Judgment 2.

National Consumer Disputes Redressal Commission, New Delhi

Manmohan Kaur …Appellant
Versus
M/s. Fortis Hospital &Ors. …Respondents

Before:-
Hon'ble Mr. Justice R. K. Agrawal, President
Mrs. M. Shreesha, Member

Dated: 29th June 2018

Order: -

1. The challenge in this First Appeal, under section 19 of the Consumer Protection Act, 1986 (for short "the Act"), by the Complainant, is to the order, dated 07.09.2015, passed by the Punjab State Consumer Disputes Redressal Commission at Chandigarh (for short "the State Commission"), in Consumer Complaint No. 58 of 2013. By the impugned order, the State Commission has dismissed the Complaint, inter-alia, holding that there was no negligence on the part of Respondent No. 2/Opposite Party No. 3 in the Complaint, while performing colonoscopy procedure on the Complainant.

2. Succinctly put, the facts, giving rise to the present Appeal, as culled out from the Complaint, are as follows:
2.1. In the month of December, 2006, the Complainant, a lady, aged about 55 years, started having stomach pain and disorder in the digestive system (irritation in the stomach/food pipe). She consulted one Dr. Neeraj Nagpal at Hope Gastrointestinal Diagnostic Clinic, Chandigarh. Treatment continued between the period from February, 2007 and April, 2008. Since, she did not get complete relief, she went to M/s Fortis City Centre, Sector-9, Chandigarh, Opposite Party No. 2 in the Complaint and consulted Dr. Arvind Sahni(for short "the Treating Doctor"), Opposite Party No. 3, in the Complaint, in the month of May, 2008. Even though the Complainant took treatment for about nine months and underwent several diagnostic tests, including Gastroscopy, she did not get complete relief. Then, she consulted another Specialist, Dr. Sandeep Dhavan at Dhavan's Jeevandeep Nursing Home at Chandigarh, where also she was subjected to several tests, including Video UGI Endoscopy on 29.07.2011 and 03.03.2012. Still she did not get complete relief.
2.2. On 16.05.2012 the Complainant again consulted the Treating Doctor, who advised her to undergo various tests from time to time, including blood tests, Histopathology, Endoscopy, Barium tests, food allergy tests. On 20.06.2012, the Treating Doctor advised her full-length colonoscopy to rule out colonic malignancy or colitis. MRCP was done on 21.06.2012. According to the Complainant, though she was reluctant to undergo colonoscopy as it was an invasive procedure, performed with the help of a Colonoscope through the anus, but on the assurance of the Treating Doctor that it was a safe procedure and no harm would be caused to her, she agreed for the said test. Colonoscopy procedure was ultimately planned for 04.07.2012.
2.3. As advised on 02.07.2012, the Complainant took Peglec powder on 03.07.2012, to clean the colon. Colonoscopy procedure was conducted on 04.07.2012 by the Treating Doctor. According to the Complainant, on insertion of colonoscope, she felt severe pain and requested the Treating doctor to discontinue the procedure. However, it was not stopped, which resulted in perforation in the colon, resulting in deterioration in her condition. Her abdomen swelled like a football; there was acute pain; and she became unconscious, necessitating her transfer to the ICU. She was put on oxygen and other devices/life-saving drugs.
2.4. The Treating Doctor informed the family members of the Complainant that it was a case of pneumoperitoneum, which required Exploratory Laparotomy to save her life. The said operation was conducted in emergency by Dr. J.D. Wig, a Surgeon, Opposite Party No. 4 in the Complaint. As per the operation notes the pain/distension in the abdomen was felt by the Complainant immediately after

the Colonoscopy procedure: on opening of the abdomen, a perforation of the size 0.5 x 1.0 c.m. was noticed in the sigmoid colon, resulting in pneumoperitoneum (collection of air in peritoneal cavity), which was sealed by performing the said surgical procedure. Before the procedure, she was asked to deposit a sum of 1,30,000/-. The Complainant remained admitted in the hospital for 5 days. Some further amounts were charged at the time of discharge, which the Complainant claims to have paid under protest.

2.5. In the said background, alleging medical negligence on the part of the Treating Doctor on account of:

(i) in not taking due precautions while performing colonoscopy on 04.07.2012, by use of force while inserting the colonoscope;

(ii) not abandoning it when she complained of acute pain;

(iii) prescribing unnecessary investigations, like abdomen CT, bone mineral density etc. in order to make money;

(iv) the test reports as well as the prescription slips did not correlate with each other; (v) charging excess amounts by Fortis Hospital, Opposite Party No. 2, (for short "the Hospital") under several heads,

(v) the Complainant was still under treatment and was unable to lead normal life, inasmuch as she was unable to walk properly and take proper food: her capacity to work had also decreased, and she had become dependent on others, the afore-noted Complaint came to be filed before the State Commission.

The Complainant prayed for a direction to the Opposite Parties, to pay to her, jointly and severally a total compensation of 51,73,565/- under different heads, along with interest @ 18% p.a. from the date when Colonoscopy was done i.e. 04.07.2012, till realization, as also a sum of 25,000/- towards litigation costs.

