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IN THE STATE CONSUMER DISPUTES REDRESSAL COMMISSION

STATE OF GUJARAT

COURT -5

CONSUMER COMPLAINT NO. 115 OF 2015

COMPLAINANT: PARESH SHAMBHUBHAI PATEL

“Shreeji Krupa” Block No. 4/A/2,
Shantinagar Society, Street No.4,
Jamnagar. 361006

V/s

OPPONENTS: [1]. Dr. KALPANA BHATT

Vikslp Hospital for Woman,
Summer Club Road,
Jamnagar. 361005

[2]. Dr. DIPEN SHAH

C/o. Krishna Hospital & Critical Care Centre
“Kavya” Shrinivas Colony, Street No.2
Summer Club road,
Jamnagar- 361005

[3]. Dr. RAKESH DOSHI

Vikslp Hospital for Woman
Summer Club Road,
Jamnagar. 361005

CORAM: Mr. R N Mehta Presiding Member

Appearance: Mr. Meet Pansuria, Adv. For Complainant

Mr. M M Desai Adv. For opponents.

(Order by Mr. R N Mehta, Presiding Member)

- [1]. This complaint has been filed by husband of deceased Joshnaben, for whose treatment, services of the opponents were hired. It is alleged that she lost her life untimely, due to negligence and careless attitude on the part of the opponents herein and therefore claims compensation of Rs.44,60,669/- under the provisions of the Consumer Protection Act, 1986 (herein after referred as “The Act” or “Act”).
- [2]. It is averred in the complaint that Joshnaben (herein after referred as “Patient” or “She”) had complaint of abdominal pain for which she had consulted Dr. Kalpana Bhatt, the opponent no.1 (herein after referred as “Surgeon”) on 1/12/2014. After examining patient, surgeon felt that she had tumor and therefore it was advised to remove it and also to verify whether it is malignant or not. The surgeon recommended removal of tumor through non surgical procedure which is publically known as “laparoscopy”. The patient continued with follow up treatment on 5/12/2014 and 31/12/2014. It was informed to the patient and complainant that during the procedure above named, tumor will be removed through only three holes on her stomach and will be given discharge earliest instead long hospitalization in other methods. It is alleged that trusting the surgeon, patient got admission at the surgeon’s hospital on 1/1/2015 and Laparoscopy was scheduled on 2/1/2015 at 9.30 a.m. It is alleged that when complainant was waiting outside the theatre, all of a sudden, movements of staff personnel increased and therefore he tried to inquire as to what had happened but none replied. It is averred that after some time, one of the nurse informed complainant that patient had become serious and other doctors have been called from outside. It is alleged that complainant also tried to meet surgeon and offered to call a doctor of his choice, but the request was turndown as intimated by the nurse.
- [3]. It is alleged further that later on it was informed to complainant that patient had suffered shock during procedure and it caused serious problem to her heart and lungs and requiring shifting of patient to Critical Care Unit. It is stated that Dr. Doshi(anesthetist) and Dr. Dipen Shah (Physician) accompanied patient whereas complainant reached to Critical Care Unit of his own. It is alleged that when the doctors at Critical Care Hospital asked both doctors to give in writing about status of patient at that point of time, they refused. Even Dr. Kalpanaben was requested to come and disclose correct facts, but she did not. At last Dr. Doshi gave in few words in writing but without authorizing the same by his signature. It is alleged that during procedure, patient had become unconscious and was requiring support of ventilator. After so many discussions with surgeon, it was then advised for shifting of patient to Sterling Hospital at Rajkot which was done as last resort. It is alleged that despite all efforts for

reviving patient, she breathed last on 3/1/2015 and was declared dead at 11.09 hrs. Thus the complainant's wife lost her life, that too, within short duration treatment of less than 48 hours.

[4]. It is averred in the complaint that post mortem was recommended which was done and report revealed that apart from three holes (as canvassed) there was evidence of an incision on the stomach of the patient. The discharge summary issued by Surgeon showed that there was anesthetic problem during procedure and as a result thereof, patient went into shock and to manage the patient services of Dr. Dipen Shah were necessitated. It is also evident from the PM report that incision on abdomen was measuring about 14cms which is usually done for routine abdominal operations. It is alleged that as and when patient had encountered a problem during surgery, it would have been better, if patient would have been transferred to Critical Care Unit immediately. However, the opponents killed time in trying through general surgery. The complainant alleged that though surgeon informed him about removal of tumor, he apprehends that no such procedure was carried out. He also further stated that had it been removed in fact, obviously it would have been sent for analysis but none production of any such report suggest that it was not removed. He alleged that neither surgeon explain the reason for abdominal incision especially when procedure was to be done through three holes nor provided Compact Disc (CD) of surgical procedure carried out. On the aforesaid premises, complainant alleged gross negligence and claims that the opponents are liable to pay compensation under the provision of the Act. It is stated that she was working woman and had earned about Rs.481308/- for last 21 months (proof of ITR produced on record). The complainant has placed on record, bills of expenditure incurred for medicines, hospitalization, treatment, expenses of investigative and diagnostic reports etc and overall claimed Rs.44,60,669/- from the opponents. The complainant has filed affidavit in support of complaint and also produced on record, OPD consultation / treatment papers of opponent no.1, reports of pathological and other investigations, copy of discharge summary given by opponent no.1, copies of receipts for the expenditure paid, copy of note written by Dr. Doshi without date and signature, case paper of Jamnagar Critical Care Centre, copy of narrative summary written by sterling hospital, copy of bill of sterling hospital, copy of PM report, copy of final cause of death report given, prescriptions and bills of medicines purchased, copy of income tax returns etc.

