Consumer Disputes Redressal Forum, Kottayam
Kottayam

Complaint Case No. CC/43/2019
(Date of Filing : 28 Mar 2019)

1. Ansamma Varghese
Lanjirathumootil House Amara P O Madappally Changanacherry
Kottayam
Kerala ....Complainant(s)

Versus

1. Karithas Hospital
The director Karithas hospital Thellakam P O Kottayam
Kottayam
Kerala
2. Dr.Jojo V Joseph
Carithas Cancer Institute, Thellakam P O Kottayam
Kottayam
Kerala ....Opp.Party(s)

BEFORE:

HON'BLE MR. V.S. Manulal PRESIDENT
HON'BLE MRS. Bindhu R MEMBER
HON'BLE MR. K.M.Anto MEMBER

PRESENT:

Dated : 24 Nov 2023

Final Order / Judgement

IN THE CONSUMER DISPUTES REDRESSAL COMMISSION, KOTTAYAM

Dated this the 24th day of November, 2023

Present: Sri.Manulal.V.S, President

Smt.Bindhu.R, Member

Sri.K.M.Anto, Member

CC No.43/2019 (Filed on 28/03/2019)

Complainant : Ansamma Varghese,

Kanjirathummoottil House,

Amara P.O, Amaramuri,

Madappally, Changanacherry,

Kottayam - 686 501.

(By Adv: K. Karjet)

Vs.

Opposite parties : (1) Caritas Hospital,

Thellakam P.O,

Kottayam – 686 630,

Represented by its

Director.

(By Adv: Preetha

John.K)

(2) Dr.Jojo.V. Joseph,

Caritas Cancer Institute,

Thellakam P.O,

Kottayam – 686 630.

(By Adv: M.C. Suresh)

O R D E R

Sri.Manulal.V.S, President

The complaint is filed under Section 12 of the Consumer Protection Act 1986.

The complainant was admitted in the first opposite party hospital on 30/08/2017 for the treatment for breast cancer. After the investigations and examinations of the complainant, mastectomy was done by the second opposite party doctor on 1/09/2017 and was discharged on 9/09/2017. After the surgery a drainage tube was attached to the breast for the collection of seroma puff and other fluid materials which oozed out from the breast where the surgery was conducted. On 8/09/2017 the drainage tube attached to the breast was detached by the second opposite party prior to the stoppage of seroma collection without due care and caution. As a result of the earlier detachment of the drainage tube before the stoppage of the drain collection the seroma and other fluid waste materials accumulated in the surgery part on the breast of the complainant and it got infected and puss was formed due to infection and further to that the complainant was again admitted at first opposite party hospital on 23/09/2017 with vomiting, fever and severe pain on breast. She had to be admitted there for 14 days and was discharged on 5/10/2017. Due to the infection high doses of antibiotics were given to the complainant to control the infection.

It is submitted in the complaint that chemo port inserted to the complainant and only at the first time of therapy the black flush came out and the subsequent 5 times of the therapy the black flush did not came out. On 3/04/2018 the complainant went to the opposite party hospital for chemo port flushing and consulted the second opposite party for the same. On examination of the chemo port, it was found that the chemo port was blocked and no front and back flush could be done due to the blockage. While removing the embolished chemo port by the second opposite party the tip of the chemo port got broken and unable to remove the broken tip of the chemo port from the chest of the complainant. Then the complainant was again admitted at cardiology ICU and removed the broken tip of the chemo port through angiography which was conducted by a Cardiologist. After angiography the wound was not properly stitched by the Cardiologist as a result the sutures were broken and the wound got infected and the complainant was discharged from the hospital on 4/04/2018 with an advice to take antibiotics to cure the wound.

It is averred in the complaint that this was happened due to the second opposite party cut the drainage tube and that he inserted chemo port in careless and negligent manner so as to endanger the life of the complainant and thereby put her to physical pain, mental agony and sufferings. Due to the negligent act of the opposite parties the complainant had to spent Rs.1,35,744/- for her treatment expenses. The complainant issued a notice to the first opposite party on 19/09/2018 demanding refund of the treatment expenses of Rs.1,35,744/- along with a compensation of Rs.5 lakhs. In reply to the said notice the first opposite party issued a notice dated 5/01/2018 stating that a patient will be lucky if she undergoes all these treatments without any complications.