3. Upon notice, all the Opposite Parties contested the Complaint. The allegations in the Complaint were contested by all the Opposite Parties. A common Written Version was filed on behalf of the Hospital and Dr. J.D. Wig. The Treating Doctor, Dr. Arvind Sahni, filed his separate Written Version. No Written Version was, however, filed on behalf of Escorts Heart Institute & Research Centre, New Delhi/Opposite Party No. 1. Instead, an application for deletion of its name from the array of parties, was filed but the same was never pressed. Nevertheless, in these proceedings, on the oral prayer made on behalf of the Complainant, vide order dated 12.05.2016, the said hospital was deleted from the array of parties name.

4. In their Joint Written Version, the Hospital and Dr. Wig contested the Complaint on diverse grounds, which included preliminary objections to the very maintainability of the Complaint, on the ground it was frivolous and vexatious: filed in order to malign and blackmail them: it was bad for non-joinder and mis-joinder of necessary parties, in as much as Escorts Heart Institute & Research Centre, New Delhi, had no role to play in the case and there was also no allegation against Dr. Wig, the General Surgeon. On merits, while admitting that the Complainant was under their treatment for stomach pain since December, 2006 as she had problem with her digestive system, and on 04.07.2012 Colonoscopy procedure was conducted on her, it was, inter alia, pleaded that the said procedure was conducted as per standard procedure and protocol accepted all over the world; she had consulted the Treating Doctor for the first time in the month of May, 2008; though she continued treatment till November, 2008, but did not get complete relief from her problems; she had also taken treatment from other Doctors, including Dr. Neeraj Nagpal at Hope Gastrointestinal Diagnostic Clinic, Chandigarh, from February, 2007 to April, 2008, and Dr. Sandeep Dhawan at Dhawan Jeevandeep Nursing Home, where two Video GI Endoscopies were conducted on her on 29.07.2011 and 03.03.2012; when she did not get any relief, she again consulted the Treating Doctor on 16.05.2012; taking into consideration the fact that she was suffering from abdominal pain since the year 2006, the Treating Doctor advised various tests, including Colonoscopy, to detect ulcer, colonpolyps, tumor and areas of inflammation or bleeding, as also screening for any malignancy in the colon or rectum; as per the report, Sigmoid Diverticulum were noticed in the sigmoid colon area; the Complainant never requested for discontinuance of the colonoscopy procedure nor she was unconscious. As regards the pain, which the Complainant complained of, there were contradictory statements in the Complaint, in as much as, while in para-5 of the Complaint, the Complainant had stated that it was during the

procedure that she felt pain and asked for discontinuance of the procedure but in para-6, she had averred that she had felt pain after the colonscopic procedure. In fact, it was only after the procedure was completed that she showed signs of pain and distension in the abdomen, which was immediately attended to. Thereafter, the Complainant was taken for x-ray, which showed pneumoperitonaeum (air in the abdominal cavity). She was immediately admitted as an indoor patient and, after managing her condition with a number of medicines - IV as well as oral, she was taken for surgery by the General Surgeon, under general anesthesia, as there appeared to be a sigmoid perforation. The said operation was conducted without any post-operative complications: the Complainant was stable, and was discharged on 09.07.2012. When the Complainant came for follow-up, her clips were removed and the wound had healed. It was pleaded that Sigmoid perforation during Colonoscopy, is a well-documented complication, which was managed as per the standard protocol, accepted all over the world: she was immediately attended to and treated accordingly: no medical procedure, major or minor, is devoid of risks: complications do occur in the best of institutions during the course of medical or surgical treatment and it can, in no manner, be termed as a negligent act on the part of the Doctor: the Treating Doctor is well-qualified to handle the case and he did so correctly; and the complication was promptly diagnosed and a known and well-documented medical procedure was followed by the General Surgeon. It was asserted that tested on the touchstone of the principle laid down in --Bolam v. Friern Hospital Management Committee, (1957) 1 WLR 582], the Opposite Parties were not guilty of any kind of negligence, as the Treating Doctor and the General Surgeon had acted in accordance with an accepted and proper practice, recognized all over the world: while the Treating Doctor, a very qualified Gastroenterologist, having vast experience of performing 35000 endoscopy/ colonoscopy procedures successfully, had been in practice since 1984; Dr. Wig, the General Surgeon, had been the Head of Surgery, PGIMER, Chandigarh; no doctor would intentionally commit an act of omission which would result in loss and injury to a patient. As per the law laid down by the Hon'ble Supreme Court, a medical professional can be held guilty of negligence only if he is not in possession of the requisite skill which he professes to have possessed or he did not exercise with reasonable competence in a given case, the skill which he did possess, it is not the case of the Complainant that the Doctors of Hospital did not possess the skill to conduct the procedure and surgery, nor it was the case where the Doctors had not exercised the skill possessed by them. As regards the allegation relating to over-charging, it was stated that as against the approximate treatment cost of 1,30,000/-, final bill amounting to 1,23,565/-, after accounting for Senior Citizen discount, amounting to 4830/-, was prepared and balance amount was paid/refunded to the Complainant at the time of her discharge, which shows that she was rightly charged towards the treatment given to her and no excess charges were levied. Further, it was averred that it was not understandable as to in what context the Complainant was stating that there was no correlation between the test reports and the prescription slip. As regards negligence and use of force by the Treating Doctor, it was pleaded on behalf of the answering Opposite Parties that various studies carried out on colonoscopic perforations clearly reveal that several factors make the bowel segment vulnerable to injury. These factors include a sharp angulation at either the rectosigmoid junction or the sigmoid-descends colon junction and the great mobility of the sigmoid colon. Further, diverticulum formation and pelvic adhesions are also contributory factors leading to incidents of sigmoid perforation. As regards the allegation that the Complainant was unable to walk properly and take her proper food etc., it was averred that no prescription of any doctor, stating the said fact, had been produced by the Complainant. In fact she had been visiting the Treating Doctor post-operatively as well and had been walking normally to his clinic and hence, the Complaint was wholly devoid of any merit and deserved to be dismissed.

