NATIONAL CONSUMER DISPUTES REDRESSAL COMMISSION NEW DELHI

CONSUMER CASE NO. 785 OF 2017

1. MOHIT JAIN HOUSE NO.5, 1ST FLOOR, SUKH VIHAR. DELHI-110051Complainant(s) Versus 1. M/S. MAX SUPER SPECIALTY HOSPITAL & 4 ORS. THROUGH ITS CHAIRMAN. MAX SUPER SPECIALITY HOSPITAL, 108 A, INDERPRASTHA EXTENSION, PATPARGANJ. DELHI-110092 2. DR.SANJEEV KUMAR, INTERNAL MEDICINE. THROUGH ITS CHAIRMAN. MAX HOSPITAL SPECIALITY HOSPITAL, 108A, INDERPRASTHA EXTENSION, PATPARGANJ. DELHI-110092 3. DR. RAHUL NAITHANI, HEAD HEMATOLOGY. THROUGH ITS CHAIRMAN. MAX HOSPITAL SPECIALITY HOSPITAL, 108A, INDERPRASTHA EXTENSION, PATPARGANJ. DELHI--110092 4. DE. MANSI SACHDEV, HEMATOLOGY (PEDIATRIC ONCOLOGY). THROUGH ITS CHAIRMAN. MAX HOSPITAL SPECIALITY HOSPITAL, 108A, INDERPRASTHA EXTENSION, PATPARGANJ. DELHI-110092 5. MAJ.(DR.) INDRANIL MUKHOPADHAY, MEDICAL SUPERINTENDENT. THROUGH ITS CHAIRMAN. MAX HOSPITAL SPECIALITY HOSPITAL, 108A, INDERPRASTHA EXTENSION, PATPARGANJ. DELHI-110092Opp.Party(s)

BEFORE:

HON'BLE DR. S.M. KANTIKAR, PRESIDING MEMBER

For the Complainant : For the Opp.Party :

Dated : 23 Mar 2023

ORDER

Appeared at the time of arguments:

For the Complainant

: Mr. Prashant Vaxish, Advocate

Mr. Rishabh Sharma, Advocate

with the Complainant in person

Mr. Pulkit Mehrotra (Assistant)

For the Opp. Parties : Mr. Debasish Moitra, Advocate

Pronounced on: 23rd March, 2023

ORDER

It would not be conducive to the efficiency of the medical profession if no doctor could administer medicine without a halter round his neck.^[1]

It clearly emerges from the exposition of law that a medical practitioner is not to be held liable simply because things went wrong from mischance or misadventure or through an error of judgment in choosing one reasonable course of treatment in preference to another.[2]

The Hon'ble Supreme Court of India

- Bench of Hon'ble Mr. Justice Ajay Rastogi

and Hon'ble Mr. Justice Abhay S. Oka

1. Facts:

1.1 The facts narrated by the Complainant – Mr. Mohit Jain (for short, the 'patient') are that on 06.04.2015, in the morning, he consulted Dr. Sanjeev Kumar (OP-2) at Max Super Specialty Hospital, Patparganj, Delhi (OP-1) (for short, the 'Hospital') for the complaints of fever, fatigue / bony pains, visible blood spots/bruises on both his arms & legs and recently had vomited with blood clot. The OP-2 prescribed few lab investigations viz. CBC, PBS, Urine Analysis, Urine Culture, Dengue Serology and Malaria. Few reports were available in the evening and same were informed to OP-2 on mobile. It was alleged that the OP-2 enquired about Complainant's Insurance cover and upon determining it, he advised the Complainant to get admitted immediately through emergency and he shall visit hospital from 8pm to 8.30 pm. Accordingly, he got admitted in the hospital (OP-1) through emergency, where the provisional diagnosis of Viral Hemorrhagic Fever (VHF) was made. The platelet count was 10000 / cmm, which was critically low and other findings were suggestive of hemolytic anemia. The patient was also examined by the Hematologist - Dr. Rahul Nethani (OP-3) and Dr. Mansi Sachdev (OP-4). The doctors, on 08.04.2015, arrived at the final diagnosis of Immune Thrombocytopenic Purpura (ITP) and reconfirmed hemolytic anemia. It was alleged that though he was admitted in Medicine Dept. and his primary consultant was OP-2, but having diagnosed as blood disorder, he should have immediately transferred to Hematology Dept. The OP-2 kept the patient under medicine with intention to raise the hospital bills. The doctors at OP-1 had allegedly been playing with his life. He was forced to discharge on 13.04.2015, instead of transferring to Hematology. The patient's stool for occult blood was positive for three occasions, but no steps were taken to check the GI bleeding. On 17.04.2015, the nuclear scan to check GI bleed was done, but patient was not examined by Gastroenterologist. The patient was scheduled to undergo for colonoscopy at 11.00 am on 20.04.2015 though his condition was deteriorating. Finally, he was

transferred to Hematology Dept. on 20.04.2015. He suffered tonic seizures and became very critical. He was intubated and kept in ICU. It was alleged that Dr. Amit Batra (Neurologist) was not summoned in time and he came after 60 minutes to examine the patient. The Complainant suffered seizure before NCCT could be started.