It is alleged in the complaint that the complainant had suffered much physical discomfort, mental agony and heavy loss due to the negligent act of the opposite parties in treating the complainant and that amounts to deficiency in service on the part of the opposite parties. So this complaint is filed by the complainant for an order to direct the opposite parties to refund Rs.1,35,744/- which is the amount spent by her for the treatment along with the compensation of Rs.5,00,000/-.

Upon notice from this Commission the opposite parties appeared before the Commission and filed separate versions.

First opposite party filed the version contending as follows :

There was no negligence, carelessness or deficiency in service on the part of the first opposite party or other doctors or staff attached to the first opposite party hospital. The patient was examined and treated by the second opposite party along with other specialized doctors of the cancer institute of the opposite party as per universally accepted standard medical protocol bestowing all care, caution and attention.

The complainant who is aged 57 years approached first opposite party hospital on 1/08/2017 and consulted the second opposite party who is an Oncology Surgeon with complaint of right breast lump. The fine needle aspiration done elsewhere was suggestive of carcinoma breast to the complainant. So further investigations and other clinical examinations were advised by the second opposite party.

The complainant was on treatment for hypertension and dyslipidemia and had appendicectomy done elsewhere. The CT scan report of the chest showed multiple old fractures involving right clavicle and few posterior right ribs at patchy late atelectasis right lower lob and lingula as she

had a history of RTA about 20 years by necessitating chest tube insertion. As further clinical as well as lab investigation reports confirmed right rust carcinoma requiring all three modalities of treatments such as surgery, chemotherapy and radiation and these facts were explained to the complainant.

Though the complainant was admitted in the first opposite party hospital for right modified radical mastectomy on 7/08/2017 as the patient had chronic obstructive pulmonary disease on pre-operative evaluation the surgery was postponed and she was treated conservatively in consultation with Pulmonologist attached to the first opposite party hospital. During her stay in the hospital trucut biopsy of the breast lump was done on 16/08/2017 and the patient was discharged on 22/08/2017. Thereafter the complainant was admitted in the hospital for surgery on 30/08/2017 and the surgery was done by second opposite party on 1/09/2017 under all aseptic precaution with utmost care and caution and she was discharged on 9/09/2017 without any complaints. The biopsy report revealed that it was invasive carcinoma breast, Grade III, Pathological stage pT2 N1a M0- Comprehensive stage-IIB. The tumor was ER negative, PR negative, Her2 neu Negative and K67 was 40 %. During review the complainant consulted Dr.Unni.S Pillai for chemotherapy. The complainant had infection seroma a known complication of surgery and she got admitted in the hospital on 23/09/2017 and antibiotic treatments were started as per standard protocol and got discharged on 5/10/2017. When she was reported with infection immediate culture was done and antibiotics were started as per culture report and infection was settled completely. During her stay in the hospital chemo port session was also done on 29/09/2017 and she was found normal.

The complainant had reviews with the second opposite party as well as with Dr.Unni.S. Pillai in outpatient department. On 12/10/2017 the first course of chemotherapy was started as outpatient basis and she underwent six courses of chemotherapy successfully along with one unit packed red cell transfusion at 4th chemo as her haemoglobin level became very low then. Thereafter the complainant underwent twenty five fractions of radiation treatments successfully from 20/02/2018 to 27/03/2018. She was advised to have periodical reviews. During chemo port removal since the tube was found broken, she was sent to Dr.Deepak Davidson, Interventional Cardiologist for its removal. After getting consent from patients' husband its removal was done by femoral approach the best and safest method well accepted internationally by the said doctor and the patient was discharged on the very next day with an advice to have review after two weeks. The tube detachment and tube breakage are rare but not complication which cannot be termed as deficiency in service of treating doctors.

