Medicolegal Insight

SURGERY PERFORMED ON THE WRONG PATIENT IS A 'NEVER EVENT'

A patient who was hospitalized in a dedicated Trauma Centre run by the Delhi government with head and face injuries that he sustained in an accident, instead underwent surgery under general anesthesia for a fractured leg, as reported in TOI. The surgeon mistook him for another patient admitted in the same ward who had a leg fracture. A small hole was drilled into the patient's right leg to put a pin. As the procedure had been done under general anesthesia, the patient could not realize or object to it. However, the pin was removed within hours following a corrective surgery after it was brought to the attention of the authorities. A committee examined the case found merit in the allegations and a disciplinary action was initiated against the doctor, a senior resident, who has been barred from conducting surgeries without supervision with immediate effect.

Res ipsa loquitur is a Latin term, which literally translates as "the thing speaks for itself". The doctrine of *res ipsa loquitur* is a rule of evidence in cases of medical negligence. It infers negligence from the very nature of an accident or injury in the absence of direct evidence on how any defendant behaved. *Res ipsa loquitur* is not applicable when determining the liability for criminal negligence; it applies only in cases of civil negligence.

To prove medical negligence, usually three components have to be established:

- There was an element of duty to be performed
- There was breach of duty
- Resultant damage.

If the patient is not harmed by the physician's error, then the patient cannot recover damages arising out of the error.

This case answers 'yes' to all the three components of medical negligence: there was a duty of care, there was a breach in the duty of care and the patient did suffer damage as a direct result of the breach.

In *res ipsa loquitur*, these three components of medical negligence elements are inferred from an injury that does not ordinarily occur without negligence, i.e., negligence is evident and the complainant does not have to prove anything as the "thing proves itself" as also in this case.

This is a medical error and can be classified as a 'never event', i.e., event that should never occur under any circumstance. Never events are defined as adverse events that are serious, largely preventable, and of concern to both the public and health care providers for the purpose of public accountability. They are usually a direct result of a negligent action and no trial of expert's evidence is necessary

The US National Quality Forum has defined 29 never events segregated into seven categories: surgical, product or device, patient protection, care management, environmental, radiologic and criminal.

"Surgery or other invasive procedure performed on the wrong patient" is included in list of surgical never events along with "surgery or other invasive procedure performed on the wrong body part, wrong surgical or other invasive procedure performed on a patient, unintended retention of a foreign object in a patient after surgery or other procedure".

The World Health Organization (WHO) has developed a Surgical Safety Checklist, *to be read out loud*, to decrease errors and adverse events for use in any operating theatre environment. The checklist has three phases as below:

"Sign In": Before induction of anesthesia

- Has the patient confirmed his/her identity, site, procedure and consent?
- Is the surgical site marked?
- Is the anesthesia machine and medication check complete?
- Does the patient have a: Known allergy, Difficult airway/aspiration risk or Risk of >500 mL blood loss (7 mL/kg in children)?

"Time Out": Before start of surgical intervention

- Have all team members introduced themselves by name and role?
- Surgeon, Anesthetist and Registered Practitioner verbally confirm: What is the patient's name? What procedure, site and position are planned?
- Anticipated critical events (surgeon, nurse, anesthetist)
- Has the surgical site infection (SSI) bundle been undertaken? Antibiotic prophylaxis within the

last 60 minutes • Patient warming • Hair removal • Glycemic control

- Has venous thromboembolism (VTE) prophylaxis been undertaken?
- Is essential imaging displayed?

"Sign Out": Before any member of the team leaves the OR

- Registered Practitioner verbally confirms with the team:
  - Has the name of the procedure been recorded?
  - Has it been confirmed that instruments, swabs and sharps counts are complete (or not applicable)?
  - Have the specimens been labeled (including patient name)?
  - Have any equipment problems been identified that need to be addressed?
- Surgeon, Anesthetist and Registered Practitioner: What are the key concerns for recovery and management of this patient?

However, when deciding the quantum of punishment, the mitigating circumstances need to be considered.

Does the hospital have a protocol in place to avoid such mistakes? Generally, a minimum of two ID marks are required to be checked at the time of surgery. More than 1 patient can have the same name; room numbers may not be reliable as an identification mark. Matching of HUID no. is important.

Being overworked, lack of resources and infrastructure, insufficient staff, etc. is no excuse for not following such a checklist.

There should be guidelines and/or protocols in place, which should be strictly implemented. If there are no guidelines, then there is an urgent need to develop them as per requirements. The checklist must be completed for each patient who undergoes a surgery, including under LA. It also must be documented in the patient chart.

By following these few but crucial steps, such errors can be minimized. It also ensures effective team work.

This mistake is not just that of the doctor alone. It is also a result of system failure and administration error.

