NATIONAL CONSUMER DISPUTES REDRESSAL COMMISSION
NEW DELHI

FIRST APPEAL NO. 228 OF 2013

(Against the Order dated 30/01/2013 in Complaint No. 28/2010 of the State Commission Andhra Pradesh)

1. DR. SVSS PRASAD & 2 ORS.
Medical oncologist, Apollo Hospitals, Apollo Health City Campus, Jubilee Hills,
Hyderabad-033
Andhra Pradesh
2. DR. VIJAYANAND REDDY,
Director Department of Oncology, Apollo Hospitals, Apollo Health City Campus, Jubilee Hills,
Hyderabad-033
Andhra Pradesh
3. APOLLO HOSPITALS,
REP. By its Director, Apollo Health City Campus, Jubilee Hills,
Hyderabad-033
Andhra Pradesh .....Appellant(s)

Versus

1. N. SHASHANK REDDY
S/o. N. Venkat Ramana Reddy, Plot No. 321, Road No. 10 C, MP/MLA Colony, Jubilee hills,
Hyderabad
Andhra Pradesh .....Respondent(s)

BEFORE:
HON'BLE DR. S.M. KANTIKAR,PRESIDING MEMBER
HON'BLE MR. DINESH SINGH,MEMBER

For the Appellant : Mrs. K. Radha, Advocate with
Appellant No.1 in person

For the Respondent : Mr. Pankaj Bhagat, Advocate with
Mr. SadreAlam, Advocate
Mr. IshitaRawat, Advocate
Mr. Upender Chaudhary, Advocate

Dated : 10 Jun 2021

ORDER

ORDER

PER DR. S. M. KANTIKAR, PRESIDING MEMBER

1. This Appeal filed against the Order dated 30.01.2013 in CC No. 28 of 2010 by A.P. State Consumer Disputes Redressal Commission, Hyderabad, wherein the Complaint was partly allowed holding medical negligence during the treatment and directed the Appellants to pay Rs. 7 lakh plus Rs. 10,000/- towards cost.

2. Brief facts that the Complainant N. Shashank Reddy's mother Kamala about 54 years (since deceased, hereinafter referred to as the 'patient') on 22.09.2009 consulted Dr.Rajesh Reddy and Dr. Alok Ranjan at Apollo (the Opposite Party No. 3). The MRI revealed high grade Glioma of brain. The PET scan advised by Dr. Vijayanand Reddy, the Opposite Party No. 2 revealed small activity in the lymph nodes near lungs, however the lymph node biopsy ruled out any malignant deposits and it was suspected as tuberculosis (TB) lymph node. On 01.10.2009 biopsy from the brain lesion confirmed the diagnosis of Primary Central Nervous System lymphoma (PCNSL). The Opposite Party No. 1- the medical Oncologist Dr. SVSS Prasad the treating medical Oncologist decided to adopt DeAngelis protocol for treatment which gives less neurocognitive impairment and increase the chances of survival about 24 to 36 months. As requested by the Complainant the Opposite Party No. 1 had telephonic discussion and emails exchange with the patient's relative Dr. Praveen Reddy (Hematologist and Oncologist) based at USA. The Opposite Party No. 1 assured the facility to treat the patient with DeAngelis protocol was available at Apollo Hospital (Opposite Party No. 3). Therefore, on such assurance from the Opposite Party No. 1 the Complainant dropped to take his mother to USA for treatment.

3. On 06.10.2009 the patient got admitted in the Opposite Party No. 3 –hospital and her bone marrow biopsy was performed. The 1 st cycle of chemotherapy was started on 08.10.2009 by infusing 2700mg High Dose of Methotrexate (HDMTX). It was alleged that for next two days the MTX level was not monitored to rule out MTX toxicity. As per protocol to minimize the MTX toxicity and complications 'Leucovorin' rescue was to be started at 24 hours after HDMTX administration. It was alleged that the Opposite Party No. 1delayed it for 48 hours and did not monitor daily the Urine pH, serum creatinine, blood urea nitrogen and electrolytes. The patient was discharged on 11.10.2009. Thereafter, patient developed dizziness and drowsiness and again admitted on 19.10.2009 to the Opposite Party No. 3 Hospital. It was diagnosed as Hyponatremia(low blood Sodium), it was 107 mEq/lit (Normal134-145). The hospital took 9 days to correct Sodium level which usually takes 3 to 4 days. On 28.10.2009 the Opposite Party No. 1 started 2 nd cycle of chemotherapy with administration of 4600 mg of HDMTX, but the urine pH level was not tested or confirmed. It was alleged that during 1 st and 2 nd chemotherapy cycle the Opposite Party No.1 did not follow the DeAngelis protocol i.e. did not monitor Urine pH, serum creatinine, blood urea nitrogen and electrolytes. At the time of discharge, the Opposite Party No. 1 prescribed two Neupogen shots at home instead of the recommended dose of 5 to 7 shots. The patient was again admitted on 03.11.2009 due to MTX toxicity which caused bone marrow suppression and low blood counts. The kidneys got affected badly and dialysis was done on

09.11.2009, however the patient developed renal failure and septicemic shock. On 10.11.2009, she suffered minor cardiac arrest and she was put on ventilator, but her condition did not improve and the patient died on 12.11.2009.

