

Practice Guidelines for Intravenous Conscious Sedation in Dentistry (Second Edition, 2017)

Developed By The Japanese Dental Society of Anesthesiology for Dentists Practicing Sedation in Japan

Intravenous sedation is a method of intravenously administering a sedative so that a patient can receive dental treatment safely and comfortably; it is a patient management method that reduces or eliminates fear and anxiety during treatment.^{1,2} This method is a specialized treatment that is used worldwide and responds to the need to prevent medical complications, underlying disease exacerbation, and stress during oral/dental surgical treatment under local anesthesia in patients with dental phobia or medical compromise.^{3,4}

Dental treatment is characterized by the fact that the surgical field and the airway are the same site; the use of a mouth prop narrows the airway, and water stored in the oral cavity easily flows into the pharynx/larynx due to the use of dental rotary and cutting equipment. Maintaining consciousness, swallowing and upper respiratory tract reflexes, and sufficient respiration during dental treatment is extremely important in preventing airway obstruction and aspiration.^{1,5} Conscious sedation is a procedure in which the level of sedation is regulated so that consciousness is maintained. Anxiety and fear of dental treatment and oral surgical procedures are frequently eliminated; calm is maintained, and the patient can respond to verbal command or light physical stimuli.^{5,6} The term *conscious sedation* that is used in Japan is equivalent to the term *minimal to moderate sedation* in the American Dental Association (ADA) guidelines⁷ and *minimal to moderate sedation/analgesia* in the American Society of Anesthesiologists (ASA) guidelines.⁸

However, in clinical dentistry, there are cases in which behavioral management is performed with sedation to deliberately cause a loss of consciousness for a period of time.⁹ This state is called “deep sedation.” Deep sedation is associated with more side effects and

complications, such as airway obstruction and aspiration, compared with conscious sedation. Moreover, because advanced knowledge and techniques are required, it is necessary to perform perioperative management similar to that for general anesthesia.^{6,10}

The ASA statement regarding monitored anesthesia care notes that providers of moderate sedation must be qualified to recognize deep sedation, manage its consequences, and adjust the level of sedation to a moderate or lesser level.¹¹ In Japan, several clinicians fail to understand the difference between “conscious sedation” and “deep sedation” in terms of the common practices, concepts, and indications. The reason is that there are no comprehensive guidelines on proper management under “conscious sedation,” which is a basic technique of intravenous sedation. Therefore, in these guidelines, similar to the first edition, standard guidelines have been presented, so that management of intravenous conscious sedation can be performed safely and effectively in adults.

The first edition of these guidelines was issued in September 2009. It was decided that a revised version of that report should be issued, since the first publication was issued 7½ years ago. Since evidence regarding relatively new sedative drugs in dental practice is lacking, these new drugs are not covered in this revised edition. However, evidence indicating the utility of propofol, a conventionally used sedative, has been reported and was added to this revised edition. In our principle of conscious sedation, no analgesic drugs were included, and benzodiazepine and propofol were included when used alone or in combination. Intravenous sedation with propofol should be performed only by appropriately trained practitioners.

We should explain the legal status of the provision of sedation/general anesthesia in Japan. General anesthesia can be legally provided by any dentist in Japan. Dental students receive more than 50 hours of lectures on anesthetic management in dental school, with the total varying between universities. The faculties in Departments of Dental Anesthesiology are responsible for training in dental anesthesia. Thus, the national examination for licensing of dentists includes the field of anesthetic management. Undergraduate education qual-

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ifies a dentist in Japan to provide anesthetic care, including general anesthesia, for dental treatment. It is, however, obvious that further coursework is required to ensure the safe provision of anesthetic care in dentistry. The Japanese Dental Society of Anesthesiology is responsible for overseeing such training courses. In 1977, the Japanese Board of Dental Anesthesiologists was established as a qualifying examination for anesthesia providers. Most anesthesia providers in dentistry have taken specific residencies in a Department of Dental Anesthesiology and have passed a board examination after approximately 3 years of full-time training. As dental anesthesiologists, we generally advise trainee dentists, including oral surgeons and general practitioners, who are willing to learn dental anesthesia that they should provide intravenous sedation by themselves in a private office only after they obtain certification by the Japanese Board of Dental Anesthesiologists (ie, completed residency training in dental anesthesiology). However, some oral surgeons and general practitioners train in providing intravenous sedation under previously trained oral surgeons or medical anesthesiologists who are skilled at sedation management. Even though serious adverse events related to dental anesthesia are quite rare in Japan, our society continues to provide education and continuing education in safe anesthetic practices for health care providers in this field. Thus, this guideline is one of the methods our society uses to promote safe dental anesthesia management.