[5]. After preliminary hearing, this Commission had admitted complaint and ordered to issue notice to the opponents. On receipt of notice, the opponents appeared through advocate and filed detailed reply and denied that there was any negligence or carelessness on their part.

[a]. The surgeon stated that all the pre-operative and post operative check list and procedures were followed, procedure was explained to patient and her relative, consent of

patient as well as relative were obtained, and treatment was rendered as per standard medical practice with due diligence. It is stated that unfortunately, patient developed pulmonary edema when tumor was removed from bed through laparoscopic procedure, which is a known “complication” in such type of laparoscopic surgery. Even then patient was given best possible treatment, medical assistance, and all steps were taken as per standard medical practice. She was shifted to ICCU under the guidance of experts and as such there was no negligence but to extort money complainant has filed this complaint. It is also stated that patient had tumor in the broad ligament of uterus and to confirm diagnosis Color Doppler as well as 125 was also done. From the report it revealed that it was non-cancerous but since it was painful to patient, decision for removal was taken. It is stated that Laparoscopic Myomectomy, a major surgical procedure requiring general anesthesia. Patient and her husband had given consent for the same. She was admitted in hospital on 1/1/2015 after satisfying with full disclosure about procedure, pros and cons of surgery and surgery was scheduled on 2/1/2015 at 9.30 a.m. It is also stated that live demonstration of surgical procedure was arranged so that relatives can see the entire procedure even outside the theatre. It is stated that just after the tumor dissected out of bed, patient developed pulmonary edema and therefore Dr. Dipen Shah was given call. Dr. Shah also had an occasion to examine patient for preoperative check-up. It is submitted that when known complication occurs, surgeon cannot be made liable. She was then shifted to Critical Care Unit as she was requiring need for prolonged ventilator support. It is also incorrect to say that only physician and anesthetist visited Critical Care Unit. Surgeon and her assistant Dr. Jayesh Solanki also reached there. Dr. Doshi had given his conclusion in writing. Joshnaben was unconscious because she was under the effect of general anesthesia and was shifted with ET tube because of better oxygenation. It is stated that when patient’s condition deteriorated further, she was shifted to Sterling Hospital at Rajkot and it came to know later that she expired on 3/1/2015. Regarding Post Mortem report, it was explained that it shows three holes and fourth hole was done to remove tumor since condition deteriorated was not permitting to continue with laparoscopy and therefore it was removed through abdominal route. It is stated that incision was made to remove separated tumor from abdomen. From this it is submitted that there was no negligence and everything was done according to standard practice and video recording has been provided to Police authority since complainant has filed criminal proceedings also. It is in these circumstances, the complaint should be dismissed.

[b] Dr. Dipen Shah, Physician has filed reply contending therein that complainant has not come with clean hands and suppressed material information. All pre-operative and post operative check list and procedures were followed. Consent was obtained and during procedure patient developed pulmonary edema for which standard treatment rendered

immediately and then shifted to ICCU under his observation. She was given ventilatory support and pharmacological support instantly. The complainant was informed that his wife had serious pulmonary problem and therefore requiring to be shifted to Jamnagar Critical Care and therefore me and Dr. Doshi accompanied patient. She was unconscious because she was under effect of general anesthesia. When her condition further deteriorated, she was shifted to Sterling Hospital Rajkot. Being Physician, he had very limited role to play and there was no negligence on his part and prayed for dismissal of complaint.

[c]. The anesthetist has filed his reply and denied any liability on his part and submitted that complaint should be dismissed only on ground of suppression of material facts. It is stated that patient had pulmonary edema during procedure and it is known complication of laparoscopic procedure. She was shifted to ICCU and complainant is well aware about all these facts but just to extort money this complaint has been filed. It is stated that laparoscopic procedure is mostly done under general anesthesia and it commonly uses CO₂ because of high solubility in the blood stream and at Vikalp hospital it is very common practice. It is submitted that risk associated with laparoscopic surgery and acute pulmonary edema after “Carbon Dioxide Embolism” during Laparoscopic Ovarian Cystectomy as well as Pulmonary edema after removal of sand bag at the end of open Cholecystectomy due to unknown cause and Carbon Dioxide embolism during laparoscopic sleeve gastrectomy are well recognized. It is stated that being an anesthetist he has limited role to play. He submitted that Laparoscopic myomectomy F/by laparotomy for broad ligament fibroid done under G/A by using induction Inj. Propofol 120 mg IV slowly, Inj. Succinylcholine 90 mg IV stat, then intubation with oral cuffed, portex ET No 7 and maintenance with Oxygen + N₂O + Atracurium + Isoflurane + IPPV with Continuous monitoring of Pulse, BP, ECG, SPO₂ and ETCO₂ by side stream ETCO₂ monitor. During intra operative period, patient developed Hypertension which is controlled with Inj. Nitroglycerine infusion (25mg in 250 ml of DNS) at the rate of 5 microgram/minute as continuous IV infusion. Then patient’s BP came to 130/84 mm/Hg. After enucleating, suddenly patient developed Hypercapnia and ventilator settings suggestive of high inspiratory pressure, surgeon was asked to stop surgery and remove the pneumoperitonium. So CO₂ insufflations stopped, Pneumoperitonium removed and Trendelenburg position removed and then patient was hyperventilated with high frequency and low tidal volume to bring ETCO₂ to normal level. N₂O stopped and Inj. Hydrocortisone 200 mg IV given. After 20 minutes of all these efforts, patient’s ETCO₂ came to 54 levels. Then plan for relaparoscopy was abandoned and Laparotomy was done to remove the enucleated tumor. At the time of closure, patient developed Pulmonary edema froth was coming out of tube. So patient was ventilated with IPPV with 100 % O₂ and inj. Frusemide 20 mg followed by further 20 mg given. Then physician was called and patient’s relatives were informed

