

# Clinical Judgment and Limitations in Prenatal Imaging: No Negligence Originates

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## ABSTRACT

A child after birth had significant abnormalities, underdevelopment of the Fetal Femur Length, lumbar and sacrum. This type of abnormality can be detected in an ultrasound before birth, for which the doctors get an ultrasound done for prenatal care. All the findings were indicated as normal. On repeated ultrasounds at different intervals report was given as normal development. Following the birth of her child, the MRI revealed that the child's lower lumbar spine and sacrum were either absent or severely underdeveloped.

In a complaint before DCDRC, the complaint was allowed, directing the opposite party to pay damages. In an appeal preferred by Doctor/Hospital, SCDRC did not find medical negligence and the Impugned judgment and order passed by the District Commission, Haridwar, was set aside.

**Keywords:** Congenital Anomaly, USG Study, MRI, Expert Committee, Error of Diagnosis, Medical Negligence, Compensation.

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## INTRODUCTION

Congenital abnormalities are the anatomical, functional and metabolic anomalies that occur during foetal life but can be detected before or after birth.<sup>1</sup> Detection of foetal abnormalities is usually done using 2D-US, 3D-US and MRI imaging. After birth, Echocardiography, X-ray and CT scan are also used.<sup>1,2</sup>

The most commonly involved system is the musculoskeletal system, and is followed by the cardiovascular system. Congenital anomalies may not be preventable, but they can definitely be reduced by early detection and proper counselling, and this helps to reduce the anguish of the parents.<sup>1</sup>

MRI is better and more sensitive than 3D scans and 2D scans in detecting CNS anomalies, as MRI provides crucial additional information which can help in management, as well as in prognosis and counselling, but it shows a high false positive result for subtle CNS findings as compared to ultrasonography. Ultrasound 2D, 3D, and MRI had similar sensitivity for non-CNS anomalies. Specificity was higher with 3D-US for all the anomalies. But the use of ultrasound is more common than MRI due to cost factors and better availability.<sup>2</sup>

## Background of the Case

This appeal under Section 15 of the Consumer Protection Act, 1986, has been directed against the judgment and order dated 31.10.2018 passed by the learned District Consumer Disputes Redressal Forum, Haridwar (the District Commission) in consumer complaint No.576 of 2014 styled as Smt. Renu vs. Dr. Manoj Singh, wherein and whereby the complaint was allowed, directing the opposite party to pay Rs. 8,00,000/- as compensation and Rs. 3,50,000/- towards mental and physical agony, a total sum of Rs. 11,50,000/- together with interest @

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6% per annum from the date of filing of consumer complaint, i.e., 17.10.2014, till the date of actual payment along with Rs. 10,000/- towards cost of litigation.<sup>3</sup>

## Facts of the Case

The complainant gave birth to a child on 22.04.2014 in the Himalayan Hospital, Jolly Grant. After the birth, she found that the child had significant abnormalities, including absence or severe underdevelopment of the Fetal Femur Length, lumbar and sacrum. These anomalies resulted in the child's inability to sit, stand, or move the lower part of the body independently. On inquiring from the doctors, it was found that this type of abnormality is detected in an ultrasound before birth, for which the doctors get an ultrasound done for prenatal care. The complainant, too, had undergone an ultrasound at the opposite party's clinic on 14.10.2013 before the birth of her child. According to the report provided by the opposite party, the foetus was measured to be 8 weeks and 4 days old. All the findings were indicated as normal. The complainant underwent subsequent ultrasound examinations at the opposite party's

clinic on 19.12.2013 and 03.03.2014 and later on 26.03.2014, i.e., just before the delivery. In each of these reports, the clinic reported that the foetus was developing normally and did not indicate any abnormalities.

### **Investigation and Treatment at Himalayan Hospital, Jolly Grant, Jolly Grant, Dehradun**

Following the birth of her child, the complainant obtained an MRI. The MRI revealed that the child's lower lumbar spine and sacrum were either absent or severely underdeveloped. The doctors indicated that such anomalies are detectable during three months of pregnancy. Despite undergoing multiple ultrasound examinations at the opposite party's clinic during her pregnancy, the complainant was informed that the foetus was developing normally with no abnormalities reported.

### **Referral to AIIM, New Delhi**

Following the refusal for further treatment at the local hospital, she shifted her child to AIIMS Hospital, New Delhi, seeking appropriate medical care. There, the doctors also indicated that the above disability was due to the absence or severely underdeveloped Lower Lumbar Spine and Sacrum and that the opposite party had committed gross negligence and gross deficiency in providing medical services.