To introduce this revised version to dental practitioners around the world who perform sedation, we hereby publish an English version. It should be noted that some newer guidelines of other organizations were not available at the time of the Japanese publication. Therefore, reference is made to the most recent guidelines of other organizations as of 2017, when this guideline was published in Japanese.

These guidelines were prepared in accordance with the procedure manual of “evidence-based medical care”¹² by the Working Group of the Japanese Dental Society of Anesthesiology consisting of board-certified dental anesthesiology specialists and reviewed by six societies in related fields (Japanese Society of Oral and Maxillofacial Surgeons, Japanese Society for Disability and Oral Health, Japanese Society of Oral Implantology, Japanese Society of Pediatric Dentistry, Japanese Society of Gerodontology, Japanese Society of Dentistry for Medically Compromised Patients).

Details concerning the targets of the literature search, evidence levels, and recommendation levels are described, as follows.

1. We clarified the clinical questions (CQs) regarding intravenous conscious sedation that are performed at

present and searched the literature concerning each CQ.

2. To select relevant references, working group members were divided to perform searches of the literature, mainly using *Igaku Chuo Zasshi* (ICHUSHI) and PubMed. Independently collected papers were also used as references. The evidence levels and recommendations extracted from the reference literature were discussed among the working group members, and a final draft was created.
3. The recommendations and evidence levels used in these guidelines are shown below.

Degree of recommendation

- Grade A: Strongly recommended to be performed
- Grade B: Recommended to be performed
- Grade C: The evidence for recommendation is unclear
- Grade D: Not recommended to be performed

Evidence level

- Level I: Systematic review/meta-analysis
 - Level II: One or more randomized controlled trials
 - Level III: Nonrandomized controlled trial/prospective clinical trial
 - Level IV: Analytical epidemiological study (cohort study or case-control study)
 - Level V: Descriptive study (case report or case series)
 - Level VI: Opinion of technical committees and experts; not based on patient data
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Evidence Levels I and II are classified as degree of recommendation A, evidence level III as degree of recommendation B, and evidence Levels IV to VI as degree of recommendation C. When reports that met level I and II criteria could not be found, if the items were determined to be highly or moderately recommended by the working group members, they were marked as “degree of recommendation A or B evaluated by the Working Group on Guidelines Development.” When a quoted statement was not derived from evidence-based medicine, although it was from a systematic review, it was classified as “Level VI in I” and Grade B. In practice, there were some CQs for which it was difficult to find evidence, and they were consolidated as the opinion of the working group.

The purpose of these guidelines is to support medical treatment, but they do not restrict the discretion of the dentist/physician or limit medical treatment. How these guidelines are used in the clinical setting should be determined by the patient’s needs and the expert knowledge and experience of the dentist/physician.

It is our hope that patients who cannot receive standard dental treatment will be able to receive appropriate dental treatment by undergoing safe and effective intravenous conscious sedation and that these guidelines contribute to the progress of dental care and patient health.

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The various clinical issues are addressed in a question and answer format.

PREOPERATIVE MANAGEMENT

1. CQ: How should the general status of the patient be assessed?

Recommendation. Although it is desirable to follow the guidelines for general anesthesia, it is important to focus on the detailed medical interview (medical interview) and recording of vital signs (degree of recommendation: A evaluated by the Working Group on Guidelines Development). If the patient has or is suspected to have a systemic illness, it is advisable to consult with the attending physician (medical inquiry) via medical records (degree of recommendation: B evaluated by the Working Group on Guidelines Development). Comprehensive evaluation should be carried out by the attending dentist or dentist in charge who is knowledgeable and skilled (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

Refer to: CQ 2–6). What education and training are necessary for intravenous sedation?

Scientific Basis. In general, patients with ASA physical status classification I or II are considered appropriate for intravenous sedation in dentistry. It is necessary to verify whether or not medical treatment is being performed based on the latest guidelines for each disease (refer to Medical Information Network Distribution Service). Moreover, it is also necessary to confirm whether or not adequate medical management is being performed.^{13,14}

Perform a detailed verbal examination (medical interview), which covers disease history, current disease state, medications taken, family history, discomfort level during past dental treatments, and any allergies to food, medicine, etc (level IV).^{5,15,16} After the medical interview and measurement of vital signs, preoperative screening tests and comprehensive assessment of the patient's general status should be performed, and, if necessary, written inquiries to the treating physician (medical information request form) should be made. This is relatively acceptable if there is only one complicating factor and medical management is sufficient; however, there are cases in which the patient visits multiple medical institutions for multiple systemic or chronic diseases or is administered medication for long periods, and it is appropriate to

evaluate the general status of the patient based on all of his or her information. Furthermore, the goal of patient evaluation should be determined by how well the patient can tolerate the planned dental treatment, which sedation method is optimal for the patient, and so on (level IV).^{17,18}

Explanation. Particularly in cases of intravenous sedation in outpatients, it is necessary to perform more detailed preoperative interviews before surgery (interviews of family members or accompanying persons may be necessary in some cases) and measure vital signs. It is important to accurately perform preoperative evaluations, since management after patients return home is not possible.