1.2 The Complainant further alleged that during 13 critical days (from 8 - 20 April) doctors did not mention blood test reports in the progress sheet. The Peripheral Blood Smear (PBS) screening was negligently done and Schistocytes in PBS was not detected; therefore the diagnosis of life threatening Micro-Angiopathic Hemolytic Anemia (MAHA) was delayed. It was further alleged that during his 29 days of hospitalization, the OP- 3made only 8 scattered visits and he was absent from the critical stages of diagnosis and treatment, but the billing was done for 39 visits. He further alleged that the hospital did not provide treatment summary despite repeated requests, therefore his wife was not able to take second opinion. He was forced to stay in confinement of OPs at their mercy. He further alleged that the OPs fabricated the treatment record. From 20.04.2015, twelve plasma exchange (PEX) sessions were held and the doctors told that ITP was a lifelong disease, which may relapse at any time. He further alleged that before PEX, patient's HIV and Hepatitis-B & C viral markers were not done. He was discharged from the hospital on 04.05.2015 with follow-up advice for a month. He paid bill amount of around Rs. 16 lakh towards the hospitalization. He further alleged that the discharge report was incorrect on facts, vague and misleading. It was sub-standard which lacks key details, does not give a clear and accurate progression of the patient condition and treatment. For a long time he was under follow-up of Neurologist - Dr. Amit Batra at OP-1, who put the Complainant on anti-epileptic drugs for 6 months and medication for anxiety regularly which he was consuming even as on date. He consulted several doctors about his treatment and they have commented adversely on the correctness of final diagnosis of Thrombocytopenic Thrombotic Purpura (TTP) and the delayed treatment. During follow-up OPD visits, he was subjected to humiliation. The Complainant's other allegations are that OPs were indulged in billing malpractices, double billing for doctor's visits, billing for tests which were not done and he did not get proper response from the OPs.

1.3 Thereafter, on 07.06.2015, he approached Chief Minister, Deputy CM and Health Minister of Delhi. He also approached various Govt. authorities like Director of Health Services (DHS) and Delhi Medical Council (DMC). He further alleged that the OPs did not co-operate with the Govt. authorities and not filed medical records there. The DGHS, in its report dated 07.11.2016, mentioned that the hospital and doctors were found indulged in unethical practices. The copy of report was sent to DMC on 20.12.2016, but the DMC passed nonspeaking Order on medical negligence. The Complainant challenged the DMC Order by filing Appeal before the MCI. After huge delay, the hospital provided voluminous medical record about 657 pages to him on 25.02.2017. The records were alleged to be different from those placed before the Govt. authorities. Therefore, fabrication, manipulation, interpolation of the medical record by OPs cannot be ruled out. The OPs failed to make differential diagnosis of TTP. There was no family history of TTP, but doctors told about the risk of inheritance to their children, therefore he and his wife (couple) suffered severe mental anguish and trauma. The Complainant raised the allegations of administrative issues, functioning of hospital, billing and malpractices. Being aggrieved, the Complainant filed the instant Complaint before this Commission, seeking overall compensation to the tune of Rs. 20,33,44,867/-.

2. <u>Defense:</u>

2.1 The hospital filed the reply through Medical Suptd. (OP-5) and denied any negligence during diagnosis and treatment of the patient. It was submitted that OP-1 is a super specialty hospital and the doctors are qualified and experienced for more than a decade in their specialty of medicine and Hematology. The Complainant filed this complaint, which is devoid of the facts and it is based on assumptions and beliefs.

