

IN THE STATE COMMISSION: DELHI

(Constituted under Section 9 of the Consumer Protection Act, 1986)

Date of Decision: 07.07.2017

Complaint Case No. 84/2002

In the matter of:

Sh. N K Sharma

S/o Sh. M L Sharma

R/o C-211, Gautam Marg

Hanuman Nagar

Jaipur, Rajasthan

.....Complainant

Versus

1. The Medical Superintendent

G B Pant Hospital

New Delhi

2. Professor (Dr.) S K Sarin

Head, Department of Gastroenterology

G B Pant Hospital

New Delhi

3. Dr. Sri Ram

Resident Surgeon

Department of Gastroenterology

G B Pant Hospital

New Delhi

4. The Secretary

Ministry of Health & Family Welfare

Government of N C T of Delhi

New Secretariat Building

Delhi

.....Opposite Parties

CORAM

N P KAUSHIK

-

Member (Judicial)

- | | | |
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| 1. | Whether reporters of local newspaper be allowed to see the judgment? | Yes |
| 2. | To be referred to the reporter or not? | Yes |

N P KAUSHIK – MEMBER (JUDICIAL)

JUDGMENT

- 1) In brief the complainant Sh. N K Sharma underwent liver biopsy in G B Pant Hospital Ltd. on 07.04.2000. Need of this

test arose as the complainant was diagnosed as having HBs AG+ve. The complainant went for the staid test on the advice of OP-2 Dr. Prof. S K Sarin HOD of the Gastroenterology of G B Pant Hospital Delhi. Biopsy test was done by Dr. Sri Ram Resident Surgeon, Department of Gastroenterology G B Pant Hospital Delhi (OP-3). Dr. Sri Ram (OP-3) applied local anesthesia on the chest of the patient and injected a needle for taking out the sample for biopsy.

- 2) Grievance of the complainant is that he immediately started spitting blood and continued doing so. His body started trembling and jumping 2-3 feet high. It was revealed that the lung of the complainant had been punctured.
- 3) Patient was shifted to ICU. Complainant submitted that his life could be saved only with the intervention of Dr. S K Sarin. Condition of the complainant got stabilized but both of his kidneys failed. Patient was put on dialysis. In such circumstances the complainant/patient had to shift to Sir Ganga Ram Hospital Delhi, where he got admitted on 10.04.2000. He remained hospitalized there upto 22.04.2000. He had to undergo treatment for revival of his kidneys.

- 4) Complainant submitted that he suffered huge loss of earnings which was to the tune of Rs. 1,20,000/-. He sought an amount of Rs. 8,196/- on medicines in G B Pant Hospital and another amount of Rs. 1,79,714/- spent in Sir Ganga Ram Hospital Delhi. Compensation to the tune of Rs. 15,00,000/- has also been claimed. Complainant has thus in all claimed an amount of Rs. 18,27,910/- from the OPs.
- 5) Defence raised by OP-2 Dr. (Prof.) S K Sarin was that there was no negligence either on his part or the attending doctors. Dr. S K Sarin submitted that the attendants of the complainant took the complainant to Sir Ganga Ram Hospital Delhi against his advice. He further submitted that the complainant was independently advised liver biopsy by some other doctor. It was only thereafter that he consulted him (OP-2). Complainant was examined for his multiple liver related problems which included presence of hepatitis B infection, presence of low serum albumin and the underlying diabetes mellitus. Liver biopsy was required to decrease extent damage caused to the liver. Patient and his attendants were explained the risk involved in liver biopsy. A proper informed written consent was taken. After a joint decision by a team of doctors, it was unanimously decided to proceed

with the liver biopsy. There was no contra indication existing in the case. OP-3 was a qualified gastroenterologist who had regularly been carrying out liver biopsy for the last four years prior to the biopsy in question. Biopsy was conducted in the room in which the patient was admitted. In most such cases procedure is carried out on bed side. OP-2 relied upon the medical literature in support of his defence that a pre-existence of a disease could cause renal failure.