4. Being aggrieved the Complainant N. Shashank Reddy the son of deceased instituted a Complaint before the State Commission seeking compensation on the ground that his mother suffered an untimely death due to the medical negligence of the treating doctors of the Opposite Party No. 3 hospital,who failed to follow the agreed DeAngelis protocol for treatment of PCNSL.

5. By its order/judgment dated 30.01.2013, the State Commission came to the conclusion that a case of medical negligence was established. An amount of Rs. 7 lakh was awarded to the Complainant by way of compensation, together with cost of Rs.10000/-.

6. Being aggrieved the Opposite Parties filed this Appeal.

7. Heard the arguments from both the sides. The appellant Dr. SVSS Prasad was also present during argument.

8. Assailing the decision of the State Commission, learned counsel appearing on behalf of the appellant/ the Opposite Party No. 1 submitted that:

There was no negligence during the diagnosis and treatment of the patient. The PCNSL is a high grade malignancy needs aggressive treatment with chemotherapy. Commonly DeAngelis protocol is one of the best protocols used to treat CNS lymphoma and same was adopted by the Opposite Party No. 1. The complications of chemotherapy were explained to the patient and her attendants. After consent from the Complainant and his father, the treatment was started.

9. The learned counsel for the appellant further submitted that estimation of serum MTX level was not available in the Apollo Hospital and even at many reputed institutions in India. The Leucovorin rescue was started at 24 hours from the time of MTX administration and Leucovorin 15 mg was given every 6 hourly for 72 hours to make serum MTX level below the risk. The patient was given IV fluids for hydration and for alkalinisation sodium bicarbonate, Sodamint tablets were given. Thus, there was no negligence during treatment.

10. The patient was cooperative during the course of the treatment. On 10.10.2009 the blood parameters were normal and the patient was passing good amount of urine. The Pancytopenia (anemia, neutropenia and thrombocytopenia) was known complication of chemotherapy. In the instant case the complications occurred despite the best possible care. There was no negligence or lapse on the part of the opposite parties.

11. On the other hand, learned counsel appearing on behalf of the respondent/complainant reiterated the facts and brought our attention to the findings of the two expert opinions and AIIMS report.

12. The submissions now fall for our consideration.

13. We have perused the evidence on record, the medical literature son treatment of PCNSL and the DeAngelis protocol. We have also perused the opinion from the board of medical experts from AIIMS and *interalia* two separate expert opinions filed by the Complainant from Dr. Narotham R. Thudi and Dr. Hari Kolla the Clinical Oncologists and Hematologists in USA.

14. The Complainant's main grouse that the during treatment of PCNSL the Opposite Party No. 1 had not strictly followed the DeAngelis protocol i.e. the Leucovorin rescue was delayed up to 48 hours and failed monitor HDMTX level, hydration and urine pH (alkalinisation) which led to MTX toxicity and renal failure.

15. Let us understand about DeAngelis protocol.

The De Angelis protocol consists of infusion of HDMTX and Leucovorin rescue. Proper monitoring is essential during De-Angelis and HDMTX protocol. It is summarized as under:

a) pH Level > pH level should be always maintained above 7 as before /during/after chemotherapy (HDMTX) to prevent drug precipitation in renal tubules and drastically decrease the chance of renal damage. IN clinical practice, it is customary to begin the HDMTX infusion only after the urine pH is >7.

b) MTX Level > It is also customary to check plasma MTX levels at 24, 48, and 72 hrs after the start of the HDMTX infusion. By checking MTX levels the toxicity levels of the body can be known thereby altering/modifying the medical dose, etc. If toxicity in the body remains longer then the patient suffers from renal failure, septicemia etc.

c) Serum creatinine: Serum creatinine should be checked daily. A rise in the serum creatinine above the normal levels indicates renal dysfunction and delayed MTX elimination. If levels are above normal then patient's medical dose will be adjusted accordingly to prevent/ minimize life threatening complications.