2.2 On 06.04.2015, the patient was admitted in night through Emergency under OP-2 in medicine dept. It was provisionally diagnosed as a case of Viral Hemorrhagic Fever (VHF). The laboratory investigations showed low Platelet count 10000/cmm and Hb was 12.3g%. The PBS did not show evidence of Schistocytes and hemolysis. The blood parameters were not deteriorated so fast as alleged by the Complainant. The OP-2 was a Senior Consultant in Department of Internal Medicine; he was competent to treat such cases. A reference was made to the hematologist Dr. Rahul Nathani (OP 3) who reviewed the case on 07.04.2015. The patient's Platelet count

was 30,000/cmm and on 08.04.2015 Bone Marrow (BM) Biopsy was done. The differential diagnosis of Immune Thrombocytopenic Purpura (ITP) was made as ITP is a diagnosis by exclusion. The patient was treated on the line of UTI with secondary ITP. The differential diagnosis of VHF was also there. Hence steroids were not given. Therefore, in view of UTI with secondary ITP, it was the conscious decision of OP-2 to keep the patient in medicine dept. At that time there was no special need to transfer the patient to Hematologist. In the OP-1 hospital, the OP-3 was working as Consultant in Hematology & Bone Marrow Transplant with his team consists of Dr. Mansi Sachdev (OP 4) and Dr. Manoj who works on all days. All the in-patient are billed under the name of unit head (primary consultant), not for a single doctor. Therefore, the bill was shown under OP-3 as Consultant, though the OP-4 saw the patient.

2.3 On 09.04.2015 the patient suffered an episode of passing blood (occult) in stool; however it was denied that no Gastroenterologist (GI) saw the patient till 18.04.2015. The duty doctor has sent a referral request to GI dept. and on 10.04.2015 the patient was examined by GI team and ruled out frank bleeding. The team recommended Endoscopy in case of significant drop in Hb% or if there any frank GI Bleed.

2.4 On 17.04.2015, CBC picture was high TLC and the PBS showed myelocytes and metamyelocytes. Thus PBS was suggestive of leucoerythroblastic blood picture. The OP-3 suspected GI malignancy as all other common causes were ruled out by the investigation like ANA, CECT Chest & abdomen, Coombs test. The JAK2 test was ordered because of leucoerythroblastic blood picture. Patient's blood samples were sent regularly in the morning to OP-1 lab for various tests. For Fibrinogen level - one of the special test, the sample was sent to laboratory at Max Hospital, Saket, the sample receiving was acknowledged by that lab at 12:22pm, it was shown as time of collection in the report.

2.5 On 20.04.2015 at around 9.30 AM, the patient developed neurological symptoms (irrelevant talking). The duty doctor and OP4 have seen the patient and noted the disorientation and hematuria. It was suspected as intracranial hemorrhage in view of low platelets with other bleeding manifestations like hematuria and GI bleeding. Immediate NCCT Head was advised and call was sent to Neurologist Dr. Amit Batra, who attended the patient immediately and arranged for NCCT. The patient, while shifting to the CT room, had an episode of seizure in triage.

2.6 The OPs denied that, at any point of time there was tampering with the records. On 20.04.2015, CBC was reported in morning and the Pathologist viewed the stained PBS slide at around 12.15 pm and noted presence of Schistocytes. The hematologist- OP-4 went to the lab and reviewed PBS and discussed the findings with OP-3. To confirm the RBC morphology, fresh blood sample was called again. There was no provision or category in billing for finger prick sample.

2.7 The patient was initially given IVIG 36g and transfusion of RBC and platelets. The OPs further submitted that the diagnosis of TTP was made on 20.04.2015. The duration of treatment for such patient depends upon the condition of the patient. Initially 5-6 sessions of PEX were planned but since the platelet count was gradually increasing, the treatment plan was revised and 12 PEX sessions were carried out as lifesaving measure. The patient was treated with standard protocol. The patient was discharged in good condition on 04.05.2015. The patient himself acknowledged that he did not suffer repeat episodes.

2.8 It was further submitted that the 'ADAMTS 13 Test' is diagnostic test for TTP. It was not available in India and expensive, costs around Rs 95000/- which needs about 45 days for reporting. However, its result does not change the line of treatment. The OPs discussed about the decision of not doing the test on financial ground with Complainant's wife, whom she duly agreed; it was recorded in the post discharge audio-visual recording.

2.9 The OPs further submitted that the Delhi Medical Council (DMC) observed that diagnosis seems to have been arrived in a reasonable period of time and managed the patient. DMC has already held that, no case of medical negligence was made out.

2.10 The parties on both the sides have filed their respective evidence by the way of affidavits. The Complainant in his support filed email communication and replies / opinions from Dr. H. P. Pati, Dr. Brig Ajay Sharma, Dr. Upender Srinivas.

