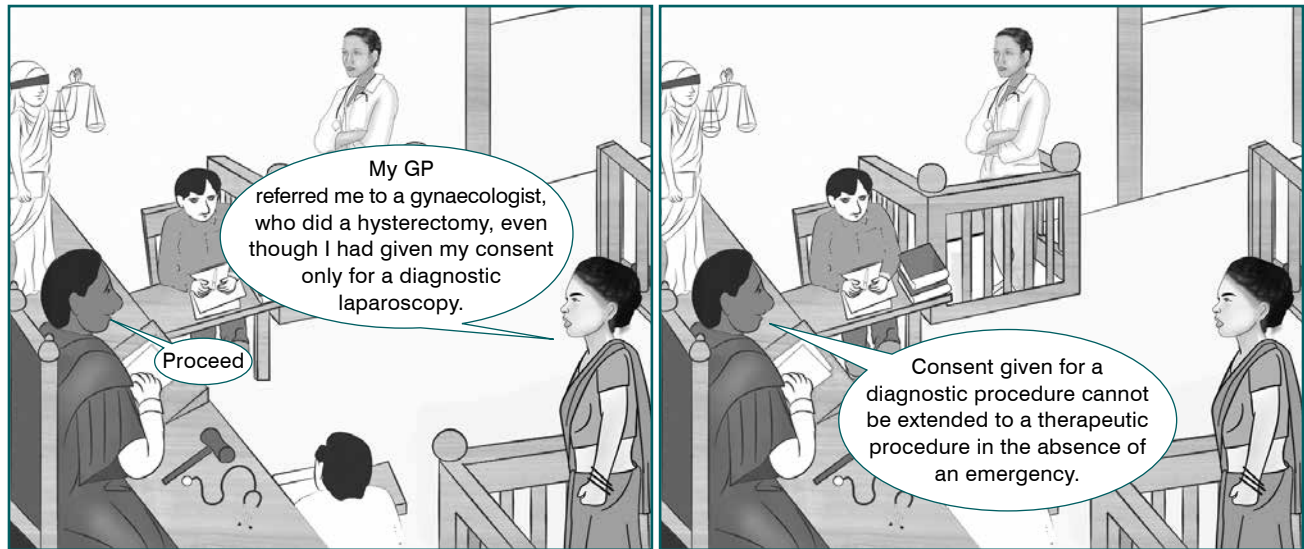


Consent for Diagnostic Procedure cannot be Extended to Therapeutic Procedure



Lesson: In the landmark *Samira Kohli vs. Dr Prabha Manchanda & Anr* on 16 January, 2008 Appeal (civil) 1949 of 2004, the Supreme Court of India held "19. ...in Medical Law, where a surgeon is consulted by a patient, and consent of the patient is taken for diagnostic procedure/surgery, such consent cannot be considered as authorisation or permission to perform therapeutic surgery either conservative or radical (except in life-threatening or emergent situations). Similarly, where the consent by the patient is for a particular operative surgery, it cannot be treated as consent for an unauthorised additional procedure involving removal of an organ, only on the ground that such removal is beneficial to the patient or is likely to prevent some danger developing in future, where there is no imminent danger to the life or health of the patient."

CASE SUMMARY

- **May 9, 1995:** The patient 'X', an unmarried woman aged 44 years, consulted Dr 'A' complaining of prolonged menstrual bleeding for 9 days. An ultrasound was done and after examining the report, patient was advised to come back the next day for laparoscopy to make an affirmative diagnosis.
- **May 10, 1995:** Patient was admitted to the clinic and laparoscopy was done under general anaesthesia. While the patient was still in the OT and under anaesthesia, consent for hysterectomy was taken from the mother. Abdominal hysterectomy and bilateral salpingo-oophorectomy was done by Dr 'A'.
- **May 15, 1995:** Patient left the clinic without settling the bill.
- **May 23, 1995:** Dr 'A' filed a complaint with the Police alleging threat from the patient's friend, who got her discharged against medical advice and without clearing the bill.
- **May 31, 1995:** Patient filed a complaint against the doctor alleging negligence and unauthorised removal of her reproductive organs.
- **June 6, 1995:** A legal notice was issued by the doctor to the patient demanding Rs. 39,325/- as fees.
- **January 19, 1996:** Patient filed a complaint before the National Consumer Disputes Redressal Commission (NCDRC) claiming compensation of Rs. 25 lakhs from Dr 'A' alleging negligence and that removal of her uterus and both ovaries was "unlawful, unauthorised and unwarranted". She claimed compensation "for loss of reproductive organs, loss of opportunity to become a mother, diminished matrimonial prospects, loss of vital body organs, irreversible body damage as well as for pain and emotional trauma."

- **November 19, 2003:** NCDRC dismissed the complaint and decided in favor of the doctor. The Commission held that *"the patient had voluntarily gone to the clinic for treatment ... the hysterectomy had been done with adequate care and caution and the surgical removal of uterus, ovaries etc. was necessitated as the appellant was found to be suffering from endometriosis (Grade IV), and if they had not been removed, there was likelihood of the lesion extending to the intestines and bladder and damaging them."*
- Patient filed an appeal in the Supreme Court against this decision of the NCDRC.
- **January 11, 2008:** The Supreme Court delivered judgement in favour of the patient.

SOME SALIENT COURT OBSERVATIONS

- *"14. Consent in the context of a doctor-patient relationship, means the grant of permission by the patient for an act to be carried out by the doctor, such as a diagnostic, surgical or therapeutic procedure. Consent can be implied in some circumstances from the action of the patient. Except where consent can be clearly and obviously implied, there should be express consent. There is, however, a significant difference in the nature of express consent of the patient, known as 'real consent' in UK and as 'informed consent' in America..."*
- The Court also summarised the principles relating to consent.

