NATIONAL CONSUMER DISPUTES REDRESSAL COMMISSION
NEW DELHI

CONSUMER CASE NO. 297 OF 2014

1. SMT. DIMPY KHANNA & 2 ORS.,
W/o Shri Aman Khanna, 2949, Ward No. 9,
KHARAR - 140301.
2. AMAN KHANNA S/O LATE SHRI RAVI KHANNA
R/o 2949, Ward No.9 Kharar,
PUNJAB-140301
3. AMIT KHANNA S/O LATE SHRI RAVI KHANNA
R/o 2949, Ward No.9 Kharar,
PUNJAB-140301 .....Complainant(s)

Versus

1. DR. A. S. SOIN & 2 ORS.,
Chief Liver Transplant & Hepatobiliary Surgeon, Chairman, Medanta Institute of Liver Transplantation & Regenerative Medicine, Sector-38,
GURGAON.
2. MEDANTA INSTITUTE OF LIVER TRANSPLANTATION & REGENERATIVE MEDICINE,
Through Dr. A S Soin, Chief Liver Transplant & Hepatobiliary Surgeon, Chairman, Medanta Institute of Liver Transplantation & Regenerative Medicine, Sector-38,
GURGAON.
3. MEDANTA THE MEDICITY,
Through its Chairman, Dr. Naresh Trehan, Sector-38,
GURGAON. .....Opp.Party(s)

BEFORE:

HON'BLE DR. S.M. KANTIKAR,PRESIDING MEMBER

FOR THE COMPLAINANT :

Dated : 06 June 2023

ORDER

Appeared at the time of arguments:

For the Complainant : Mr. Varun Bedi, Advocate

with Mr. Aman Khanna, in person

For the Opp.Party : Ms. Shyel Trehan, Advocate

Mr. Rohan Poddar, Advocate

Pronounced on: 06th June 2023

ORDER

Primary liver cancer is the third most common cause of cancer-related deaths worldwide. Despite careful selection for liver transplantation (LT) of patients with hepatocellular carcinoma (HCC), HCC may still recur after LT and is frequently associated with dismal outcome[1].

1. The present Complaint has been filed under Section 21 of the Consumer Protection Act, 1986 (in short, the 'Act, 1986') by the Complainants against the Dr. A. S. Soin & Medanta Hospital for the alleged medical negligence causing death of the patient.

2. Mr. Ravi Khanna (since deceased, hereinafter referred to as the 'patient'), a non-smoker and non-alcoholic person, who was suffering from off and on fever, weakness, loss of weight and appetite, approached Dr. M. Chhabra. After triphasic CT Scan of abdomen and other investigations it was diagnosed as multifocal hepato cellular carcinoma (liver cancer). Therefore, for further treatment, on 05.04.2012, consulted Dr. A. S. Soin (OP-1) at Medanta, the Medicity (OP-3). He confirmed the liver cancer and advised immediate liver transplant. Patient was informed about the standard liver transplant package for Rs. 23,50,000/- + additional applicable expenses. It was alleged that, the OP-1 assured that after liver transplant patient would be able to lead normal life without any complications. Accordingly, patient was told to arrange liver donor. As commercial donor was not available, therefore, his daughter-in-law Dimpy Khanna (Complainant-1) agreed to donate her liver. The OP-1 issued certificate on 01.05.2012 and subsequently, NOC was obtained on 02.05.2012 from Punjab State Authorization Committee under the Transplantation of Human Organs Act, 1994. The approval was subject to Surgeons being doubly sure that no metastasis of HCC are present in the patient's body at the time of transplant surgery. The patient underwent liver transplant successfully on 04.05.2012 and discharged on 22.05.2012 with follow-up advice. The patient visited OPs on 17.08.2012, underwent blood test, which revealed high AFP value i.e. 4780 as compared to 2120 seen in the report dated 05.04.2012. Thus, it was clearly indicative of presence of cancer cells in the body. After four months in the month of September, 2012 patient's condition deteriorated. For second opinion he consulted Dr. Manmohan Singh, who advised MRI Dorso Lumbar Spine. The MRI revealed cancer cells spread in the spinal cord of the patient. It came surprise and complete shock to the patient and his attendants, because the OP-1 misled the Complainants that after transplant surgery all cancer cells had been successfully removed from the body. Thus, it was alleged negligence of the OP-1 who never removed the cancer cells, but it spread to spine and subsequently the patient died on 02.04.2013. The Complainant incurred heavy expenses in crores for the treatment, thus being aggrieved, the Complainants – Smt. Dimpy Khanna (daughter-in-law) and two sons of the deceased filed the Consumer Complaint and prayed compensation of Rs. 5 Crores from the OPs jointly and severally along with litigation cost of Rs. 55,000/-.