As the complainant complained of pain of right shoulder on review consultation with Orthopaedic Surgeon Dr.Anand was given. It is common that after removal of breast due to cancer in the absence of regular shoulder exercise patients may develop periarthritis or other shoulder problems. Though she advised for an MRI right shoulder to assess the cuff the patient has not visited first opposite party thereafter. The reason for infection is not the accumulation of waste blood as alleged in the complaint. The complainant got infection after two weeks of discharge from the first opposite party hospital. The post surgical infection can be caused due to various reasons beyond the control of treating doctors and when she reported with infection serum culture was done immediately and antibiotic were started as per culture report and infection was settled completely. The chemotherapy second stage of treatment was started when she was fully recovered from the infection and she was successfully completed 6 chemotherapies as advised and thereafter third stage of 25 fractions of radiation treatments as outpatient basis without many difficulties. It is submitted in the version that the second opposite party is a qualified Onco Surgeon having sufficient experience in the respective field.

The version of the second opposite party is as follows:

The complainant consulted the second opposite party with a lump in the right breast which was diagnosed to have carcinoma breast on the basis of MRI mammogram and FNAC. As per clinical history the complainant was having hypertension, bronchial asthma, severe chronic obstructive pulmonary disease dyslipidemia, left heart dysfunction and pulmonary artery hypertension. Since the complainant having all these serious systemic illnesses, she was managed with by team of doctors from various specialities like Pulmonology, Cardiology, Anaesthesia and General Medicine. After standard staging work up the complainant was advised mastectomy+ Auxiliary clearance. The complainant got admitted for mastectomy on 30/08/2017 and underwent necessary preoperative investigations and check up, she was explained with risk of factors involved in the procedure especially since she was suffering from various systemic illness. On 1/09/2017 the second opposite party conducted right modified Mastectomy + Axillary clearance with care and aseptic sterile precautions as per the standard protocol followed all over the world. Intra operative and post operative periods were uneventful and the complainant was treated as inpatient for 9 days instead of usually required 6 days in normal course and after modified mastectomy, she was on steroids for severe COPD which might delay the wound healing process and drain. On 9/09/2017 the drain output was brought down to normal and the wound was healthy with no collection in axilla. Hence the complainant was discharged with an advice for review with the specific instruction to report back if any collection occurred. Histopathology report showed invasive carcinoma breast, Grade III, Pathological Stage pT2 N1a M0- Comprehensive stage-IIB. The tumor was ER negative, PR negative, Her2 neu Negative and Ki 67 was 40%.

The complainant reported with complaint of vomiting and pain on 23/09/2017 and on examination she was found to have seroma collection which was drained and corrugated as per protocol. Pus was sent for culture and sensitivity and the report showed Staphylococcus Aureus and for which she started on antibiotics and supportive care accordingly in consultation with Physician. The condition of the complainant became better with antibiotics and infection settled down and wound was clean and healthy. Once breast wound was healed well and the complainant became clinically better, she was referred to the second opposite party for chemo port insertion by the Medical Oncologist. The chemo port was inserted by the second opposite party on 29/08/2017 and the procedure was uneventful. Back flow was checked after healing chemo port wound and the complainant was sent back to the Medical Oncology department for further management. Chemotherapy, radiation and other treatments were done by doctors attached to the Medical and Radiation Oncology Departments and the second opposite party attached to the Surgical Oncology Department was not involved in the said course of treatment.

During chemotherapy the complainant never reported any problem with the back flow to the second opposite party and she came up for consultation with the second opposite party for removal of chemo port after chemotherapy and radiation. Under all aseptic precautions and care the second opposite party removed chemo ports and during the procedure tip was found to be broken and hence the complainant was referred to Interventional Cardiologist Dr Deepak Davidson for its removal. He removed tip of the broken chemo port from the body by femoral approach which is the internationally accepted best and safest method and the patient was discharged on the very next day with an advice for review. During follow up review wound healing was good and it is pertinent fact that prolonging the process of wound healing is attributable to poor general condition of the patient as well as long term anti-cancer treatment with chemotherapy and radiation. The tube detachment and tube breakage are rare but reported

known complications involved in the procedure which cannot be termed as due to negligence or deficiency in service on the part of the second opposite party.