### **Treatment at AIIMS Hospital, Rishikesh**

On getting the child examination in AIIMS Hospital, Rishikesh, the doctor also indicated that the opposite party did not give correct ultrasound report at the right time and informed very belatedly about physical disability of the child due to which the child is unable to sit, stand or move the lower part of the body independently and he was physically handicapped.

As a result of the above-mentioned actions by the opposite party, the complainant has faced significant mental, physical and financial distress. The failure to detect and communicate such abnormalities during the ultrasounds constitutes a serious breach of medical duty. This is indicative of gross medical negligence and a deficiency in the standard of care expected from medical professionals.

Subsequently, the complainant lodged a complaint before the District Commission seeking relief and compensation for hardship due to gross medical negligence and deficiency in providing medical services by the opposite party.

### **Investigation of Treatment of BHEL, Haridwar**

In a written statement, the opposite party stated that the facts presented by the complainant are fabricated and wrong. The answering opposite party stated that the complainant was referred to him by BHEL, Haridwar, for examination of the fetal well-being of the baby through a basic 2D ultrasound for fetal well-being. The opposite party also stated that he had an agreement with BHEL Hospital to conduct a 2D basic ultrasound as a part of the empanelment arrangement.

According to the opposite party, the ultrasound was correct because it is not clear to tell about the abnormalities of the

Lumbar and Sacrum in a basic 2D ultrasound. The opposite party also stated that when the MRI was done after the delivery, the MRI report showed that the femur, lumbar and sacrum bones of the child were underdeveloped.

He did not do an MRI, nor were any instructions given by the BHEL Hospital to conduct any test other than a 2D ultrasound in respect of the complainant. He has no instructions regarding the child's fetal biophysical profile level II ultrasound/anomaly scan/3D/4D ultrasound, which would have provided detailed information about the child's growth in the fetus. The opposite party has agreement and instructions for conducting a 2D ultrasound only. The opposite party has stated that he saw the movement and growth of the child in the foetus of the complainant through a 2D ultrasound, which was normal.

The opposite party further stated that BHEL Hospital, Himalayan Hospital Jolly Grant, and AIIMS New Delhi have not been made parties in this complaint. The opposite party contended that the complainant had not submitted any evidence indicating that any doctor from any hospital had/reported any error or deficiency in the examination conducted by the answering opposite party.

The opposite party further stated that he has conducted a 2D ultrasound as per modern medical techniques and has not committed any negligence. Therefore, the complaint is liable to be dismissed with costs.

The District Commission, after hearing both parties and taking into consideration the facts and evidence on record, has passed the impugned judgment and order dated 31.10.2018, whereby the District Commission has allowed the complaint in the above terms.

### **Appeal before SCDRC**

Having been aggrieved by the aforesaid judgment and order of the District Commission, the opposite party has preferred the present appeal.

In the appeal, the learned counsel for the appellant-opposite party has contended that the impugned judgment and order of the Commission below are against law, facts and merits of the case; the Commission below has not considered the written statement and evidence filed by the appellant.

Because the District Commission has not taken into consideration the reply, evidence and report constituted by the Chief Medical Officer, Haridwar. The District Commission has ignored the fact that the appellant neither committed any negligence in conducting the ultrasound nor, due to such ultrasound report, any harm was caused to the respondent or her child. The respondent has also failed to submit any expert report or any affidavit from any doctor that proves any carelessness or negligence on the part of the appellant.

### **Alleged Failure to Recommend Further Investigation**

On the contrary, the findings of the report of the committee constituted by the Chief Medical Officer, Haridwar, no

negligence or malice was found against the appellant. The District Commission has also ignored the fact that the respondent was suffering from diabetes during her pregnancy and the treating doctors Dr. Sangeeta Singhal and Dr. Sharda Swaroop of BHEL Hospital, should have recommended/prescribed for higher level diagnostic test, such as level II ultrasound/anomaly scan / 3D/ 4D ultrasound / MRI to know the status of foetus. Instead, the appellant was directed to conduct a 2D (fetal well-being) ultrasound test on all occasions.

### Issue of Contractual Agreement

It is important to note that the appellant's contractual agreement with BHEL was only for providing 2D (fetal well-being) ultrasound and did not have any contract regarding the 4D and level II or any other higher-level test.

