDIA PVT LTD**
   UNIT NO. 805-807, DLF TOWER B, DISTRICT CENTRE, JASOLA, NEW DELHI-110019
   (Through: Mr. Uttam Singh, Advocate)

…Opposite Parties

CORAM:
HON'BLE JUSTICE SANGITA DHINGRA SEHGAL (PRESIDENT)
HON'BLE MS. PINKI, MEMBER (JUDICIAL)
HO'BLE MR. J.P. AGRAWAL, MEMBER (GENERAL)

Present: None for Complainant.
Dr. Lalit Bhasin & Mr. Lakshay Luthra, Counsel for the Opposite Party No.1
Mr.Uttam Singh, Counsel for the Opposite Party No.2

PER: HON'BLE JUSTICE SANGITA DHINGRA SEHGAL, PRESIDENT

JUDGMENT

1. The present Complaint has been filed by the Complainant before this Commission alleging deficiency of service on the part of Opposite Parties and has prayed for the following reliefs:

   "1. To grant a sum of Rs.90 lacs (Ninety Lakhs only) alongwith pendente lite and future interest at the rate of 18% per annum till realization along with the cost of the present proceedings in favour of the Complainant due to deficiency in service, physical and mental agony caused to the Complainant by the Opposite Parties.

   2. May pass any other order or orders which this Hon'ble Commission may deem fit proper under the facts and

circumstances of the case against the Respondents and in favour of the Complainant"

2. The brief facts necessary for the adjudication of the present Complaint are that the Complainant is the brother of the deceased Mr. Tesfaye Alamu *(hereinafter referred to as the patient)*, who was a resident of Addis Ababa, Ethiopia. The patient was having breathing problems and the Doctors in Ethiopia recommended him treatment abroad. In order to get the patient's medical treatment done, the Complainant got in touch with the Opposite Party No.1-Hospital branch at New Delhi. Subsequently, the Opposite Party No.1 vide its email dated 27.04.2015 confirmed its ability to give the medical treatment as required. The Opposite Party No.1 further facilitated issuance of the Visa from the Indian Embassy by issuing Supporting Documents. On 12.05.2015, the patient accompanied by Complainant's wife Ms. Adanech Solomon and Complainant, travelled to India to seek medical attention in the Opposite Party No.1-Hospital. Based on the report sent from Addis Ababa, Opposite Party No.1 confirmed that they could treat the patient at a total cost of USD $6,500. Thereafter, the patient was received by Dr Anoop K. Ganjoo, Consultant Cardiac Surgeon of Opposite Party No.1 who prescribed some routine medical tests and told the patient to come back the following day for Angiography Test. Subsequently, Angiography Test was conducted by Dr. R.K .Rajput, Sr. Consultant Cardiology, under I.D. No. 10489568 on the next day i.e.13.05.2015. Thereafter, Dr. Rajput came out of the procedure room and told Complainant *"Congratulations! Your brother is fine*

he does not need a PaceMaker!" However after a couple of hours, Dr. Anoop K. Ganjoo told the Complainant that patient would need a pacemaker. The Complainant was shocked to hear this because no reason was provided for a sudden change in opinion by Opposite Party No.1. Furthermore, Opposite Party No.1 told Complainant that they would do ECHO test the following day and would decide on the next course of action. The ECHO test was undertaken on patient on 13.05.2015 and 15.05.2015 which also showed normal results. Despite the fact that the patients parameter were normal, Opposite Party No.1 doctors still insisted for implantation of ICD (Implanted Cardioverter Defibrillator) device. The Opposite Party No.1 stated that the UCTR may or may not help the patient but the ICD will help to stop any potential heart attack.