The second opposite party had followed medically accepted treatment procedure for the diagnosed disease of the complainant. During the surgical treatment for carcinoma breast there is possibility for infection due to seroma formation despite proper drainage and this condition was induced by factors beyond the control of the treating doctor. When the complainant reported with complaint of symptoms of infection she was thoroughly investigated and based on culture and sensitivity report antibiotics were started under supportive care. Infection due to Staphylococcus Aureus can be contacted in any circumstances as this organism is a species of gram positive anaerobes commonly present on the skin and mucous membrane and it was not caused due to any negligence in treatment. Infection was completely cured with the antibiotics. No damage has been caused to the complainant by the treatment of the second opposite party and carcinoma breast successfully treated and cured.

It is submitted in the version that a medical practitioner is not an insurer against the risk and complications involved in the procedure adopted for treatment and the second opposite party is a well qualified and experienced Surgical Oncologist and had exercised reasonable skill and care throughout the treatment of the complainant. The complainant was taking steroids for COPD and had been suffering from various systemic illness with comorbidities and this condition may affect wound healing and drain.

Evidence part of this case consists of deposition of PW1 and PW2 and Exhibits A1 to A31 from the side of the complainant. Second opposite party was examined as DW1. No documentary evidence what the part of the opposite parties.

On evaluation of complaint, version and evidence on record we would like to consider the following points :

(1)Whether the complainant had succeeded to prove any negligence on the part of the opposite parties in her treatment ?

1. If so, what are the reliefs and the costs ?

For the sake of convenience we would like to consider Point Nos.1 and 2 together.

POINTS 1 & 2 :-

The complainant had undergone mastectomy on 1/09/2017 by the second opposite party doctor at first opposite party hospital. It is alleged in the complaint that on 8/09/2017 the drainage tube attached to the breast was detached by the second opposite party prior to the stoppage of seroma collection and the complainant was discharged by the second opposite party on 9/09/2017. Due to the earlier detachment of the drainage tube carelessly without accessing the drainage volume caused seroma collection and infection therefore the complainant to get admitted and treated from 23/09/2017 to 5/10/2017.

It is proved by Exhibit A1 that the complainant who has the complaints of carcinoma right breast was admitted in the first opposite party hospital on 30/08/2017. She underwent right simple mastectomy+ Axillary clearance on 01/09/2017. It is proved by Exhibit A1 that the complainant was discharged from the first opposite party hospital on 9/09/2017.

It is further proved by page number 107 of Exhibit A31 that the complainant was again admitted in the first opposite party hospital on 23/09/2017 with complaints of post MRM seroma, vomiting and pain. According to the PW1 who is the complainant, due to the earlier detachment of the drainage tube on 8/09/2017 i.e, before the stoppage of drain collection seroma and other fluid waste materials accumulated in the surgical part on the breast of the complainant and it got infected and puss was formed due to infection that led to her second admission in the hospital.

DW1 who is the second opposite party deposed before the Commission that the drainage tube was detached on 9/09/2017. He further deposed before the Commission that on 8/09/2017 seroma collection was 130 ml. On perusal of Page number 247 of Exhibit A31 which is the progress record of the complainant we can see that on 6/09/2017 there was seroma collection of 180 ml. and on 7/09/2017 the drain collection was 190 ml. and on 8/09/2017 the seroma collection was 130 ml. On 9/09/2017 it was recorded that there was collection on two times. On perusal of Page number 294 of Exhibit A31 which is the nurses daily record we can see that it was recorded at 8:00 p.m that the patient is having control drain and surgical wound. Therefore it is clear that the drainage tube was not detached by the second opposite party on 8/09/2017 as alleged by the complainant.

The counsel for the complainant relied on Bailey and Love's Short Practise of Surgery where in it has been stated that drains should be removed as soon as possible and certainly once the drainage has stopped or became less than 25 ml./day.