regarding her condition. Physician came, took ECG and further readings, and after talk with her relatives, patient was shifted to ICCU for further ventilator management. However, relatives took approximately 30 minutes for giving consent regarding shifting to ICCU. It is denied that he had refused to give in writing on the contrary he had given his conclusion in writing. It is stated that he followed the standard procedure and was shifted with endotracheal tube and also assisted with ventilatory support. He then denied any liability for alleged negligence and prayed for dismissal of complaint.

[6]. The complainant has filed affidavit in rejoinder (page 145) and stated that Dr. Doshi has admitted in his reply that patient developed Hypercapnia itself is suggestive that ETCO₂ was increased to confirm that it is case of Carbon Dioxide Embolism. It is stated that facts stated in reply cannot be accepted unless there is proof to have done accordingly. Dr Doshi also admitted that patient was under respiratory distress. It is also further stated that during open abdomen surgery, patient developed pulmonary edema. From the case papers given to complainant, it seems that there was no adequate equipments for proper ventilation and as a result thereof patient suffered.

[7]. Neither complainant nor opponents have any oral evidence. However, the complainant has placed on record case papers given to him and these are the only papers of treatment available on record. None of the doctors placed on record any documents in support of their version. Therefore this Commission has to decide this matter only from limited evidence available.

[8]. Both sides have submitted written submissions on record:

[a]. It is submitted that pre-operative consultations and hospitalization at opponent hospital is not denied requires no further evidence. Patient was accepted for surgery on 2/1/2015 is also not in dispute. Thereafter the complainant was informed after some time that his wife is serious and other doctors have been called from outside. He was given understanding that during surgery, she encountered a problem in heart and lungs and she is in critical condition and requiring shifting in another hospital for Critical Care. Thereafter patient was shifted to Sterling Hospital at Rajkot where she breathed last on 3/1/2015. Complainant relies upon the Post Mortem report, Discharge Summary given to him by the opponent no.1. It is submitted that from the papers it reveals that opponent subsequently tried for General abdominal surgery (laparotomy) for which no consent / permission was ever obtained. The cause of death mentioned in the Post Mortem Report is ***“Died due to Cardio-respiratory failure on account of surgery (operation) and its complications”*** Referring medical literature it has been submitted that the opponents failed to discharge its duty diligently and she had lost her life because of opponents’ carelessness. It is submitted on the basis of precedents that Hon’ble NCDRC has awarded substantial amount even to home

maker whereas income of deceased proved through ITR. Relying upon judgment of Hon'ble Supreme Court in Dr. Laxman B Joshi vs Dr. TrimbakBapu Godbole (AIR-1969-SC-128) it is submitted that the opponents failed to exercise reasonable care and failed to discharge duty of care. It is submitted that complaint should be allowed with cost and compensation as prayed for.

[b]. Dr. Kalpana Bhatt submitted that complaint should be dismissed only on suppression of material information. The patient had tumor in broad ligament of uterus and color Doppler and CA 125 not only confirmed but revealed that it is non cancerous. Removal was planned only because it was not only big but paining to patient. It is written in OPD case papers that Laparoscopic Myomectomy, a major surgery would be necessary and in such surgery generally preferred is general anesthesia. Consent was obtained after explanation. Date of operation is not in dispute. Arrangement of live telecast of surgical procedure is a practice of hospital. However, patient developed edema after removal of tumor from bed. Dr. Dipen was called for assistance. Pulmonary edema is known complication and therefore surgeon cannot be made liable for alleged medical negligence. Dr. Bhatt submits that complainant has not proved deficiency in service. There is no expert evidence in support of case of complainant. Dr. Bhatt has relied on many judgments to submit that in absence of expert opinion / evidence negligence of doctor cannot be established. It is also submitted that mistake in the medical treatment cannot be said negligence on the part of doctor. Facts stated on oath by the opponents are not controverted in any manner and therefore it is deemed to be established.

[c]. Dr. Dipen also adopted submissions canvassed by the opponent no.1 and also submitted further that his role was limited as was called in emergency and condition of the patient was critical requiring Critical Care Unit facility. Patient was given best possible medical treatment for acute Pulmonary Edema which includes ventilator and pharmacological support. According to him, all standard protocol was followed.

[d]. Dr. Doshi also adopted submissions made by Dr. Kalpanaben Bhatt and also further added that he had followed pre and post operative check list in true sense. Pulmonary edema developed to patient during surgery and to meet with all standard care was taken and procedure has been explained in reply has been strictly followed. Patient was treated diligently and was shifted to ICCU with care and caution and therefore no negligence on his part.

[9]. On the basis of aforesaid facts and submissions following facts are not disputes or say not requiring any further evidence.