2. CQ: What are the indications/contraindications of intravenous sedation?

Recommendation. Indications/contraindications of intravenous sedation are considered to include the following (degree of recommendation: B).

1. Indications

- 1) Patients with dental phobia
- 2) Patients in whom vasovagal reflex, hyperventilation syndrome, panic disorder, and so on are likely to develop from dental treatment
- 3) Patients with a strong vomiting reflex or abnormal gag reflex
- 4) Patients who require stabilization of intraoperative circulatory dynamics (patients with hypertension, heart disease, etc)
- 5) Persons with disabilities who require sedation (see note)
 - (1) Patients with cerebral palsy who have severe athetosis or spasticity
 - (2) Patients with Parkinson's disease who have severe tremor

(Note) The purpose of intravenous sedation is to relieve stress. It is necessary to differentiate this from deep sedation for the purpose of behavior modification in persons with disabilities and uncooperative children. In the case of patients with cerebral palsy, muscle tension and involuntary movements are frequently worsened by stress and can be relieved by intravenous sedation. In patients with Parkinson's disease, tremor at rest can be reduced by intravenous sedation.

- 6) Patients undergoing highly invasive treatment

2. Contraindications

- 1) Patients in early stages of pregnancy

- 2) Patients who have an allergy to the sedative
- 3) Patients who are using a contraindicated drug
 - (1) Patients with myasthenia gravis (diazepam, flunitrazepam)
 - (2) Patients who are using a protease inhibitor (eg, ritonavir) for treatment of HIV (diazepam)
 - (3) Patients with acute angle-closure glaucoma (diazepam, flunitrazepam)
3. Patients who require special care when undergoing intravenous sedation
 - 1) Patients with diseases associated with upper airway obstruction (eg, severe obesity, micrognathia, tonsillar hypertrophy, obstructive sleep apnea syndrome, severe cerebral palsy)
 - 2) Patients who are thought to have residual stomach contents
 - 3) Patients with severe systemic illness, especially those with decreased respiratory or cardiovascular reserve capacity
 - 4) Patients who have previously experienced an adverse event due to intravenous sedation
 - 5) Patients receiving oral long-term psychotropic or antipsychotic drug administration
 - 6) Patients with muscular dystrophy

Scientific Basis. The application of intravenous sedation is wide ranging, and it can be used in most patients (level VI).⁵ However, care is especially needed when performing intravenous sedation in patients who require special care (level VI, level IV in level I).^{8,19}

Explanation. The incidence of complications during intravenous sedation, especially respiratory complications, such as respiratory depression and airway obstruction, is high; in some cases, intraoperative airway management by mask ventilation and endotracheal intubation may be necessary. Therefore, caution is needed with intravenous sedation in patients in whom airway management is difficult (eg, severe obesity, short neck, neck tumor, cervical spine injury, mandibular micrognathia, trismus, tonsillar hypertrophy, cerebral palsy).

3) CQ: Are routine preoperative screening tests (ie, hematologic tests, chest radiography, electrocardiography) necessary?

Recommendation. For intravenous sedation, routine preoperative screening tests not based on specific indications are not necessary (degree of recommendation: A). However, after recording the patient's medical history and performing a physical examination, if necessary, a preoperative evaluation should be performed similar to

one performed before surgery with general anesthesia (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

Scientific Basis. There were no significant differences in the rate of complications between the group who received and the group who did not receive a routine preoperative screening test (level II).^{20,21} In the absence of specific indications, routine preoperative laboratory tests contribute little to patient care (level IV).²² Medical history evaluation and careful physical examination are important for the preoperative evaluation of patients, and based on this information, it must be determined whether further preoperative evaluation is necessary (level VI).²³

4) CQ: How to provide a description of the procedure and obtain consent (informed consent) from patients?

Recommendation. The attending anesthesiologist should provide a description of the procedure to the patient and obtain consent (informed consent) after distributing the descriptive pamphlet in advance (degree of recommendation: B). A description by an anesthesiologist with extensive experience and knowledge is more effective in relieving anxiety of intravenous sedation compared with one by an inexperienced anesthesiologist (degree of recommendation: B).

