

THE WEST BENGAL CLINICAL ESTABLISHMENT
REGULATORY COMMISSION.

Present: Justice Ashim Kumar Roy, Chairperson.

Dr. Sukumar Mukherjee, Member.

Dr. Abhijit Chowdhury, Member.

Dr. Madhusudan Banerjee, Member.

COMPLAINT ID: HOW/2017/000246.

Shri Kanai Lal Saha.....Complainant.

-versus-

Dr. Roy's Diagnostic Centre & others.....Respondents.

Date of judgment: 18th May, 2018.

J U D G M E N T .

It is the case of the complainant that his brother, a Bangladeshi national, has been under the treatment of Dr Abhijit Chowdhury for last 16 years for his liver problem and was under his regular follow up. On September 6, 2017, his brother consulted Dr Abhijit Chowdhury and he advised a CT Scan for routine checkup of liver. The CT Scan revealed a tumour in the mid pole of right kidney along with renal cortical cyst and gall stone. Becoming upset with such report, they consulted Dr Makhanlal Saha, Prof. of Surgery, IPGME&R, Kolkata. He advised for ultrasonography for abdomen and other investigation to reconfirm the CT Scan report. Accordingly, on September 8, 2017, they had been to Roy's Diagnostic Centre Pvt. Ltd, B. K. Pal Avenue, Kolkata. At the center, the procedure was done by Dr M C Nandi, which revealed that neither there was any gall bladder stone or any tumour in right kidney. However, cortical cyst in kidney, found in CT Scan was confirmed. After the report, on being insisted by Dr Makhan Lal Saha, they attended Medanta- Medicity, Gurgaon, Haryana for further

assessment. They consulted Dr Rajiv Yadav on September 11, 2017 and Dr Yadav advised his brother to go for CT Dynamic Study for kidney and USG abdomen. The report of both the procedure was received on September 11, 2017 and September 14, 2017 respectively. CT Scan report revealed a cortical based, focally exophytic, enhancing nodular lesion in the interpolar region of right kidney anteriorly, reaching upto the renal medulla. Gallbladder is distended. A 4.5 mm radiodense calculus is seen in the neck/ cystic duct junction. USG Upper Abdomen report revealed a gall bladder calculus of size 10.5 mm in its Visualized neck region. Right kidney measures 9.8x5.5 cm. Few cortical cyst are seen in its lower Pole, largest measuring 36x34 mm. An isoechoic lesion measuring 38x36 mm is seen at its upper pole. Based on these reports his brother was admitted at Medanta – The Medicity on September 19, 2017 under Dr. Yadav and operation was successfully done on September 18, 2017. He underwent robotic surgery at Medanta- The Medicity. A partial nephrectomy including the tumour in the kidney and gall bladder alongwith stone were removed.

Kidney cancer is dreaded disease and spread very rapidly to other sites. Trusting the USG report of Roy's Diagnostic centre Pvt. Ltd., if the complainant's brother would have returned to Bangladesh without further treatment, his life would have been in danger and he would have died shortly.

It is further alleged Ultrasonography is a procedure conducted through machine and operator dependant examination and it was alleged that doctor doing the procedure, was not careful while doing the examination.

2. Immediately upon receipt of the complaint, the notice was issued against the clinical establishment seeking their response.

3. Both the clinical establishment and Dr Narayan Chandra Nandi, who conducted the procedure, filed their reply in the form of affidavit separately.

a) Clinical establishment in their affidavit stated that the patient Uttam Kumar Saha was referred to their centre on September 8, 2017 by Dr Makhan Lal Saha for Ultrasonography. The ultrasonography was done by their senior most radiologist Dr Narayan Chandra Nandi and he himself recorded the findings and submitted the report. Only after receipt of an online message along with the complaint of Mr Kanai Lal Saha, they came to learn about the incident and immediately sought for an opinion from Dr Nandi. They claimed that the centre had no role to prepare such USG report except providing infrastructure to concerned radiologist.

It was added the USG machine with 4 probes, manufacturer Philips Electronics India Limited was purchased in April, 2013 and for providing better service to the patient, the said machine including all probes are under regular maintenance. The centre had a comprehensive maintenance contract dated January 12, 2017 with Marc Medical Services of Philips for the period from 25.01.2017 to 24.01.2018 for regular maintenance of both the machine and the probes so as to ensure better services to the patient. Both the invoice and the maintenance contract were enclosed with the affidavit. In terms of the said contract, the maintenance took place on July 18, 2017, August 10, 2017 and October 3, 2017. All three aforesaid maintenance reports were also enclosed. It is added during booked maintenance on August 10, 2017, the concerned service engineer found noise in images and in the S4-2 Probe. Accordingly the probe was changed for cross checking and it was detected that the problem was in the earlier probe. It was asserted that S4-2 Probe is especially Cardiac Sector Probe and after installation of new probe, the centre was asked by the service engineer to watch the machine for a day so as to confirm that the defect was due to the earlier probe and thereafter no complaint was forthcoming from any doctor. The service engineer also remarked "Job Completed" after proper maintenance of USG machine. It is then added that among the 4 Probes, C5-2 High Resolution Imaging Probe is used for USG of abdomen. It is asserted that the centre provides necessary infrastructure, qualified doctor, machinery and management for USG of whole abdomen of the patient and the clinical establishment is in no way responsible for any deficiency in service as alleged by the complainant. It is also stated that the clinical establishment is running with a good reputation since 1967, i.e. more than 50 years, providing due and reasonable patient care service in the diagnostic field.

