Special Article

Standards of care for procedural sedation: Focus on differing perceptions among societies

Address for correspondence:
Dr. Satyen Parida, Department of Anesthesiology and Critical Care, JIPMER, Puducherry, India.
E-mail: jipmersatyen@gmail.com

Satyen Parida, Pankaj Kundra, V. K. Mohan, Sandeep K. Mishra
Department of Anesthesiology and Critical Care, JIPMER, Puducherry, India

ABSTRACT

Adherence to established standards of care is important for anaesthesiologists to avoid undesirable legal consequences of their actions. The judiciary lays stress on the need to perpetuate healthy doctor–patient correspondence, good documentation, and to bestow a justifiable standard of care. But what defines standard of care and who delineates such standards is something that lacks clarity. The American Society for Gastrointestinal Endoscopy (ASGE) has recently released updated guidelines on the use of sedation and anaesthesia for gastrointestinal endoscopic procedures. Almost simultaneously, the American Society of Anesthesiologists (ASA) has brought out practice guidelines for moderate sedation and analgesia. In contrast to the ASA recommendations, ASGE does not view capnography as an essential monitoring modality for endoscopic procedures with moderate sedation because it has apparently not been shown to improve patient safety. However, they do agree that evidence supports its deployment during deep sedation. These differences in views between guidelines published by societies of substantial academic and clinical standing can confuse the agreement over what constitutes standard of care for the particular speciality. It is the expectation that guidelines and consensus statements in anaesthesiology be preferably issued by national or international organizations of the same speciality.

Key words: Capnography, endoscopy, guidelines, sedation, standard of care

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INTRODUCTION

“Standards of care” for provision of medical services by a clinician are poorly defined. It could, depending on variable perception, be defined by the evidence base, by what clinicians of identical professional stature do, by what groups of clinicians agree upon as the justifiable level of care, or by what expert panels enunciate as best practices. The American Society for Gastrointestinal Endoscopy (ASGE) has released updated 2018 guidelines on the use of sedation and anaesthesia for gastrointestinal endoscopic procedures. These guidelines have been published in the journal Gastrointestinal Endoscopy.[1] Significantly, the ASGE guidelines depart from the American Society of Anesthesiologists (ASA) guidelines on the use of capnography.[2,3] In contrast to the ASA recommendations regarding capnography, ASGE states that integrating capnography into patient monitoring protocols for endoscopic procedures with moderate sedation has not been shown to improve patient safety. However, the ASGE does concede that there is evidence to support its use in procedures targeting deep sedation. The guidelines also recommend use of this modality of monitoring sedation during complex endoscopic procedures, patients with multiple medical comorbidities, or those at risk for airway compromise. The ASGE does, however, concur with the ASA position that sedation is a continuum ranging from minimal sedation or anxiolysis to general anaesthesia.[3] It is worth pondering over how many patients originally targeted to have moderate sedation could actually progress to deeper levels resulting in transient hypoxemia, which however, the ASGE perceives as being inconsequential, since the

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relationship between these events and the occurrence of serious cardiopulmonary events has not been established.

Basis of guideline recommendations

These new directions from the ASGE are representative of the problems that can crop up when guidelines, advisories, or consensus statements depend on the obtuse exposition of available evidence accrued from different sources. The ASGE guidelines base their submission on the topic, on the results of a randomized clinical trial[4] undertaken in a fairly limited and carefully chosen patient subset, the results of which are being extended to a much wider patient population, whereas the ASA guidelines for moderate sedation in 2018, which makes a strong pitch for the use of capnography, draw conclusions from a set of randomised trials[4-8] that also includes the one that ASGE bases its statement on.

Capnography in moderate sedation

So, should capnography be a necessary accompaniment for monitoring moderate sedation? The plane of sedation is not so easy to fix. Different patients have different sensitivities to sedative agents. There are some patients who are at a higher risk of airway obstruction/hypoventilation due to coexisting conditions even at moderate levels of sedation. Further, despite careful titration of drugs, either through target controlled infusion (TCI) or otherwise, there is always a possibility the patient can slip either way, i.e., to light sedation or deep sedation and it may take a while for the patient to get back to a level of moderate sedation following drug adjustments. The time when a patient is in deep sedation even for a few minutes can prove to be catastrophic. Meta-analysis of randomized controlled trials indicates that the use of capnography corresponds with a reduced frequency of hypoxemic events, defined as SpO_2 <90%, when compared to monitoring without capnography during procedures with moderate sedation.[3] However, findings for this comparison were equivocal for randomized controlled trials communicating severe hypoxemic events, defined as oxygen saturation less than 85%,[4,5,7] and for oxygen saturation levels of 92, 93, and 95%.[6,8-10] However, it is eminently debatable whether avoidance of only the severe hypoxemic events should be the aim of monitoring patients undergoing moderate sedation.

The aim of monitoring is not only to identify problems and complications, but to avoid those. In the present scenario, it would be deemed inappropriate to even talk about saturation of 92% or 85%, leave alone checking if it causes cardiovascular or cerebral compromise. Monitoring $EtCO_2$ will give early warning about the possibility of desaturation, and hence, interventions start before the patient actually desaturates.