Scientific Basis. After the information describing the anesthetic procedure was given to patients in advance, they could deepen their understanding of the procedure with the anesthesiologist's description (level III).²⁴ Compared with a description by an anesthesiologist with less experience and less knowledge, a description by an anesthesiologist with extensive experience and deep knowledge significantly reduced patients' anxiety (level III).²⁵

5) CQ: Is preoperative oral intake restriction necessary? If so, what type of restriction is necessary?

Recommendation. It is recommended that preoperative oral intake restriction be implemented for intravenous sedation (degree of recommendation: A evaluated by the Working Group on Guidelines Development). Even for subjects who undergo conscious sedation, oral intake restriction is necessary because if the patient unintentionally enters a deep state of sedation, the possibility of aspiration cannot be ruled out.

The following are recommended as oral intake restrictions (degree of recommendation: B).

- Up to 2 hours before: intake of clear liquids (water, fruit juice containing no pulp, carbonated beverages,

tea, functional soft drinks such as sports drinks, black coffee) acceptable

- Up to 6 hours before: milk and light meals (toast and clear liquids) acceptable
- Up to 8 hours before: intake of normal meals acceptable

Scientific Basis. In the “Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists” of the ASA, it is recommended that preoperative oral intake restriction be implemented (level IV in level I).⁸ However, evidence on oral intake restriction for intravenous sedation during dental treatment is poor, and no conclusion has been reached. One report suggests that if the level of sedation is similar to that of conscious sedation, there is no need for preoperative oral intake restriction (level V).^{26,27} However, there is also an opinion that even under conscious sedation, intake restriction should be applied similar to deep sedation and general anesthesia (level IV).²⁸

When performing intravenous sedation, some form of oral intake restriction was implemented in 21 out of 23 university hospital dental anesthesiology departments in Japan (level VI).²⁹ The results of a questionnaire on intravenous sedation from 70 institutions showed that some type of absolute fasting was implemented in 50 to 60% of facilities. However, 10% of facilities did not implement any type of fasting (level VI).⁵

The ASA guidelines list recommended preoperative oral intake restriction methods (level I).⁸ According to a study by Kurozumi et al,²⁹ the mean fasting time was 8.3 ± 2.3 hours, and the mean liquid fasting time was 6.8 ± 3.1 hours (level VI). In a report by Campbell and Smith,³⁰ 200 patients older than 65 years who underwent an oral surgical procedure were allowed to ingest solid food up to 8 hours before and drink clear liquids up to 3 hours before intravenous sedation was performed. No intraoperative or postoperative nausea, vomiting, aspiration, or dehydration was noted. Morse et al³¹ administered a survey to Japanese dentistry departments and dental university hospitals; they found that the mean fasting time was 5.5 ± 3.0 hours (0–12 hours), and the mean liquid fasting time was 3.7 ± 2.4 hours (0–9 hours; level VI).

Explanation. There are no reliable data on the incidence of vomiting and aspiration during dental procedures under intravenous sedation. However, severe aspiration has been reported in endoscopic surgery under intravenous sedation. As various dental procedures can induce vomiting, it is important to adhere to preoperative oral intake restriction.

6) CQ: What education and training are necessary for intravenous sedation?

Recommendation. To safely perform intravenous sedation, it is necessary to receive training in anesthetic pharmacology, anesthesia technique, systemic physical management, and emergency resuscitation (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

Scientific Basis. According to the “Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists” of the ASA (level VI in I),⁸ when sedation is performed by a nonanesthesiologist, it is strongly recommended that the practitioner receive training in anesthetic pharmacology, anesthesia technique, systemic management, and emergency resuscitation. In addition, in the “Policy Statement: Use of Sedation and General Anesthesia by Dentists” (level VI),³² “Guidelines for the Use of Sedation and General Anesthesia by Dentists” (level VI),⁷ and “Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students” (level VI),³³ the ADA provides guidance on education and training and recommends practitioners undergo this training before performing sedation.

Explanation. In predoctoral (dental student) dental education in Japan, the following classes are offered for dental anesthesiology: “anesthesia and the nervous system,” “anesthesia and the respiratory system,” “anesthesia and the circulatory system,” “anesthesia and the endocrine system,” “anesthesia and the urinary system,” “anesthesia and circulatory disorders,” “anesthesia and immunity,” “action of anesthetics,” “application and pharmacokinetics of drugs,” “side effects and adverse effects of drugs,” “preoperative examination and systemic diseases,” “vital signs and systemic complications,” “sedation technique,” and “cardiopulmonary resuscitation; basic life support and advanced life support.”³⁴

7) CQ: What are the skills needed to administer sedatives intravenously?