- (i). Joshnaben had consulted opponent no.1, she advised for laparoscopic surgery to remove tumor.
- (ii). Surgery was planned on 2nd January 2015 and preoperative tests and examinations were carried out and patient was fit for surgery.
- (iii). During surgical procedure, patient become serious and was requiring ventilator support and was shifted to Critical Care Unit. Patient was accompanied by Dr. Doshi and Dr. Shah while shifting and Dr. Doshi gave in writing as to cause of status of patient.
- (iv). Patient died on 3/1/2015 and Post Mortem was carried out shows cause of death as “*Died due to cardio respiratory failure on account of surgery (operation) and its complications*”

Before adjudicating other issues it is to be kept in mind that all the pre-operatives reports and findings have established that condition of Joshnaben was fit for surgery. Secondly, it is not disputed that patient developed health problem when she was under complete management of opponents and it is also true that she lost her life immediately after surgery. Ordinarily, it is the complainant who has to prove his case of negligence with all evidences. But the facts mentioned herein above categorically suggest that incidence has taken place inside the operation theatre where complainant cannot have any access. In these circumstances, the explanation as to happening of events inside the theatre must come from the persons who are in possession of personal knowledge as to facts. It can be seen from the overall view of the facts that at relevant point of time (i.e. during surgery) only surgeon and anesthetist were in charge of treatment apart from the assisting staff. Discharge summary given by surgeon to complainant suggests that physician was given call when surgeon was informed about increase of ETCO₂ and request was made to stop surgery. Thus there are only two persons who can say about the actual happening of facts and they are duty bound to prove these facts. In *Savita Garg vs Director, National Heart Institute (2004-4-CPJ-40(SC))*, the Hon’ble Supreme Court held as under:

“Once a claim petition is filed and the claimant has successfully discharged the initial burden that the hospital was negligent, and that as a result of such negligence the patient died, then in that case, the burden lies on the hospital and the doctor concerned who treated that patient, to show that there was no negligence involved in the treatment. Since the burden is on the hospital, they can discharge the same by producing the doctor who treated patient in defence to substantiate their allegation that there was no negligence. It is the hospital which engages the treating doctor, thereafter it is their responsibility. The burden is greater on the institution /hospital than that on the claimant. In any case, the hospital is in better position to disclose what care was taken or what medicine was administered to the patient. It is the duty of the hospital to satisfy that there was no lack of care or diligence.”

The onus of proof therefore not on the complainant but on the opponents to prove that actions taken were standard and as per approved line of medical science. Obviously, though the complainant has placed on record Discharge Summary given by the surgeon, he cannot be burdened with liability to prove the contents of the said document. Unless the contents of documents produced on record proved by concrete and corroborative evidence, it cannot be held that facts stated by the opponents are proved facts. None of the doctors have given any authorized treatment papers except the aforesaid Discharge Summary.

- [10]. Although, provisions of law of evidence are not strictly applicable to summary procedure under this Act. But, at the same time, it cannot be denied that even broad principles of law of evidence are also not applicable to the cases undertaken for adjudication under this Act. “Res Ipsa Loquitur” is essentially an evidential principle and is intended to assist a claimant, who for no fault of his own, are unable to adduce evidence as to how the incident has occurred. The Hon’ble Chief Justice Erle explained the principle in the case of Scott vs London (1865-3-H&C-596) in the following manner:

“...Where the thing is shown to be under the management of the defendant or his servants, and the incident is such, as in the ordinary course of things does not happen, if those who have management use proper care, it affords reasonable evidence, in the absence of explanation by the defendants, that the incident arose from want of care”

Since, in the case in hand, the existence of facts can be assumed from the “proved circumstances” and more particularly where no proper explanation has come from the opponents herein. It is well recognized that “Res” will not apply in all cases, but will apply only in those cases, where the applicant has no access or knowledge of facts that have taken place in his absence. It is rather admitted fact that complainant was not in the operation theatre and facts stated above are not in dispute means proved circumstances. Therefore, unless the opponents explain the chain of events and establish their case with concrete and corroborative proof, presumption can be made that the incident has occurred because of their carelessness. In this case, to prove their case, the doctors have not placed on record any evidence, except their own affidavits. The affidavits cannot be considered conclusive proof unless facts stated therein is supported by corroborative proof. Mere bald statements made on affirmation cannot be treated as contents proved. This assumes importance, because, it is the case of the opponents that pulmonary edema is a “known complication” so far laparoscopy procedure is concerned. According to the Discharge Summary given by the Surgeon, “*severe Pulmonary edema took place*” immediately after the tumor was removed from the bed. In this summary, it is also categorically mentioned that the surgeon was informed prior to removal of the tumor that the patient had developed ETCO₂ level and she was requested to stop surgery. Dr. Doshi, in his reply said that when he saw an increased level of ETCO₂, he had requested

the Surgeon to stop surgery. Thus, facts that can be said proved is problem of ETCO₂ observed first and as a result thereof “Pulmonary edema” took place. Unless it is shown that increase of ETCO₂ has any direct nexus with removal of the tumor from bed, it cannot be said pulmonary edema had taken place because of known complication. If increase of ETCO₂ is not treated timely, it leads to Pulmonary edema as it mentioned in the medical literature which will be discussed herein after. It is in this circumstance, “Pulmonary Edema” caused to patient not because complication of laparoscopy surgery but because of no timely treatment to ETCO₂ which is an independent cause. Thus, anesthetist is duty bound to give a plausible explanation for the occurrence of increase of the ETCO₂ level and timely treatment for the same.