3. <u>Arguments:</u>

3.1 I have heard the arguments at length. The Complainant was present in person; he was allowed to argue the matter with his Counsel. The Complainant filed voluminous written arguments, some medical literatures and legal citations. The learned Counsel for Complainant brought my attention to the email replies of the experts and the replies received from health authorities on his complaints.

3.2 The learned Counsel for the OPs argued the matter and reiterated their evidence. He further submitted that the DMC and MCI have already held no negligence on the part of hospital or the treating doctors. He relied upon the standard text books and the medical journals on the subject. Therefore, prayed for dismissal of the Complaint.

4. **Observations and Reasons:**

4.1 After the discharge from OP-1, the Complainant wrote emails to three experts in Hematology and sought clarification/opinion on his treatment. The sum and substance of those replies are as below:

4.1.1 **Dr. H.P. Pati,** Professor, Department of Hematology, AIIMS New Delhi has pointed out that PBS has to be done in low platelet counts. Indeed PBS was performed on hospital admission itself and it was found to be normal. On 18.04.2015 the PBS seen by OP 3 noted leucoerythroblastic blood picture. It was noted in the Patient's file. On 18.04.2015 the patient did not have TTP because of low Fibrinogen and high D-Dimer values. It is pertinent to note that Complainant has deliberately not submitted the lab findings of 20.04.2015 to Dr. H. P. Pati wherein the PS showed. Schistocytes and the PT, aPTT and Fibrinogen levels were normal and the Patient was diagnosed as TTP. The Patient has deliberately suppressed about high TLC and Myelocytes and Metamyelocytes in his PS and also evidence of Reticulin and Fibrosis in his bone marrow. Therefore to rule out the chronic myeloproliferative disorder JAK-2 test was performed.

4.1.2. Another expert **Dr. Brig. Ajay Sharma**, Professor and Head, Department of Hematology & Centre for Stem Cell Transplantation, Army Research and Referral Hospital, Delhi Cantonment has pointed out - that the Patient initially did not have TTP and it was brought and it was brought into the picture only at a later stage when the Patient had a seizure. Admittedly the patient suffered seizures on 20.4.2015

4.1.3 **Dr. Upendra Srinivas**, DM (Hematopathology) AIIMS has also ruled out TTP at the initial phase as discussed in the expert opinion and reply of Dr. H.P. Pati. With respect to JAK2 test, his opinion is similar to opinion of Dr. Brig. Ajay Sharma.

4.1.4 On careful perusal of the emails, it is pertinent to note that the Complainant made specific queries; he has not sent entire treatment record to the experts. In my view, those email replies (*supra*) were based on the information which ever provided by the Complainant. The possibility of half or incomplete information was given to the experts and/or suppression of material facts cannot be ruled out. The experts have, with good intention, replied to the emails of the Complainant. In my view, such email communications are not construed as expert opinions. The experts were not called by the Complainant to file affidavits or to adduce evidence. Thus, the email communications are not sufficient to hold the treating doctors for negligence or deficiency in service.

4.1.5 I have perused a printed (typed) prescription of Dr. Rahul Bhargava, the Hematologist from Artemis Health Institute, Gurgaon dated 02.06.2015. It is a printed prescription (assessment sheet), wherein, a hand written note was seen as an insertion. Its text is 'and delayed diagnosis and management of TTP from 6/4/15 - 20/4/15 & --*illegible* – Tonic clonic seizure – 9650373043". Such insertion creates more doubt, why Dr. Rahul Bhargava made such insertion in the specific area of prescription. It appears to be afterthought interpolation under emotional pressure of the patient. The said assessment sheet is not considered to be evidence.

4.1.6 The main allegation of Complainant that failure to detect presence of Schistocytes in PBS, which resulted in delayed diagnosis of MAHA and its treatment. The contention of the Complainant that OP-4

recorded the presence of 25 nRBC on PBS but it was totally ignored presence of Schistocytes. It was gross negligence and case of *Res Ipsa Loquitur* as not following the Standard operating procedures (SOP).

4.1.7 It is evident from the medical record that on 20.04.2015 numerous Schistocytes were seen in PBS, however the presumption of Complainant that such numerous Schistocytes would not have developed suddenly on 20.04.2015. In my view the OP-3 & 4 have ordered PBS along with CBC, from 21 to 25 April and same was billed. In CBC report for each of those dates, presence of Schistocytes was reported. There was no evidence that Schistocytes were present in the PBS before 20.04.2015, it was an imagination or presumption of the Complainant that the OPs-2, 3 & 4 failed to detect presence of Schistocytes on any date prior to 20.04.2015.

