NATIONAL CONSUMER DISPUTES REDRESSAL COMMISSION
NEW DELHI

CONSUMER CASE NO. 3 OF 2005

1. G. VIJAYASHANKAR & ANR.
Son of Shri. G. Gopalakrishnan Nair, Resident of "Sruthi" No. 2/9, Anantha Ramakrishnan Street Devaraj Nagar, Saligramam
Chennai - 600 093.
2. Ms. Chitra Vijayashankar
Wife of Mr. G. Vijayashankar, Resident of "Sruthi" No. 2/9, Anantha Ramakrishnan Street,
Devaraj Nagar, Saligramam
Chennai - 600 093. ....Complainant(s)

Versus

1. MADRAS MEDICAL MISSION & ORS.
Which owns and manages: Institute of Reproductive Medicine & Women's Health 4-A, 5th Floor, Dr. J.J. Nagar,
Mogappair
Chennai - 600 050.
2. Dr. (Mrs.) Thankam Varma
Medical Director, Institute of Reproductive Medicine & Women's Health (A Unit of Madras Medical Mission) 4-A, 5th Floor, Dr. J.J. Nagar
Mogappair, Chennai - 600 050.
3. Unioted India Insurance Co. Ltd.
No. 24, Whites Road,
Chennai - 600 014. ....Opp.Party(s)

BEFORE:

HON'BLE MR. JUSTICE R.K. AGRAWAL,PRESIDENT
HON'BLE DR. S.M. KANTIKAR,MEMBER

For the Complainant :
For the Opp.Party :

Dated : 01 Apr 2021

ORDER

For Complainants : Mr. Rahul Sharma, Advocate

Mr. Bipin K. Dwivedi, Advocate

For OPs Nos. 1 & 2 : Mr. Balwant Choubey, Advocate

For OP No. 3 : NEMO

Pronounced on: 1 st April 2021

ORDER

PER DR. S. M. KANTIKAR, MEMBER

FACTS:

A married couple, Mr. G. Vijayashankar (Complainant No.1) and Mrs. Chitra Vijayashankar (Complainant No. 2, hereinafter referred to as the 'patient') was unable to conceive for about 15 years. The couple, for their treatment of infertility, approached Dr. Thankam Verma (hereinafter referred to as the 'Opposite Party No. 2') the specialist in Assisted Reproductive Technique (hereinafter referred to as the 'ART') at the Madras Medical Mission, Chennai (hereinafter referred to as the 'Opposite Party No. 1'). The Opposite Party No. 2 examined the couple and suggested In-Vitro Fertilization (hereinafter referred to as the 'IVF') treatment. The patient underwent IVF procedure twice, but failed to conceive. Therefore, the Opposite Party No. 2 advised to try for Intra Uterine Insemination (hereinafter referred to as the 'IUI'). In the year 2001 during the 1 st cycle of IUI patient conceived but unfortunately it resulted into missed abortion. Thereafter again in April 2002 during 2 nd IUI cycle she got conceived, it was twin gestation (pregnancy) confirmed by Ultra Sonography (USG). However, at 5 th week of pregnancy one embryo got destroyed internally – known as 'the vanishing twin syndrome'. The surviving embryo was monitored as a singleton pregnancy. During the antenatal checkup period (hereinafter referred to as the 'ANC') series of USG scans were carried out at the Opposite Party No. 1 hospital. On 18.06.2002, the Opposite Party No. 1 performed Nuchal Translucency (hereinafter referred to as the 'NT') scan to rule out possibility of Down's syndrome. The Complainant alleged that the NT scan was not a diagnostic test for Down's syndrome and being super specialty hospital, the doctors did not follow the standard procedures to manage such high risk pregnancy. It was further alleged that the treating doctor failed to provide genetic counselling to the couple as it was elderly pregnancy with previous history of missed abortion. Certain diagnostic tests like Amniocentesis or Cordocentesis for detection of Down's syndrome were not advised. The Complainant No. 1 denied that the couple refused to undergo those tests. It was further alleged that the Opposite Parties did not place any record to prove that the genetic counselling was done. The Complainants submitted that though all the USG were performed by Sonologist, the Opposite Party No. 2 as a Medical Director is responsible in her personal capacity for the negligence.

