



Letter to the Editor

Awareness during anaesthesia... Its medicolegal threat... How to tackle it?

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ABSTRACT

Awareness during anesthesia is an infrequent but a grievous complication with an estimated incidence of around 0.1% and 0.2% in western world. It is not only troublesome for the patient but can pose a serious medicolegal threat for anaesthesiologist as well. Preoperative assessment targeting patient's characteristics and the type of surgery helps in stratifying the risk of awareness during surgery and provides a better chance at counseling the patients for the same. Preinduction phase of anaesthesia is an important phase which includes equipment check and function of monitors and preparation of an adequate plan of anaesthesia taking into consideration the risk of awareness. Errors in this phase leads to majority of cases of awareness. With the advent of advance monitoring techniques, the management of anaesthesia has become even more balanced and helps detect signs of awareness in early stage which can be curtailed immediately. Postoperative phase can be the most neglected part of anaesthesia in terms of assessment for any incidence of awareness. A detailed follow-up is always recommended even after discharge and if awareness is confirmed postoperatively, one must provide explanation to the patient about what has happened and must be offered both psychological and psychiatric support. In this letter we are going to briefly talk about factors associated with awareness and measures to avoid them taking into consideration the medicolegal aspect of the same.

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1. Introduction

Awareness expressed as a recall of surgical procedure during general anesthesia is an infrequent but a grievous complication. Despite being uncommon, it may pose serious problem with long-term psychological effects on the patients. The estimated incidence of awareness in the western world is reported to be around 0.1% and 0.2%¹ which is even more in cardiac, gynaecological and obstetric surgeries which is around 1.1-1.5% and 0.4% respectively.² This same increased incidence is seen in paediatric population as well (0.8-1.2 % incidence).³ At the end of a case, even if we think that we did a very sound perioperative management and patient has no complaints of postoperative pain, yet he may later recall about the intraoperative events. Moreover, patients who

have intraoperative or post operative pain, are more likely to develop long term complications like post-traumatic stress disorders, anxiety and panic attacks. Hence, there can be serious medicolegal implications of awareness for an anaesthesiologist as well.

This ever growing problem of awareness during anaesthesia was handled by a Task Force on Intraoperative Awareness which issued an advisory guideline in 2006.⁴ This is described in terms of preoperative, intraoperative and postoperative management of patients directed towards one single of avoiding awareness and its treatment if occurred.

1.1. Preoperative Assessment

Patient characteristics which are suggestive of increased chances of awareness are:

1. Age (higher in extremes of ages)
2. Gender (females more than males)

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3. ASA status of the patient (ASA III or higher have increased chances of awareness) - Pharmacokinetics (can lead to underdosing of anaesthetic drug)
4. Past history of recall or awareness increases the probability of awareness in the next surgery as well.
5. Patients with difficult airway and those with reduced or limited cardiac reserve or hemodynamically unstable patients are more susceptible to awareness than normal population.
6. Certain group of patients who have chronic pain are usually analgesic abusers (opioids) and the develop tolerance to them so requirement of analgesics will be higher in such patients are other alternative analgesics should be preferred.
7. Drug addicts (cocaine abusers) for the same reason also come in the high risk group as above.
8. The above mentioned patient characteristics should be duly identified in preoperative period and the patient should be properly counseled and explained about the higher chances of awareness in this group.

The type of surgery is also an important factor in determining the chances of awareness. Emergency surgeries in itself has a higher incidence of awareness as the use of reduced anaesthetic doses have also been implicated like in the presence of rapid sequence induction, paralysis and total intravenous anaesthesia.^{5,6}

1.2. Preinduction phase of anaesthesia

There must be a checklist protocol for checking the working of anaesthesia machine and equipments and one must follow them strictly everyday and before every case in order to prevent errors related to machines. Before taking the patient inside the o.t. we should check whether the intravenous access is working properly or not and ensure there shouldn't be any leak in various connectors, infusion pumps and three ways. Awareness can occur due to anaesthetic concentration delivery error as well. Bergman and his colleagues studied 8372 incidents of awareness where the incidence was around 0.96 % out of which 0.19% cases were because of volatile anaesthetic agent delivery error and 0.38% were because of use of muscle relaxant inadvertently in awake patients leading to paralysis.⁷

Prophylactic administration of benzodiazepines like midazolam, diazepam and lorazepam should be made on a patient to patient basis. The efficacy of prophylactic midazolam was evaluated in one study which stated a lower incidence of awareness in patients receiving prophylactic dose of the same.⁸

There are many modalities to monitor the depth of anaesthesia which not just includes brain function monitors but also the clinical techniques and assessment using routine monitoring. Some clinical methods are assessing the purposeful or reflex movements and isolated forearm

technique. Respiratory monitoring and assessment of breathing is especially important when muscle relaxants are not used. Surgery should not be started until and unless adequate plane of anaesthesia is achieved which is usually Guedel's stage 3 plane III level of ether anaesthesia. Unfortunately no such studies or trials have been done which examines the sensitivity for detecting awareness using the above mentioned monitoring modalities intraoperatively.