3. The OPs filed their reply and denied any negligence. They have treated the patient with highest standard of medical care at OP-3. On 07.04.2012, whole body PET – Triphasic CT Scan was performed and confirmed diagnosis of liver cirrhosis with portal hypertension and Multifocal Hepato Celluar Carcinoma (HCC) and multiple metabolic indeterminate nodules in the lung. From the report underlying metastasis in lungs could not be ruled out. The 99m Tc-MDP Bone Scan was conducted on previous day ruled out the definitive evidence of skeletal metastases. Since the whole body PET- Triphasic CT Scan revealed the possibility of Lung Metastasis, on 11.4.2012, a biopsy was conducted from left lingual and lower lobe which revealed, "No evidence of malignancy and the specimen is suggestive of usual interstitial pneumonia". In order to mislead the Commission, the Complainant in the pleadings has suppressed the material fact that the OP conducted a whole body PET-Triphasic CT Scan, 99m Tc-MDP Bone Scan and a biopsy. As there was no extra hepatic spread, the Patient was considered for Liver transplant. It was the Complainant's own case that the cancer re-occurred in the spine. OPs submitted that no medical treatment can prevent the recurrence of cancer cells and failure to prevent recurrence of cancer does not constitutes medical negligence, when there are no pre-emptive treatment proved to be effective in preventing such recurrence.

4. It was further submitted that the Complainant suppressed the Consent form obtained prior to the Liver Transplant. A specific High Risk Informed Consent for Orthotopic Liver Transplant was obtained on 3.5.2012 from the Patient (Annexure 4). The possibility of recurrence of diseases such a Viral Hepatitis (of all types), Cancer, auto-immune hepatitis etc was explained. It was highlighted that the recurrence of cancer could be rapidly progressive. Early recurrence after Surgery is seen to be aggressive and rapidly progressive by which survival becomes less. It is submitted that the Complainant has filed an extremely selective record in order to mislead this Commission.

5. The OPs took all pre transplant care. The cardiac evaluation by the Cardiac Consultant was done. The CT Coronary Angiography (CAG) was done on 26.4.2012 revealed Triple Vessel Disease (TVD), therefore conventional CAG was performed on 27.04.2012. The patient was further advised coronary artery bypass grafting. The patient was cleared for surgery from the multidisciplinary team. In view of the critical cardiac functions, the Patient was again reviewed. The multidisciplinary meeting consists of panel of experts from Cardiology, Hepatology, Anaesthesia and Liver Surgery confirmed fitness for transplant. Accordingly, it was decided to conduct both surgeries “Liver Transplant and CABG in the same sitting. The said decision was made in view of the fact that the poor heart condition of the Patient would not be able withstand the stress of a 16-18 hours Liver Transplant and similarly the critical condition of the Patient's liver would not be able to withstand a CABG. Accordingly, it was decided that the CABG would be performed first followed by Liver Transplant Surgery on 4.5.2012.

6. It was submitted that the Patient and the attendants were explained the known complications and risks in detail at various occasions in OPD and during admission. In view of the critical condition and comorbidities of the patient, on 03.05.2012 High Risk Consent from the patient’s son was obtained for both the surgeries .On 04.05.2012, the patient underwent OPCAB (Off Pump Coronary Artery Bypass) CABG with 3 grafts (LIMA to LAD, RSVG to Dl & RSVG to PDA) and thereafter in the same sitting the Liver Transplant was performed. During the Liver transplant the operative findings confirmed that the patient

was suffering from end stage Cirrhosis. The entire liver was explanted and as per standard protocol the explanted specimen was sent for histo-pathological examination. Both the surgeries were successfully conducted without any complications.

7. Post-operatively the patient was managed in the ICU. The histopathology report was received on 10.05.2012 and the final diagnosis was well differentiated Hepatocellular Carcinoma. It also showed Lymph Vascular invasion and involvement of 1 or more hepatic veins and of major branch of portal vein which were removed during the Liver Transplant surgery. On 11.5.2012 and 14.5.2012, ECHO revealed normal cardiac functions. The Patient was discharged in a stable condition on 22.05.2012. The Patient was prescribed appropriate medication including antibiotics, immunosuppressive drugs, anti-viral and antifungal drugs. He was instructed to repeat certain blood and radiological investigation periodically and meet the treating doctors from team Liver and Cardio Thoracic.

8. The allegation of complainant that the AFP value in April 2012 was 2120, which after transplant increased to 4780 in August 2012, meaning thereby the cancer cells were still present in the body. In my view it was wrong and contrary to medical literature. Increased or decreased values of AFP are not an indicator of a successful or unsuccessful Liver Transplant but it is an **indicator of recurrence**. Since early recurrence of liver cancer is known, thus it is incorrect to assume that due to residual cancer after 3.5 months of transplant AFP was raised. It was demonstrative of reoccurrence, and follow up was advised with Dr. Soin. In 18% of patients recurrence is known. It is clear from the record that the entire liver was explanted (removed) and a healthy liver from a healthy donor was transplanted in the Patient, therefore, there was no residual cancer in the Patient after the Surgery.