- [11]. An extract from review article “***Carbon Dioxide Embolism during Laparoscopic Surgery***” authored by Dr. Ki Jun Kim (Department of Anesthesiology and Pain Medicine, Anesthesia and Pain Research Institute, Seoul, Korea) provides relevant information as under:

“Laparoscopy has become a routine method for diagnosis and treatment of gynecological and intra-abdominal disease. To do so requires insufflations of carbon dioxide for accurate visualization and operative manipulation. Consequently, carbon dioxide embolism may arise there from. Carbon Dioxide embolism is a rare but potentially serious complication of laparoscopic procedures. It is caused by entrapment of Carbon Dioxide in an injured vein, artery or solid organ, and results in blockage of the right ventricle or pulmonary artery. There have been reports of carbon dioxide emboli occurring in various procedures including laparoscopic appendectomy, laparoscopic cholecystectomy, endoscopy, hysteroscopy and other gynecological laparoscopic surgeries.

PATHOPHYSIOLOGY, CLINICAL SIGNS AND SYMPTOMS: Carbon Dioxide is the most widely used insufflations gas. Most serious cases of carbon dioxide embolism reported in the literature occurred at the beginning of the procedure due to misplacement of the Veres needle directly into a vein or parenchymal organ. Smaller amounts of carbon dioxide may also enter circulation through an opening in injured vessels, either in the abdominal wall or at the operative site, which may be one of the mechanisms that can explain the late onset of carbon dioxide embolism. Carbon dioxide is well suited for creating a Pneumoperitonium because it is chemically inert, colorless, inexpensive, readily available and less combustible than air. Carbon Dioxide is highly soluble in blood which allows rapid absorption into the bloodstream across the peritoneum. At the same time, Carbon Dioxide can cause hypercapnia, metabolic acidosis, cardio respiratory compromise, and greater postoperative pain as well as having adverse effect on intraperitoneal immune function, even increasing the risk of portsite tumor metastasis in experimental models. The clinical effects of Carbon Dioxide embolism depend on the balance between the volume of carbon dioxide entering circulation and the amount of carbon dioxide that is removed.... Carbon Dioxide embolism can manifest itself through a “gas lock” effect, causing obstruction to RV ejection, right and left cardiac failure, paradoxical embolism with or without patent foramen ovale, arrhythmia, pulmonary hypertension, systemic hypotension and cardiovascular collapse.”

- [12]. A study material titled “*Carbon Dioxide Embolisms during Laparoscopic Surgery*” authored by Jobin, Leanne M (school of Nurse Anesthesia) University of New England reads as under:

Carbon dioxide Embolisms during Laparoscopic surgery

Laparoscopic surgery is a commonly used approach for a number of procedures as it is a *minimally invasive technique* that provides less postoperative pain, faster recovery and a shorter hospital stay.

A Carbon Dioxide Embolism is defined as ***an entrapment of carbon dioxide that inadvertently enters the vascular system.*** Carbon Dioxide Embolism can have *devastating effects on the cardiovascular and respiratory system and can quickly lead to cardiac arrest requiring immediate resuscitation.* *As an anesthesia provider, it is critical to identify a suspected carbon dioxide embolism immediately and to be able to respond in a safe and effective manner.*

Establishing the Pneumoperitonium

Laparoscopic procedures require that a Pneumoperitonium be created to generate space in the peritoneal cavity for the surgeon to be able to see intra-abdominal structures and to allow manipulation of instruments with clear visualization. *This decreases the risk of accidental injury while safely performing the surgical procedure.* To create an artificial Pneumoperitonium, air or gas is installed into the peritoneal cavity under a *controlled pressure*. Carbon Dioxide is commonly used due to its high diffusion rate and *should be installed under a pressure of 15* mm of Hg to reduce the physiologic effects on the different body systems. There are two main techniques commonly used to create an artificial Pneumoperitonium: the closed technique, *with a Veress needle* and the open procedure extremely thin, obese, or those with known abdominal adhesions are at increased risk of entry-related injuries when the closed technique at the umbilical entry point is used compared to the open or left upper-quadrant entry technique.

The closed technique is a commonly used technique and involves using the Veress needle, a spring-loaded needle. *The Veress needle is used to penetrate the abdominal wall either below or into the umbilicus.* *An intra-abdominal pressure of 10 mmHg or less has been shown to be a reliable measurement of correct placement.* Once placement is confirmed, carbon dioxide is instilled to create the Pneumoperitonium by increasing the intra-abdominal pressure, raising the abdominal wall off organ structures to create space for instruments. After the Pneumoperitonium is established, a trocar is inserted either blindly or *under direct vision to allow the insertion of instruments into the abdominal cavity.*

Characteristics of Carbon Dioxide

Carbon dioxide is the gas of choice when insufflating the abdomen to create a Pneumoperitonium of laparoscopic surgery. There are numerous reasons why it is superior to using air. Carbon dioxide is colorless, non-toxic, non-flammable, and highly soluble in blood. It is also inexpensive and readily available. *Its' characteristics make one of the safest gases to use during laparoscopic surgery and has the lowest risk of gas embolism due to its high diffusion rate.* If an embolism occurs that creates significant physiologic compromise, the carbon dioxide embolism, by principle, should eventually dissolve into the blood. ***However, Carbon Dioxide does have negative side effects including: hypercapnia, metabolic acidosis, cardio-respiratory compromise, and increased postoperative pain.*** Due to its associated side effects that can occur, other gases are being investigated.