Recommendation. Sedatives are administered continuously or intermittently during intravenous sedation. In addition, in some cases, administration of an inotrope or emergency drugs may be required during patient management. Therefore, during sedation, it is necessary to pay attention to complications that arise from venous access itself and acquire the necessary skills to prevent them (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

Scientific Basis. According to the results of a questionnaire survey on intravenous sedation administered to 77 institutions, including dental universities and dental schools throughout Japan, the actual treatment time during intravenous sedation was as follows: within 1 hour, 37.8%; within 1 to 2 hours, 34.9%; within 2 to 3 hours, 16.9%; within 3 to 4 hours, 7.6% (level IV).⁵

Cases of seizures, hyperventilation syndrome, and cardiac arrest following severe vasovagal reflex caused from the establishment of intravascular access in intravenous sedation have been reported (level V).^{35,36} There have also been reports of vasovagal reflex with suppression of the circulation requiring use of circulatory agonists and/or emergency treatment (level V).^{37,38}

Explanation. During intravenous sedation, it is necessary to secure venous access over a relatively long period of time; it is desirable to select an indwelling catheter to avoid vascular injury or fluid leak when body movements occur and to select a large blood vessel to prevent vascular pain or postoperative phlebitis. Furthermore, it is necessary to have humane and appropriate puncture technique.

INTRAOPERATIVE MANAGEMENT

1) CQ: Can the practitioner performing intravenous sedation also perform the dental treatment?

Recommendation. If the level of sedation is within the range of conscious sedation, the practitioner performing the dental treatment can also perform intravenous sedation. However, the practitioner needs to acquire considerable knowledge and skills concerning sedation and emergency treatment. It is also necessary to have 1 or more assistants devoted to monitoring patient status (degree of recommendation: C).

Scientific Basis. Although there are little data on the subject, in principle, intraoperative sedation management should be performed by a person who is not performing the dental treatment (level VI).⁵ However, there are no studies that form the basis for the recommendations in the “Guidelines for Sedation and Analgesia by Non-anesthesiologists” of the ASA⁸ and the sedation guidelines of the American Academy of Pediatrics/American Academy of Pediatric Dentistry.³⁹ Therefore, the expert committee determined who should perform intravenous sedation according to the target level of sedation. That is, if the target sedation level is moderate (conscious sedation), the practitioner performing the dental procedure may also perform intravenous sedation, but the practitioner must be a person with expert knowledge and skill who can sufficiently handle emergencies. In addition, one assis-

tant assigned to monitor the condition of the patient is necessary. However, it has been noted that when implementing deep sedation, the specialist devoted to patient management must be assigned separately from the surgeon (level VI).

Rodgers investigated 2889 patients who underwent intravenous sedation that was performed by an oral surgeon during the 7-year period from December 1994 to November 2001; the reported incidence of complications was 2.67% (77/2889; level V).⁴⁰ In this study, the oral surgeon who performed intravenous sedation was knowledgeable about anesthesia practices (National Dental Board of Anesthesiology certified) and received advanced cardiovascular life support training every 2 years. Intraoperative patient monitoring was performed by a dental assistant who had taken a course on anesthesia practices. In addition, Rodgers and colleagues conducted a similar study from December 2001 to November 2008 and reported that the incidence of complications was 1.80% (60/3320; level V).⁴¹ The sedation level ranged from moderate to deep sedation in most patients, but no patients received intravenous general anesthesia.

Lee et al reported that there was no difference in the incidence of intraoperative complications (0.4 and 0.25%, respectively) when intravenous sedation was performed by the oral surgeon performing dental treatment or when performed by an anesthesiologist or a nurse anesthetist (level V).⁴²

Explanation. During sedation, continuous monitoring of the patient’s breathing status, circulatory dynamics, and so forth must be performed. It is also necessary to respond appropriately to the degree of sedation, which constantly changes because of the conditions of the surgery. Furthermore, when there is a sudden change in the condition of the patient, prompt response is required. When the person performing the dental treatment also performs intravenous sedation, it is difficult to fully understand the status of the patient under sedation; conversely, when the practitioner concentrates on patient management, the progress of the dental treatment is hindered. Based on the above findings, it is the authors’ opinion that it is desirable for intravenous sedation to be implemented by a different person from the one performing the dental treatment. In recent years, it has been reported that intravenous sedation, including deep sedation performed by the oral surgeon who is performing the dental treatment, has been performed safely; however, in such cases, it was also essential to have a well-trained nurse familiar with intravenous sedation and methods of evaluating the general status of the patient to concentrate on patient monitoring during the procedure.

2) CQ: How long is the treatment duration under intravenous sedation?

Recommendation. It is preferable that the duration of treatment under intravenous sedation is less than 2 hours (degree of recommendation: B evaluated by the Working Group on Guidelines Development).

