THE WEST BENGAL CLINICAL ESTABLISHMENT REGULATORY COMMISSION.

Present: Justice Ashim Kumar Roy, Chairperson.

Dr. Sukumar Mukherjee, Member.

Dr. Gopal Krishna Dhali, Member.

Dr. Makhan Lal Saha, Member.

Dr. Madhusudan Banerjee, Member.

Dr. Maitrayee Banerjee, Member.

COMPLAINT ID: NPG/2017/000140.

Mr. Ashok Das .....Complainant.

-versus-

Apollo Gleneagles Hospital & others.....Respondents.

Date of judgment: 16th February, 2018.

J U D G M E N T.

The letter of complaint that was received by the Commission from the complainant Mr. Ashok Das against the Apollo Gleneagles Hospital and the treating doctor Dr. Archana Sinha contains the following allegations.

On June 19th, 2017 the wife of the complainant Smt. Sandha Das was admitted at Apollo Gleneagles Hospital (in short *'Apollo'*) for incision of a tumour in uterus, under Dr. (Mrs.) Archana Sinha at a consolidated package of Rs.60,000/-. On July 20, 2017 she was operated

upon and the complainant was told by the surgeon Dr. Sinha that the operation was successful and she would gradually recover. Thereafter, on June 22nd, 2017, suddenly the complainant was informed by Dr. Sinha that on that day, his wife will be discharged. Since his wife was complaining of flatulence, no stool and otherwise unwell, he requested Dr. Sinha to keep her in the hospital and when the package was for 6 days. But Dr. Sinha insisted when a doctor advised for discharge, the party to follow it. As per her advice, his wife was taken home on June 22nd, 2017. When her condition started rapidly deteriorating by formation intestinal gas, frequent loose motion and high fever. Immediately, the complainant contacted Dr. Sinha over phone when she asked him to continue all the medicines earlier advised and prescribed two more medicine in whatsapp. However, there was no improvement and by passage of time her condition become more critical having abdominal pain with high fever. Left with no option, the patient was again brought to Apollo. When Dr. Sinha examined the patient and told the complainant that everything is alright and there is some minor problem due to formation of gas and advised for re-admission. On June 24, 2017 around 12 noon his wife was readmitted at Apollo against payment of Rs.14,000/-. Except a few tests, on June 24, 2017 and June 25th, 2017, there was no treatment was given and there was no change in her condition. On June 26, 2017, the condition of the patient became bad to worse, when Dr. Sinha sent a call to Dr. Debashis Roy. However, Dr. Roy examined the patient on the next day, June 27, 2017 and advised for C.T Scan. Following the C.T. Scan Dr. Roy told the complainant that there was some fault in first operation and a perforation has occurred in her abdomen and further surgical intervention is necessary for its repair. The operation was done on that day and that continued from 7 pm till 12.30 mid night. The complainant was informed by Dr. Roy that the operation was successful but a portion of the stomach was removed since same had become infected. He was further told that the operated part could not be stitched for 7 to 10 days and rectum shall remain outside until the next operation after 6 month and the patient shall be discharged after the infection subsided.

According to the complainant, this is a clear case of medical negligence and due to wrong operation by the doctor and deficiency in service of the Apollo, his wife has to face

immense pains and sufferings. The perforation in abdomen was caused due to such negligence of the doctor. At the beginning his wife admitted in the hospital for operation against a package of Rs.60,000/- which the complainant could have recovered from Medi Claim but now again he has to incur further expenses for negligent treatment. Earlier complainant was never informed by Dr. Sinha due to her fault the perforation occurred in the abdomen of the patient. In the mean time, the Apollo has realized 2 lakhs from the Insurance Company and when he expressed his inability to pay any further charges, he was asked to take her wife back in that critical condition.

2. In response to the above complaint, Apollo has submitted a written reply on July 18th, 2017 stating as follows and filed the bed head ticket:-

The patient, aged about 44 years and mother of a 16 years boy admitted at Apollo with lower abdominal pain on right side with a previous history irregular cycle for the last five months and with scanty period for last one year. An USG done on 03-06-2017 and intramural uterine myoma anterior wall of the uterus with ld hydronephrosis of right kidney was diagnosed . She gave history of stenting right kidney in 2009 and appendectomy 10 years back.