b) Dr Narayan Chandra Nandi in his affidavit stated as follows,

It was not disputed that the patient Uttam Kumar Saha was referred by Dr Makhan Lal Saha for USG and on September 8, 2017 he had done the procedure, prepared the report and handed over the report to the patient party.

It is claimed that either before or during ultrasonography, he was not provided with CT film and the report of the patient done on 6.9.2017 at Indian Institute of Liver and Digestive Sciences, West Bengal nor even he was verbally informed about the history although as a matter of routine before starting the procedure the patient was asked about the same.

It was claimed that the USG was done with due care and the kidneys being retroperitoneal structures, are better assessed by CT Scan than USG and CT Scan is the investigation of choice for assessing focal space occupying lesion of kidneys specially a renal tumour. It was submitted that he was not informed by the patient about the presence of an enhancing lesion in the mid pole of right kidney which was revealed in a CT Scan done on 6.9.2017. It is claimed that as per literature renal USG detected 26% of CT confirmed lesion of <1 cm, 60% of lesion of 1-2 cm, 82% of 2-3 cm and 85% of > 3 cm. It was asserted that during his examination, no calculus was revealed in gall bladder in the neck/cystic duct region of gall bladder which might be obscured due to presence of bowel gas resulting from poor bowel preparation which happened in this case. It is added that as per literature sensitivity of USG for detecting gall bladder stone is about 95%, hence, a small percentage of stone may be missed in USG. It was further claimed, he was not informed about the findings gall bladder stone mentioned in CT Scan report dated 6.9.2017. It was pointed out that the patient did not report back to him regarding the discrepancies in the findings of CT Scan dated 6.9.2017 and USG dated 9.9.2017 which could have given him the opportunity to review and do the needful. It is submitted that in case of poor bowels preparation, he used to remark after impression that scan after proper bowels preparation is suggested, which he missed in this case.

4. The members with medical expertise have taken active part in the deliberation and rendered their valuable opinion and with their views the Commission arrives at the following conclusion.

5. The primary premises of discontent of the complainant involves an ultrasound report of his brother that was done at Roys Diagnostic Centre on his brother, by Dr Narayan Chandra Nandi. Neither in his evidence on affidavit nor in his oral submission before the Commission, Dr. Nandi disputed that he performed such ultrasound and gave the report. It appears that the report does fall short of picking up a kidney lesion (tumour) that was present and later got operated at Medanta-Medicity, Gurgaon, Haryana. It further appears from the evidence on affidavits, and the oral submissions before the Commission that the complainant already had a clear diagnosis in hand by CT Scan done elsewhere before the ultrasound in question. Although, in his affidavit, Dr Nandi claimed that in the single prescription of Dr (Prof) Makhan Lal Saha, with which the patient reported to him for ultrasonography, no CT Scan findings were recorded, except an advice of USG for whole abdomen but in his counter affidavit, the complainant claimed that in the prescription of Dr Saha it was noted "*gall stone disease with (R) Renal mass*". However, the case of Dr Nandi that the report of CT scan done at Indian Institute of Liver and Digestive Sciences was not shown to him, has not been disputed by the

complainant. Undoubtedly, CT scan is superior in delineating structural renal lesions than ultrasound, therefore, the pathology was already obvious and the purpose of ultrasound was to corroborate the findings of CT scan and to exclude any other pathology, if any. The patient was operated couple of days later in Delhi and another CT scan was done there. All these happened in a week's time.

While the failure to demonstrate the obvious lesion on ultrasound by the doctor was academically imprecise and might have led to potential harm if used as a sole diagnostic tool, however, in the case at hand, the ultrasound report, did not lead to any negative impact in subsequent medical decision making process and in patient care. Although failure to detect the tumour in kidney by the sonologist, was undoubtedly a serious shortcoming but due to the timely intervention by the doctors at Medanta- Medicity, Gurgaon, the patient got required relief. Merely because the medical condition of the patient was managed in another institution by further diagnostic procedure, that does not rule out the question of medical negligence on the part of the sonologist who performed the Ultrasonography.

It is well-known that ultrasonography is diagnostic imaging technique based on application of ultrasound and used to see internal body structures such as tendons, muscles, joints, blood vessels and internal organs. Its aim is often to find a source of disease or to exclude any pathology. The success/outcome of such procedure essentially depends on correct reading and interpretation of imaging.