3. Thereafter, on 19.05.2015, the Patient was admitted for the surgery and the ICD device manufactured by Opposite Party No.2, Model IFORIA 5 VR-T with serial number 60739150 was implanted in the patient's heart. The patient was discharged on 21.05.2015 and was advised to come back after a week. Meanwhile, the Opposite Party No.2 sent a doctor for a final checkup on the ICD and it was revealed that the device does not give sufficient shock to prevent a heart attack, hence, the wounds of the patient had to be opened again to adjust the device in the patient's heart. It is submitted that the Complainant strongly raised his complaint before the Opposite Party no.1 to which the Dr. Ganjoo and Dr. Rajput apologised for such mistake and told the Complainant that no charges are to be paid for re-adjusting the device.

4. Further, after the installation of ICD device Opposite Party No.1 informed Complainant that the ICD device would now cost up to USD 25000 instead of USD 6500 as agreed initially, without providing any cogent reasons. However, the Complainant agreed to make increased payment as the patient was in a life threatening situation. After a couple of days, Complainant returned to Addis Ababa, Ethiopia. On 15.12.2015, the patient took his car and drove to an office to receive his retirement benefit. He parked his car, went to the office and after talking to the cashier, he said he felt tired and sat on a bench where he collapsed soon after. An emergency ambulance came and they took him to the nearest clinic but unfortunately, he was already dead.
5. The Complainant has submitted that the ICD device planted by Opposite Party No.1 failed to work and save the Patient. It is further submitted that the ICD device was defective and couldn't save the Patient from heart attack. Secondly, it is submitted that the Opposite Party No.1 paid an amount of Rs.16,392/- as payment for re-adjusting the ICD device which clearly amounts to admission of negligence on part of the Opposite Party no 1. Lastly, it is submitted that the Complainant sent legal notice dated 29.08.2016 demanding payment of damages but the Opposite Parties failed to reply to the said notice. Aggrieved by the aforesaid conduct of the Opposite Parties, the Complainant has filed the present complaint.
6. The Opposite Party No.1 has filed its written statement and has raised preliminary objection therein that the Complaint has been filed by the brother of the patient and not by the legal heir of the

patient nor any legal heir has been impleaded or arrayed as a party to the Complaint. It is further submitted that the Complainant has no locus standi to file the present Complaint since he does not hold any valid will/succession certificate to represent the Complaint and therefore, cannot claim to be the legal heir/representative of the patient. Secondly, it is submitted that the Opposite Party no.1 has a professional indemnity insurance policy with the United India Insurance Company Ltd which has not been impleaded as a necessary party. Thirdly, it is submitted that the Complainant has concealed material facts and has not filed any treatment records of the patient prior to his admission to the Opposite Party No.1-Hospital. Lastly, it is submitted that AICD prevents only sudden cardiac death due to arrythmia in majority of cases and patients continue to be at risk because of LV dysfunction. Thus, it is submitted that the patient was treated with due care and caution by the treating consultants and the Complaint is liable to be dismissed.

7. The Opposite Party No.2 has filed its written statement and raised preliminary objections therein that it is nowhere stated in the Complaint that the deceased was not survived by his children or wife. It is submitted further that no document has been produced to show that as per the laws of Ethiopia the Complainant is the legal heir of the deceased-patient. Secondly, it is submitted that the Complaint is barred by limitation since the operation regarding which the deficiency has been alleged took place on 19.05.2015. However, the Complaint was filed only in late December 2017. Thirdly, it is submitted that the deceased has spent a sum of

Rs.7,12,183/- and as such this Commission lacks the pecuniary jurisdiction to entertain the present Complaint. Lastly, it is submitted that the device was working properly and the Complainant has not filed any document to show that the doctors be it Indian or Ethiopian or Atlantean ever found fault with the implanted device nor the patient ever informed the company about any defect in the product. Therefore, no manufacturing defect is found in the device and the Complaint is liable to be dismissed.