5. The Written Version filed on behalf of the Treating Doctor being almost repetition of the afore-said Written Version, we deem it unnecessary to burden the order by repeating his defence.

6. On appraisal of the evidence adduced by the parties before it, the State Commission has dismissed the Complaint, observing thus:
"8. In view of the allegations made in the complaint it is necessary to understand as to what is colonoscopy and in what circumstances the same is to be performed. As defined in DORLAND's ILLUSTRATEDMEDICAL DICTIONARY (31 ST EDITION), "Colonoscopy" is the examination by means of colonoscope. A colonoscope is an elongated flexible endoscope for visual examination of the entire colon; called coloscope. As per available literature and which has formed part of the record,

since the introduction of colonoscopy into clinical medicine, flexible fiber-optic colonoscopy has had a great impact on diagnosis and management of diseases of the colon and rectum. This colonoscopy has the complications as have been laid down in various books by different authors. However, over the last three decades, advances in endoscope design, bowel preparation, and the array of instruments and techniques available have made colonoscopy one of the safest of invasive procedures. Complications and adverse effects still happen, of course, but their frequency is low. Complications can occur during both intubation or extubation of the colon. Usually, most traumatic damage is done on the way in and most therapeutic damage is done on the way out. Some complications, such as perforation (as the case is in the present complaint), can be done either way. The ideal colonoscopic technique is gentle, unhurried, and efficient, using an economy of action and minimizing loops. Patients with disease colons are more likely to have a perforation and so the incidence of perforation in completely normal colons is tiny. Colonoscopists must be aware of situations in which the risk of perforation is increased. As per the "Complications of Colonoscopy" by Dr. Owen Epstein, colonoscopy is a highly efficient imaging modality but by its nature it is invasive and thus carries with it an intrinsic potential for a range of adverse events ranging from quite mild right upto and including death. Every colonoscopy should, therefore, be performed by a fully trained operator or by a trainee with close support.

9. Opposite Party No.3, who had done the colonoscopy, proved on record his affidavit Ex. OP-3/A. It is very much clear from his affidavit that he is an expert in the field. He is Director of Gastroenterology in the opposite party-Hospital. He deposed in the affidavit that he is very qualified Gastroenterologist having vast experience of doing endoscopic procedures. Till date he has done approximately 35000 procedures (endoscopy/colonoscopy) successfully. He made the complete Curriculum Vitae Ex. OP3/2 part of his affidavit. As per that document, he is MBBS, MD, DM, MRCP (UK), FRCPE. He had been Junior Resident in the PGI from 1984 to 1987 and then as a Senior Resident in the same Institute upto 1990. Then he had been Registrar at Royal Belfast Hospital, U.K., and thereafter he had been doing the job at different places and he was Gold Medalist in Final Professional at CMC, Ludhiana. There is no doubt from his qualification and experience that he was well qualified and experienced to conduct the colonoscopy.

10. It is very much clear from the evidence produced by the complainant herself that the colonoscopy had become must for the diagnosis of her disease, as she had undergone endoscopy and other clinical and hospital tests and the cause of her abdomen pain was not diagnosed and she was not relieved of the same. She was suffering from the same since the year 2006.

11. It cannot be made out from the evidence produced by the complainant that she had not consented to undergo this colonoscopy. She deposed in her affidavit Ex.CA that opposite party No.3 suggested this test on 20.6.2012 and the other test (MRCP), which was got done on 21.6.2012. She herself gone for colonoscopy on 4.7.2012. She has nowhere stated in her affidavit that she never consented for this colonoscopy but has tried to depose that she was hesitant to undergo the same being an invasive test done with the help of colonoscope through anus and that opposite party No.3 had assured that no harm shall be done and it is on his assurance that she agreed to go for the test. That clearly proves that she consented for this colonoscopy.

12. Was opposite party No.3 bound to disclose the complications of the test to the complainant? In respect thereof, learned counsel for the opposite parties has placed reliance on Queen's Bench Division judgment rendered in Bolam's case (supra). In that case Bolam was suffering from mental illness of depressive type and was advised by the Doctor attached to the respondent-Hospital to undergo elctro-convulsive therapy. Prior to the treatment, Bolam signed a form of consent to the treatment but was not warned of the risk of the fracture involved. Even after the treatment Bolam did not sustain any fracture but when the treatment was taken second time he sustained fractures. No relaxant drugs or manual control were used except that a male nurse stood on each side of the treatment couch throughout the treatment. About that treatment there were two bodies of opinion, one of which favoured the use of relaxant drugs or manual control as a general practice, and the other opinion was for the use of drug that was attended by mortality risks and confined the use of relaxant drugs only to cases where there are particular reasons for their use and Bolam case was not under that category. It was held by the Queen's Bench that the Doctors were not negligent and the following principle was laid down:-

"A Doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art."