Scientific Basis. In the questionnaire survey, the percentage of cases according to actual treatment duration during intravenous sedation was as follows: within 1 hour, 37.8%; from 1 to 2 hours, 4.9%; from 2 to 3 hours, 16.9%; from 3 to 4 hours, 7.6%.⁵ However, the percentage of procedures that were considered to have appropriate treatment durations were as follows: within 30 minutes, 1%; within 1 hour, 25.7%; within 1.5 hours, 14.3%; within 2 hours, 44.3%; within 3 hours, 14.3% (level VI).⁵ In a study of intravenous sedation in 200 elderly patients (mean age: 72 ± 4.2 years) who received oral surgical treatment, the treatment duration ranged from 6 to 129 minutes (level VI).³⁰ Lepere and Slack-Smith⁴³ performed dental procedures under intravenous sedation in 85 patients in private dental clinics. Treatment duration was 8 to 185 minutes (mean time: 71.4 ± 37.5 minutes; median time: 64 minutes). Messieha et al⁴⁴ performed independent intravenous sedation (using fentanyl, midazolam, propofol, etc) in 100 patients and retrospectively investigated the treatment duration and complications. The mean treatment duration was 97.5 ± 42.39 minutes, and complications occurred in 6 cases.

Explanation. There are no highly reliable studies that have examined the length of treatment time, quality of sedation, and incidence of complications during intravenous sedation. However, when the treatment time under intravenous sedation is prolonged, the patient often becomes agitated, making it difficult to maintain sedation. In an investigation of the treatment duration under intravenous sedation, most cases were completed within 2 hours, and there were few reports of serious complications. Therefore, it is considered reasonable to set the guideline for treatment duration under intravenous sedation to 2 hours.

3) CQ: What intraoperative complications may occur?

Recommendation. During intravenous sedation, caution is needed regarding the occurrence of the following complications (degree of recommendation: A).

- 1) Respiratory complications
 - Hypoxia (decreased SpO₂)
 - Airway obstruction/glossoptosis/snoring

- Respiratory depression/respiratory arrest
 - Cough (cough reflex)
 - Aspiration pneumonia
- 2) Cardiovascular complications
 - Hypertension/hypotension
 - Tachycardia/bradycardia
 - Cardiac arrest
 - Arrhythmia
 - Vasovagal reflex
 - 3) Other complications
 - Nausea/vomiting
 - Restless/excited state (agitation)
 - Vascular pain/phlebitis
 - Anaphylaxis

Scientific Basis. During intravenous sedation, respiratory complications, such as respiratory depression and glossoptosis, frequently occur (level VI).⁵ According to one study that analyzed the causes of intravenous sedation failure, the most common reason why the scheduled treatment could not be performed was patient disturbance/excitement (agitation; level V).⁴⁵ Refer to the section on medication and the side effects caused by each drug that is used in intravenous sedation.

Explanation. In implementing intravenous sedation, it is important to recognize the possibility of these complications, and practitioners must adequately monitor patients and prepare countermeasures against these complications.

4) CQ: When establishing intravenous access, what are the points to consider to avoid nerve damage?

Recommendation. The puncture sites for intravenous access include the dorsum of the hand, radial side of the wrist joint, antecubital fossa, and so on. When selecting the cephalic vein, it is recommended to avoid puncturing at a site close to the wrist joint (degree of recommendation: C). If puncturing at the antecubital fossa, it is desirable to select a cutaneous vein on the radial side of the antecubital fossa (degree of recommendation: C). If the patient feels an abnormal sensation or numbness in the punctured area, remove the needle promptly. Care is also necessary when removing the needle (degree of recommendation: C). Although the incidence of nerve injury and tissue damage accompanying venipuncture is small, it should be performed after fully understanding the anatomy of the surrounding region of the puncture site (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

Scientific Basis. The nerves that may be damaged from intravenous puncture include the antebrachial cutaneous nerve in the antecubital fossa, the superficial

branch of the radial nerve at the wrist, and the dorsal sensory branches in the hand (level V).^{46–48} When puncturing the cephalic vein of the wrist, it has been reported that puncturing should be performed on the central side at 12 cm or further from the styloid process to avoid nerve damage to the superficial branch of the radial nerve (level V).⁴⁹ It has been reported that, when performing venous puncture at the cubital fossa, the median basilic vein should be avoided.⁴⁸

The incidence of nerve damage accompanying venipuncture is rare. When minor cases were included, the incidence was 1 out of 6300, and when limited to patients with a recovery period of 1 month or longer, the incidence was 1 out of 20,500 cases⁵⁰; 3 out of 560,000 patients took more than a year until fully healed⁵¹ (level V).