(from various articles and books)

16. Now let us see whether there was any omission from the Opposite Party No. 1 during treatment with the DeAngelis protocol. The following points are for our consideration:

i) Monitoring of MTX level and dosage of MTX

ii) Delay in Leucovorin rescue

iii) Hyponatremia and Chemotherapy

iv) Hydration and Alkalinisation

17. We have carefully perused the opinion given by the Board of experts from AIIMS dated 02.02.2018 which discussed the above mentioned points.

i) Monitoring of MTX level and dosage of MTX

a) As per the AIIMS report the Monitoring of serum methotrexate level is desirable , but methotrexate can be administered with reasonable safety without serum methotrexate level monitoring, if proper hydration, alkalinisation and urinary pH monitoring is done with timely administration of Leucovorin rescue.

b) As per the AIIMS board's report the MTX dose was appropriate and high dose of MTX was not administered. It opined that:

- As per DeAngelis protocol methotrexate 2500mg/m2, procarbazine 100 mg/m2 for 7 days, Vincristine 1.4 mg/m2 (max 2.8mg)
- Doses administered in first cycle Methotrexate 2700mg, Vincristine 2.8mg, Leucovorin 15 mg and mabthera (Rituximab) 100mg
- Doses administered in 2 nd cycle Methotrexate 4600 mg, procarbazine 200mg OD for 6 days, Vincristine 2.8 mg
- In first cycle reduced dose was administered and in 2 nd cycle dose was increased relative to first cycle. The dose administered in 2 nd cycle is appropriate as her body surface area which is 1.8 (Weight 80kg and height 155 cm as per nursing records).

In the instant case during 2009 in India most of the higher centers have no facility for estimation of blood level of MTX.

ii) Delay in Leucovorin rescue.

a. Leucovorin is sometimes called a "rescue" medicine. It is taken in an effort to "rescue" the normal cells in the body from the side effects of methotrexate. It is often called " **Leucovorin rescue".** Leucovorin rescue should begin as soon as possible within or at 24 hours of methotrexate administration. Leucovorin 10 mg/m ^{2} should be administered IM, IV, or orally every 6 hours until serum methotrexate level is less than 0.1 µM.
b. In the instant case the complainant's allegation that it was initiated after 48 hours of infusion of Methotrexate. On careful perusal of medical record (page 391) we note that the MTX was given from 2 am to 4 am on 29.10.2009 (after completing Mabthera and Zofer infusions which started at 6.15 pm on 28.10.2009). It was after midnight; however the on duty nurse erroneously entered it as 2 am in the column dated 28.10.2009 instead of 29.10.2009. In our view there was no delay for Leucovorin rescue, it was started promptly at 2.00 am on 30.10.09 i.e. exactly 24 hours from the start of MTX (29.10.2009; 2 am). Therefore, the allegation complainant about delay of 48 hrs for Leucovorinrescue is not sustainable.

iii) Hyponatremia and delay in chemotherapy:

a. It pertinent to note that the patient developed hyponatremia (low Sodium level) therefore immediately to start 2 nd cycle of chemotherapy was not advisable. Asper the records the Sodium level was corrected gradually from 19.10.2009 to 26.10.2009 and the patient recovered from hyponatremia without any complications.
b. In the case of hyponatremia fluid restriction is necessary to prevent a recurrence of hyponatremia, consequently at the same time for DeAngelis protocol mandates daily adequate hydration and monitoring the kidney function and electrolytes level.

c. We agree with the opinion of AIIMS that, once Sodium level became 131 mEq/l the 2 nd cycle was started on 27.10.2009. Thus, t he delay for correction of symptomatic hyponatremia was reasonable and it was essential before 2 nd cycle of chemotherapy.

iv) Hydration and Alkalinisation

a. To prevent HDMTX toxicity; in addition to appropriate Leucovorin therapy the patient requires continuing hydration and urinary alkalinisation, and close monitoring of fluid and electrolyte status. Hydration (3 L/day) and urinary alkalinisation with sodium bicarbonate solution should be given concomitantly; sodium bicarbonate dose should be adjusted to maintain urine pH at 7.0 or more.
b. As per AIIMS board report

- Sodamint (Sodium bicarbonate) tablet was given from 28/10/09 and on 29/10/09 Sodium bicarbonate 2 ampoules in 500ml NS was given over 24 hour.
- On 28/10/09 input/output 1000/2000 ml
- On 29/10/09 input/output 800/1400 ml

Once that pH is attained then MTX is administered. Urine pH is maintained till administration of Leucovorin.

Urine pH is monitored after each void. Prior, to discharge renal functions are checked. The board did not find records of pH monitoring and post methotrexate renal function test as indicated.

18. Regarding the Primary CNS lymphoma (PCNSL), its treatment and the De Angles Protocol we have gone through the standard books on Oncology namely "Manual of Clinical Oncology" by Casciato Dennis, "Cancer Principles and Practice of Oncology" by Devita Hellman and Rosenbergs. The PCNSL is a rare malignancy with peculiar clinical and biologic features, aggressive course, and unsatisfactory outcome. It represents a challenge for multidisciplinary clinicians and scientists as therapeutic progress is inhibited by several issues. The clinical and neuro-radiological presentation of primary CNS lymphoma is often non-specific, and histopathological confirmation is necessary.