8. The parties have filed their Evidence by way of affidavit in order to prove their averments.
9. We have perused the material available on record and heard the counsels for the Opposite Parties at length.
10. The ***first preliminary question*** that falls for our consideration is ***whether the Complainant has any locus standi to file the present Complaint.***
11. On a bare perusal of facts of the present case, there is a clear finding that it was the Complainant who took the patient to the hospital and made the arrangements for his admission and treatment there. Thus the Complainant was the person who had hired the service of the hospital and the patient was only the person for whose benefit the arrangement was made. Hence in the present case, there cannot be any doubt that the Complainant having himself hired the service, squarely falls within the definition of the expression "consumer" contained in Section 2 (l)(d) of the Act.

12. The ***second preliminary issu***e that falls for our consideration is ***whether the Complaint is maintainable for want of pecuniary jurisdiction***
13. To resolve this issue we deem it appropriate to refer to section 17 of the Consumer Protection Act 1986:

    "17. Jurisdiction of the State Commission: Subject to the other provisions of this Act, the State Commission shall have jurisdiction- (a) to entertain- (i) complaints where the value of the goods or services and compensation, if any, claimed exceeds rupees fifty lakhs but does not exceed rupees two crores;"
14. A perusal of the aforesaid statutory position makes it clear that the State Commission is empowered to adjudicate cases where the value of the goods or services and compensation, if any, claimed exceeds rupees fifty lakhs but does not exceed rupees two crores. In the present case, it is to be noted that the value of the services availed and the compensation amount as prayed by the Complainant is over ninety lacs. Therefore, it is clear that the present complaint squarely falls within the pecuniary jurisdiction of this Commission.
15. The ***third preliminary issu***e that falls for our consideration is ***whether the Complaint is barred by limitation.***
16. To deal with this issue, it is imperative to refer to ***Section 24A*** of the ***Consumer Protection Act, 1986*** wherein it is provided as under:

    "***24A. Limitation period.***-

    (1) The District Forum, the State Commission or the National Commission shall not admit a complaint unless it

> *is filed **within two years from the date on which the cause of action has arisen**.*
> *(2) Notwithstanding anything contained in sub-section (1), a complaint may be entertained after the period specified in sub-section (1), if the Complainant satisfies the District Forum, the State Commission or the National Commission, as the case may be, that he had sufficient cause for not filing the complaint as this such period:*
> *Provided that no such complaint shall be entertained unless the National Commission, the State Commission or the District Forum, as the case may be, records its reasons for condoning such delay."*

17. Analysis of Section 24A of the Consumer Protection Act, 1986 leads us to the conclusion that this Commission is empowered to admit a complaint if it is filed within a period of two years from the date on which cause of action arose. It is the contention of the Complainant that the patient suffered death on account of the faulty ICD device implanted in the patient's heart and on account of the surgery pertaining to the said implant. On a perusal of record, we find that the cause of action lastly arose in the present Complaint when the patient suffered death and if we calculate two years from the date when the cause of action lastly arose, it is clear that the present Complaint has been filed on 15.12.2017 i.e. within two years from 15.12.2015, the date on which the patient expired. Therefore, the contention of the Opposite Parties holds no merit and is answered in negative.
18. Having dealt with the preliminary objections, ***the first question*** that falls for our consideration is ***whether the ICD device was installed***

for unjust enrichment from Complainant by the Opposite Party No.1.

19. The facts reveal that the patient was suffering from breathing problems and was advised by doctors in the home country to seek medical attention from Indian Doctors. A perusal of the Medical Case Summary of Addis Cardiac Hospital, Ethiopia prepared by Dr. Meberatu Amogne, MD, Internist & Cardiologist *(Annexure A annexed at page 12 alongwith the Complaint)* clearly reflects that the patient was diagnosed as case of Coronary Artery Disease with wide complex Left Ventricular (LV) dysfunction, tachycardia with complete Left Bundle Branch Block, LVEF - 30 - 40%, Grade II MR, mild AR with calcified valve, grade III TR and severe Pulmonary Artery hypertension. The said summary further reveals that the patient was recommended to undergo angiography and ICD+CRT under the head "*Recommendations*". Therefore, it is more than clear that the patient was recommended to get an ICD+CRT implant from the doctor in Ethiopia itself.
20. Furthermore, on approaching the Opposite Party No.1-Hospital, the patient was directed to get the Angiography Test done in pursuance of the recommendations in the medical summary by Dr. R.K. Rajput- Senior Consultant Cardiology of the Opposite Party No.1 Hospital.
21. The Complainant has submitted that as per the Angiography tests conducted on 13.05.2015, Dr. R.K. Rajput- Senior Consultant Cardiology came out of the procedure room and apprised the Complainant *" Congratulations! Your brother is fine and does not*