It becomes clear from the reading of this judgment that for not warning of the risk involved in the procedure by the Doctor does not amount to negligence. This Bolam's test was accepted by the Hon'ble Supreme Court as providing the standard norms in cases of the medical negligence. This very judgment was discussed by the Hon'ble Supreme Court in V. Kishan Rao v. Nikhil Super Speciality Hospital & Another [2010(5) SCC 513]. It was laid down therein that the Bolam Test has not been uprooted, though it came under some criticism. In England that test is now considered merely a rule of practice or of evidence and not a rule of law but that Test was accepted as correctly laying down the standards for judging the cases of medical negligence in Jacob Mathew v. State of Punjab (2005) 6 SCC 1. Thus, the non-explaining of the risk involved in the test by opposite party No.3 does not amount to medical negligence on his part. No such medical literature was brought to our notice nor any judgment was cited on the point that non-disclosure of such a fact amounts to medical negligence on the part of the Doctor.

13. A number of judgments mentioned above have been cited by the learned counsel for the opposite parties. However, except the judgment in Bolam's case (supra), no other judgment is relevant in the present case keeping in view the submissions raised by the complainant and which have been noted in para No.6.

14. In view of the literature on the "Complications involved in colonoscopy" it (sic) was necessary for opposite party No.3 to stop the procedure as soon as the complainant complained of pain. The question of fact arises, as to whether the complainant complained of such pain during that colonoscopy? In her affidavit Ex.CA she deposed that during the procedure of colonoscopy, opposite party No.3 did not take all the precautions duly required from a specialist and as a result thereof, there was rupture on the portion of the colon, which she could feel immediately in the form of severe pain, which was neglected by the Doctor but despite repeated requests by her did not discontinue the procedure. That fact was duly denied by opposite party No.3 in his affidavit Ex.OP3/A. The deposition made by that Doctor stands corroborated from the report prepared by him and which was proved on the record by the complainant herself as Ex.C16 and the Discharge Summary Ex.C17. It is very much clear from the Discharge Summary that after the colonoscopy the complainant was conscious and well oriented to time, place and person. She never disclosed at that time that during colonoscopy she had pain and opposite party No.3 continued with the procedure inspite of the complaint made by her. It cannot be believed that a Doctor with such qualification and experience will continue with a procedure, which was causing pain to the patient.

15. No expert evidence was produced by the complainant in support of her contentions made in the complaint in order to assess the situation and to determine the medical negligence on the part of opposite party No.3. This Commission, vide order dated 7.6.2013 sought the expert opinion from the PGIMER, Chandigarh. The Director of that Institute was asked to send some expert Doctor in Gastroenterology to give his expert opinion. Dr. S.K. Sinha, Additional Professor, Department of Gastroenterology was deputed, who produced on record the expert opinion and the same was tendered in evidence by the complainant as Ex.C-21. Thus, she is relying upon this expert evidence.

16. For proper appreciation of the act, so attributed to opposite party No.3 by the complainant and which according to her amounts to medical negligence the said expert opinion is reproduced below:-

"Subject: Regarding expert opinion.

Sir,

Reference your letter No. SCDRC/PB/13/8214 dated 19.06.2013 on the subject noted above and seeking expert opinion thereupon.

As per the provided records, colonic perforation was detected on the same day on which colonoscopy was performed. Chronologically, the two events seem to be related. Colonic perforation is a rare but known complication of colonoscopy. As per the available medical literature, various risk factors have been identified for colonic perforation following colonoscopy; some are related to conditions from which patients are suffering while others are related to the equipment and operator. Patient related risk factors for colonic perforation during colonoscopy include presence of colonic diverticula or colonic diverticulitis(as per the provided records, the index patient has been reported to have this), deep ulcers in colon, adhesion of colonic loops (the index patient has been reported to have this), presence of necrotic or gangrenous segment in bowel etc. As to the factors related to equipment and excessive use of force by the operator or poor colonoscopy technique, it is not possible to make out from the records and thus it is not possible to comment on these factors. But occurrence of colonic perforation during colonoscopy is not always solely due to use of excessive force by operator or poor

technique of operator, there are multiple factors which determine such an event in a given clinical setting. Timely recognition of such complications is important and determines the final outcome.
Thanking you.
Yours sincerely

Sd/- 26.7.2013	Sd/- 26.7.2013
Dr. S.K. Sinha	Prof. Kartar Singh
Additional Professor	Head
Deptt. of Gastroenterology	Deptt. of Gastroenterology
PGIMER, Chandigarh	PGIMER, Chandigarh."

This report makes it crystal clear that the colonic perforation is rare but known complication of colonoscopy. In the case of the complainant, the same was on account of her own physical condition. So far as the use of excessive force by opposite party No.3, during that procedure is concerned, there is no such evidence produced by the complainant on the basis of which it may be said that he used more or excessive force during that procedure nor the same can be made out from the said report. It is not even the case of the complainant so pleaded in the complaint. It becomes clear from this expert report that opposite party No.3 was not to be blamed for that colonic perforation.

17. The present case stands totally covered by the recent judgment given by the Hon'ble Supreme Court in Mrs. Kanta v. Tagore Heart Care and Research Centre Pvt. Ltd. and another 2014(4) R.A.J. 490. In that case the Doctor had performed angiography. The complainant alleged that during the angiography procedure she felt severe pain in the abdomen and brought the said fact to the notice of the Doctor but he ignored the same and continued with the procedure. The opinion of Dr. Trehan was obtained in that case and he opined that aorta dissection had taken place during the angiography procedure done by the said Doctor. The complainant filed the complaint alleging medical negligence on the part of that Doctor while conducting angiography resulting into dissection of aorta. The question arose, as to whether the same was the result of any negligence or rash act committed by the Doctor while conducting the angiography? It was found that the complainant was found stable after third day of angiography and no emergency operation was done. It was held that it was probable that due to such associated causes the passage of the catheter through aortic space was not smooth. There was no material to infer that Doctor had taken any adventurous step. There was nothing on the record, which pointed out that the Doctor used any brutal force to push the catheter. The mere completion of the angiography does not rule out aorta dissection during the procedure.