### Issue of Accurate Diagnosis

The District Commission has ignored the important fact that the basic 2D ultrasound test may not detect the anomalies in the lumbar or sacrum. Advanced imaging techniques such as level II ultrasound/anomaly scan / 3D/ 4D ultrasound / MRI are often necessary for accurate diagnosis of such conditions.

### Duty of Referral /Radiologist/Ultrasonologist

The responsibility for determining the appropriate disease lies with the treating doctor. The Sonographer / Radiologist performs the ultrasound examination as prescribed by the treating doctor. The Sonographer / Radiologist are not authorised to independently examine without a referral/prescription from the treating doctor.

The respondent has not made BHEL, Hospital, a party to the suit, which is a necessary party. The District Commission overlooked the fact that the respondent must have undergone multiple prenatal tests, including an ultrasound, before the delivery procedure. Despite this evaluation, no fetal deformities were detected at that time. It was only after delivery through the MRI scan – a more advanced diagnostic technique – that the deformation was identified. Notably, the respondent has not submitted any ultrasound or related reports conducted before the operation.

The District Commission below ignored the fact that abnormalities in the lower lumbar and sacrum are seen in only one patient out of 75000 to 100000 and are not detected by a 2D ultrasound, i.e. first-level test.

The District Commission has ignored that the respondent is neither a consumer of the appellant nor does she fall under the category of a consumer because the respondent got her treatment done in BHEL Hospital and did not make any payment to the appellant. Any charges incurred by the complainant, if applicable, were paid to the BHEL Hospital. The appellant operates under the contractual agreement with BHEL Hospital, wherein BHEL pays the amount to the appellant on a monthly basis.

The District Commission has also ignored the fact that according to the established medical guidelines, Level II ultrasound/anomaly scan / 3D/ 4D ultrasound / MRI are

conducted between 20 to 24 weeks of pregnancy because it provides to assess all parts of foetus including brain, face, spine, heart, stomach, bowel, kidneys & limbs etc. The District Commission has also overlooked the fact that the respondent has filed a complaint against the appellant with the BHEL Hospital; however, BHEL Hospital did not take any action, as the allegations made against the appellant were found unsubstantiated. The District Commission has passed the impugned judgment and order based on surmises and conjectures. Hence, the appeal is allowed, and the impugned judgment and order are liable to be set aside.

### Observations of SCDRC

During the arguments, learned counsel for the appellant stated that the appellant performed only a 2D ultrasound examination as prescribed by the doctors of BHEL Hospital. This was following the agreement between the appellant and the BHEL Hospital, which authorises the appellant to conduct a 2D ultrasound only. The appellant adhered to the medical protocol and procedure; therefore, there was no medical negligence on the part of the appellant.

### Case Law Relied

In support of his contention, learned counsel for the appellant has cited the case laws.<sup>4,5</sup>

SCDRC observed that in the case of Hemlata vs. Dr. Vipin Premi [2] (supra), the Commission concluded that the ultrasound report should not be considered conclusive proof of internal organ conditions. Such diagnostic tools are interpretative and should be corroborated with additional evidence to establish definite conclusions.<sup>4</sup>

SCDRC observed that in the case of Senthil Scan Centre (supra), the Hon'ble Apex Court has held that the ultrasound is not a perfect depiction of the foetus and the scan result cannot be 100% conclusive.<sup>5</sup> Further, at para No.3 of this judgment, the Hon'ble Apex Court has observed in *Martin F. D' D'Souza v. Mohd. Ishfaq* 2009<sup>5</sup> SCC 1, this Court had adopted the above test as applicable to cases of medical negligence in this country. This Court relied upon the following passage from *Hunter v. Hanley*, 1955 SLT 213, which deals with the tests applicable for establishing negligence in diagnosing or treatment on the part of a doctor.<sup>6</sup>

"In the realm of diagnosis and treatment, there is ample scope for genuine difference of opinion and one man is not negligent merely because his conclusion differs from that of other professional men.... The true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of if acting with ordinary care...."

Applying the above test recognized by precedent in this country to the case at hand, we are of the view that the State Commission and also the National Commission fell in error in holding that service was deficient since the centre had failed to detect the deformity with which the respondent gave birth to her child. What is significant is that the respondent-



complainant had not led any expert evidence to controvert the case of the centre that the doctor who conducted the ultrasound was highly qualified and that the ultrasound was done with due care and diligence. There was also no evidence to show that the failure to detect the deformity was due to any negligence on the part of the doctor conducting the ultrasound.”