The patient was admitted for surgery with proper counseling and consent. She underwent total laparoscopic hysterectomy + bilateral salpingo-oophorectomy + adhesiolysis + vaginal morcellation under GA on 20-06-2017 from 11.20 AM to 1.20PM. The OT findings were mild adhesions between omentum and anterior abdominal wall. Uterus was bulky, anteverted and mobile. Bilaterally ovaries were bulky, bilaterally tubes were normal. She was given inj. Ceftraixone 1 gm IV thrice daily (total 3 doses; 1st dose in OT at 1.20 PM); inj Metrogyl (100gms) IV thrice daily (total 2 doses, 1st dose in OT at 1.20 PM).

Her post-operative stay was managed conservatively and the patient kept under close observation with regular monitoring of vitals. She was hemodynamically stable, abdomen was soft, tolerated oral diet on 21-06-2017 at 1.30pm and was planned for discharge, on the coming

morning and the patient family was informed accordingly. As such, the allegation of sudden or forced discharge was not correct.

Wound care was explained to the patient and her family. The patient did not pass stool on 22-06-2017 at 8 AM, but when Dr. Sinha came for her rounds at 12 noon, the patient herself stated that she had passed stool by then since the patient was ambulatory. Hence, the.allegation that patient was discharged without passing of stool was wrong. The allegation that the patient had abdominal distention prior to discharge is not correct. She was discharged in a hemodynamically stable condition. When to seek urgent and emergent care was documented in the discharge summary and explained to the patient family.

The patient's husband brought to the notice of the consultant after going home that the patient was having abdominal distension, with passage of loose stools and fever. She was advised two medications by the consultant through whatsapp to ensure correctness of the medication. As there was no relief to the patient's symptoms, she consulted Dr. Archana Sinha and was readmitted on 24-06-2017 at 12.25 PM with complains of abdominal distension, pain abdomen, one episode of fever and one episode of vomiting.

On examination, she was hemodynamically stable, abdomen was slightly distended with slight tenderness. IPS was positive. Patient passed stool with enema. She was advised soft diet along with Inj Reglan, Inj Zanocin, Inj Ornidazole, Syr Diovol.

On 25-06-2017, the patient was hemodynamically stable, distension present, IPS positive. Her routine parameters and whole abdomen USG were within normal limits. In the evening the patient complained of pain abdomen specially after eating, stool not passed.

On 26-06-2017, the patient did not pass flatus, abdomen was soft, distension present and IPS was positive and she had one episode of vomiting in the afternoon. She was referred to

Dr. Debasish Roy, consusltant Surgeon following the advice of Dr. Archana Sinha. She was hemodynamically stable.

Therefore, the clinical team advised all routine examination and was vigilant in monitoring the parameters and referral to surgeon was made promptly on indication.

On 27-06-2017, she was hemodynamically stable, abdomen was distended, non-tender, IPS negative and she was passing loose motions. She was advised to be nil orally, Ryle's tube drainage, continuous suction, catheterization and CECT whole abdomen. CECT abdomen revealed small bowel obstruction, perforation, fluid with air pockets. Ryle's Tube aspiration was drawing bile. A diagnosis of intestinal perforation was made which is a rare but known complication of Total Laparoscopic Hysterectomy. (1,2).

On 27-06-2017 at 6pm, exploratory laparotomy and proceed +/- stoma formation, was planned by Dr. Debasish Roy. The patient family was counseled and procedure explained to them.

The patient was transferred under Dr. Debasish Roy. She them underwent exploratory laparotomy under GA by Dr. Debasish Roy on 27-06-2017 from 7.10 PM to 10.10 PM after procuring appropriate consent. Perforation was identified Left colon, sigmoid colon and rectum mobilized upto perforatioin site, splenic flexure not mobilized. Sigmoid colon upto perforation excised in 2 pieces and sent for Histopathological examination. Rectal stump was closed with 2/0 vicryl. End colostomy fashioned in Left Iliac Fossa with 3/0 vicryl rapide. Wash out saline given and 3 drains were positioned in left paracolic gutter, right lower pelvis and right upper subdiaphragmatic. Closure loop PDS, skin and subcutaneous tissue were left open as standard clinical procedure. She was put on Inj Tazact 4.5 gms thrice daily. Inj Targocid 400 mgs IV twice daily, Inj Metrogyl 500 mgs IV thrice daily. Inj Tramazac 50 mgs IV thrice daily, continuous RT drainage. She was put on TED stockings.