19. The disease, if left untreated, leads to death within weeks or months. For the decades, radiotherapy was the exclusive treatment for patients with PCNSL, but the chemotherapy has significantly improved the outcome. However, several studies showed that combined chemo-radiotherapy is superior to radiotherapy alone and this is the most commonly used approach. The treatment strategies are often associated with severe neurotoxicity, especially among elderly patients. The CHOP Regimen is a chemotherapy combination that is used to treat non-Hodgkin lymphoma and other types of cancer. It includes the drugs Cyclophosphamide, doxorubicin hydrochloride (Hydroxydaunorubicin), vincristine sulfate (Oncovin), and Prednisone.

20. Chemotherapy plays a vital role in the management of PCNSL. Its efficacy is limited by several factors. Most regimens include drugs with high doses (MTX) able to cross the Blood Brain Barrier (BBB). Conversely, drugs with poor BBB penetration that cannot be administered at high doses because of dose-limiting toxicity (i.e., Anthracyclines, Vinca-alkaloids) are inefficient in PCNSLIf the patient's general condition permits, treatment should consist of a high-dose

chemotherapy based on methotrexate (HD-MTX) combined with rituximab and other cytostatic drugs that penetrate the blood–brain barrier.

21. It would be apt to quote from Jacob Mathew's case, (2005) 6 SCC 1 in which the Hon'ble Supreme Court observed that higher the acuteness in emergency and higher the complication, more are the chances of error of judgment. The court further observed as under:-

> *"25 .....At times, the professional is confronted with making a choice between the devil and the deep sea and he has to choose the lesser evil. The medical professional is often called upon to adopt a procedure which involves higher element of risk, but which he honestly believes as providing greater chances of success for the patient rather than a procedure involving lesser risk but higher chances of failure. Which course is more appropriate to follow, would depend on the facts and circumstances of a given case. The usual practice prevalent nowadays is to obtain the consent of the patient or of the person in-charge of the patient if the patient is not be in a position to give consent before adopting a given procedure. So long as it can be found that the procedure which was in fact adopted was one which was acceptable to medical science as on that date, the medical practitioner cannot be held negligent merely because he chose to follow one procedure and not another and the result was a failure."*

Thus in our considered view before starting 2 nd chemotherapy cycle it was necessary to correct patient's hyponatremia which was done by the Opposite Party No.1. It was a reasonable delay for correction of Sodium level.

22. As the DeAngleis protocol mandates monitoring of MTX level, Serum Creatinine, blood Urea Nitrogen level, urine pH regularly and adequate hydration. We may accept that due to non-availability of instrumentation, the MTX estimation was not possible. We further note that from 28.10.2009 to 30.10.2009 the patient's intake and output for was adequate and for alkalinisation Sodamint tablets orally and Sodium bicarbonate in Normal saline IV was given. Therefore, clinically the Opposite Party No. 1 felt that the urine became alkaline and therefore urinepH was not repeated prior to the 2 nd cycle. The urine pH test is a simple routine test, but the Opposite Party No. 1 failed to test it, but he presumed the urine pH might be alkaline or more than 7; in our view such presumption was not a reasonable standard of care.

23. It is well settled from many legal precedents that the skill of medical practitioner differs from doctor to doctor and may be more than one course of treatment which may be advisable for treating a patient. However, negligence cannot be attributable as along as the doctor if he has performed his duties to the best of his ability and with due care and acceptable to the medical profession. However in the instant case we find though the doctors made correct diagnosis and took decision to adopt DeAngelis protocol for treatment of PCNSL, but it was an act of omission from the Opposite Party No.1 who failed to follow the DeAngelis protocol by not monitoring the patient's urine pH.

24. The doctors are bound to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing. If a practitioner presents himself or herself as a specialist, a higher degree of skill is required of than of one who does not profess to be so qualified by special training and ability.

25. In the instant case the Opposite Party No. 1, based on clinical signs of the patient, made a presumptive approach that urine might be alkaline i.e pH 7 or more. Such customary, usual or routine practice itself proves that the method was not within the standard of care in this case.

26. Based on the entirety of the discussion above, and considering the reasoned appraisal made by the State Commission, as also giving careful thought to the report of experts from AIIMS, we do not find any merit in the instant Appeal. We concur with the view taken by the State Commission.

27. The Appeal is dismissed.

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DR. S.M. KANTIKAR
PRESIDING MEMBER

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DINESH SINGH
MEMBER