SCDRC concluded that negligence was not proved. The principle laid down in both citations applies to the case in hand.

Learned counsel for respondent Nos. 1/2 to 1/4 has stated that the appellant has conducted four ultrasounds during the complainant’s pregnancy, but the appellant failed to detect any fetal anomalies. This omission on the part of the appellant reflects a breach of his duty amounting to medical negligence.

On perusal of the record, it is admitted that the appellant has conducted four ultrasound tests on 14.10.2013, 19.12.2013, 03.03.2014 and 26.03.2014. The prescription/referral schedule of ultrasound examinations conducted on 14.10.2013 and 19.12.2013 is not available on record. However, the ultrasound reports to this effect indicate that the complainant was referred to the appellant by the BHEL Hospital (papers Nos. 26 & 27). Further, these reports indicate that the foetus was 8 weeks & 4 days old on 14.10.2013 and 18 weeks & 5 days old on 19.12.2013, respectively.

The prescription/referral schedule for ultrasound conducted on 03.03.2014 and 26.03.2014 is available on record. (Prescription/referral schedule dated 25.02.2014, paper No. 28 and prescription/referral schedules dated 26.03.2014, paper No. 30). These prescription/referral schedules were for the diagnosis complete Fetal Profile and Fetal well-being. These prescription/referral schedules established that the complainant was referred to the appellant by BHEL Hospital for an ultrasound for fetal well-being. The appellant performed a 2D ultrasound examination as per the directions of the doctors of BHEL Hospital. The BHEL Hospital empaneled the appellant to conduct a lower abdomen in pregnancy for fetal well-being & fetal weight (paper No. 32), and the appellant was not authorised or empanelled for conducting MRI and the child’s fetal bio-physical profile II ultrasound/ anomaly scan/3D/4D ultrasound. This empanelment was further renewed for one year on 03.04.2014 (paper No. 33). It is also admitted that the complainant was suffering from high BP and diabetes during the pregnancy.

### Issue of the involvement of the Necessary Party

It is further admitted by the complainant (paper No. 43) that Dr. Sangeeta Singhal of BHEL Hospital kept insisting that the complainant, as treating doctor, till the end that the child was normal and healthy; therefore, in our opinion, she should be impleaded as a necessary party to the complaint case but the same was not done.

### Report of the Committee: Medical Report

SCDRC observed that [We] have also perused the finding of the report of Committee doctor consisting by the Chief Medical Officer, Haridwar (paper No. 46) which states that

the complainant was suffering from Congenital Abnormality, which is a rare disease, probability of which is one case in 75000 to 100000 and its probability increases further in mothers suffering from diabetes. As per the report, the detection rate of this disease by 2D ultrasound (normal ultrasound) is only 15 to 20%.

The report states that BHEL Hospital referred the complainant for a normal ultrasound and was neither asked nor referred for a level II / 4D ultrasound. The report further states that the BHEL Hospital should have referred the complainant for Level II ultrasound / 3D/ 4D ultrasound examination, keeping in view the High Blood Pressure in the previous pregnancy and the risk caused by diabetes during this pregnancy.

The committee concluded that the investigation conducted by the appellant was without malice and did not constitute negligence. Thus, the above expert report does not reveal that there was any medical negligence on the part of the appellant. Moreover, the complainant has not filed any such expert report wherein it was observed that the appellant was negligent in conducting the ultrasound and making his report. It is also pertinent to mention that the MRI was conducted on the child of the complainant after the birth of the child, and no such report was filed on record by the complainant that any fetal deformity was detected in prenatal tests, including ultrasound, before the delivery procedure.

## CONCLUSION

Given the above, SCDRC finds no merit in the complaint. The respondent Nos. 1/2 to 1/4 have failed to substantiate their claim by adducing cogent and trustworthy evidence that there was any deficiency in service on the part of the appellant. Accordingly, SCDRC is of the considered opinion that the impugned judgment and order passed by the District Commission lack adequate reasoning and fail to account for relevant facts, evidence of the case. The impugned judgment and order are perverse and have suffered from illegality and irregularity in passing the same; thus, the impugned judgment and order are liable to be set aside, and the appeal is also to be allowed.

SCDRC concluded that, accordingly, the appeal is allowed. Impugned judgment and order dated 31.10.2018 passed by the District Commission, Haridwar, is hereby set aside.

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