On 28-06-2017 (POD1) she was hemodynamically stable, abdomen was distended but soft, RT aspirate 100 ml, drain was erous, pelvic rain 26 ml, subdiaphragmatic drain 20 ml, Left paracolic drain 50 ml. She was maintain an SPO2 of 93% with 2 litres/min O2, Colostomy was non-functioning yet.

On 29-06-2017, dressing was changed under asceptic conditions, Ryle's Tube aspirate was 425 ml bilious, stoma colour was good and movement was present, non-functioning yet. Drains were pelvic 55ml, subdiaphragmatic 63 ml and left paracolic 85 ml, abdomen was soft, mildly distended and non-tender. She was advised incentive spirometry.

Again on July 18, 2017, the patient was re-admitted at Apollo under Dr. Debasish Roy. The wound was clean, daily dressing was done with necessary supportive care, with a plan for abdominal wound closure within a week, if the patient remains clinically stable.

The estimate for the first admission (June 19, 2017 to June 22, 2017) as given to the insurance company/TPA was around Rs. 60,000/- and the bill was Rs. 68,220/- which is within permissible limit depending on the lineal requirement of the patient.

The hospital denied that there was any deficiency in service and the discharge of the patient 4 days after her admission although the package was for 6 days, was the decision of the treating doctor Dr. Archana Singh and Apollo or its management has no role to play. It is also denied that there was any refusal of treatment over the issue of payment. It is also the case of the hospital after she was readmitted for the second time, the operation has been successfully done by Dr. Debashis Roy, free of cost and no charge was levied for patient care and medical facilities provided to her. From the side of the hospital by swearing an affidavit it is submitted that not only they have not charged for the second operation after her readmission, they assured they will not levy any charge for the next procedure proposed to be held sometime in January, 2018. It is further assured the Apollo will not raise any bill for any treatment which in future may be necessary for the patient, Ms Sandhya Das, if any complication arises in

connection with her first operation (Total Laparoscopic hysterectomy+ Bilateral salpingo-oophorectomy+ adhesiolysis+ vaginal morcellation on 20.06.2017).

3. The doctor Dr. Archana Sinha while appeared before the Commission twice, Dr. Debasish Roy for once. Both of them were heard at length. On October 18, 2017 they filed their respective replies in the form of affidavit. The Complainant was also present and gave out his case.

We have gone through the replies of the doctors filed in the form of affidavits and also carefully examined the clinical notes in the bed head ticket pertaining to first and second operation.

Dr. Sinha referred the scientific literature on Bowel-related Complications of Operative Gynecological Laparoscopy and occurrence of gut injuries(perforation) following laparoscopic gynecological surgery from Chapter 29 of the Textbook and Atlas of Laparoscopic Hysterectomy by Dr. MS Chandramouli.

According to her, the literature so referred revealed that Bowel – related complications of operative gynecological laparoscopy is not unknown in the medical field. Since the patients are often discharged quickly after minimal invasive procedures, complications may not be apparent until they are recovering at home. It is further contended that according to the said literature the most common sites of injury are small bowel (55%), colon (35%) and stomach (10%). It is estimated that up to half of all injuries happen during entry phase of laparoscopy that is veress needle and trocar insertion. The extent of adhesiolysis performed intraoperatively has been found to be significant risk factor for intestinal injuries.

In addition to the mechanical injury occurring at entry or adhesiolysis, inadvertent thermal injury is an important complication of laparoscopic procedures including hysterectomy.

Study shows that only 30-50% of intestinal injuries are recognized during surgery. The remaining of them present in time from day 1 to 30 days after surgery and this depends on the site and type of bowel injuries. Post-operatively, antibiotic use and narcotic medications for

post-operative pain may mask the classical symptoms and may pose a diagnostic dilemma for even the most experienced surgeon. Small bowel injuries usually occur between 2 to 14 days while colon injuries tend to occur between 1 to 29 days.

Considering all these facts, this patient may have the index case following laparoscopic surgery and delay in the diagnosis in a perforation take little longer time and she had to be handled by general surgeon that with a long procedure.

4. Now going through the above materials and the case of the complainant coupled with what transpires from the affidavit of Dr. Debashis Roy, it tends to make a case of medical negligence on the part of the Dr. Archana Sinha, which is beyond the purview of section 38 of the West Bengal Clinical Establishments, in terms of first proviso to sub section (iii) thereof. It is an admitted position that the complainant has already approached both the West Bengal Medical Council and for compensation the West Bengal State Consumer Forum.

