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CRITICAL REVIEW

Consent for Treadmill Test (TMT) and Issue of Medical Negligence

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ABSTRACT

Hon'ble SC in a case [Spring Meadows Hospital and Anr. Vs. Harjot Ahluwaliaand Anr. (1996)] observed that with the emergence of the Consumer Protection Act, no doubt in some cases patients have been able to establish the negligence of the doctors rendering service and in taking compensation thereof, but the same is very few in number.

In recent days there has been increasing pressure on hospital facilities, falling standard of professional competence and in addition to all, the ever-increasing complexity of therapeutic and diagnostic methods and all this together are responsible for the medical negligence. There has been a growing awareness in the public mind to bring the negligence of such professional doctors to light.

This paper deals with critical analysis of one such case in which a patient died during Treadmill Test due to medical negligence of doctors/hospital. NCDRC (National Consumer Disputes and Redressal Commission) awarded a compensation of Rupees Seventeen Lac after analysis and discussing issues related to 'lack of consent', res ipsa loqutur, lack or precautions to be taken, etc.

The aim of writing this paper is to highlight issues which may lead to medical negligence, medical fraternity should be aware of legality and complexity involved in such life saving and life threatening medical interventions/procedures.

Keywords: TMT, NCDRC, Medical Negligence, Compensation, Res Ipsa Loqutur

INTRODUCTION

The Hon'ble Apex Court in Spring Meadows Hospital and Anr. Vs. Harjot Ahluwalia and Anr. (1996)¹ has observed as under "In the case in hand we are dealing with a problem which centres around medical ethics and as such it may be appropriate to notice the broad responsibilities of such organizations who in the garb of doing service to the humanity have continued commercial activities and have been mercilessly extracting money from helpless patients and their family members and yet do not provide the necessary services. The influence exhorted by a doctor is unique. The relationship between the doctor and the patient is not always equally balanced. The attitude of a patient is poised between trust in the learning of another and the general distress of one who is in a state of uncertainty. Such ambivalence naturally leads to a sense of inferiority and it is therefore, the function of medical ethics to ensure that the superiority of the doctor is not abused in any manner."

Hon'ble Supreme Court clarified that it is a great mistake to think that doctors and hospitals are easy targets for the unsatisfied patient. It is indeed very difficult to raise an action of negligence.¹ Not only there are practical difficulties in linking the injury sustained with the medical treatment but also it is still more difficult to establish the standard of care in medical negligence of which complaint can be made.

Address for correspondence and reprint: *Director/Principal/Dean Siddhant School of Medical Science and Hospital Manipuri, U.P. Mobile: 08527063514 Email: drmukesh65@yahoo.co.in All these factors together with the sheer expense of bringing a legal action and the denial of legal aid to all but the poorest operate to limit medical litigation in this country.¹

In recent times there has been an increasing pressure on hospital facilities, falling standard of professional competence and in addition to all, the ever-increasing complexity of therapeutic and diagnostic methods. All these together are responsible for medical negligence.¹ There has been a growing awareness in the public mind also, a reason to bring the negligence of such professional doctors to light.

BRIEF FACTS OF THE CASE²

Facts of the case, in brief, are that complainant No.1, Shri S.N. Verma(husband) and the complainants no 2 and 3 are son and daughter respectively of Late Smt. Sunita Verma, who was 47 years old at the time of her death. She was taken to Indraprastha Apollo Hospital for a whole body check-up (W.B.C.) on 02.04.1999.

Complainant was asked to fill-up a form, in which, he inter-alia filled-up the name of the patient, name of the guardian and address and also the name of the doctor (Dr. Khursheed Anwar) who had referred the case.

Allegations of Medical Negligence (It was submitted)

- That a healthy woman died during the course of the Treadmill Test which proves that there was gross medical negligence of the doctors/staff of the hospital.
- That the stand taken by the opposite parties that the patient did not give information relating to her past medical history is absolutely wrong. Full details of the past history were given along with medical records issued by the earlier doctor, Dr. Anwar who had treated the patient.
- That before conducting the TMT, reports of the doctors/staff of the hospital in respect of the earlier tests conducted by them were not evaluated. If it was done, it would have revealed whether the patient was fit enough or not for TMT.
- That only a technician was present during the TMT though it is claimed by the opposite parties that Dr. Indermeet was present. Neither, he has filed his affidavit nor his qualifications have been revealed.
- As there was no doctor in the TMT room, the patient was not asked to stop exercising as soon as ECG

changes appeared or symptoms of chest pain or discomfort or breathlessness were felt as the result of which she collapsed during the TMT.

- That apart from TMT report and ECG report, no other hospital records were given to the complainants though a special messenger Mr. Kalu Ram was sent as per the directions of the Director/Medical Superintendent who was requested to make available the test report.
- She categorically refused to give the test reports of the other tests and also did not acknowledge the receipt of the letter-dated 07.06.1999.