2. It was submitted that the child born with Down's syndrome carries various risks and wide range of medical problems. There is no definitive treatment or cure for the Down syndrome. The medical cost in bringing up the child with Down syndrome would be huge. The instant baby of the Complainants had suffered cardiac anomaly known as Patent Ductus Arteriosus (PDA). The Complainant No. 1 is a businessman and the Complainant No. 2 is a playback singer; both have suffered severe mental trauma and depression knowing upon their first child affected with Down syndrome, therefore they could not dream or afford to have another child in future. Being aggrieved, the Complainants-couple filed a Consumer Complaint before this Commission and prayed compensation of Rs. 2.5 Crores from the Opposite Parties.

DEFENCE:

3. The Opposite Parties Nos. 1 & 2 have filed their joint Written Version and denied the entire allegations. The Opposite Party No. 2 submitted that she is a Medical Director of Institute of Reproductive Medicines & Women Cell at Opposite Party No. 1 Hospital. The patient approached her on 23.05.2000. The patient was 36 years old and had no issue since13 years of married life. Previously she took treatment in Malaysia and underwent ART procedure twice. Again, in India, she underwent IUI 5 to 6 times in 1997 under care of Dr. Gopinath. In November 1997 she underwent IVF procedure from Dr. B. N. Chakraborty at Calcutta and subsequently the embryo transfer in May 1998, but all efforts were unsuccessful. In May, 2000, the patient approached the Opposite Party No. 1 Hospital and investigated. There was no serious problem. The couple underwent another IVF cycle on 24.11.2000, but it was unsuccessful. Therefore, for further management with IUI was suggested. The 1 st IUI was performed on 29.10.2001 and she got conceived but the fetus did not show cardiac activity. Therefore, ERPC suction was done and the couple was advised for genetic assessment during next pregnancy. On 15.04.2002, IUI was performed and the patient conceived. She was given controlled ovarian hyper stimulation by using gonadotrophins. On 06.05.2002, the USG confirmed twin gestation sac, however subsequently the USG done on 13.05.2002, revealed abortion of one sac and viable pregnancy in other sac. On 18.07.2002 genetic screening/ invasive techniques (CVS, amniocentesis and Cordocentesis) to confirm karyotyping was discussed. It was also told to the Complainants those 1 in 100 chances of Down's syndrome and in the event of invasive investigation / procedures, the chance of losing the pregnancy was 1 in 100. The decision was left to them. the Complainants were happy and decided to continue the pregnancy without invasive procedures because it was very long awaited pregnancy for 15 years. However the Complainants did not agree and same was recorded by the Opposite Party No. 2 wrote on medical prescription as ' <u>decided to leave, things all alone</u> '.

4. It was further submitted that the Nuchal Translucency (NT) scan was done at 11 weeks gestation, it was 1.4mm wherein the cut-off level of 2.5 mm for further evaluation. The option for Triple test was there but it was not the correct screening because the patient was conceived after ART which involved use of gonadotropins. During antenatal period the Opposite Party No.2 performed detailed anomaly fetal scan twice and found no obvious anomalies. As the patient developed Gestational Diabetes, therefore elective cesarean section was performed on 18.12.2002 and a female baby was delivered which showed Down syndrome.

SUBMISSIONS:

5. We have heard the arguments from both the sides. The Parties have filed their respective brief synopsis of Written Arguments and relevant Medical Literature on the subject.