4.1.8 Another allegation of the Complainant is that though it was diagnosed as blood problem (hematology), the OP-2 should have immediately transferred him from Medicine to Hematology. It was not done in spite of his several verbal and written requests even marked as 'Urgent'. In my view, OP-2 was specialist in internal medicine, having experience and Hematology is an integral part of medicine, thus he can treat the patient of ITP. Thus, OP-2 was neither prohibited to treat nor it was mandatory for him to shift the instant patient to hematology. Moreover, if necessary, there was always inter departmental consultation or referral was possible in the OP-1 hospital. Thus, the OP-2 has adopted a reasonable approach for the patient's care. This view dovetails from the case **Dr. Laxman Balkrishna Joshi v Dr. Trimbak Bapu Godbole**, it was held by Hon'ble

Supreme Court that if a doctor adopted a practice that is considered "proper" by a reasonable body of medical professionals who are skilled in that particular field, he or she will not be held negligent only because something went wrong. Doctors must exercise an ordinary degree of skill.

4.1.9 Let us examine was there any delay in diagnosis of TTP? From the literature and text books, it is described that the course of TTP is rapid and fatal. Therefore proper diagnosis is important, because 90% mortality seen in untreated TTP patients, which can be reduced with prompt plasma exchange (PEX). About 50% deaths occur within 24 hrs of presentation[4]. Early deaths (50%) still occur within 24 hrs of presentation. In the instant case, on 18.04.2015 the patient's clinical presentation and the blood reports were not suggestive of TTP. The OP 3 seen the PBS and documented leucoerythroblastic blood picture. No Schistocytes were seen. Thereafter, TTP was diagnosed on 20.04.2015 after the PBS findings of presence of Schistocytes, it was reconfirmed by the hematologist on calling fresh blood sample again. Then, the treatment for TTP was started with PEX. Thus, in my view there was neither delay nor failure to in diagnosis of TTP.

4.1.10 It is pertinent to note that, the Complainant filed a complaints before various Government authorities DHS & DMC. He challenged the Order of DMC before Board of Governors of MCI by filing an appeal which was also dismissed. The Observations made by the Ethics Committee of the Board of Governors dated 25.09.2019 are more crucial in the instant case. The relevant paragraphs are reproduced as below:

- 7. The Ethics Sub Committee noted the appeal of the appellant that from 05.05.2015 to 06.06.2015, the period was eventful with follow ups, negligence, delayed diagnosis, medical malpractices. On 07.06.2015, after getting no positive response from the respondents the appellant approached tie Chief Minister, Deputy Chief Minister and Health Minister Of Delhi: Directorate General of Health Services (DGHS) took the cognizance of the complaint and sought explanation from the respondent hospital and its doctors. After receiving a reply, the DGHS directed the appellant to file a rejoinder. On 11.12.2015, the appellant fled a rejoinder with annexures (1 set for DHS, 6 sets for DMC with a request to take up the complaint and 1 set to be sent to the respondent, MAX Hospital).
- 8. The Ethics Sub Committee noted that on 15 02.2016, the Delhi Medical Council directed the appellant to appear before them and asked to file a review of the complaint if not satisfied. On 06.04.2016 the appellant received a letter from Delhi Medical Council (DMC) informing that the representation dated 15.02.2016 of Sh. Mohit Jain does not constitute a complaint under Rule 32 of DMC Rules, 2003 and hence cannot be entertained. Thereafter, several other complaints and representations were made to the Delhi Medical Council by the appellant. The appellant slated that DMC did not pay much heed to their complaint and were not clear of their own rules.

12. Dr. Rahul Naithani appeared before the Ethics Sub Committee of the Medical Council of India and stated that he was the treating doctor of Sh. Mohit Jain with a low platelet count. He further stated that the patient was primarily the patient of Dr. Sanjeev Kumar as the initial working diagnosis was Viral Hemorrhagic Fever (VHF) which was revised to Idiopathic Thrombocytopenic Purpum (ITP) on 14.04.2015 and was subsequently transferred under the care of Dr. Rahul Naithani. The patient was duly attended by the Hematologist. The respondent denied all the allegations pointed out by the appellant.

13. It was further noted by the Ethics Sub Committee that Dr. Rahul Naithani stated that the patient used to message and call him stating that he has not cured him and was dying because of his treatment. He alleged that it was a mental harassment for him as frequently on calls, e-mails and messages he used to harass him pointing out negligence. A complaint of this activity was also made to the Medical Superintendent of MAX Hospital, Patparganj New Delhi.