Brain function monitoring is a bit expensive in Indian setup and so it is not routinely advocated, however if available, it can be used selectively in patients where chances of awareness is expected to be high. The commonly available brain function monitors are:

1. Monitors for studying evoked brain electrical activity: this include auditory evoked response potential monitor also known as Danmeter.
2. Monitors for studying electroencephalographic activity of brain : commonly used devices are
 - Narcotrend - developed in Germany by Monitor Technik
 - Entropy monitor - developed in Wukeshu, WI by GE Healthcare Technologies.
 - Patient state analyser - developed in North Billerica, MA by Physiometrix.
 - Bispectral index – developed by aspect medical systems, MA.
 - SNAP index – developed in Chesterfield, MO by Everest Biomedical Instruments.
 - Cerebral state monitor – developed in Odense, Denmark by Danmeter A/S.

1.3. Postoperative management

It is always advised to assess the patient postoperatively as we II and keep a detailed record of the patient's experience. There may be no trials or studies suggesting for this practice however, doing the same may help medicolegally and may allay postoperative anxiety and helps in better management of postoperative pain and other problems. Moreover, these records may even help the other anaesthesiologist for a better management if at all anaesthesia is required in the future. If awareness is confirmed postoperatively, one must provide explanation to the patient about what has happened and must be offered both psychological and psychiatric support. Such patients should be followed up on routine basis and one should look for any disturbance in sleep pattern, anxiety during daytime or any other neuropsychological sequelae. At the same time, one should consider the medicolegal aspect of the incident as well; and the surgeon, patient's nurse, hospital lawyer and anaesthesiologist's insurer should be notified. After the patient is discharge from the hospital, it is advised to keep a follow up on them by telephone or during OPD visits till the

patient has recovered completely. Being such a rare entity in itself, every single case needs to be reported for quality management and statistical purpose as well.

An important data that was discussed in National Audit project 5 (NAP5) was that total incidence of awareness also included the cases where awareness occurred during sedation, which may seem strange as many anaesthesiologists consider that provision of sedation does not include the guarantee that awareness will not occur. However, this may show a mismatch between anaesthesiologist's and patient's expectations. Here comes the role of communication, and therefore it should be very clear to the patients as to what they should expect from the type of anaesthesia they are going to be provided and anaesthesiologist should also look into the demands and expectations of the patients and look forward to fulfill them if the clinical state of the patient allows it. For procedures requiring sedation, patient should be told that there are chances of likely recall of some parts of procedure however, they are usually non-painful. In the above group of patient who were found to have awareness during sedation, it was found that major complaint by most of the patients was paralysis however, no paralytics was administered in those cases. This shows that recallable memory is indeed a complex process and can be unreliable and difficult to predict as well. One such example of inaccurate recollection of paralysis experience was a criminal case of sexual assault during sedation⁹ which could be explained based on the above facts. Again as said before, a precounselling before surgery regarding the above risk can significantly reduce the risk of patients panicking and reporting perceived paralysis.

If we talk about Indian population, the reported incidence of awareness will be even lower than the NAP5 data and even fewer may go on to litigate. This should not make us relaxed as the majority litigated cases of awareness are preventable and human error is amongst the most prominent cause. The much cited cause by anaesthesiologist is actually equipment failure, which is in fact, amongst the rarest cause in litigated cases. There are certain features regarding anaesthesiologists like overworking, exhaustion, pressure to perform fast, lack of familiarity with packaging of drugs, distraction etc which clearly can lead to human errors causing increased risk of awareness.

It has been agreed upon widely that 'res ipsa loquitur' cannot be argued upon litigation. This statement that "the thing speaks for itself" has an assumption that non-negligent explanation cannot explain a complication with credibility. Moreover, certain factors like variability in patients for dose requirement, masking of awareness signs by pathology or drugs, and machine failure when combined together may make this assumption of fault inappropriate.

Despite the above facts, an anaesthesiologist should not be too reassured as it becomes very hard to defend if the documentation of the litigated case is inappropriate. Here lies the importance of good record keeping. In this

advanced era, the automated record keeping appears to be more reliable and convincing than the one that is hand made by the anaesthesiologist himself. However, a high quality hand-written record can be very effective and at some instances even better than the automated ones. A problem with automated record keeping is that they may sometimes show no hemodynamic signs which are consistent with light anaesthesia despite the adequate concentration of anaesthetic in the record even in presence of lighter plane. This may be attributed to interindividual variability in dose requirements. Such documents come in great importance while filing sound defence upon litigation.

Patient's personal experience in some literature describes the terror and helplessness, they undergo, despite being under the care of anaesthesiologist. It is therefore important that we must listen to them with compassion and care and activate local departmental protocols for awareness without any further delays.

2. Conclusion

Henceforth, we would conclude by saying that awareness in anaesthesia is one of a major complication and should not be taken lightly. It has a serious medicolegal threat for the anaesthesiologist as well as a major neuropsychological impact on patients. It needs to be handled carefully and tact fully which requires a skilled anaesthesiologist who masterly monitors patient during the anaesthesia phase and avoids any human errors and machine or equipment related complications along with obtaining a sound preoperative consent describing in details about chances of awareness and to clear out any anxiety or stress related to it in patient's mind.

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4. Conflict of Interest

None.

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