SOME COMMON MISTAKES IN TAKING MEDICINES

- **Prescribing liquid medications in teaspoons and tablespoons:** A teaspoon (tsp) can be confused with a tablespoon (tbsp). Their sizes may vary. Hence, all liquid medications should be prescribed in milliliters (mL) and they should be taken with a dosing device such as a small cup which should have mL markings.
- **Pill splitting:** Tablets that are not scored should not be split into two. They can crumble or are divided into unequal halves affecting the dose strength. Sustained or extended-release tablets and enteric- or film-coated tablets are generally not considered appropriate for tablet splitting. Film coating masks taste; therefore, splitting film-coated tablets may unmask the taste.
- **Sound-alike drugs can cause confusion** e.g. a hypertensive patient called up his family physician who asked him to take Amlopress AT but the patient took amlopress 80 mg. After sometime, he developed dizziness, flushing, palpitation, nausea, abdominal pain. Another example of sound-alike drugs is the patient received Isoprin IV in place of Isoptin and nearly died.
- **Misinterpreting decimal points**: *Using a trailing zero after a decimal point*, e.g., do not write 5.0 mg. There are chances that the patient may get 50 mg; 5.0 mistaken as 50 mg if the decimal point is not seen. *Lack of a leading zero before the decimal point*, if the dose of a drug is less than one, may cause a decimal point to be missed. E.g., writing .25 mg may result in the patient taking 25 mg instead, so write 0.25 mg.
- **Mistaking "U" as zero**. Do not write 'U' for units; always write the complete word 'units'. E.g. 4U insulin may be mistaken to be 40 units of insulin when the doctor meant 4 U (4 units).
- **8-2-8 mistake:** The time interval should be written more clearly as 8 am 2 pm 8 pm. Or, the patient may consider it to be the number of tablets to be taken 8 in the morning, 2 in the afternoon and again 8 at night.
- **Taking medicines with inadequate quantity of water or lying down immediately after taking the drug** can cause pill esophagitis by direct esophageal mucosal injury. It is commonly seen with drugs such as nonsteroidal anti-inflammatories (NSAIDs), tetracycline, doxycycline, alendronate, antiviral drugs, iron supplements.
- **Some medicines need to be taken "before meals" or "on an empty stomach"** because food

can prevent absorption of some medicines and reduce their effectiveness. E.g., Levothyroxine and rifampicin should be taken on an empty stomach.

- **Taking medicines with fruit juices:** Grapefruit, orange, and apple juices decrease the absorption of many drugs such as fexofenadine, cancer chemotherapy (etoposide), antibiotics (ciprofloxacin, levofloxacin), itraconazole, antihypertensives (atenolol), immunosuppressant (cyclosporine)
- **Skipping doses:** This may be dangerous especially with antiepileptic drugs or anticoagulants.

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Severe Maternal Morbidity and Risk of Recurrence

Women who develop severe morbidity during the first pregnancy are at significant risk of experiencing a recurrence of morbidity in a subsequent pregnancy, suggests a new study of over 8,00,000 women from Quebac, Canada published in the *American Journal of Obstetrics & Gynecology*.[1,2] Women with cardiac complications or uterine rupture at first delivery were particularly at risk.

Women who had at least two hospital-based singleton childbirths between 1989 and 2021 were included in this study. These women had experienced a complicated first delivery with severe maternal morbidity from 20 weeks of gestation up to 42 days postpartum. The aim of this study was to determine the impact of severe maternal morbidity in the first pregnancy on the risk of severe maternal morbidity in the second delivery. Various types of severe maternal morbidity examined included severe pre-eclampsia or eclampsia, uterine rupture, severe obstetrical hemorrhage, acute heart failure, acute renal failure or dialysis, cerebrovascular accidents, shock, embolism, sepsis, disseminated intravascular coagulation, assisted ventilation, surgical complications, intensive care unit admission and other grave disorders.

A total of 8,19,375 participants were included in the study and 43,501 (3.2%) had suffered severe morbidity at the time of the first delivery. Among these, the recurrence rate of severe maternal morbidity, which was the primary study outcome, was 65.2 per 1,000 deliveries in women with severe maternal morbidity in the earlier delivery compared to 20.3 per 1,000 deliveries in women with no history of severe morbidity. The adjusted relative risk (aRR) was 3.11. The aRR for recurrence was 2.94 with one type of severe maternal morbidity, 4.06 with two types of maternal morbidity. Women who had experienced 3 or more types of severe maternal morbidity were at the highest aRR of experiencing a severe maternal morbidity in the subsequent delivery compared to women who did not have any maternal morbidity. The aRR was 5.50. History of cardiac complications in the first delivery was associated with the highest risk of severe maternal morbidity in the next delivery with aRR of 5.06. Those who had severe pre-eclampsia or eclampsia were also at similar elevated risk with aRR of 5.85. The aRR was highest for cardiac arrest at 7.27 with uterine rupture following (aRR 6.22).

Women with severe maternal morbidity in the first delivery were 3 times more likely to experience acute renal failure, severe hemorrhage, embolism, shock and disseminated intravascular coagulation, and need for intensive care in the next delivery. Those who had needed intensive care or assisted ventilation in the earlier pregnancy were 4 times more likely to experience severe maternal morbidity again in a subsequent pregnancy.

This study showed that the occurrence of severe maternal morbidity in a previous pregnancy increased the risk of severe maternal morbidity recurrence in the next pregnancy. Women with cardiac complications or uterine rupture at first delivery were most likely to experience a recurrence. It has also determined the association of different types of morbidities with the risk of recurrence. These findings highlight the need for pre-pregnancy counseling for informed decision making about future pregnancies. Monitoring of maternal health in such cases must be continuous and not stop at childbirth or postpartum period. Also, they must be kept under close observation in their subsequent pregnancy.

References

1. Ukah UV, et al. Risk of recurrent severe maternal morbidity: a population-based study. Am J Obstet Gynecol. 2023;229(5):545.e1-545.e11.
2. Krewson C. Contemporary Ob/Gyn News. Available at: https://www.contemporaryobgyn.net/view/recurrent-severe-maternal-morbidity-risks-in-subsequent-pregnancies. Dated Nov. 15, 2023. Accessed Nov. 18, 2023.