18. In the present case also the colonic perforation is alleged to have been done during colonoscopy and there is no evidence on the record that opposite party No.3 used excessive or more force, as required for conducting the same. The condition of the complainant was such that perforation was the natural result of that colonoscopy, which was being done for diagnosing the exact ailment. In all these circumstances it cannot be held that opposite party No.3 was guilty of medical negligence."

(Underlined for easy reference and emphasis).

7. Hence, the present Appeal.

8. From the afore-extracted paragraphs of the impugned order, it is apparent that the final conclusion of the State Commission to the effect that the Treating doctor was not guilty of medical negligence, is based on the following findings on points of law and facts: (i) the Complainant had given consent for colonoscopy; (ii) non-explaining of the risk involved in the procedure by the treating doctor did not amount to medical negligence on his part; (iii) after the colonoscopy, the Complainant was conscious and well oriented to time, place and person but she did not disclose to the Treating doctor that during the procedure she had pain and he continued with the procedure in spite of her request to stop it; (iv) report of the Experts makes it clear that the Colonic perforation is rare but known complication of colonoscopy; (v) the perforation was on account of Complainant's own physical condition and a natural result of the colonoscopy and (vi) there was no evidence on record to show that the Treating doctor had used more or excessive force as necessary for conducting the procedure.

9. Questioning the legality and correctness of the impugned order, Mr. Siddharth Mittal, Learned Counsel appearing for the Complainant, strenuously urged that the finding by the State Commission to the effect that the Complainant had given her consent before colonoscopy procedure was

performed is ex-facie perverse, in as much as no documentary evidence in that behalf has been produced by the Opposite Parties, despite specific direction in these proceedings. It was argued that non-production of the consent form, on the plea that the same was destroyed due to water seepage, is an afterthought. Rather the said stand goes to show that no such consent was ever taken from the Complainant before subjecting her to colonoscopy. Pressing into service the decision of the Hon'ble Supreme Court in Samira Kohli Vs. Dr. Prabha Manchanda (2008) 2 SCC 1 and the decisions rendered by this Commission in Sita Ram Bhartia Institute of Science and Research Vs. Vidhya Bhushan Jain &Ors. II (2017) CPJ 580 (NC) and in Suresh Chandra Mytle & Anr. Vs. United India Insurance Company Ltd. (RP No. 2115/2015), Learned Counsel stressed that apart from the mandatory legal requirement of obtaining informed consent from the Complainant, the consent, if obtained, was neither real nor valid, since the Complainant had to be explained the risk involved in the invasive procedure, like Colonoscopy; it should have been voluntary and based on adequate information about the procedure, which, admittedly was never done by the treating doctor. It was pleaded that the observations by the State Commission to the effect that non-explaining of the risk involved in the procedure by the Treating doctor to the Complainant, did not amount to medical negligence, is in the teeth of the ratio of the afore-noted decisions. It was pleaded that in fact the said observation by itself proves the negligence of the Treating Doctor as well as the Hospital. Relying on medical literature, Learned Counsel contended that the ideal colonoscopic technique is gentle, unhurried and efficient: using an economy of action and minimizing loops: 'pushing through' or 'sliding-by' are high risk manoeuvres and should be used as a last resort: pain is a sign to stop pushing: the pain should act as a 'red flag.' But in the present case the stated standard protocol on the subject was ignored by the Treating doctor in conducting the procedure. It was asserted that in the instant case the discharge summary, wherein it is noted that "pain abdomen and distention immediately after sigmoidoscopy, increased abdominal distention was noticed after colonoscopy. Abdominal X-ray showing pneumoperitionaeum" shows that the Complainant suffered pain in abdomen immediately after sigmoidoscopy and increased abdominal distention after colonoscopy. According to the Learned Counsel, under these circumstances the Treating doctor should have abandoned the procedure but his continuing with it resulted in perforation, for which the Complainant had to undergo a life saving surgery. Finally, it was argued that the reliance placed by the State Commission on the report of the Experts, to reach the conclusion that perforation was on account of Complainant's own health condition, is also misplaced in as much as the Experts have merely stated that it is not possible to make out from the record that the perforation occurred due to excessive force or poor colonoscopy technique, which cannot be treated as conclusive.

10. Per contra , Ms. Alka Sarin, Learned Counsel appearing for the Respondents/Opposite Parties, while steadfastly supporting the afore-stated findings in the impugned order, contended that since neither in the Complaint nor in the pleadings as also in the evidence there was any allegation that the consent of the Complainant was not taken and this point was raised only during the course of oral arguments, before the State Commission and hence the Respondents were deprived of an opportunity to bring material on record to prove that the consent form was destroyed in a water seepage in the record room. It was submitted that in the light of a clear admission in the Complaint to the effect that on the assurance of the Treating doctor, "the Complainant agreed to go for the test", the Respondents were not required to prove the factum of consent. It was asserted that colonoscopy being an OPD procedure, her consent was 'got signed by the staff' in the OPD room (No. 167) and was kept together with the other consent forms of other Patients, in the colonoscopy/endoscopy room, till the time these are transferred to the medical room. Relying on several decisions, rendered by the Hon'ble Supreme Court, particularly in Jacob Mathew Vs. State of Punjab &Anr. (2005) 6 SCC 1 and by this Commission, laid down the basic principles to be borne in mind while examining the allegation of medical negligence against the medical professional, it was stressed that the Complainant was treated in accordance with the highest standards of medical practice and therefore, no deficiency of service or negligence, could be attributed to the Respondents.