need a pacemaker!" but after some deliberations with Consultant Cardiac Consultant-Dr. Anoop.K Ganjoo, changed his stance and told the Complainant that the patient shall need a pacemaker without giving any cogent reasons for the sudden change in medical opinion.

22. A perusal of the Angiography Report *(annexure A annexed at pg 26 alongwith the Complaint*) reflects that the patient had CAD (distal LAD) along with severe Left Ventricle (LV) dysfunction which stands for Coronary Artery Disease (distal left anterior descending coronary artery, branch of left main coronary artery, which supplies blood to the front portion of left ventricle). From the reading of medical literature on the subject, it has come to our knowledge that Distal LAD disease is presence of plaques in the vessel beyond two major branches. Therefore, it is clear beyond doubt that the patient was suffering from Heart Disease.

23. Here, it is to be noted further that no expert medical opinion has been placed on record to suggest that the patient did not need a pacemaker or ICD device. Furthermore, the Complainant has not placed on record the documents pertaining to the past medical history of the patient. A bare perusal of the record makes it clear that the Complainant has merely made a bald averment without placing on record any cogent material to substantiate his claims when the Angiography Report suggests to the contrary. No cogent material has been placed on record to show that Dr. R.K. Rajput-Senior Consultant Cardiology came out of the procedure room and apprised the Complainant *" Congratulations! Your brother is fine and does not need a pacemaker!* It is to be noted that even if it is

assumed that the doctor changed the mode of treatment, the same cannot be the sole ground to arrive at an adverse finding against the treating consultants.

24. Here it is important to remark that it is a common practice among medical professionals to change the course of treatment after having due deliberations and sharing opinions on a particular case with specialists. It is worthwhile to note that a doctor owes a duty of care in deciding what treatment to give and merely choosing an alternative course of action doesn't create a presumption as to dereliction of duty, in the absence of any cogent proof to the contrary. Therefore, we opine that the contention of the Complainant that the ICD device was installed by the Opposite Party No.1 even though the patient did not require the same, holds no water.

25. The ***second question that falls for our consideration is whether the death of the patient can be attributed to the device manufactured by the Opposite Party No.2.***

26. In this regard we deem it appropriate to refer to decision of The Hon'ble Apex Court in ***C.P. Sreekumar (Dr.), MS (Ortho) v. S. Ramanujam (2009) 7 SCC 130*** , wherein it was held that the Commission ought not to presume that the allegations in the complaint are inviolable truth even though they remained unsupported by any evidence as under:

> *"37. We find from a reading of the order of the Commission that it proceeded on the basis that whatever had been alleged in the complaint by the respondent was in fact the inviolable truth even though it remained*

> *unsupported by any evidence. As already observed in Jacob Mathew case [(2005) 6 SCC 1 : 2005 SCC (Cri) 1369] the onus to prove medical negligence lies largely on the claimant and that this onus can be discharged by leading cogent evidence. A mere averment in a complaint which is denied by the other side can, by no stretch of imagination, be said to be evidence by which the case of the complainant can be said to be proved. It is the obligation of the complainant to provide the facta probanda as well as the facta probantia."*

27. On a thorough perusal of the record, we are unable to find any document filed by the Complainant to show that the ICD device was a faulty one or had any inherent defect. <u>It is pertinent to mention here that the patient returned to Ethiopia after getting his surgery done. However, no report of doctors whether Indian or Ethiopian, has been placed on record to indicate that the ICD device was defective or malfunctioned.</u>