5 (i) **Submission on behalf of the Complainants:**

The learned Counsel for the Complainant submitted that the Opposite Party No. 2 at no point of time done genetic counselling. She did not enquire about the past family history wherein the first cousin of the patient had a 15 years daughter with Down syndrome. The Counsel further submitted that for diagnosis of Down's no invasive tests or even blood tests were advised by the doctor. He submitted that for the diagnosis of Down's syndrome during first 8-12 weeks of pregnancy, there are two diagnostic tests viz. invasive and non-invasive. The non-invasive tests are USG & blood tests which are indicative and not confirmatory of Down's syndrome. Therefore, in the elderly mother (35 years or more) with high risk pregnancy, invasive tests like Amniocentesis/ Cordocentesis are mandatory, having 99% accuracy. The learned Counsel further submitted that as per the Medical Board report there was no record to prove genetic counselling or invasive tests were offered. The Opposite Parties stated that the record was misplaced. The Opposite Parties did not produce evidence to prove that the patient refused the tests. The consent forms were simply the declaration given under Pre Natal Diagnostic Techniques (Regulation of Prevention of Misuse) Act, 1994 (for short PNDT Act) which has no bearing on this case. The learned Counsel further submitted that the hospital issued two discharge summaries after two months of delivery on 20.02.2003. One did not mention about the details of baby and genetic counseling etc., whereas the second one talks about the condition of the baby and that the Opposite Party was not aware of Down's child in the Complainant's family. The 2 nd discharge Summary was prepared as an afterthought to cover up their mistakes. Both the discharge summaries are devoid of new born details like birth weight and APGAR score.

The learned Counsel for the Complainant filed following medical literature:

1.Guidelines issued by U.K. National Screening Committee for Screening of Down Syndrome

2.Guidelines issued by U.S. for Screening for Down Syndrome

3. Article on Screening for Down Syndrome by Len Leshin's

5 (ii) Submission on behalf of the Opposite Parties :

1. The learned Counsel argued that the Opposite Party No. 2 discussed the scope of Triple test but the patient did not undergo it. The triple test is usually done at 15 to 16 weeks from the blood, has higher false positive result specifically in twin pregnancies and in elderly pregnancy requesting from ART.

2. The allegation of two discharge summaries is misconceived. As requested by the Complainant No. 1, the details of abnormality was not mentioned in one discharge summary. The complete discharge summary was not issued at the time of discharge on 05.01.2003 because the baby's karyotyping report was awaited.

3. Regarding triple screening test, the counsel submitted that the scope of non-invasive and the invasive tests were discussed with the couple. The OP-1 Hospital has started the first trimester screening test which consist of measurement of NT, PAPP-A, free beta HCG. The triple test's validity in assessing fetal status may be less because of twins pregnancy or in

the pregnancy occurred due to ART techniques as beta HCG levels may be higher. He further submitted that in India the Quadruplet tests, Integrated screening test and comprehensive tests facilities were not available during 2005.

4. The Opposite Parties Nos. 1 & 2 relied upon the following judgements:

5. Savita Sachin Patil & Ors. Vs. Union of India & Ors., 2017 LawSuit (SC) 1070

6. M. Kochar Vs. ispita Seal & Anr., National Commission I (2018) CPJ 41 (NC)

7. K.L. Nijhawan & Anr. Vs Sir Ganga Ram Hospital & Ors., III (2009) CPJ 150 (NC)

8. Kusum Sharma & Ors. Vs. Batra Hospital & Medical Research Centre & Ors., I (2010) CPJ 29 (SC)

9. Dr. Harkanwaljit Singh Saini vs. Gurbax Singh and the National Insurance Co. Ltd., 1986-2005 Consumer 8674 (NS)

6. **DISCUSSION:**

We have given our thoughtful consideration and perused the entire material on record including the Medical Record and the Medical Literature.

(i) The Medical Record revealed that the patient signed 'Patient Protocol for IVF Form' on 13.11.2000, therein it was clearly mentioned that she was given suitable opportunities to take part in counseling about the implications of the proposed treatment. The invasive techniques and Karyotyping were discussed. On 01.07.2002 in the Medical Record, it was mentioned that in view of the advanced maternal age NT/Triple Screen was suggested, however the couple ' decided to leave things alone, patient did not agree for invasive procedures '. It is also pertinent to note that the couple suppressed the vital information that the daughter of patient's first cousin of about 15 years of age was detected with Down's syndrome.

ii) We have perused the expert opinion from the Medical Board, AIIMS, New Delhi, dated 06.01.2014 which observed and concluded that:

1. Triple screening was suggested in view of her advance maternal age (Page 90) but treatment record does not reveal any documentation of test being performed or laboratory report of triple screen test.