Park describes how the clinical effects of carbon dioxide embolisms depend on the ration of the volume of carbon dioxide entered into circulation to the amount of carbon dioxide that is removed from the circulation. *Conducted a study that found that a mean of 300 milliliters of carbon dioxide was necessary to cause death in a 35-kilogram(kg). Which translated to requiring over 600 mL to cause death in a 70 kg human.* It seems that it would take a significant amount of inadvertent carbon dioxide infusion into circulation to cause fatality.

Incidence

According to study reports of different places, *majority of these embolisms show respiratory and cardiovascular compromise that were usually resolved spontaneously.* The incidence of a significant carbon dioxide embolism occurs as low as 0.001% to 0.59% of the time, but when it does occur, the mortality rate is as high as 28.5%. Carbon dioxide embolisms can occur at any time during laparoscopic procedures ***if there are intravascular openings that have a lower pressure than the intra abdominal pressure. It can also occur if the Veress needle is incorrectly placed and carbon dioxide is in inadvertently instilled into an intra abdominal vessel.***

Pathophysiology

A large amount of carbon dioxide must enter circulation through an artery, vein, or solid organ such as, the liver. The carbon dioxide embolism travels up the inferior vena cava, through the right atrium and right ventricle, and lodges itself into the pulmonary artery or pulmonary circulation. This mechanism is also referred to as a “gas lock”. This disruption causes an increase in right ventricular workload leading to right ventricular failure, increased pulmonary artery pressure that can lead to pulmonary arterial hypertension, and decreased pulmonary venous return. Left untreated, the decrease in venous return leads to decreased left ventricular preload, decreased cardiac output, severe hypotension, asystole, and cardiovascular collapse. Carbon dioxide embolisms produce similar, but less significant effects than air because carbon dioxide has the ability to diffuse into the blood and alleviate the physiologic response to the embolism.

Signs and Symptoms

*In a patient under general anesthesia, signs and symptoms include: a sudden decrease in end-tidal carbon dioxide, a sudden rise in end-tidal nitrogen, increased pulmonary artery pressures, marked hypotension, dysrhythmias, hypoxia, cyanosis, pulmonary edema, and a “mill” wheel murmur that can be auscultated with a precordial or esophageal stethoscope. The auscultated of the classic mill wheel murmur means that two milliliter per kilogram or more of carbon dioxide is entrained into the right side of the heart. ***When this much carbon dioxide is entrained in the heart, there will be significant hemodynamic effects that occur such as, tachycardia, hypotension, cardiac dysrhythmias, cyanosis, and electrocardiogram changes indicative of right sided heart strain*** ***ETCO₂ reading has a sudden increase and then rapid decrease that may progress to a complete loss in ETCO₂ waveform tracing.*** The sudden drop in ETCO₂ is caused by a reduction in pulmonary blood flow resulting in significant decreased perfusion ECTO₂ can either increase or decrease during a carbon dioxide embolism; however, most reports stated that there was a sudden decrease rather than increase in ETCO₂. ***A rise in ETCO₂ is from carbon dioxide that has entered circulation and is being readily dissolved into the blood;*** whereas, a sudden drop in ETCO₂ is due to an abrupt obstruction from an embolism in the pulmonary vasculature.*

Diagnosis:

Diagnosis of carbon dioxide embolisms are dependent on the rapid recognition of the physiologic signs and symptoms of embolism and direct visualization of an embolism in the right side of the heart and in the pulmonary vasculature, including the pulmonary artery. Transesophageal echocardiography is known to be the most sensitive diagnostic tool used in detecting carbon dioxide embolisms and can detect an embolism as small as 0.1 mL/kg. While in use, *the provider must be holding it and have constant attention on the device making extremely hard to maintain other aspects of anesthesia care such as, fluid administration, medication administration, and airway management.* ***In reality, it would require a second anesthesia provider to remain in the room at all times.***

Treatment

Rapid recognition is essential in the prompt treatment of carbon dioxide embolism. Failure to recognize and treat a carbon dioxide embolism can quickly result in a fatal outcome, such as, cardiac arrest. Once a provider recognizes the signs that a carbon dioxide embolism is suspected, he or she must first, inform the surgeon to discontinue the carbon dioxide insufflations and to let down the Pneumoperitonium to direct the surgeon to flood the surgical field with saline to prevent further carbon dioxide from entering the vasculature. Help should be called immediately into the room, as well as, a code cart.

Second, give 100% oxygen and discontinue nitrous oxide if being used. While applying 100% oxygen, the respiratory rate and tidal volume should be increased, as well as, increasing positive end-expiratory pressure to decrease the carbon dioxide entrainment.

Third, place the patient in left lateral decubitus with steep Trendelenburg or also termed the "Durant's position"

Fourth, increase the administration of intravenous fluid administration to adequately hydrate the patient to reduce further entry of gas, which increase the central venous pressure in the heart and supports blood pressure management.

Fifth, consider the insertion of a central venous catheter to allow aspiration of the carbon dioxide from the right atrium.

Sixth, resuscitation efforts should be initiated as fast as possible, including: administration of vasopressors and inotropes to maintain an adequate cardiac output and initiation of cardiopulmonary resuscitation if cardiac arrest occurs..

Prevention

There are a number of measures that can be taken to help reduce the risk of carbon dioxide embolism. Prevention measures must take place on both the surgical side, as well as, the anesthesia side of the operation room.