28. Here, we deem it appropriate to refer to para 11, 12 and 13 of the Complaint reproduced hereunder as:

> *"11. The ECHO test was undertaken on patient on 13th and 15 May 2015 which also showed normal results. The ECHO confirmed that the pumping of the two chambers was balanced, the two horses were pulling the cart simultaneously and equally.*
>
> *12. That no anomaly was found in the ECHO test in the Patient's heart condition. However, Opposite Party*

No.1 doctors still recommended that it would still help to have ICTR or ICD installed in the Patient heart.
13. Despite the fact that the patients parameter were normal, Opposite Party No.1 doctors still insisted for implantation of ICD (Implanted Cardioverter Defibrillator) device."

29. We further deem it appropriate to refer to para 31 & 32 of the Complaint reproduced hereunder as:

"31. That the ICD device planted by Opposite Party No.1 failed to work and save the Patient. That the ICD device was defective and couldn't save the Patient from heart attack.

32. In view of the above, it is submitted that Opposite Party No.1 and OPPOSITE PARTY NO.2 has committed gross criminal negligence in implanting device which was defective resulting in the death of the patient"

30. It is crucial to mention here that the stand taken by the Complainant is self-contradictory in as much as at one place the Complainant has stated that all the parameters of the patient were normal and there was no need for the ICD whereas at other places the Complainant has stated that the death of the patient was caused due to insufficient shock provided by the ICD device. Moreover, it is pertinent to note that the Opposite Party No.2 simply being a seller, has no role in installing the device. Therefore, in the absence of any cogent proof

indicating defects in the ICD device, we conclude that the ICD was not defective. Thus, no liability can be fastened on the Opposite Party No.2 for the alleged defects in the ICD.

31. We are now faced with the ***main question*** that ***whether the conduct of the Opposite Party No.1 can be attributed to the death of the patient and whether such conduct amounts to medical negligence.***

32. Here, we remark that invasive surgical procedures like ICD implantation are often required for treatment of heart related morbidities and play a crucial role in saving lives of patients, however, some patients suffer loss of life despite intensive efforts. Procedure related complications and Post Implantation Complications continue to be a complex challenge that health care organizations face.

33. In this regard, we deem it appropriate to refer to the decision of the Hon'ble Apex Court in ***Civil Appeal No. 1658 Of 2010*** *titled as* "***Bombay Hospital & Medical Research Centre Vs. Asha Jaiswal & Ors" decided on 30.11.2021***, hereunder as:

> *"42. When a patient dies or suffers some mishap, there is a tendency to blame the doctor for this. Things have gone wrong and, therefore, somebody must be punished for it. However, it is well known that even the best professionals, what to say of the average professional, sometimes have failures. A lawyer cannot win every case in his professional career but surely he cannot be penalised for losing a case provided he appeared in it and made his submissions.*

34. In another judgment reported as ***Kusum Sharma and Others v. Batra Hospital and Medical Research Centre and Others (2010) 3 SCC 480*** , a complaint was filed attributing medical negligence to a doctor who performed the surgery but while performing surgery, the tumour was found to be malignant. The patient died later on after prolonged treatment in different hospitals. The Hon'ble Apex Court held as under:

> *"47. The ratio of Bolam case [(1957) 1 WLR 582 : (1957) 2 All ER 118] is that it is enough for the defendant to show that the standard of care and the skill attained was that of the ordinary competent medical practitioner exercising an ordinary degree of professional skill. The fact that the respondent charged with negligence acted in accordance with the general and approved practice is enough to clear him of the charge. Two things are pertinent to be noted. Firstly, the standard of care, when assessing the practice as adopted, is judged in the light of knowledge available at the time (of the incident), and not at the date of trial. Secondly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that point of time on which it is suggested as should have been used.*
>
> *78. It is a matter of common knowledge that after happening of some unfortunate event, there is a marked tendency to look for a human factor to blame for an untoward event, a tendency which is closely linked with the desire to punish. Things have gone wrong and, therefore, somebody must be found to answer for it. A professional deserves total protection. The Penal Code, 1860 has taken care to ensure that people who act in good faith should not be punished. Sections 88, 92 and*