9. **Medical Literature on HCC**:

I have perused the Standard books on Hepato Cellular Carcinoma viz Hepatocellular Carcinoma: Future Outlook, Hepatobiliary and Pancreatic Cancer, Surgical Pathology by Anderson. Also the research articles on recurrence of HCC, micro vascular metastasis.

10. Liver transplantation (LT) provides an excellent option for the long-term survival of patients with unresectable hepatocellular carcinoma (HCC) based on the Milan criteria[2]. Despite careful selection of patients, HCC may still recur after LT, which represents the most important negative predictor of post-transplant survival. The growing demand for LT in HCC has led to the expansion of patient selection criteria, with a resultant increase in the risk of post-transplant HCC recurrence. Numerous tumor and host factors predict HCC recurrence. The morphological, histological, and serological characteristics of tumors in predicting HCC recurrence have been extensively studied.

11. In another article from PLOS ONE [3], the Hepatocellular carcinoma (HCC) is one of the most common malignancies and is the third leading cause of cancer-related deaths worldwide . Although the treatment of HCCs is evolving, hepatic resection or liver transplantation (LT) remains the possible treatment to cure HCCs for eligible patients. Nevertheless, the tumor recurrence is 70% after curative resection and 15%-30% after LT at 5 years. Microvascular invasion (MVI), which can be diagnosed only by microscopic observation (mainly in small vessels such as portal vein branches in portal tracts, central

veins in noncancerous liver tissue, and venous vessels in the tumor capsule and/or noncapsular fibrous septa) is regard as one of the most well-known independent risk factors for recurrence and poor prognosis . Furthermore, the presence of MVI may indicate the necessity of a more extensive resection and neoadjuvant treatments with curative intent . Therefore, an accurate preoperative prediction of MVI can help surgeons choose appropriate surgical procedures or select suitable patients for LT based on risk-benefit assessment. However, identification of the MVI requires a definitively histological evaluation of surgical specimens obtained after resection and transplantation, which limits its usefulness on preoperative clinical-decision making.

12. Microvascular invasion (MVI)[4] is associated with a more aggressive biologic behaviour in hepatocellular carcinoma (HCC) and is an important risk factor for postoperative recurrence and reduced survival. Hepatic microvascular invasion is more frequently observed in HCCs with a lower degree of differentiation and confers aggressive tumor biology. HCCs with extranodular growth and contiguous multinodular growth patterns are prone to microvascular invasion. HCCs give rise to intrahepatic and remote metastases with high frequency. Risk factors for metastasis comprise macro- and microvascular invasion, large tumor size, multi-focality, and poor histologic differentiation.

Thus, based on the literature, in the instant case there was **recurrence** of HCC in the transplanted liver, but it was not due to any **residual tumour**. It appears the Complainant wrongly alleged that the HCC was developed due to Residual tumour after liver transplant, but it was 'recurrence' of HCC.

13. The Hon'ble Supreme Court, in various cases, has laid down standard principles/ guidelines required to be kept in mind while deciding cases of medical negligence. In the case of **Kusum Sharma & Ors. V. Batra Hospital and Medical Research Centre & Ors**[5], the Hon'ble Supreme Court applied certain standard principles to establish that the doctors in the said case were not guilty of medical negligence. The Supreme Court specifically held that:

> "As long as the doctors have performed their duties and exercised an ordinary degree of professional skill and competence, they cannot be held guilty of medical negligence."

In the same judgment the Hon'ble Supreme Court laid down certain principles (i to xi) while holding the doctor negligent.

14. Based on the foregoing discussion, to conclude, I do not find any dereliction of duty from the OP-1 at OP-2. It was unfortunately a case of recurrence of HCC, for which the OP-1 was not liable. The team of doctors performed their duties with standard skills and competence. No case of medical negligence is made out.

The Consumer Complaint is dismissed. There shall be no order as to costs.

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[1] Annals of Hepatology, Volume 27, Issue 1, January–February 2022, 100654

[2] Ann Surg. 2011;254:108-113

[3] PLOS ONE | https://doi.org/10.1371/journal.pone.0197488 May 17, 2018

[4] Zimmermann, A. (2017). Invasion Patterns and Metastatic Patterns of Hepatocellular Carcinoma. In: Tumors and Tumor-Like Lesions of the Hepatobiliary Tract. Springer pp 91–119

[5] AIR 2010 SC 1050

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DR. S.M. KANTIKAR
PRESIDING MEMBER