It is stated in Cureus on drainage after modified radical Mastectomy - a methodological mini review that

"Time of drain removal

Opinions that early removal of the drainage systems limits injuries, infections and the time of hospital stay, but increased the incidence of seromas seems to be the reigning ones while considering the time of drainage removal [30-33]. However, there is no unanimous opinion on the optimal time for the removal of the drainage system after surgery. Based on the general results, seemingly the best patient outcome with the least complications occurs when the drains are removed on the second or third postoperative day, or preferably when the amount of drained fluid in the last 24 hours reaches below 50 millilitres".

It is stated in Annals how long should suction drains stay in after breast surgery with the auxiliary dissection that suction drainage has been shown to reduce the incidence of seroma formation but not prevent it. Keeping the drains in situ for an extra day did not protect against the seroma formation.

On perusal of Exhibit A31 we can see that the complainant had outpatient consultation with the second opposite party on 14/09/2017. On that day the complainant has no case that there is a considerable discharge from the surgical site or she has any complaints of pain or other complaints. It was noted by the doctor that the wound is healing.

Based on the above discussion we are of the opinion that the case of the complainant that the infection was due to the earlier detachment of the drain tube by the second opposite party cannot be accepted.

Another contention of the complainant is that the chemo port which was inserted on 20/09/2017 seen blocked on 4/03/2018. While removing the embolised chemo port by the second opposite

party without any due care and diligence the tip of the chemo port got broken and which resulted into an emergent situation warranting the Interventional Cardiologist to remove the broken tip of the chemo port.

PW2 who is the Interventional Cardiologist of the first opposite party hospital deposed before the Commission that in Exhibit A17 Discharge Summary, it is recorded that the complainant was admitted for removal of embolised chemo port. He further deposed that he removed the tip of the broken chemo port from the body of the complainant by femoral approach by snaring procedure which is the internationally accepted best and safest method. It is further deposed by PW2 that the breakage of the chemo port is a medically reported and accepted complication in chemotherapy treatment procedure. He deposed that during his career for 10 years he had attended 4 other cases of the same nature. He further deposed that the breakage of the chemo port is not due to the negligence on the part of the second opposite party. The complainant did not take any effort to examine any expert from Surgical Oncology or Interventional Cardiologist to support her case.

The counsel for the first opposite party relied on the decision of the Honourable NCDRC in LT Col, Surjit Singh(rtd) Vs. Silver Oaks Hospital and another(2018(1)CPR 104 (NC) wherein it has held that there is no deficiency in treatment or negligence where the treatment was given to patient as per clinical assessment and after proper investigation.

In Girish Chandra V Bhatt and ors Vs. Sterling hospital 2018(2)CPR 296 (NC) It was held that expert witness plays an essential role in determining medical negligence.

The Honourable NCDRC has held in Kannaya Chityyar and another Vs. Nair Service Society and others(2018(2)CPR 653(NC) that failure of operation does not imply medical negligence.

In Dr.Samir Rai and another Vs. Medanda hospital and others (2021(2)CPR 30 (NC) Hon'ble National Commission held that simply proving the suffering of ailment by parties after surgery does not amount to medical negligence.

In Vinod Kumar Dhanda Vs. Batra hospital and Medical Research Centre and others(2021(2)CPR 169 (NC) It was held that no surgeon can assure that outcome of any surgery would be beneficial.

It was held by the Hon'ble National Commission in a case reported 2019(4)CPR 73 (NC) that merely because a patient dies it cannot be construed to be on account of negligence of the doctors unless it is established that the doctors have not adhered to standards of normal medical parlance. Negligence can be attributed to the treating doctors only if they have not exhibited skill and reasonable care in treating the patient.

It was held by the National Commission in Nandidi Bandyopadhyay Vs. belly vue clinic and others 2021(2)CPR 473 (NC) that no cure is not negligence of doctors.

During the cross examination PW1 who is the complainant deposed that she had underwent 6 chemotherapies and 25 radiations in the first opposite party hospital.