> *370 of the Penal Code give adequate protection to the professionals and particularly medical professionals."*

35. It is worthwhile to mention here that all medical procedures have some level of risk, particularly those involving the heart. It is not uncommon for individuals experiencing heart problems to be fitted with a pacemaker around the world. However, there are inherent risks to pacemaker implants. A doctor may make an error that can cause a complication, but in some cases, complications happen even though the doctor acted within the standard of care. Pacemakers are implanted into patients every day throughout the world. In fact, it is considered a routine procedure. Millions of people have undergone pacemaker implant procedures but there are still inherent risks associated with pacemaker implants. Some errors may be deemed errors in judgment, meaning that a reasonable physician could have conceivably made the same mistake. In other cases, medical complications may arise due to the procedure's inherent risks, which are known to the patient and are included in any assumption of risk.

36. The Hon'ble Apex Court in a celebrated judgment titled as ***Jacob Mathew v. State of Punjab and Anr*** (***2005) 6 SCC 1***, held that simple lack of care, an error of judgment or an accident, is not a proof of negligence on the part of a medical professional. The Court held as under:

> *"48. We sum up our conclusions as under: (1) Negligence is the breach of a duty caused by omission to do something which a reasonable man guided by those considerations which ordinarily regulate the conduct of human affairs would do, or doing something*

which a prudent and reasonable man would not do. The definition of negligence as given in Law of Torts, Ratanlal & Dhirajlal (edited by Justice G.P. Singh), referred to hereinabove, holds good. Negligence becomes actionable on account of injury resulting from the act or omission amounting to negligence attributable to the person sued. The essential components of negligence are three: "duty", "breach" and "resulting damage". Negligence in the context of the medical profession necessarily calls for a treatment with a difference. To infer rashness or negligence on the part of a professional, in particular a doctor, additional considerations apply. A case of occupational negligence is different from one of professional negligence. A simple lack of care, an error of judgment or an accident, is not proof of negligence on the part of a medical professional. So long as a doctor follows a practice acceptable to the medical profession of that day, he cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused followed.

When it comes to the failure of taking precautions, what has to be seen is whether those precautions were taken which the ordinary experience of men has found to be sufficient; a failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. So also, the standard of care, while assessing the practice as adopted, is judged in the light of knowledge available at the time of the incident, and not at the date of trial."

37. What is to be gleaned from the aforesaid decisions is that a simple lack of care, an error of judgment or an accident, is not proof of

negligence on the part of a medical professional. To establish a claim for medical negligence, it is imperative to meet the following criterion i.e. **firstly**, the patient was owed a duty of care. **Secondly,** that duty was breached by a deviation from accepted standards of care. **Thirdly**, the patient suffered damages and **fourthly,** the damages suffered were a direct result of the medical provider's breach of duty.

38. Returning to the facts of the instant case, is clear from the record that the patient was treated as per standard medical protocol and there was no deviation from the standard medical procedure. To rule out Coronary Artery Disease (CAD), after informed consent and pre-cath investigations, patient was taken up for Coronary Angiogram. Detailed ECHO was conducted to look for ECHO parameters of desynchrony to further decide whether he needs CRT-D or AICD. ECHO of the patient showed that there was no significant LV desynchrony. The treating consultant after reviewing the test reports and explaining about the detail procedure to the patient and his family, decided to proceed with AICD implantation.