11. Before adjudicating upon the core issue of consent, on which there is serious differences between the parties, the objection raised by Learned Counsel for the Respondents to the effect that the State Commission should not have entertained and decided the question of non-obtaining of the consent before performing the colonoscopy procedure, needs to be addressed. Although it may be

true that the said point was not explicitly raised in the Complaint but having failed to raise any objection in this regard during the course of hearing before the State Commission or seeking permission to adduce additional evidence in support of the plea that informed consent had in fact been obtained from the Complainant but the relevant document got destroyed because of water seepage, it is too late in the day for the Respondents to raise such a plea at this stage. The objection is rejected accordingly.

12. In the light of the aforestated rival submissions, on behalf of the parties, the first and the foremost issue arising for consideration is whether or not 'informed consent' as understood in the legal and medical parlance, was obtained from the Complainant before subjecting her to colonoscopy procedure?

13. The question pertaining to 'consent' has two limbs:- (i) whether consent of the patient before performing the colonoscopy procedure, is at all necessary and (ii) if so, whether in the present case, a valid consent was taken.?

14. The doctrine of Consent, stems from the notion that every adult human body, with a sound mind, has a right of self-determination and personal autonomy to decide what shall be done with his own body, a fundamental aspect of the right to health - the basic principle, which permeates through all cases. As we shall notice hereafter, Consent is not a mere acceptance of a medical intervention, but a voluntary informed decision by the patient, whether or not to opt for a particular medical procedure. It may be conceded that while Consent by the Patient for simple procedures may sometimes be implied but it needs little emphasis that invasive treatments do require explicit Consent. Therefore, the question for consideration is whether Colonoscopy is an invasive procedure.? We may note that in so far as this aspect of the case is concerned, both the counsel seemed to be ad-idem that the consent of the Complainant was required to be taken before undertaking the said procedure. Hence, in so far as the first limb of the question is concerned, being a medical invasive procedure, performed on a live body, we have no hesitation in reaching the conclusion that a valid/informed consent was required to be obtained from the Complainant before subjecting her to colonoscopy procedure. Gravamen of the controversy between the parties is whether consent was at all taken and if taken, whether it was a valid consent?

15. Based on the developments, domestically and internationally on the point, the word "consent" has now assumed the nomenclature as "informed consent". The Bolam (supra) test, accepted and applied in a catena of pronouncements by the Hon'ble Supreme Court, as a measure of doctor's duty to disclose information to the patient about potential consequences and risks of proposed medical treatment/diagnostics, has undergone a radical change in the Country of its origin, viz; the United Kingdom, in Montgomery Vs. Lanarkshire Health Board, Scotland – (2015) UKSC 11. Inter-alia, observing that there is no reason to perpetuate the application of the Bolam (Supra) test, it has been observed as under:
"An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.
The doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient's health. The doctor is also excused from conferring with the patient in circumstances of necessity, as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision."

16. Nevertheless, in so far as our country is concerned, the concept/principle of "consent", "informed consent" or "real consent" whatever expression one may like to use, is to be examined on

the touchstone of the principles lucidly enunciated in Samira Kohli (Supra). Speaking for a three Judge Bench, R.V. Raveendran J, culled out the principles as follows:-

"(i) A doctor has to seek and secure the consent of the patient before commencing a "treatment" (the term "treatment" includes surgery also). The consent so obtained should be real and valid, which means that: the patient should have the capacity and competence to consent; his consent should be voluntary; and his consent should be on the basis of adequate information concerning the nature of the treatment procedure, so that he knows what he is consenting to.

(ii) The "adequate information" to be furnished by the doctor (or a member of his team) who treats the patient, should enable the patient to make a balanced judgment as to whether he should submit himself to the particular treatment or not. This means that the doctor should disclose

(a) nature and procedure of the treatment and its purpose, benefits and effect;

(b) alternatives if any available;

(c) an outline of the substantial risks; and

(d) adverse consequences of refusing treatment. But there is no need to explain remote or theoretical risks involved, which may frighten or confuse a patient and result in refusal of consent for the necessary treatment. Similarly, there is no need to explain the remote or theoretical risks of refusal to take treatment which may persuade a patient to undergo a fanciful or unnecessary treatment. A balance should be achieved between the need for disclosing necessary and adequate information and at the same time avoid the possibility of the patient being deterred from agreeing to a necessary treatment or offering to undergo an unnecessary treatment.

(iii) Consent given only for a diagnostic procedure, cannot be considered as consent for therapeutic treatment. Consent given for a specific treatment procedure will not be valid for conducting some other treatment procedure. The fact that the unauthorized additional surgery is beneficial to the patient, or that it would save considerable time and expense to the patient or would relieve the patient from pain and suffering in future, are not grounds of defence in an action in tort for negligence or assault and battery. The only exception to this rule is where the additional procedure though unauthorized, is necessary in order to save the life or preserve the health of the patient and it would be unreasonable to delay such unauthorized procedure until patient regains consciousness and takes a decision.