Endoscopy is not a procedure which can be comfortably done in patients who are capable of communicating. They often require deeper planes of anaesthesia. When patients gag, or move, the tendency is to increase the dose of the drug. For upper gastrointestinal diagnostic procedures which are short, the only time patients have significant discomfort is when the scope passes through the pharynx. However, procedures like Endoscopic retrograde cholangiopancreatography (ERCP), which take more time, and more manipulation, moderate sedation at all times may not be adequate. When sedation is being given by a non-anaesthesiologist, monitored parameters should actually be more than when an anaesthesiologist does it. A person who is not professionally trained to assess respiratory movements and changes thereof might pick up problems late. And the whole purpose of monitoring during sedation is to detect problems early.

Anaesthesia guidelines from non-anaesthesiology societies

Sedation for endoscopic procedures is done by medical workers at many levels in different countries. Sedation is pursued, in certain practices, by nurses and junior doctors working under the supervision of the endoscopist. This obviously has prompted drafting of these guidelines by ASGE. It would appear, however, that the ASGE has in this case brought forth guidelines that are clearly under the purview of the science of anaesthesiology, even though the care being delivered could be by a non-anaesthesiologist. The point of contention here is certainly not the intent of the ASGE in providing clinical guidance to what appears to be non-anaesthesiology clinicians in safe provision of sedation for patients undergoing gastrointestinal endoscopic procedures. ASGE appears, in this particular recommendation about the use of end-tidal CO_2, to have assumed that moderate and deep sedation are compartmentalized clinical entities, with no possibility of one proceeding to the other, a concept that most clinical anaesthesiologists would not concur with. There is no doubt that ASGE is a highly respected clinical organization. It should also be amply evident that an organization such as this, when it frames guidelines, would do so based on the recommendations of an expert panel of the

highest order, who would without a doubt, undertake a punctilious perusal of the available data. However, it is apparent from the stated procedure employed for drafting these guidelines, that there was no attempt to garner opinions of other clinicians who may have a stake in development of these guidelines in any relevant clinical meetings, as is done in several other clinical societies. The strategem of the ASA for developing guidelines is, on the other hand, extremely rigorous with the 2018 guidelines on moderate sedation going through a seven-step process.[3] This includes a systematic process that clearly determines the precise level of evidence spanning across all the strata of evidence assembled.

Who determines standard of care?

This brings us back to the very important question: Who determines what is the standard of care for a medical speciality? Unfortunately, the response is not straightforward and rests to a large extent on the situation, with no clarity on who could prescribe such standards. In the Indian judicial system, since it is not easy to represent distinct standards for all facets of clinical execution and all phenomena, the courts have fashioned the “reasonable and prudent” doctor. In most judicial perceptions, the doctor must demonstrate a justifiable degree of skill and mastery over his science and must exercise an equitable degree of care, neither of which need necessarily, be of the highest standards. Despite disclaimers by societies which bring out guidelines such as the one under consideration, that these should not be construed as legal standards of care, doubts can arise when the practising doctor in an area does not follow a clinical execution guideline that is well-documented.

Guidelines galore

There are currently many institutions, societies, and groups which are coming out with communications, guidelines, and frameworks for anaesthetic applications. The trend needs to be discouraged. First, it is often evident that small groups funded either directly or indirectly by pharmaceutical agencies are often not of the levels desired to bestow guidelines, practice parameters, or consensus statements, notwithstanding the credentials of the experts in the group. It is imperative that issuing guidelines, practice parameters, or consensus statements should be undertaken only by the population germane to that medical speciality. For anaesthesiology, for instance, this should involve national and international societies devoted to anaesthesiology as a whole, or national and international societies constantly related to the sub-specialities thereof, since these institutions would have the necessary number of clinicians to appropriately fund criterion buildout, and their summits would have the requisite delegates to review the parameters proposed during open conventions.

Summary

Well-organized testing of distinct society advocacies is a must. It is imperative that these advocacies in any consensus statements be revoked by new authentication in scientific literature. It is also essential that groups and institutions without a rigorous strategy and/or extremely high levels of credibility for drafting these guidelines should leave the compilation of consensus statements, parameters, and practice guidelines to others with ample resources and adherents to appropriately draft and review those.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Announcement

Conference Calendar - 2018

ISACON 2018 Agra
66th Annual National Conference of Indian Society of Anaesthesiologists
Dates: 25th to 29th November 2018
Venue: Jaypee Palace & Convention Centre, Agra
Org. Secretary: Dr. Ranvir Singh Tyagi
Mobile No.: 9837047812
E Mail ID: isaconagra2018@gmail.com
Website: isacon2018.org

ISACON South 2018
Annual South Zone Conference of Indian Society of Anaesthesiologists
Date: 7 to 9 September 2018
Venue: Thirupathi, AP
Organising Chairman: Prof. M.Hanumantha Rao (drmhraosvims1957@gmail.com)
Organizing Secretary: Dr Madan M. Reddy, Mobile:9849794934