On the surgical side, the surgeon must correctly place the Veress needle and confirm placement before instilling carbon dioxide into the intra-abdominal space to avoid massive transfusion of carbon dioxide either intravenously or into a solid organ. Correct placement can be accomplished by aspiration before insufflations and testing the inflation with a few milliliters of carbon dioxide. As an anesthesia provider, it is also our role to ensure that the surgical team is adhering to low insufflations pressures.

For the role of the anesthesia provider, there are several measures that can be taken to decrease the risk of hemodynamic collapse if a carbon dioxide embolus were to enter circulation. Firstly, increase the central venous pressure by administering an adequate amount of intravenous fluids help reduce the risk of a carbon dioxide embolus from causing entrainment in the right side of the hear. Ways to ensure adequate hydration without the use of a central venous pressure monitoring system include: calculating fluid deficit and maintenance rates based on weight, assessing fluid status of the patient based on dry mucus membranes, and the presence of respiratory variation on the oxygen saturation waveform. Placing the patient in steep Trendelenburg would force gas bubble or emboli that are present to rise to the apex of the right side of the heart and prevent it from advancing to the pulmonary circulation. The use of PEEP may reduce the pressure gradient between the vessel opening and the heart; therefore, decreasing the risk of carbon dioxide entry into the vasculature. Best measures to take in preventing carbon dioxide emboli as the anesthesia provider is to ensure:

- 1. Low insufflations pressure less than 15mmHg*
- 2. Hydration*
- 3. PEEP*

4. Trendelenburg positioning

Conclusion :

Laparoscopic surgery is a common surgical approach. It is associated with less postoperative pain, faster recovery, and short hospital stays. While it has many advantages, providers must keep in mind that the rare complication of carbon dioxide emboli is possible.

Anesthesia providers play a crucial role in prompt recognition and treatment of carbon dioxide embolisms to provide life-saving measures to patients undergoing laparoscopic surgery. Communication between the anesthesia provider and the surgeon is an important step providing prompt, efficient, and safe interventions to adequately resuscitate a patient suffering from a carbon dioxide embolism. If left unrecognized and untreated, carbon dioxide emboli can have devastating effects, including death.

- [13]. In the instant case, Dr. Doshi in his reply stated that “during intra-operative period, patient developed Hypertension which was controlled with Inj. Nitroglycerine infusion at the rate of 5 microgram / minute as continuous IV infusion. Then patient’s BP came to 130/84 mm of hg. After enucleating suddenly patient developed Hypercapnia and ventilator settings suggestive of high inspiratory pressure so the surgeon was asked to stop surgery and remove the Pneumoperitonium so CO₂ insufflations stopped.”

All these admissions on the part of opponents suggest that CO₂ embolism had taken place is also established. As it mentioned in the aforesaid literature, CO₂ embolism starts with *beginning* when procedure starts with *placement of veress needle*. It is therefore necessary for the Surgeon and Anesthetist to prove on record that before entering the veress needle all reasonable care and caution was taken regarding confirmation of site where it was to put. To prove this fact there is no evidence except bare statements that they followed standard line of treatment. Obviously, these facts were only within the personal knowledge of the opponents and despite that none of them has proved it through corroboration that they have taken such care. Thus, the opponents have failed to adduce best available evidence to discharge their burden. Merely because “known complication” has taken place, it cannot be said responsibility of the treating doctors ceases. There are ways and measures to meet with eventual condition but doctor must come with true facts that these steps have been taken and despite that this has happened. Surprisingly, none of the opponents have produced on record any of their case papers. The anesthetist, in his reply narrated facts but to support those facts, no documents have been produced. Being anesthetist, he is supposed to prepare a note regarding the actions taken during surgery. However, no such anesthetist’s note have been produced on record and therefore presumption also can be drawn that note is suppressed for the reasons best known to them. The anesthetist had given in writing at Critical Care Unit reads as under:

“Laparoscopic dissection of Rt sided 10 cms broad ligament fibroid done under G.A on 2/1/15. Direct trocar entry pneumo started under vision. After some time pt had high ETCO₂ and emphysema so Pneumoperitonium & procedure stopped and mymoa removed by small

incision. Pt was treated by support of Oxygen with anesthetist & later on shifted to J. C. C ICU with pulmonary edema (Massive).

This is the only document which was written on that day and it speaks about nothing. This document no way establishes the actions taken by the doctors in charge of treatment were adequate. Whatever line of treatment mentioned in reply can be said an afterthought till any supportive and corroborative proof is produced. Discharge summary written by the surgeon will not mention the action taken by the anesthetist. Carbon Dioxide Embolism is subject matter of anesthetist to take care of. Therefore, it is always expected from the anesthetist to give complete accounts of events and he has to establish the course of action taken by him to prevent, occurrence, minimize the effects thereof through effective treatment and to manage patient. Unfortunately, there is nothing on record. The facts stated in reply must have some documentary support to place reliance on the said facts. In absence of any such information it cannot be believed that he acted diligently just because he states on oath. Having accepted the patient for treatment, it is for the doctor to explain what preventive actions have been taken using reasonable “foresights” to minimize the effects of the known complications. The above literature also canvassed that presence of another anesthesia provider in the room all times to encounter Carbon Dioxide Embolism. In the instant case, no other anesthetist was present. Therefore this is a fit case, where presumptions can be made for absence of care on the part of doctors applying the aforesaid rule of “Res Ipsa Loquitur”.