- 6) Relying on the averments made by OP-2, OP-3 Dr. Sri Ram Agarwal submitted that he undertook biopsy procedure under local anesthesia with due diligence at about 2:30 pm on 07.04.2000. Liver biopsy initially was attempted in 8th ICS and then in 9th ICS but failed and the patient developed hemoptysis about 20ml, dyspnoea and B.P. 210/110 mmHg.
- 7) Defence raised by the OP-3 is that puncture of other viscera(Right lung-lower most edge of right lung which was anatomically situated just beneath, behind and near to the liver of the complainant) was a known complication of liver biopsy.
- 8) This Commission on the request of the complainant referred the matter for expert opinion vide orders dated

26.11.2013. The relevant portion of the expert's opinion is reproduced below:

I. Whether there was any necessity to conduct liver biopsy upon the complainant keeping into mind his matured age and past clinical/pathological findings, in the light of facts that the result of ALT/AST had persistently been found normal from the beginning i.e. 06/04/2000 till today?

II. Whether in the light of advice/opinion expressed by an eminent Gastroenterologist of SMS Hospital & Medical College, Jaipur Rajasthan, Liver Biopsy was required upon the applicant?

Ans. The committee felt that the liver biopsy was required in the case under consideration. The case under consideration was HbsAg Positive. Even in the presence of normal ALT, the liver biopsy was indicated because his albumin was low & he was diabetic.

III. Whether Liver biopsy is such a simple procedure that it does not require operation theater and can be performed inside the room of the patient?

Ans. Liver Biopsy is an invasive procedure and is performed by trained doctors (Residents/Pool Officers/Consultants). Liver biopsy is performed mostly as a bed side procedure & is not required to be done in operation theatre.

IV. Whether process of conducting liver biopsy can lead to oozing vomiting of blood?

Ans. During Liver biopsy if the lungs are injured, there could be oozing of the blood from the mouth (Hemoptysis). Injury to the lungs due to its proximity to liver is a known complication of liver biopsy.

V. Whether process of liver biopsy can lead to renal disorder in normal circumstances?

Ans. Under normal circumstances, liver biopsy does not lead to renal disorder. However renal disorder may appear because of aggressive treatment instituted for management of complications of liver biopsy. Underlying diabetic

status of the patient predispose the individual to renal damage.

VI. Whether required facility including dialysis facility was available in the G B Pant Hospital, New Delhi on 07/07/2000?

Ans. Dialysis facility was available at LokNayak Hospital which is an associated Hospital with G B Pant Hospital.

VII. Whether a patient/person suffering serious liver disease can survive and remain free from any such symptom for a period of more than 12 years?

Ans. Person suffering from a liver disease can survive and may remain symptom free for long time.

9) Short controversy in the matter is whether OP-3 Dr. Sri Ram Agarwal was negligent in performing liver biopsy upon the complainant. Ld. Counsels for the Complainant Sh. K K Malviya Advocate and Sh. Vinod Kumar Advocate have taken this Commission through an article of the website 'Johns Hopkins Medicine'. Relevant portion of the said article is given below:

- ***Percutaneous or needle biopsy.*** After a local anesthetic is given, the doctor inserts the special biopsy needle into the liver to obtain a sample. Ultrasonography or fluoroscopy (a type of X-ray "movie") may be used to guide the biopsy needle insertion. Most liver biopsies are performed using this technique.
- ***Laparoscopic or open biopsy.*** After a general anesthetic is given, the doctor makes an incision in the skin and surgically removes a piece of the liver. Depending on the lab findings, further surgery may be performed.
- ***Transvenous biopsy.*** After a local anesthetic is given, the doctor makes an incision into a vein on one side of the neck and inserts a specially designed

hollow tube called a sheath through the vein down to the liver. One or more tissue samples are removed through the tube.