2. Patient treatment record (Page 86) dated 18 th June 2012 reveals that invasive techniques to confirm karyotyping was discussed – CVS/Amnio-cordocentesis but no follow up could be traced in the records.

Thus, it confirms the treating doctor suggested triple screening which the patient did not do.

iii) Admittedly the patient was conceived after 15 years of infertility, it was, thus, precious pregnancy. She had previous missed abortion and after genetic counseling, she did not opt for the invasive investigations to avoid miscarriage or losing the existing pregnancy. At the 11 th week of pregnancy on 18.06.2002, a non-invasive NT scan ruled out to the risk of Down's syndrome.

Thereafter, the subsequent USG assessment was done during 18-20 weeks and no structural abnormality was found. There was ample time for the couple to consider invasive tests which could have usually done around 16-18 week gestation; as per literature invasive tests carry risk of 1 in 100 chances of abortion. The couple decided not to take the risk.

iv) Moreover, the instant pregnancy was twin gestation. At 5 th week of pregnancy one fetus was destroyed internally- known as vanishing twin syndrome and the singleton pregnancy was continued. Nuchal translucency (NT) screening increases chances of antenatal detection of Down syndrome (DS) compared to maternal age-based screening. The NT scan was performed by qualified Radiologist Dr. Lata at 11 th week. It was found to be within normal limits. We have gone through some references from the International Journal of Ultrasound in Obstetrics and Gynecology. The article on "Screening for Down syndrome based on maternal age or fetal nuchal translucency: a randomized controlled trial in 39 572 pregnancies" Ultrasound Obstet Gynecol 2005; 25: 537–545

v) It is apparent from the record that during the year 2002, the treating doctor tried her best to attempt the diagnosis of Down's syndrome. In fact she was in tune with the time. It was the limitation of the screening test and quality of the then available USG machines in India, which showed drastic changes and advancement in the last decade. The much higher performance can be achieved when ultrasound is combined with concurrent first-trimester four-marker biochemistry.

7. It is worth to rely upon few decisions of Hon'ble Apex Court on Medical Negligence. In the case - **Kusum Sharma and others v. Batra Hospital and Medical Research Centre and Others,** (2010) 3 SCC 480 held that:

'the medical professionals are entitled to get protection so long as they perform their duties with reasonable skill and competence and in the interest of the patients. The interest and welfare of the patients have to be paramount for the medical professionals".

In **Achutrao Harbhau Khodwa Vs. State of Maharashtra,** 1996 Vol 2 643 the Hon'ble Supreme Court has held:

> "The skill of medical practitioner differs from doctor to doctor. The nature of the profession is such that there may be more than one course of treatment which may be advisable for treating a patient. Courts would indeed be slow in attributing negligence on the part of a doctor if he has performed his duties to the best of his ability and with due care and caution. Medical opinion may differ with regard to the course of action to be taken by a doctor treating a patient, but as long as a doctor acts in a manner which is acceptable to the medical profession and a court finds that he has attended on the patient with due care skill and diligence and if the patient still does not survive or suffers a permanent ailment, it would be difficult to hold the doctor to be guilty of negligence."

In the case in hand the Complainant's main allegation that proper genetic counseling was not done by the treating doctor or the hospital. Factually for more than a decade the couple was under treatment from different hospitals in India and abroad. The couple is highly qualified and had adequate knowledge of various methods and the pros & cons of Assisted Reproductive Techniques. Moreover, from the Medical Record of opposite party No.1 we note counselling of couple was done and advised for the invasive tests for prenatal diagnosis of Down's syndrome.

8. Based on the discussion above, in our considered view, it was an accepted standard of practice in the year 2002. The Complainants fail to prove the act of omission or medical negligence of the Opposite Parties. We find no merit, the Complaint stands dismissed.

There shall be no order as to costs.

......................J
R.K. AGRAWAL
PRESIDENT

....
DR. S.M. KANTIKAR
MEMBER