- [14] There is another way of looking also. According to surgeon, patient was fit for surgery and when procedure started there was no immediate threat to life of the patient. It is admitted fact that when patient was shifted to Critical Care Unit, she was in unconscious state of mind therefore what has happened to the patient is to be explained by the doctors. Page 67 of the compilation is final cause of death certified by the Forensic expert suggesting that she died due to *cardio respiratory failure on account of surgery and its complications*. When patient was under effect of general anesthesia, management of his / her respiratory system was the obligation on the part of doctor who was in charge as anesthetist. How the patient lead to failure of cardio respiratory system is to be explained by him. Examination of pericardium shows that *all chambers of heart filled with clotted blood*. All coronaries are patent. Thus it is clear from these observations that it was loaded with blood to confirm failure of system. There were observations for stitches suggests that no loosening, no oozing which suggests that no incident of hemorrhage has taken place which would requiring supply of blood to put abnormal pressure on heart. Thus, the doctors failed to convince this Commission that diligent efforts have been made during treatment and therefore I have no hesitation in holding that Surgeon and Anesthetist are liable for not providing efficient services to the patient Joshnaben. Their action lead to irreversible condition of patient and died on next day suggests

that it is direct nexus with the cause of death of patient.

- [15]. One of the submission that was canvassed from the opponents side that the complainant has not came out with any expert's opinion that services rendered were not proper. The Hon'ble Supreme Court in the case of **V Kishan Rao vs Nikhil Super Speciality Hospital** (2010-3-CPJ-1(SC)) held as under:

“Before forming an opinion that expert evidence is necessary, the Fora under the Act must come to a conclusion that the case is complicated enough to require opinion of an expert or that facts of the case are such that it cannot be resolved by members of the Fora without assistance of expert opinion. In these matters, no mechanical approach can be followed by these Fora. If a decision is taken that in all cases medical negligence has to be proved on the basis of expert evidence, in that event, efficacy of remedy provided under the Consumer Protection Act will be unnecessarily burdened and in many cases such remedy would be illusory.”

Thus, it is not necessary for the complainant to bring expert opinion in all cases. More particularly, in this case, burden is upon the opponents to lead sufficient evidence in support of actions stated to have been taken by them.

It is in these circumstances, all the authorities cited by the opponents regarding expert's evidence would be not helpful to them.

- [16]. When the case of deficiency in service is established, the complainant is entitled for the compensation to the extent of loss suffered by him. As such value of a life of a person cannot be determined in terms of money. It is to be kept in mind that even if lady is home maker her services to the family cannot be underestimated and there are decisions of Hon'ble Supreme Court where notional income of house wife assessed at Rs. 10,000/- per month. However in this case, she was earning woman and her income proof have been submitted in the form of ITR return. Her last return before death was showing her annual income of Rs. 2,46,151/- and her subsequent return was showing income of Rs. 2,35,157/- for last nine months. Income for assessment year 2014-15 cannot be ignored as the same was filed on 22/7/2014, because it was filed prior to death and obviously she would not have any idea that her condition would deteriorate to that extent. Thus, she was earning Rs.20,500/- per month. She was 43 years when consulted for the first time on 1/12/2014. She had no other health issues and therefore she would have lived normal life at least upto age of super annuation. Considering one third of her income for her personal expenses, her contribution to the family was around Rs. 1,60,000 per annum. The family had loss of 15 years contribution which comes to Rs. 24,00,000/- and the same is payable to the legal heirs through her husband. Because of loss of her life, family members have suffered trauma, agony, harassment, etc. for which I would like to award Rs.2,00,000/-. The complainant has placed on record bills and vouchers for the

expenses incurred which comes to about Rs.100000/- out of which Rs. 30,000/- was payable to opponents. Therefore, even otherwise also complainant would not be entitled to this amount. Thus, I will allow only Rs. 70,000/- towards medical expenses. Although the complainant has claimed loss of income including future prospect at 50% of income, I think that rise of 50 % in income is not possible from the very next year but gradually increases therefore it would be proper if lum sum Rs. 2,00,000/- is awarded, it would suffice to take care of the same. Over and above this I would like to award Rs.5,00,000/- towards loss of life. Thus in all, the complainant is entitle for Rs. 33,70,000/- (Rs.24 lakh + 2 Lakh + 70 thousand + 2 Lakh + 5 lakh) towards the compensation from the opponents.

[17]. It is also made clear that these amount should be paid by the surgeon and anesthetist only and I do not think there was any negligence on the part of Physician because he came into picture later on and by that time condition was became critical also. Therefore, physician is exonerated from the liability in this case. This case is filed in 2015 and much water have been flown there after and value of money has been decreased. To put the complainant at par with the value of 2015, I would like to award 10 % interest on the aforesaid amount from the date of complaint so as to give him just, adequate and fair compensation.

The complainant is also entitle for cost of this litigation which I quantify at Rs. 25000/-. In the circumstances mentioned above, I pass the following order:

ORDER

The complaint No. 115 of 2015 is hereby partly allowed.

The opponent no. 1 and 3 is hereby directed to pay the sum of Rs. 33,70,000/- together with interest at the rate of 10 % from the date of Complaint (i.e. 28/9/2015) to complainant.

The opponent no.2 Dr. Dipen Shah is hereby exonerated from liability in this case.

The complainant is also entitle to cost of litigation Rs. 25,000/- from the above said opponents. The order is require to be complied within 60 days from date of order, failing which, it shall carry interest @ 12 % from 15th June 2023.

The office is directed to supply copy of this order to parties free of cost at an early date.

Pronounced on this 6th March 2023.

Mr. R N Mehta

Presiding Member.