39. It is crucial to note that a perusal of the Discharge Summary (pg 2) under the head "Course in the Hospital & Discussion" clearly records that the Patient and his family were not willing for any further procedure and wanted to get it done at a later date. Accordingly, the patient was discharged on 16.05.2015 on medication, low salt diet and fluid restriction. On 19.05.15 after explaining potential/associated risks, informed consent and pre-cath investigations, AICD implantation was done with Biotronik device.

It is clear from the record that the patient was being managed in the Hospital by senior specialists as per his clinical condition. The patient was advised follow-up but he never showed up.

40. It is worthwhile to mention here that the patient had multiple co-morbidities even before approaching the Opposite Party No.1-Hospital and was already in a critical state. Patient was a known case of dyslipidaemia (blood lipid levels that are too high increasing the chance of clogged arteries and heart disease), hypertension since 10 years and was on antihypertensive medications, anti-platelets, beta blockers, diuretics and statins (cholesterol lowering medications). As per the Medical Summary the patient was a known case of Carcinoma Rectum for which he had undergone surgery in Israel in 1998 and had a colostomy bag in situ. The patient had deranged parameters as revealed in the ECHO which showed dilated LA/LV, global hypokinesia, LV apex more hypokinetic, LVEF - 22-%, severely increased LVEDP (27mmHg), severe MR, Mild AR, moderate TR, PASP - 67 mmHg. Patient also had LBBB and increased QRS duration of 134 msec. Coronary Angiogram showed diffusely diseased small sized PDA and 50-60 % lesion in distal LAD. (*(Annexure B & C, page 26-35 alongwith the Complaint)* Thus, aforesaid indications make it abundantly clear that the patient was already in a critical state with high risk co-morbidities.

41. Another plea has been taken by the Complainant that ***the conduct of the doctors was negligent in as much as the wounds of the patient had to be re-opened to adjust the ICD.***

42. Recently, the Hon'ble Apex Court in a judgment reported as ***Dr. Harish Kumar Khurana v. Joginder Singh & Others (2021) SCC Online SC 673*** held as under:

> *"11……Ordinarily an accident means an unintended and unforeseen injurious occurrence, something that does not occur in the usual course of events or that could not be reasonably anticipated. The learned counsel has also referred to the decision in Martin F.D'Souza v. Mohd. Ishfaq, (2009) 3 SCC 1 wherein it is stated that simply because the patient has not favourably responded to a treatment given by doctor or a surgery has failed, the doctor cannot be held straight away liable for medical negligence by applying the doctrine of Res Ipsa Loquitor. It is further observed therein that sometimes despite best efforts the treatment of a doctor fails and the same does not mean that the doctor or the surgeon must be held guilty of medical negligence unless there is some strong evidence to suggest that the doctor is negligent.*
>
> *Having noted the aforesaid decisions , it is clear that in every case where a mishap or accident takes place, it cannot be automatically assumed that the medical professional was negligent. To indicate negligence there should be material available on record or else appropriate medical evidence should be tendered. The negligence alleged should be so glaring, in which event the principle of res ipsa loquitur could be made applicable and not based on perception*

43. When medical devices need to be implanted into someone's body for health reasons, there is always the risk for complications. While pacemaker implantation is a relatively common procedure, it is still possible for problems to arise. However, every procedure related complication cannot be considered a result of malpractice unless it

was caused by *medical negligence*. To constitute a procedure related injury in a medical facility, the injury must have been the direct result of a medical provider's failure in providing an acceptable level of care. For instance**,** a doctor failed to diagnose or misdiagnosed a condition that affects the patient or the patient caught hospital acquired infection, or the doctor used a defective implant, the patient was overmedicated, or prescribed a medication that conflicted with another medication and/or the patient's condition was not assessed or managed correctly etc.