Issues for Considerations before National Consumer Disputes and Redressal Commission:

Following issues emerged for consideration before the NCDRC:

- 1. Issue of Medical History
- 2. Issue of Qualified Doctor, Protocol and Precautions for TMT
- 3. Issue of Consent
- 4. Issue of Medical Record
- 5. Issue of proper Evaluation of patient
- 6. Issue of Res Ipsa Loquitur
- 7. Issue of Compensation
- 8. Issue of making Necessary Parties to suit

In this paper only issue no.1 to 6 will be discussed in details and Issue No.7 and 8 will not be discussed.

ISSUE OF MEDICAL HISTORY

It was submitted that if the patient does not give past history, it is not possible for the doctor to assess the condition of the patient who may appear absolutely normal at rest. He has relied upon Extract of the book³ is quoted below:

"It is not possible to anticipate and prevent the rare instance when a small coronary artery plaque insufficient to produce detectable ischemia during even minimal exercise, may be the site of sub-intimal haemorrhage result in dislodgement occlusion of the vessel causing infarction or death. This can cause a morbidity of 10 in one lac and mortality of 0.24 in one lac." NCDRC observed that it was the case of the opposite parties that no previous history was given by the patient. This averment is not true for the simple reason that a perusal of the report of the Gynecology test dated 02.05.1999 reveals irregular long cycles, four abortions, menopause four months back and previous medical history nil. This is contradictory. The previous medical history cannot be 'nil', as the patient has revealed irregular long cycles, four abortions and menopause four months back.

ISSUE OF RES IPSA LOQUITUR

According to the defendant hospital, it is not a fit case to apply the principle of Res ipsa loquitur. Therefore, a mere accident due to gross negligence of the complainant himself would not make him eligible to receive compensation. It was further submitted that moreover doctors are not Gods and their treatment is based on their specialized knowledge in their particular field of study. NCDRC relying Supreme Court judgment [1] observed that gross medical mistake would always result in a finding of negligence. Use of wrong drug or wrong gas during the course of anesthetic will frequently lead to the imposition of liability and in some situations even the principle of Res ipsa loquitur can be applied. Even delegation of responsibility to another may amount to negligence in certain circumstances. A consultant could be negligent where he delegates the responsibility to his junior with the knowledge that the junior was incapable of performing of his duties properly. We are indicating these principles since in the case in hand certain arguments had been advanced in this regard, which will be dealt with while answering the question posed by us. A perusal of the anaesthesist's notes indicates Dr. Ghosh tried that pacemaker. He did not mention the presence of Dr. Indermeet in his report at all. A perusal of the TMT report shows the technician's name as Gloria. There is no mention of the name of Dr. Indermeet. A doctor is superior to the technician. If he was present, his name would have definitely figured in the TMT report. Hence, it is not possible to believe that Dr. Indermeet was present during the TMT.

The opposite parties have admitted that at the time of conducting TMT, shortness of breath was noticed and the patient was unfit for TMT as a result of which she died. Therefore, it is clear that if a doctor would have been present in the TMT room, the life of the patient could have been saved. In this case it is clear from the records that the patient collapsed at the TMT. During TMT, no qualified doctor was present. The responsibility of a doctor cannot be delegated to a technician. Hence, this case falls under the category of *Res ipsa loquitur* (facts speak for themselves). NCDRC observed that this is a clear case of medical negligence on the part of Indraprastha Apollo Hospital and the treating doctors.

ISSUE OF QUALIFIED DOCTOR, PROTOCOL AND PRECAUTIONS FOR TMT

NCDRC observed that in the case under consideration instead of a qualified doctor in the TMT room, only a technician was present. The death of the patient had occurred within the closed doors of the hospital room. NCDRC opined that therefore, the ratio of Spring Meadows Hospital and Anr. Vs. Harjot Ahluwalia and Anr. (1996) [1] case is squarely applicable to the case under consideration.

The complainant quoted HeartSite.com, extract of which reads as follows: "When is a Regular Stress Test ordered? A regular stress test is considered in the following circumstances:

- Patients with symptoms or signs that are suggestive of coronary artery diseases (CAD)
- Patients with significant risk factors for CAD.
- To evaluate exercise tolerance when patients have unexplained fatigue and shortness of breath.
- To evaluate blood pressure response to exercise in patients with borderline hypertension.
- To look for exercise-included serious irregular heartbeats.

The above factors were not considered in this case by the hospital before TMT was ordered. He further quoted the extract of the Apollo Clinic Koramangala, Bangalore case. List of pre-conditions before patient undergoes stress test, which are as follows: *"The following recommendations are "generic" for all types of cardiac stress tests:*

Do not eat or drink for three hours prior to the procedure. This reduces the likelihood of nausea that may accompany strenuous exercise after a heavy meal. Diabetics, particularly those who use insulin, will need special instructions from the physician's office. Specific heart medicines may need to be stopped one or two days prior to the test. Such instructions are generally provided when the test is scheduled. Wear comfortable clothing and shoes that are suitable for exercise. An explanation of the test is provided and the patient is asked to sign a consent form. How long does the entire test take? "A patient should allow approximately one hour for the entire test, including the preparation."