"32. (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 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 judgement as to whether he should submit himself to the particular treatment 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...

(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 only exception to this rule is where the additional procedure though unauthorised, is necessary in order to save the life or preserve the health of the patient and it would be unreasonable to delay such unauthorised 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 ... 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..."

- The legal notice issued by Dr 'A', wherein the patient had been asked to pay a sum of Rs. 39,325/- towards the bill amount *"also makes it clear that the appellant was not admitted for conducting hysterectomy or bilateral salpingo-oophorectomy, but only for diagnostic purposes."* The Court also pointed out an erroneous statement in the notice, which said that the video recording of the procedure was shown to the mother and both the patient and her mother were informed that because of the extensive lesion, which became evident only after diagnostic laparoscopy, *"more extensive surgery was preferable"*. *"When the laparoscopy and video recording was made, the appellant was already unconscious. Before she regained consciousness, AH-BSO was performed removing her uterus and ovaries."* So, the statement in the legal notice was factually incorrect.

- *"40. The consent form shows that the appellant gave consent only for diagnostic operative laparoscopy, and laparotomy if needed... It does not amount to consent for AH-BSO surgery removing the uterus and ovaries/fallopian tubes. If the appellant had consented for AH-BSO then the consent form would have given consent for "diagnostic and operative laparoscopy. Laparotomy, hysterectomy and bilateral salpingo-oophorectomy, if needed."*

- Dr 'A' submitted that the consent given by the mother for the additional procedure should be regarded as a valid consent. In response, the Court said: *"The appellant was neither a minor, nor mentally challenged, nor incapacitated. When a patient is a competent adult, there is no question of someone*

else giving consent on her behalf. There was no medical emergency during surgery... The respondent ought to have waited till the appellant regained consciousness, discussed the result of the laparoscopic examination and then taken her consent for the removal of her uterus and ovaries. In the absence of an emergency and as the matter was still at the stage of diagnosis, the question of taking her mother's consent for radical surgery did not arise. Therefore, such consent by mother cannot be treated as valid or real consent... Further a consent for hysterectomy, is not a consent for bilateral salpingo-oophorectomy."

- "48. We find that the Commission has, without any legal basis, concluded that "the informed choice has to be left to the operating surgeon depending on his/her discretion, after assessing the damage to the internal organs, but subject to his/her exercising care and caution". It also erred in construing the words "such medical treatment as is considered necessary for me for__." in the consent form as including surgical treatment by way of removal of uterus and ovaries."
- A diagnosis of endometriosis was made after diagnostic laparoscopy, which is managed either conservatively or by hysterectomy depending on the patient's age and stage of the disease. The Court observed: "52... worldwide studies show that most hysterectomies are conducted unnecessarily by Gynaecologists demonstrates that it is considered as a favoured treatment procedure among medical fraternity, offering a permanent cure. Therefore respondent cannot be held to be negligent, merely because she chose to perform radical surgery in preference to conservative treatment. This finding however has no bearing on the issue of consent which has been held against the respondent. The correctness or appropriateness of the

treatment procedure, does not make the treatment legal, in the absence of consent for the treatment."

- "54. In view of our finding that there was no consent by the appellant for performing hysterectomy and salpingo-oophorectomy, performance of such surgery was an unauthorised invasion and interference with appellant's body which amounted to a tortious act of assault and battery and therefore a deficiency in service... This is a case of respondent acting in excess of consent but in good faith and for the benefit of the appellant... On the facts and circumstances, we consider that interests of justice would be served if the respondent is denied the entire fee charged for the surgery and in addition, directed to pay Rs. 25,000 as compensation for the unauthorised AH-BSO surgery to the appellant."

FINAL JUDGEMENT

The Supreme Court cancelled the NCDRC order and partly allowed the patient's claim for compensation as follows: "If the respondent has already received the bill amount or any part thereof from the appellant (either by executing the decree said to have been obtained by her or otherwise), the respondent shall refund the same to the appellant with interest at the rate of 10% per annum from the date of payment till the date of re-payment. The Respondent shall pay to the appellant a sum of Rs. 25,000/- as compensation with interest thereon at the rate of 10% per annum from 19.11.2003 (the date of the order of Commission) till date of payment. The appellant will also be entitled to costs of Rs. 5,000 from the respondent."

REFERENCE

1. Samira Kohli vs Dr. Prabha Manchanda & Anr on 16 January, 2008 Appeal (civil) 1949 of 2004.

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Vaccine Effectiveness of 99.3% Observed in People Fully Vaccinated Against COVID-19: Union Health Minister

Vaccine effectiveness of 99.3% has been observed in people who are fully vaccinated against COVID-19, suggest data uploaded on India COVID-19 Tracker till January 2.

The India COVID-19 Vaccine Tracker has been developed by the ICMR, merging three national databases, CoWIN, National COVID-19 Testing database and COVID-19 India portal, stated Health Minister Mansukh Mandaviya in a written reply to the Lok Sabha. The tracker shows vaccine effectiveness against death, i.e., the potential of vaccines to reduce death, making use of person time analysis from April 12, 2021 to January 2, 2022. The minister said that according to the latest data analyzed and uploaded till January 2, a vaccine effectiveness of 99.3% has been seen in fully vaccinated individuals against COVID-19.

He further mentioned that the tracker is regularly updated and shows the effectiveness of partial and full vaccination... (TOI – PTI, February 4, 2022)