(iv) There can be a common consent for diagnostic and operative procedures where they are contemplated. There can also be a common consent for a particular surgical procedure and an additional or further procedure that may become necessary during the course of surgery.

(v) The nature and extent of information to be furnished by the doctor to the patient to secure the consent need not be of the stringent and high degree mentioned in Canterbury but should be of the extent which is accepted as normal and proper by a body of medical men skilled and experienced in the particular field. It will depend upon the physical and mental condition of the patient, the nature of treatment, and the risk and consequences attached to the treatment."

17. Thus, fundamentally, the law requires the disclosure to the patient, information relating to the diagnosis of disease: nature of the proposed treatment: potential risks of the proposed treatment and the consequences of the patient refusing the suggested line of treatment. Disclosure/explanation of such information to the patient by the Treating doctor and the patient's conscious decision, in this behalf, before venturing into the suggested procedure/treatment, is the basic attribute of an informed consent, which is considered mandatory in every field of surgical procedure/intervention. The only exception to this general rule is the emergency medical circumstances, where either the patient is not in a medical condition or mental state to take a conscious decision in this regard.

18. Bearing in mind the aforesaid principles relating to the basic doctrine of informed consent, it is time to advert to the second limb of the issues framed above. On facts at hand, the issue again needs to be examined in two parts, viz. (1) whether consent was infact taken from the Complainant and (2) if so, whether it meets the afore-noted standards, for being accepted as informed consent, as understood in the legal parlance?

19. As stated above, the stand of the Complainant has been that no consent was taken from her by the Treating doctor before subjecting her to colonoscopy. Whereas, the Respondents claim that it was taken but they were and are unable to produce the same because the form had been destroyed

due to water seepage in the room where it was kept along with other records. Since, during the course of hearing in the Appeal, it was asserted on behalf of the Complainant that the cause pleaded for non-production of the consent form was an afterthought to cover the lapse on the part of the Treating doctor, in not taking any informed consent, vide order dated 15.01.2018, the Respondents were directed to furnish on affidavit, by the Facility Director of the Hospital, information on the following points:-

"1. When strangely almost all documents, pertaining to the case, including the O.T. notes/Discharge Summary etc., maintained by the Hospital were available and filed, how only one solitary document, viz. the Consent Form, stated to have been obtained from the Complainant before subjecting her to Colonoscopy, is claimed to have been destroyed in the water seepage?

2. When in the O.T. notes, prepared before the procedure for Sigmoidoscopy was performed, it is clearly recorded that the consent had been obtained from the Complainant, why such an endorsement was not made in the O.T. notes at the time of subjecting her to Colonoscopy?

3. Why in the Discharge Summary, the cause of perforation during the Colonoscopy procedure was not recorded?

20. In pursuance thereof, an affidavit of Mr. Abhijit Singh, Facility Director of the Hospital was filed on 15.02.2018. The relevant portion of the explanation furnished on point (1) above, reads as follow:-

"It is submitted that OPD records and the IPD records are maintained separately. The IPD record starts with the time the Appellant was moved as an IPD patient and her triage history and physical sheet was recorded at 1 PM. Thereafter, as per protocol all documentation were prepared and consents taken. The documents pertaining to the case including the OT notes/Discharge summary etc. were maintained in the IPD file of the Appellant. Colonoscopy being an OPD procedure is conducted in Room No. 167 by Respondent No. 3 The consents are gotten signed in the said room itself by the staff and the same are then kept together with the other consent forms of the other patients in the colonoscopy/endoscopy room till the time they are transferred to the Medical Record Room. It is not the case where one single document has gone missing from the file. The consent form of the Appellant which was taken for the colonoscopy was kept with the other Consent Forms which were then transferred to the Medical Record Room where the same were damaged due to a water leakage. It is pertinent to point out that (sic) no OPD records (sic) of the patients are retained by the hospital and all documentation barring consent forms for OPD procedures are handed over to the patients including all investigation reports etc. Whereas as per the protocol and requirement of law all records pertaining to an IPD appellant are maintained in the Medical Records room by the Hospital."

21. Relevant portion of the explanation on point no.2 reads as follows:-

"It is submitted that the entire IPD record was produced by the respondents before the Hon'ble State Commission. The protocols where IPD patients are concerned differ (sic) from the protocols followed for the OPD patients. Where the OPD procedure is concerned viz. colonoscopy the patient after making payment goes to the Colonoscopy Room, signs the Consent Form and thereafter goes through a very short procedure and thereafter the patient goes home and does not require to stay for any length of time at the Hospital. It is humbly submitted that a perusal of the OT notes (Vol.3 of certified copies of Pleadings filed by Respondent No.1 at page 355) reveal that there is no reference to the consent for surgery having been taken. However, as a protocol, when the Appellant was admitted on 4.07.2012 as an IPD appellant, the attending doctor had advised: (a) exploratory laparotomy; (b) consent and clearances for surgery; (c) shift to OT on call; and (d) PAC urgent; and it was signed by Dr. Iqbal Singh. The said advice was given as per protocol followed in the hospital. Consent for surgery is taken from the patient/relatives and clearance for surgery has to be taken from the Anesthetist. There is no such procedure which is followed while conducting an out-patient Procedure."