NCDRC concluded that none of these preconditions were complied with and the opposite parties took none of these precautions. NCDRC observed that it is seen from the referral of Dr. Khursheed Anwar, Consultant Physician dated 05.04.1999 that there was no request for TMT (page 84 of the paper book).

Affidavit shows only the name of the technician. On the other hand, Dr. P.K. Ghosh, Sr. Consultant Cardiologist in his report at para-6 has submitted as follows: "I ran to the TMT room from CCU and reached immediately before anybody else. As I saw the patient was having a systole and needed emergency pacing, I found it no point in trying to continue resuscitation in the TMT room. Hence, I got a stretcher immediately and rushed the patient to the emergency triage which was the nearest and the quickest reachable place where all facilities are available." This clearly means that Dr. Ghosh was the first doctor to reach the TMT room.

ISSUE OF CONSENT

Despite this, the patient was asked to undergo TMT before AHMC consultant conducted a detailed physical examination. Before conducting the Treadmill Test, neither consent of the patient was obtained in writing nor it was explained to her the risks involved in undergoing the TMT though it is stated in the affidavit by Dr. (Mrs.) Ritu Rawat as follows: "As far as TMT is concerned, before it is done, every patient is described what the test involves, asked if the patient has any specific complaint and clearly told to her/him about the risks involved."

There is no record to show that the risks involved in TMT were explained to the deceased and her signature was obtained in the consent form. A photocopy of the consent form pertaining to Mrs. Sunita Verma is at page 130 of the paper book. First half of this form pertains to patient registration record. Second half pertains to authorization (consent) for operation and treatment.

This is neither signed by the patient nor by her guardian though it is claimed that the consent was obtained. In the Written Submission (WS) filed by the opposite parties Nos.1 and 2 is wrongly stated as follows: "*The WBC was* started only after taking due consent from the patient as per hospital protocol applicable to her and sent for the procedural tests with due care."

NCDRC referred to Supreme Court judgment Samira Kohli Vs. Dr. Prabha Manchanda and Anr. 2008⁴, in which it is observed as follows:

"Consent that is given by a person after receipt of the following information: the nature and purpose of the proposed procedure or treatment; the expected outcome and the likelihood of success; the risks; the alternatives to the procedure and supporting information regarding those alternatives; and the effect of no treatment or procedure, including the effect on the prognosis and the material risks associated with no treatment. Also included are instructions concerning what should be done if the procedure turns out to be harmful or unsuccessful."

In was also observed as under: A doctor has to seek and secure the consent of the patient before commencing a 'treatment' (the term 'treatment' includes surgery also). The consent so obtained should be real and valid, which means that: the patient should have the capacity and competence to consent; his consent should be voluntary; and his consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he knows what is consenting to.

NCDRC observed that the patient or her guardian neither signed the consent form. It is clear from this case that no valid or informed consent was taken from the patient before she was subjected to TMT, which involves serious risk. Therefore, it is a clear case of medical negligence.

ISSUE OF MEDICAL RECORD

NCDRC observed that replies given by the complainant substantiate the stand that no doctor was present in the TMT room. It also gives credence to the claim of the complainant that opposite parties have deliberately not given the hospital records to him. In the written submission, the opposite parties have said that a copy of the available medical record of the patient have been filed, which means that certain other medical records, were there but they have not been made available to the commission.

NCDRC observed that Medical Council of India (MCI)⁵ has stipulated that the treatment records of the patient alongwith discharge certificate or death certificate should be issued within 72 hours of the death/discharge. In this case the death certificate does not bear any date. These reports were not supplied to him. NCDRC observed that this action of the OPs invites adverse inference.

Issue of Compensation: The NCDRC awarded amount of Rs.17 lakhs by the opposite parties with 9% interest from the date of filing of the complaint till the date of payment. Opposite parties were also directed to pay Rs.15000/- as cost of complainant. NCDRC taken consideration of case law on the issue referred by the parties.^{6, 7, 8}

SUMMARY AND CONCLUSIONS

It is also important to note that Dr. Khursheed Anwar has not recommended TMT. NCDRC also pointed out discrepancies in the death certificate issued by Dr. Sandeep Khurana of the Indraprastha Apollo Hospital. The age of the patient has been written as 40 years though she was 47 years old at the time of her death and all records of the hospital show that she was 47 years old.

Secondly, cause of death is written as "? **Sudden Cardiac Death**". No information is given about the collapse at the Tread Meal.

NCDRC raised following questions:

"Why this question mark was put before cause of death? Why was collapse of TMT not mentioned?" There is need to create awareness on the part of doctors and health administrators to introspect on issues involving threat to life and provide quality of healthcare involving patient/relatives in the decision making after taking informed consent.

Ethical principles framed by the MCI⁵ in its regulations of maintaining medical records and supplying to patient/ authorized representatives whenever demanded goes in favor of doctors/hospitals in case of suit for medical negligence.

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