6. In the case at hand, the complainant has enclosed with his letter of complaint, a report dated 06.09.2017 of *TRIPLE PHASE CT SCAN OF UPPER ABDOMEN* of the patient done at INDIAN INSTITUTE OF LIVER AND DIGESTIVE SCIENCES and a report of CT Dynamic Study – Kidney of the patient done on 11.09.2017, at Medanata- Medicity, Gurgaon. We find according to the report of Indian Institute of Liver and Digestive Sciences, amongst other, there was, *2.3x2.2 cm well defined round arterially enhancing lesion in mid pole of right kidney* of the patient and according to the CT Dynamic study— kidney at Medanata Medicity, there is a cortical based, facally exophytic, enhancing nodular lesion, seen in the interpolar region of right kidney anteriorly, reaching upto the renal medulla, measuring approximately 2.4X2.6X2.4 cms.

Dr. Nandi in support of his case relied on a medical literature, *The utility of screening renal ultrasonography: identifying renal cell carcinoma in an elderly asymptomatic population*, and the copy thereof annexed with his affidavit. According to the said literature, several studies evaluated the

sensitivity and specificity of renal ultrasonography (RUS) for detecting renal tumors. Aslaksen et al. evaluated 1306 patients, finding the sensitivity and specificity of RUS to be 91% and 96%, respectively. Warshauer et al. evaluated RUS in relation to CT in a prospective study of 201 patients; RUS detected 26% of CT-confirmed lesions of <1 cm, 60% of lesions of 1-2 cm, 82% of 2-3 cm and 85% of ≥3 cm. While RUS is efficient at detecting larger lesions, the inability to detect small masses reduces its utility in screening for early RCC. In the case at hand, the nodular lesion found in the right kidney of the service recipient measuring approximately 2.3X2.2 cm in triple phase CT scan at INDIAN INSTITUTE OF LIVER AND DIGESTIVE SCIENCES and 2.4X2.6X2.4 cms at Medanta Medicity in CT Dynamic Study, therefore, what transpire from the literature relied on by Dr. Nandi is of no help.

It is noteworthy that Dr. Nandi at the very beginning of his report, categorically noted "*poor bowel preparation hindering image quality*" and in his affidavit the same finding was reiterated. Although, it is claimed that the patient was duly directed about bowel preparation by the staff of the center but no contemporaneous record of the same has been brought to the notice of the Commission. According to the case made out by Dr. Nandi in his affidavit during his examination, no calculus was revealed in Gall bladder in the neck /cystic duct region of the Gall bladder which might be obscured due to the presence of bowel gas resulting from poor bowel preparation which encounter in this case as mentioned in the report. Lastly, in the said affidavit it is admitted by Dr. Nandi that in case of poor bowel preparation, he used to write after impression that scan after proper bowl preparation is suggested, which was missed in this case. Where in a case of ultrasonography, at the beginning presence of bowel gas is found due to poor bowel preparation, a sonologist without proceeding any further with the procedure should suggest the patient to return after proper bowel preparation. By no means, it is at all justified, for a sonologist to carry out ultrasonography, even when he himself is of the opinion that due to poor bowel preparation the image quality be hindered.

Although the failure to pick up was a shortcoming by the ultra sonologist, it really did not have any impact on the patient's treatment. It also may be argued that an ultrasound after a CT scan that provided a clear lesion in such circumstances was more of an academic exercise. The doctor provided some explanations for the miss-some which are theoretical and may not be enough justification for the failure on his part.

It is already on record that the ultrasound machine in which the USG was done, was in order and under regular maintenance. The wrong report of USG which is the subject matter of issue in this

case, cannot be attributed as a deficiency in the patient care service on the part of the Clinical Establishment. However, whenever a patient approach any diagnostic centre for some procedure which requires necessary preparation, apart from the doctor advise such test, it is also one of essential the duty of the diagnostic centre to simultaneously suggest and describe the patient/ the patient party details of such preparation in writing.

7. The above facts tends to make out a case of medical negligence on the part of the doctor who performed the ultrasonography and gave the report. Now in view of provision contained in first proviso to sub-Section (iii) of Section 38 of the West Bengal Clinical Establishment (Registration, Regulation & Transparency) Act, 2017, the adjudication as to the question of medical negligence by a medical professional is outside the purview of the Commission. Therefore, with above observation, this case stands closed and disposed of.

However, this order will not prevent the complainant to approach the concerned State Medical Council, against the doctor concerned, if so advised.

Sd/-

Dr. Sukumar Mukherjee, Member.

Sd/-

Dr. Abhijit Chowdhury, Member.

Sd/-

Dr. Madhusudan Banerjee, Member.

Sd/-

Justice Ashim Kumar Roy,
Chairperson.

Authenticated



Secretary
West Bengal Clinical Establishment
Regulatory Commission