Although it is impossible to completely prevent peripheral nerve damage during vascular puncture, the necessity of avoiding puncture at sites with a high risk of nerve damage and prompt response when neurological symptoms occur has been previously stressed (level V).^{47,48} In addition, cases have been reported in which nerve damage occurred not only during venous puncture but also during removal of the catheter (level V).⁵²

Explanation. Although the incidence of peripheral vascular injury due to venipuncture is rare, when performing vascular access via the cephalic vein, sufficient anatomical knowledge is necessary to avoid complications, such as the possibility of radial nerve damage. Furthermore, when radiating pain or numbness occurs during needle insertion, stop immediately and remove the needle.

5) CQ: Is it possible to improve the safety of intravenous sedation through monitoring?

Recommendation. Consciousness, ventilation, oxygenation, and circulation (pulse rate and blood pressure) should be monitored continuously (intermittently in some cases; degree of recommendation: A evaluated by the Working Group on Guidelines Development). Monitoring of consciousness with a bispectral index (BIS) monitor and monitoring of ventilation by expiratory gas analysis is recommended to enhance the safety of intravenous sedation (degree of recommendation: A). Electrocardiography should be considered in patients with cardiovascular or respiratory disease (degree of recommendation: B evaluated by the Working Group on Guidelines Development).

1. Consciousness

- A BIS monitor is useful for maintaining an appropriate sedation depth.

- Intermittently evaluate response to verbal contact.
- ###### 2. Ventilation
- An end-tidal CO₂ monitor is useful for the prevention and early detection of respiratory depression.
 - Intermittently observe the chest movements
 - Evaluate ventilatory state through respiratory sound auscultation and conversation with patient.
- ###### 3. Oxygenation
- Continuously monitor SpO₂ level.
 - Intermittently assess the color of mucosa, skin, and blood.
- ###### 4. Circulation
- Continuously monitor pulse rate.
 - Intermittently assess blood pressure.
 - For cardiovascular and respiratory diseases, consider the use of electrocardiography.

Scientific Basis. By monitoring consciousness with a BIS monitor during sedation, appropriate sedation depth can be maintained with a lower drug dose (level II, III).^{53–55} During sedation with midazolam and propofol, protective reflexes were significantly inhibited when the BIS score was maintained below 75 (level III).⁵⁶ Monitoring of ventilation by analysis of expiratory carbon dioxide during sedation significantly inhibited the incidence of respiratory depression and hypoxia (level II).^{57,58} Respiratory sound auscultation is useful to measure respiration rate during sedation of healthy adults, but it is less reliable during sedation of patients with disabilities (level III).^{59,60} All complications that were reported in the multicenter survey on intravenous sedation (Ramsay score 2–3) using midazolam comprised cases of mildly decreased oxygen saturation (level V).⁶¹

According to the “Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists” published by the ASA (level VI in I),⁸ sedation guidelines of the ADA (level VI),⁷ and “Guidelines for Safe Performance of Intravenous Sedation” commissioned by the Japanese Dental Association (level VI),⁵ consciousness, oxygenation, ventilation, and circulation (pulse rate, blood pressure, and electrocardiography, if necessary) should be monitored continuously (intermittently in some cases). However, in the ASA’s “Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists” (level VI in I),⁸ there is no guideline on the use of BIS monitoring during sedation, and the efficacy of end-tidal CO₂ monitoring has not been established.

Explanation. The need for monitoring during intravenous sedation is not based on sufficient evidence but rather should be based on the patient’s consciousness, ventilation, oxygenation, and circulation (pulse rate and blood pressure) metrics. Other forms of monitoring

should also be considered depending on the general status of the patient.

6) CQ: Is it useful to select drugs according to the purpose of performing intravenous sedation?

Recommendation. For patients with dental phobia, the practitioner should administer benzodiazepine or propofol monotherapy or both in combination (degree of recommendation: A). For suppression of abnormal gag reflex, use propofol alone or propofol in combination with benzodiazepine (degree of recommendation: B). For patients with a comorbid disease, intellectual or physical disabilities, or undergoing minor oral surgery, use benzodiazepine or propofol alone or in combination (degree of recommendation: C). For patients with intellectual disabilities, general anesthesia may be considered when behavior management is too difficult for intravenous sedation (degree of recommendation: B evaluated by the Working Group on Guidelines Development). Furthermore, because midazolam, propofol, or their combination can increase bite forces, caution is needed at the time of conscious sedation in patients, such as those with intellectual disabilities, who intensely bite during treatment (degree of recommendation: A).