4.1.11 The Executive Committee observed the diagnosis and treatment at OP was reasonable. It also noted the conduct of the patient (Complainant), who used to harass Dr. Rahul Nathani due to frequent calls, e-mails and messages pointing out negligence. The Executive Committee held that prima facie no case of medical negligence was made out against the OPs. The doctors at OP-1 arrived at the diagnosis in a reasonable period and treated the patient. The Executive Committee observed that the TTP is a rare disorder of 0.000006%[5]. The most common precipitating factor with ITP is viral fever which at times can result in prolonged thrombocytopenia. Such cases show spontaneous recovery as initially is suspicious of ITP.

4.1.12 It is pertinent to note that the Directorate of Heath also constituted a committee of three officers with the approval of Competent Authority to look-into the grievances of the complainant with specific concern to administrative and hospital related matters (other than medical negligence). The committee examined the case with specific reference to administrative issues related with the functioning of hospital and considered following points:

- 1. Double Billing and extra charges.
- 2. Visits of consultants.
- 3. Delay in providing case summary for second opinion.
- 4. Management issues like smoking in hospital.
 - 5. Tests like HIV/Viral Markers not done but shown to have done on various occasions.
 - 6. Discharge summary prepared despite deteriorating health parameters.

The Committee based on factual position in the instant case, opined that there was double billing and the patient paid cost for number of times for the services not provided but billed. There was lack of proper, adequate and timely co-operation by hospital authority in providing case summary to patient / attendant for second opinion, there was lack of transparency in Attendance records. Whereas, in the instant case, it is reflected that there is inadequacy of the hospital management in keeping proper checks and balances. There was absence of inherent preventive measures in the system on the above-mentioned accounts which was unbecoming of being a responsive hospital administration and management. The Committee finally, under the signature of DGHS, directed in the notice to the hospital to take corrective actions within one calendar month from the date of receipt of the notice, failing which, action may be initiated against the Hospital as per Delhi Nursing Home Registration Act and Rules.

5. <u>Reference from some Medical Literature on TTP:</u>

5.1 Thrombotic thrombocytopenic purpura (TTP) is a thrombotic microangiopathy relatively uncommon disorder characterized by the formation of platelet-rich thrombi in the microvasculature. This formation results in consumptive thrombocytopenia, organ ischemia, and increased shear stress with mechanical destruction of RBS, resulting in Schistocytes. These platelet microthrombi are responsible for a mechanical hemolytic anemia, a thrombocytopenia and a multi-visceral ischemia. Although TTP often involves microangiopathic haemolytic anaemia, thrombocytopenia, fever, neurological symptoms, and renal impairment, many patients do not exhibit the full pentad of findings. Furthermore, this same combination of abnormalities can be present in other disorders such as classic haemolytic uremic syndrome (HUS), atypical HUS (aHUS), or disseminated intravascular coagulation (DIC). With high clinical suspicion of TTP is a rare but life-threatening disease in the absence of appropriate treatment (Plasma Therapy).Therefore, life-saving therapy must be started immediately.

5.2 Clinical prediction scores using readily available laboratory information (creatinine, platelet count, ddimer, reticulocyte percentage, indirect bilirubin, etc.) have proven useful for acute decision-making. The TTP has been linked to a severe deficiency in ADAMTS13 (a disintegrin and metalloprotease with thrombospondin type 1 motif, member 13) activity. The ADAMTS13 activity level of less than 10% supports the diagnosis of TTP in appropriate clinical contexts, <u>but many centers do not offer testing in-house and must send out the test to a reference laboratory with a turnaround time of several days.</u> Patients with acquired TTP receive plasma exchange (PEX) therapy. This kind of therapy removes proteins in the blood that damage the ADAMTS13 enzyme, then replaces the enzymes. The initial therapeutic regimen for acquired TTP involves immunosuppression and provides supplemental ADAMTS13. Although confirming severely decreased ADAMTS13 activity helps establish the TTP diagnosis, <u>therapy must start even before test results are available</u>.

5.3 Plasma exchange (PEX) is the most important for management of TTP and should be initiated without delay in all patients with suspected TTP. Delay in initiation of PEX is a major factor in adverse outcomes. PEX is associated with a reduced death rate and is superior to plasma infusion alone, which is the result of the additive effects of both removal of autoantibody by the exchange process (in the case of acquired TTP) as well

as supplementing ADAMTS13 activity in the exchanged plasma^[6]. Steroids are used initially to achieve relatively rapid immunosuppression.