44. From the extensive reading of medical literature and published medical writings, it has come to our knowledge that lead related problems are known to occur after device implantation and require re-exploration as a corrective measure. As per the research study titled "*Implantable transvenous cardioverter-defibrillators" by Bardy GH, Hofer B, Johnson G*, *(et al. Implantable transvenous cardioverterdefibrillators. Circulation. 1993;87:11521168. [PubMed]),*

45. Early lead displacements are the most frequent cause of reintervention, involving atrial leads in the majority of cases. Pacemaker lead displacements can be defined as any other pacemaker position change, whether the functionality of the pacemaker is affected or not. However, only those displacements that provoke a malfunction in the pacing system are clinically relevant. Chronologically speaking, there are early displacements, which occur within the first six weeks after implantation, and late displacements, after this period of time. Early displacements are

more frequent than late displacements and they usually affect atrial leads.(*NATIONAL LIBRARY OF MEDICINES (accessible at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1513524/*

46. In the present case, it is to be noted that the patient had smooth post-procedure course and was monitored constantly under the supervision of super-specialist doctors which is evident from the fact that routine interrogation of the device was carried out to ascertain whether the device was working effectively or not. During the routine interrogation, it was revealed that high voltage lead impedance or shock was out of range. Therefore, the treating doctors decided to re-explore the site wound for readjusting the AICD and to correct lead impedance. Hence, such conduct of the treating consultants sufficiently speaks of the meticulous care in the treatment extended to the patient.

47. Again, it may be mentioned here that the Complainant has led no evidence of experts to prove the alleged medical negligence except his own affidavit. The experts could have proved if any of the doctors in the Opposite Party hospital providing treatment to the patient were deficient or negligent in service. No previous medical record of the patient has been placed on record for further assessment of his condition. A perusal of the existing medical record produced does not show any omission in the manner of treatment. Thus, the possibility of breach of duty to provide reasonable care is ruled out and it cannot be said that the surgical procedure was the proximate cause of death of the patient.

48. As discussed above, the sole basis of finding the Opposite Party negligent is by way of *res ipsa loquito*r which would not be applicable herein keeping in view the treatment record produced by the Opposite Party No.1. For the application of the maxim *res ipsa loquitur* no less important a requirement is that the *res* must not only bespeak negligence, but pin it on the Opposite Party. The experts of different specialities and super-specialities of medicine were available to treat and guide the course of treatment of the patient. The doctors are expected to take reasonable care but none of the professionals can assure that the patient would overcome the ailments in all probability.
49. Lastly, ***we deal with plea taken by the Complainant that the Opposite Party No.1 charged extra for the AICD device.***
50. It is to be noted that AICD-related complications entail increased healthcare costs because the cardiac devices that control life-threatening symptoms are expensive and require an invasive procedure for implantation. It is to be noted further that sufficient material has not been placed on record to establish that the initial agreement between the parties for the treatment was USD 6,000/- and later the Opposite Party no.1 increased the cost of the device.
51. Therefore we conclude that the treating consultants and staff of the Opposite Party No.-1 Hospital have exercised reasonable competence and care while treating the patient in all circumstances. Still, despite all standards of care and precautions taken during the treatment, complications may arise. The patient was discharged in healthy condition and lived more than 6 months after the procedure,

which is in itself a conclusive proof that the patient was treated as per the standard medical procedure. However, in an unfortunate case, death may occur. Here, it is necessary to remark that sufficient material or medical evidence should be made available before an adjudicating authority to arrive at the conclusion that death is due to medical negligence. Every death of a patient cannot on the face of it be considered to be medical negligence.

52. Thus, in light of the aforesaid discussion, we conclude that no negligence is made out on part of the Opposite Parties. ***Consequently, Complaint Case No.2022/2017 stands dismissed with no order as to costs.***
53. Applications pending, if any, stand disposed of in terms of the aforesaid judgment.
54. The judgment be uploaded forthwith on the website of the commission for the perusal of the parties.
55. File be consigned to record room along with a copy of this Judgment.

(JUSTICE SANGITA DHINGRA SEHGAL)
PRESIDENT

(PINKI)
MEMBER (JUDICIAL)

(J.P. AGRAWAL)
MEMBER (GENERAL)

Pronounced On:
11.09.2023