22. Evidently, in the said explanation, the Respondents have stuck to their earlier stand, viz. that the consent was duly taken but the consent form has been destroyed because of water seepage but pertinently, the Respondents have not chosen to produce even the soiled file, stated to be containing Complainant's consent form along with other similar consents obtained in the OPD room. Besides, a very significant fact emerges from the afore-extracted explanation on point No.1, viz. the consents are got signed in the OPD room, where Colonoscopy procedures are conducted, "by the staff" and the

same were kept together with the other consent forms of other patients. The stand of the Respondents that consent forms are got signed by the staff in the OPD room, in our view, leaves little scope for doubt in our mind that the consent forms were got signed by the staff before the procedure was conducted by the Doctors, as a formality and does not meet even the basic mandatory requirements of the Treating doctor, making the Complainant aware of material risks involved in the Colonoscopy procedure, before she was subjected to the same. It is true that advances in endoscope design, array of instruments and technique available, have made Colonoscopy one of the safest of invasive procedures, yet, complications and adverse effects still happen, so much so cases of unanticipated deaths, during or after the Colonoscopy have been reported, even in ideal circumstances. According to the medical journals, death can occur from any complication of Colonoscopy: the electrolyte imbalance caused by sodium phosphate preparation; the Cardiac events brought on hypoxia from over-sedation; the sepsis that may follow perforation; or blood loss that can occur with haemorrhage, though proper management of these complications can minimise mortality. It is universally accepted that Colonic perforation is rare but known complication of Colonoscopy. That being so, the basic principle of "Consent" demands that before opting for Colonoscopic procedure, the patients must be clearly apprised of the balance of risks and benefits that apply in their own particular situations and participate in the decision making process that flows from this balance. On facts at hand, in the entire defence put up on behalf of the Respondents, there is not even a whisper that the Treating doctor had explained to the Complainant the pros and cons: the material risks involved and the benefits of the procedure, particularly keeping in view her age and health condition, now being highlighted. In our opinion, Respondent's reliance on the averment in the Complaint to the effect that though initially she was hesitant but on the assurance of the Treating doctor, she had agreed to go for the test, the Treating doctor was not required to prove the 'consent', is of no avail to them and does not establish that 'informed consent' as understood in legal parlance, was obtained from the Complainant before subjecting her to the said procedure. In our view, the finding in the impugned order to the effect that "it cannot be made out from the evidence produced by the Complainant that she had not consented to undergo this colonoscopy" is per se illegal, inasmuch in the light of Complainant's categorical stand that no informed consent had been taken from her before the procedure was performed, onus was on the Respondents, in particular the Treating doctor, to prove that it was infact taken, which, evidently, they have failed to discharge. In our opinion, apart from the fact that the explanation for non-production of the consent form, claimed to have been got signed from the Complainant, does not inspire confidence, even on merits the Treating doctor and the Hospital have failed to prove that a valid/informed consent had been obtained from the Complainant before subjecting her to colonoscopy procedure. We are, therefore, of the considered view that the Treating doctor as well as the Hospital had failed to obtain a valid consent from the Complainant and the colonoscopy procedure conducted on her was unauthorized, amounting to deficiency in service on their part. We hold accordingly. Nevertheless, in so far as Dr. J.D. Wig is concerned, we do not find any negligence/deficiency on his part. Accordingly, we exonerate him.

23. For the view, we have taken above, we deem it unnecessary to deal with other afore-noted issues viz. whether: the Treating doctor had failed to follow the standard protocol in the performance of the colonoscopy procedure; he should have abandoned the procedure when the Complainant claims to have complained of pain at the start of the procedure; the Treating doctor lacked requisite experience to conduct such a procedure; the Treating doctor did not take due precautions while performing the said procedure, resulting in pneumoperitoneum requiring emergency laparotomy.

24. That brings us to an intricate question, viz, what compensation deserves to be awarded to the Complainant for the aforestated sufferings undergone by her. We shall consider the question, bearing in mind the fact that we have not returned any final finding of negligence on the part of the Treating doctor in the performance of the procedure on her but have found deficiency on the part of the Treating doctor and the Hospital for not obtaining a valid consent for colonoscopy. In the Complaint, the Complainant has prayed for compensation amounting, to 50,00,000/- on the ground that she has suffered mentally, physically and financially on account of the aforenoted conduct of the Respondents. However, no cogent material has been placed on record to show her source(s) and scale of income. Under the circumstances, bearing in mind the observations made by the Hon'ble Supreme Court in V. Krishnakumar Vs. State of Tamil Nadu and Ors. - (2015) 9 SSC 388, wherein

computation of compensation in medical negligence cases on multiplier factor has been disapproved, we are of the opinion that the award of a lump sum compensation of 10,00,000/- in favour of the Complainant, which would include the medical expenses, stated to have been expended, for the physical and mental agony undergone by her, would meet the ends of justice. We order accordingly. The Treating doctor and the Hospital shall be liable to pay the said compensation to the Complainant, jointly and severally, as apart from the fact that it is well settled that the Hospital is vicariously liable for the negligence of its attending doctors, in the present case, the Hospital being responsible for preservation of the record of the Patient, was equally deficient in not preserving and producing the requisite document(s). The said amount shall be remitted to the Complainant within four weeks, from the date of receipt of a copy of the order, failing which it shall carry interest @9% p.a. from the date of filing of the Complaint till actual realization. The Complainant shall also be entitled to costs, which are quantified at 25,000/-.

25. The Appeal stands disposed of accordingly.