5.4 DIAGNOSTIC AND PROGNOSTIC VALUE OF ADAMTS13 MEASUREMENTS[7]

In the era before effective treatment, TTP was defined by apentad of clinical features, namely thrombocytopenia, microangiopathic hemolytic anemia, neurologic abnormalities, renal failure, and fever.[8] ADAMTS13 measurements may not assist initial diagnosis and management decisions but are important for prognosis. Although most patients with severe ADAMTS13 deficiency have no renal insufficiency, causing initial reports to suggest that ADAMTS13 activity measurements may distinguish TTP from HUS, some patients with severe ADAMTS13 deficiency have acute renal failure. ADAMTS13 activity 5% appears to be specific for TTP but does not identify all patients who may relapse; ADAMTS13 activity 10% essentially identifies all patients who are at risk for relapse but is not specific; patients with sepsis1, and liver cirrhosis may also have ADAMTS13 activity 10%.

6. Law on Medical Negligence:

6.1 Medical negligence is discussed in Catena of judgments from the Hon'ble Supreme Court and worldwide. In the cases of medical negligence, to bring successful claim the victim or victim's family bringing the action must prove the "four D's" against the erring doctor/hospital. The 4 D's of medical negligence stand for 'Duty', 'Dereliction/Deviation', 'Direct (proximate) Cause' and 'Damages'.

6.2 What does not constitute medical negligence?[9]

From the decisions of Hon'ble Supreme Court in the cases *viz*. Jacob Mathew's[10], Malay Kumar Ganguly[11] and Kusum Sharma[12] cases (*supra*). Thus it was not negligence in case of any deviation from normal practice or any accident, any error of judgement through any professional or any patient does not

favourably responded to the treatment. The doctor would not be held liable for negligence if his diagnosis is different from other fellow doctor or he treats patient from other method and taking any higher element of risk but could not save patient.

7. <u>Conclusion:</u>

7.1 On careful analysis of the facts and chronology of events in the instant case, admittedly the OP-2 to 4 are the subject specialists having experience. During the hospitalization, based on symptoms and signs, the patient was investigated and treated the patient as per the standard of reasonable practice. On 20.04.2015, at the 1st time the diagnosis of TTP was made from the PBS and treatment with PEX was started. In my view, it was mere assumption of the Complainant that before 20.04.2015, the OP-3 failed to detect Schistocytes in PBS. The patient showed recovery after PEX and discharged on 13.04.2015. As discussed above there was no delay in diagnosis and treatment of TTP. The ADAMTS13 test was not available in India, and even as on today very few centers in India have such facility. The patient was informed about high tests expenses and longtime for reporting. It is an admitted fact that, prior to starting PEX, the patient's HIV and Hepatitis-B & C viral markers were not done. It was an act of omission from OPs. However, because of such omission, the patient did not suffer any injury or loss; but in fact, the PEX Therapy was beneficial. Therefore, OPs are not liable this act of omission.

7.2 I would like to rely upon the case - Achutrao Haribhau Khodwa and others versus State of Maharashtra and others[13], wherein the Hon'ble Supreme Court held that:

"The skill of medical practitioners differs from doctor to doctor. The very 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 the Court finds that he has attended on the patient with due care skill and diligence and <u>if the patient still does not survive or suffers a permanent ailment</u>, it would be difficult to hold the doctor to be guilty of negligence."

7.2.1 In the recent judgment of the Hon'ble Supreme Court in the case of **Chanda Rani Akhouri vs M.S.Methusethupathi Mithupathi**^[14], it was held that:

27. It clearly emerges from the exposition of law that a <u>medical practitioner is not to be held liable</u> <u>simply because things went wrong from mischance or misadventure or through an error of judgment in choosing one reasonable course of treatment in preference to another. In the practice of medicine, there could be varying approaches of treatment. There could be a genuine difference of opinion. However, while adopting a course of treatment, the duty cast upon the medical practitioner is that he must ensure that the medical protocol being followed by him is to the best of his skill and with competence at his command. At the given time, medical practitioner would be liable only where his conduct fell below that of the standards of a reasonably competent practitioner in his field.</u>

7.3 In the instant case, I find, the standard medical protocol being followed by the OPs-2 to 4 to the best of their skill and with competence at their command. Thus, it is clear that out of '4 **Ds**' the Complainant has proved only the 'Duty' of hospital and doctors, but failed to prove the other ingredients of medical negligence i.e. Dereliction/*breach in duty of care* and the Direct/proximate cause (*causa causens*).