10) Ld. Counsels for the complainant have vehemently argued that the complainant was a patient aged about 63 years and suffering from diabetes mellitus. He should have not been put to the test of liver biopsy by the bed side. He should have been taken to an operation theater keeping in view his health condition. Next main contention of the complainant is that the doctor conducting biopsy should have used ultrasonography or computed tomography (CT)-guided biopsy needle insertion. On the contrary, the counsels for the OPs have contended that the liver biopsy is normally conducted on the bed side and in majority of the cases the sample is taken by adopting blind per cutaneoustechnique. Ld. Counsels for the OPs have relied upon the article written by Dirk J. Van Leeuwen, M.D. Ph.D.alongwith other two authors. OPs have also relied upon the website John Hopkins referred to above and also relied upon by the complainant. The relevant portion of this article in the present context is reproduced below:

- *The doctor will locate your liver by pressing on your abdomen and will mark the location where the biopsy will be done. Ultrasound, MRI, and CT scan may be used to locate a specific spot in the liver.*

11) Now a question arises whether in the present case ultrasound, MRI or CT scan was required to be used for locating a specific spot in the liver. The article written by Dirk J. Van Leeuwen, M.D. Ph.D and referred to above dealt with the situation. Ultrasound or computed tomography (CT)-guided biopsy is done in the following situations:

1. The physician fails to outline the liver configuration. This should be a rare event. Based on personal experience (DJvL), the single most common reason why others who have encountered a problem ("I didn't get any tissue") request help from the hepatologist is misjudgment of the liver location. Particularly in obese patient, the liver may be located much higher, with the upper edge closer to the breast nipple than it normally would be.

2. The liver is small, abundant ascites is present, or the patient is morbidly obese. If one uses too short a needle, a biopsy may easily fail in the patient with ascites. Ultrasonography provides a ready explanation: the mobile right liver lobe is being pushed away. Paracentesis preceding a biopsy should be considered.

3. A space-occupying lesion of the liver is present (see question 8)."

12) No material has been placed on record to show that in a case of diabetes mellitus, a guided biopsy is required.

13) Now coming to the controversy of renal failure disorder, the expert's opinion given by the Dean Maulana Azad Medical College Delhi stated that under normal situation, liver biopsy does not lead to unilaterally disorder. It may appear because

of aggressive treatment given to the patient for management of complication of the liver biopsy. Diabetes status predisposes the individual to renal damage. The aforesaid expert's opinion is also supported by the discharge summary of the present complainant as given by Sir Ganga Ram Hospital Delhi. The relevant portion of the said discharge summary is reproduced below:

"Hospital Course

The patient presented to us with unexplained acute renal failure severe enough to require dialytic support. Various possibilities considered were acute tubular necrosis (However, there was no history of documented hypotension or any evidence of I.V. haemolysis). Additionally, possibility of acute interstitial nephritis (? Drug induced even though there was no significant history of any offending drug intake was available). A possibility of b/l. renal papillary necrosis since patient is a diabetic, had ARF with gross haematuria was also considered. A remote possibility of Vasculitis causing ARF specially in relation to HBsAG + ve status and VII N. palsy was also considered. The patient was investigated and managed accordingly. He had remained practically anuric initially and was on regular dialysis vascular access being AV shunt made over right forearm."

- 14) Aforesaid discussion leads to the conclusion that there was no need of doing biopsy in operation theater and guided biopsy was not the need of hour. Renal disorder though temporary was necessarily an outcome of the attempted liver biopsy. Be that as it may, puncture of lungs is one of the known complications of the liver biopsy. The fundamental is

well explained in the article relied upon by the complainant and referred to above. Risk of the procedure as given in the said article reads as under:

- ***Discomfort and bruising at the biopsy site***
- ***Prolonged bleeding from the biopsy site, externally or internally***
- ***Infection near the biopsy site***
- ***Puncture of adjacent organs or structures***

15) In another article written by A Grant, J Neuberger and titled as '**Guidelines on the use of liver biopsy in clinical practice**', the chances of puncture of adjacent organs are shown as under:

"Puncture of other viscera occurs infrequently, with an incidence of between 0.01 and 0.1%.The puncture of lung, colon, kidney and gall bladder together with pneumothorax, pleural effusion, and subcutaneous emphysema are well recognized complications, which rarely require intervention."

16) As discussed above, the puncture of lung is a known complication of liver biopsy. It is not the case that the doctor performing tests lacked in educational qualifications, experience or failed to do the job with a reasonable skill. Clearly, it was not a case of negligence or carelessness on the part of doctor doing the procedure. Complaint, therefore, is dismissed.

17) Copy of the orders be made available to the parties free of costs as per rules and thereafter the file be consigned to Records.

(N P KAUSHIK)
MEMBER (JUDICIAL)