In SGS India Ltd Vs. Dolphin International Ltd. has held that ''The onus of proof that there was deficiency in service is on the complainant. If the complainant is able to discharge its initial onus, the burden would then shift to the respondent in the complaint. The rule of evidence before the civil proceedings is that the onus would lie on the person who would fail if no evidence is

led by the other side. Therefore, the initial burden of proof of deficiency in service was on the complainant "

Based on the above discussions we are of the opinion that the complainant failed to prove any negligence or deficiency on the part of the opposite parties.

In the result the complaint is dismissed.

Pronounced in the Open Commission on this the **24th** day of **November, 2023**

Sri.Manulal.V.S, President Sd/-

Smt.Bindhu.R, Member Sd/-

Sri.K.M.Anto, Member Sd/-

APPENDIX :

Witness from the side of the Complainant :

PW1 - Ansamma Varghese

PW2 - Dr.Deepak Davidson

Witness from the side of Opposite Parties :

DW1 - Dr.Jojo.V. Joseph

Exhibits from the side of the Complainant :

A1 - Discharge Summary dated 09/09/2017 issued by the

1st opposite party hospital

A2 - Copy of Pharmacy Invoice dated 23/09/20217 issued by the

1st opposite party hospital

A3 - Copy of Pharmacy Invoice dated 24/09/20217 issued by the

1st opposite party hospital

A4 - Copy of Pharmacy Invoice dated 25/09/20217 issued by the

1st opposite party hospital

A5 - Copy of Pharmacy Invoice dated 26/09/20217 issued by the

1st opposite party hospital

A6 - Copy of Pharmacy Invoice dated 27/09/20217 issued by the

1st opposite party hospital

A7 - Copy of Pharmacy Invoice dated 28/09/20217 issued by the 1st opposite party hospital

A8 - Copy of Pharmacy Invoice dated 29/09/20217 issued by the 1st opposite party hospital

A9 - Copy of Pharmacy Invoice dated 30/09/20217 issued by the 1st opposite party hospital

A10 - Copy of Pharmacy Invoice dated 01/10/20217 issued by the 1st opposite party hospital

A11 - Copy of Pharmacy Invoice dated 02/10/20217 issued by the 1st opposite party hospital

A12 - Copy of Pharmacy Invoice dated 03/10/20217 issued by the 1st opposite party hospital

A13 - Copy of Pharmacy Invoice dated 04/10/20217 issued by the 1st opposite party hospital

A14 - Copy of Pharmacy Invoice dated 05/10/20217 issued by the 1st opposite party hospital

A15 - Copy of Pharmacy Invoice dated 03/04/2018 issued by the 1st opposite party hospital

A16 - Discharge Bill dated 04/04/2018 for Rs.13,397/- issued by the 1st oppositr party hospital

A17 - Discharge Summary dated 04/04/2018 issued by the 1st Opposite party hospital

A18 - Copy of Pharmacy Invoice dated 10/04/2018 issued by the 1st opposite party hospital

A19 - Copy of complainant’s letter dated 19/04/2018 addressed

To the Ist opposite party hospital

A20 - Copy of Treatment Report issued by the 1st opposite party hospital

A21 - Copy of Lawyer notice dated 19/09/2018 issued by the advocate of the complainant to the opposite parties

A22 - Postal Receipt of A21 Notice

A23 - Postal AD Card

A24 - Copy of reply notice dated 05/10/2018 issued by the advocate of the opposite parties'

A25 - Copy of Lawyer notice dated 03/11/2018 issued by the advocate of the complainant to the 1st opposite party

A26 - Postal receipt

A27 - Postal AD Card

A28 - Postal AD Card

A29 - Copy of 2nd opposite party's reply notice dated 19/11/2018 addressed to the complainant's lawyer

A30 - Photographs

A31 - Original Hospital Records of the complainant having Pages 1 to 486

<u>Exhibits from the side of Opposite parties :</u>

Nil

By Order,

Sd/-

Assistant Registrar

[HON'BLE MR. V.S. Manulal]
PRESIDENT

[HON'BLE MRS. Bindhu R]
MEMBER

[HON'BLE MR. K.M.Anto]
MEMBER