7.4 Adverting to the administrative deficiencies, the Complainant approached DHS and the Committee of three members has noted some administrative defects like double billing, doctors' visits etc. I agree with the view taken by the DHS and the directions issued to OP-1 hospital. In my view, the complainant deserves refund

of excess amount. Therefore, the hospital is directed to be careful and meticulously look for systemic improvement in their functioning.

7.5 In the instant case, the principle of '*res ipsa loquitur*' would not be applicable, on considering the medical record. The Complainant has made several allegations on the presumptions. The Complaint runs in 48 pages, whereas the brief Written Submissions runs in 37 pages with 39 issues. In my view, mere averments/allegations cannot be taken as a gospel truth. The Complainant has not produced cogent evidence to prove his case. This view dovetails from the decision of the Hon'ble Supreme Court in **C.P. Sreekumar (Dr.), MS (Ortho)** vs. **S. Ramanujam**, wherein it was held that the Commission ought not to presume that the allegations in the complaint are inviolable truth even though they remained unsupported by any evidence. It was held as under:

"37. We find from a reading of the order of the Commission that it proceeded on the basis that whatever had been alleged in the complaint by the respondent was in fact the inviolable truth even though it remained unsupported by any evidence. As already observed in Jacob Mathew case [(2005) 6 SCC 1 : 2005 SCC (Cri) 1369] the onus to prove medical negligence lies largely on the claimant and that this onus can be discharged by leading cogent evidence. A mere averment in a complaint which is denied by the other side can, by no stretch of imagination, be said to be evidence by which the case of the complainant can be said to be proved. It is the obligation of the complainant to provide the facta probanda as well as the facta probantia."

7.6 I endorse the observations and the view taken by the Board of Governors of MCI, which held no negligence of the OPs.

7.7 The Consumer Protection Act should not be a "halter round the neck" of the doctors to make them fearful and apprehensive of taking professional decisions at crucial moments to explore possibility of reviving patients hanging between life and death. Reliance is placed on Kusum Sharma & Ors. v. Batra Hospital & Medical Research Centre & Ors. [16], wherein it was held:

"a medical practitioner would be liable only where his conduct fell below that of the standards of a reasonably competent practitioner in his field. It would not be conducive to the efficiency of the medical profession if no doctor could administer medicine without a halter round his neck. It was further held that it was our bounden duty and obligation of the civil society to ensure that the medical professionals are not unnecessarily harassed or humiliated so that they can perform their professional duties without fear and apprehension."

7.8 In conclusion, based on the findings of MCI, DHS and various medical literatures on TTP and respectfully following the precedents of Hon'ble Apex court, in my view, medical negligence is not conclusively attributable to the hospital (OP-1) and the doctors (OP-2-4).

7.9 However, the findings of DGHS on the administrative lapses of the hospital can't be ignored. The hospital is liable to that limited extent of administrative lapses. The hospital is strictly cautioned and directed to take necessary steps for systemic improvement. The Complainant has not produced detailed calculation of alleged excessive changes, therefore in the ends of justice, lump sum amount of Rs. 1,00,000/- (One lakh) will be just and reasonable compensation in the instant case. Accordingly, the Hospital (OP-1) is directed to pay Rs.1,00,000/- to the Complainant within 4 weeks from today, failing which the amount shall carry 9% interest per annum till its realisation.

With this direction, the Consumer Complaint is dismissed.

The parties shall bear their own costs.

The Registry is directed to send free copies of this Order to the Complainant and the Opposite Parties within one week from today.

- [1] (2010) 3 SCC 480
- [<u>2</u>] (2021) 10 SCC 291
- [<u>3</u>] 1996) 1 SCR 206
- 4 British Journal of Haematology, 2012,15 323-335
- [5] Brit J of. Hematology 2012
- [6] J Blood Med. 2014; 5: 15–23.
- [7] Kidney International (2009) 75 (Suppl 112), S52–S54
- [8] J Blood Med. 2014; 5: 15–23.
- [9] Int J Recent Sci Res. 11(11) pp.40080-40082
- [<u>10</u>] (2005) 6 SSC 1
- [11] (2009) 3 SCC 663
- [<u>12</u>] (2010) 3 SCC 480
- [13] (1996) 2 SCC 634
- [14] (2021) 10 SCC 291
- [<u>15</u>] (2009) 7 SCC 130
- [16] (2010) 3 SCC 480

DR. S.M. KANTIKAR PRESIDING MEMBER