Even then the hospital Apollo cannot be absolved of charge of deficiency in service. The patient was not a direct patient of Dr Archana Sinha. She came to the outdoor patient department of the Apollo and from there, she was referred to Dr. Sinha. Following that on June 20, 2017, Dr. Sinha performed hysterectomy + bilateral salpingo-oophorectomy+adhesiolysis + vaginal morcellation under GA. The patient was admitted on a 6 day package and although she was complaining of various complications, she was discharged on June 22, 2017, 3 days before the package period was over. Thereafter, when she on June 24, 2017 was readmitted at the hospital, Dr. Sinha failed to appreciate seriousness of post operative complications like gut perforation in due time between 24-26 June, 2017 and only referred the patient to Dr. Debasis Roy only on June 26, 2017 and by that time the patient had to undergo severe suffering, pain and distress and it was Dr. Roy who performed Hartmann's Procedure on June 26, 2017 to rectify the post-surgery complications.

We find that Dr Archana Sinha obtained her MS (OBG), a post-graduate degree from Patna Medical College and Hospital. Although she was registered with Indian Medical Council for her MBBS but not registered with the West Bengal Medical Council for her MS and we have been informed with supporting materials that she has applied before the West Bengal Medical

Council for registration of her additional qualification. Other than the certificate of All India Institute of Medical Sciences that she underwent an Endoscopy training in Minimally Invasive Gynaecology at Obstetrics and Gynaecology Department of the said institute from 22.02.2016 to 27.02.2016 for 6 days that was the only hand-in-training course she attended. Other documents produced indicates that she attended and participated as delegate in different endoscopy workshops. Dr. Sinha claimed to have performed and conducted 80 surgeries at Apollo from March 2015 till December 2017 but considering list furnished by him we find approximately laproscopy surgery around 25 in number. Beside that no information was furnished under the guidance of which particular senior surgeon she started to perform laproscopic surgery. In the above backdrop, we are of the opinion that the Apollo be well advised to engage and employ more trained surgeons for performing this kind of major invasive surgery.

5. It is an admitted position that Apollo in the process of making bonafide efforts to rectify the lapses committed in the first surgery by Dr. Sinha, free of cost. The Hartmann's Procedure was performed at Apollo to rectify the post surgery complication and that was done free of cost for which she remain admitted at Apollo from June 24, 2017 to July 24, 2017. Thereafter she has already undergone reversal of Hartmann's Procedure that too also free cost and remain admitted at Apollo from January 7, 2018 to January 24, 2018 and her medical condition is improving day by day. By affirming an affidavit, the Apollo has also undertaken that any clinical issues which might arise out of the said surgery will be addressed by the hospital at their cost and no such treatment related cost will be claimed from the patient. Since Apollo has undertaken that in future if any complication arises out of the first surgery performed by Dr. Sinha that would be taken care of by them free of cost and all follow up including need-based surgical intervention if any would be done at free of cost, in the light of the object and salutary purpose of awarding compensation, it may not be justified on the part of the Commission to award any further compensation.

5. We, however, make it clear that if in future Apollo declines to keep its promise as averred in the affidavit and refuses to give free medical care to the service recipient for any

complications arising out of first laparoscopy then in that case the complainant or the service recipient shall have the liberty to approach this Commission for necessary order.

6. Last but not the least, Apollo, the clinical establishment should be very careful and cautious about selection of consultants at entry level with due consideration of his or her skill, experience with training and proper accreditation from recognized centers for invasive surgical intervention and no untrained and inexperienced persons shall be engaged for performing any surgical operation or invasive procedure at their institution.

With the above observation, this case in hand stands disposed of.

Sd/-
Justice Ashim Kumar Roy
Chairperson.

Sd/-
Dr. Sukumar Mukherjee, Member.

Sd/-

Dr. Gopal Krishna Dhali, Member.

Sd/-

Dr. Makhan Lal Saha, Member.

Sd/-

Dr. Madhusudan Banerjee, Member.

Sd/-

Dr. Maitrayee Banerjee, Member.

Authenticated

West Bengal Clinical Establishment Regulatory Commission ★ Kolkata-1

6/2/2018

Secretary
W.B.C.E.R.C.
Kolkata-1