ISACON North East 2018
Annual North East Zone Conference of Indian Society of Anaesthesiologists
Date: 8 & 9 September 2018, workshops on 7th September
Venue: Jawarhalal institute of medical sciences Imphal,Manipur
Organizing Secretary: Dr. Thoibahenba, Mob. No.- 9436039818,
Email - thoibas@gmail.com

ISACON East 2018
Annual East Zone Conference of Indian Society of Anaesthesiologists
Date: 5 to 7 October 2018
Venue: Kolkata

ISACON West 2018
14th Annual West Zone Conference & 20th Annual Maharashtra State Conference of Indian Society of Anaesthesiologists
Date: 5 to 7 October 2018
Venue: St. Laurns, Shirdi, Maharashtra
Organizing Secretary : Dr. Subhash Tuvar
Email ID: drsubhashtuvar@gmail.com Mobile - 9422220700

ISACON TN 2018
Annual Conference (ISACON TN 2018) of the Indian Society of Anaesthesiologists, TN State Chapter
Date: 21& 22 July 2018
Venue: Coimbatore
Org. Secretary: Dr. S. M. Senthil Nathan
Mobile: 9944635015, **E Mail:** drnathas@gmail.com

ISACON Telangana 2018
4th Annual Telangana State Conference of Indian Society of Anaesthesiologists
Date: 26 to 29 July 2018
Venue: KIMS, Sreepuram, Narketpally, Nalgonda
Org. Secretary: Dr. N Gopal Reddy
Mobile: 9848094021
E Mail: drgopalreddynarra@yahoo.com
Website: isacontelangana2018.org

ISACON Karnataka 2018
34th Annual Karnataka State Conference of Indian Society of Anaesthesiologists
Date: 10 to 12 August 2018
Pre Conference Workshop on 09.08.2018.
Venue: Bapuji Auditorium, JJMMC, Davanagere
Org. Secretary: Dr. Prabhu B G, 9886720630, isaconkarnataka2018@gmail.com
Website: www.isaconkarnataka2018.in

ISACON UK 2018
Annual Uttarakhand State Conference of Indian Society of Anaesthesiologists
Date: 7-9 September 2018
Venue: AIIMS Rishikesh
Org. Secretary: Dr. Ankit Agarwal E Mail drankit80@gmail.com, Mob.; 9415030960

ISACON MP 2018
Annual Madhya Pradesh State Conference of Indian Society of Anaesthesiologists
Date: 9 September 2018
Venue: Anjushree Hotel, Ujjain
Org. Secretaries: Dr. Harshwardhan Choudhry hershoe17871@gmail.com / 9826295496
& Dr. Deepika Agrawal deepikanitin@yahoo.co.in / 9826713464
Website: www.

ISACON Rajasthan 2018
20th Annual Gujarath State Conference of Indian Society of Anaesthesiologists
Date: 22 & 23 September 2018
Venue: Sardar Patel Medical College, Bikaner
Org. Secretary: Dr. Kanta Bhati **E Mail:** drkantabhati67@gmail.com,
Mob. 9413466688
E mail : 20isaconrajasthan2018@gmail.com
Website: 20isaconrajasthan2018.com

ISACON Kerala 2018
Annual Kerala State Conference of Indian Society of Anaesthesiologists
Date: 12 to 14 October 2018
Venue: Windsor Castle, Kottayam
Org. Secretary: Dr. Aby John
E Mail: isaconkerala2018@gmail.com, 9072986205
Website: isaconkerala2018.com

ISACON Gujarat 2018
51st Annual Bihar Jarkhand State Conference of Indian Society of Anaesthesiologists
Date: 19 to 21 October 2018
Venue: The Grand Bhagwati, Magdalla Circle, Dumas Road, Surat.
Org. Secretary: Dr. Jayesh Thakrar
E Mail: isacongujarat2018@gmail.com, 9825263969
Website: isacongujarat2018.com

ISACON Bihar Jarkhand 2018
31st Annual Bihar Jarkhand State Conference of Indian Society of Anaesthesiologists
Date: 26 to 28 October 2018
Workshop on 26.10.2018, CME on 27.10.2018
Org. Secretary: Dr. Ajay Kumar E mail : kumar.ajay5174@yahoo.in , 9334087579
Venue: Vardhman Institute of Medical Science, Pawapuri, Nalanda.

ISA Sponsored CME, Madikeri
Conducted by ISA Mysuru City Branch
Venue: Hotel Coorg International, Madikeri
Organising Secretary : Dr. Pratibha Matche, 9845055453, isamysuru@gmail.com
Date : Sunday, 20 May 2018.

ISA Sponsored Workshop, Bhubanmeshwar
Conducted by ISA Bhubaneshwar City Branch
Venue: Star Hospital, Bhubanewshwar
Organising Secretary: Gaurav Agarwal, M: 7381094049
E: dr.agarwalgaurav@gmail.com
Date : Saturday & Sunday, 29 & 30 Sept. 2018.