Scientific Basis. When mental stress was applied during intravenous sedation with midazolam or propofol, midazolam inhibited sympathetic activity more than propofol, and the patients' reported stress levels were lower (level II).⁶² When invasive and noninvasive stimulation under intravenous sedation with midazolam and propofol were applied, midazolam produced a stronger amnesic effect than propofol (level II).^{63,64} When mental stress was applied under intravenous sedation with propofol or dexmedetomidine, patients who received propofol reported less stress and their satisfaction levels were higher compared with those who received dexmedetomidine (level II).⁶⁵ However, physiological and psychomotor functions recovered faster after sedation with propofol than midazolam (level II).⁶⁶ During conscious sedation used for tooth extraction, patients were more satisfied with propofol sedation than

midazolam because of the rapid recovery and lack of emotional discomfort (level II).⁶⁷ Furthermore, patients treated with midazolam or propofol showed comparable ability to hold water in their mouth, suggesting that the risk of aspiration is low with either drug (level II).⁶⁸

In patients with severe anxiety and fear of dental treatment, intravenous sedation with benzodiazepine has been conventionally performed with the expectation of good sedative and strong amnesic effect (level V)^{69,70}; however, in recent years, intravenous sedation using propofol alone or a combination of propofol and a low dose of benzodiazepine has been widely performed for regulating the depth of sedation and achieving prompt recovery after sedation (level V).⁷⁰ In patients with gag reflex, reflex control may be difficult with benzodiazepine alone; when propofol monotherapy or benzodiazepine in combination with propofol was used, the reflex was favorably controlled in a moderate or less sedative state (level V).^{56,69–73} In patients with comorbid disorders, such as hypertension or heart disease, it is useful to use benzodiazepine alone or in combination with propofol (level V).^{5,61,69,70} It has been reported that in patients with physical disabilities without intellectual disabilities, treatment could be safely performed using benzodiazepine alone or in combination with propofol (level V).^{69,74,75} In patients with intellectual disabilities, controlling the depth of sedation may be difficult with benzodiazepine alone, and it is useful to use propofol alone or in combination with benzodiazepine (level V).^{69,76} However, if behavior management is difficult by intravenous conscious sedation alone, general anesthesia may be considered (level V, VI).^{61,76} For patients undergoing minor oral surgery, it has been reported that treatment can be safely performed using benzodiazepine or propofol monotherapy or combination therapy (level V).⁶⁹

Bite force of sedated patients increases during conscious sedation (Ramsay sedation score of 2–3) using propofol and/or midazolam.^{77–79} The rate of increase was approximately 50% during conscious sedation⁷⁷ (level II). Bite force also increased with midazolam alone or in combination with propofol, and the rate of increase was approximately 50% for midazolam alone⁷⁸ and approximately 80%⁷⁹ for midazolam and propofol used in combination (level II).

Estimated dosage for healthy adults under conscious sedation, modified from Shibutani et al⁵

	Benzodiazepine			Intravenous Anesthetic
	Midazolam	Diazepam	Flunitrazepam	Propofol
Approximate dose	0.050–0.075 mg/kg	0.2–0.3 mg/kg	0.010–0.015 mg/kg	Induction dose 6–8 mg/kg/h Maintenance dose 2–3 mg/kg/h
Administration rate	0.5–1.0 mg/30 s	1–2 mg/30 s	0.1–0.2 mg/30 s	Adjustable
Estimated maximum dose	5–7 mg	20 mg	1 mg	Depends on sedation time

Explanation. Benzodiazepines are characterized by anxiety amelioration and amnestic effects, and midazolam is the most frequently used benzodiazepine. Propofol is characterized by inhibition of gag reflex and favorable control of the sedation state. Dexmedetomidine is characterized by low respiratory depression and easy arousal during sedation. If it is difficult to modify the behavior of a patient with intellectual disabilities via intravenous sedation alone, general anesthesia should be considered for safety.

7) CQ: Is it possible to increase the safety of intravenous sedation if titration is performed?

Recommendation. When performing intravenous sedation, it is recommended that every drug be administered in small increments while observing the patient in order to maintain an appropriate level of sedation (degree of recommendation: A evaluated by the Working Group on Guidelines Development). In this case, the use of a BIS monitor (degree of recommendation: A) or infusion pump (degree of recommendation: C) is useful for preventing excessive sedation.

Scientific Basis. The “Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists” of the ASA (level VI in I),⁸ “Safety Guidelines for Intravenous Sedation” of the Committee of the Japanese Dental Association (level VI),⁵ and a multicenter survey on intravenous sedation using midazolam (Ramsay score 2–3; level VI)⁶¹ reported that it was necessary to administer sedatives in small increments while observing the status of the patient in order to maintain appropriate sedation.

By monitoring consciousness with a BIS monitor during intravenous sedation, an appropriate sedation depth could be maintained with a lower drug dose (level II).⁵³ In addition, the use of an infusion pump prevented overdose of the drug (level III, V).^{80,81}

Explanation. Since there are individual variations in the drug dose required to induce an appropriate sedative state, it is important to administer sedatives in small increments while observing the status of the patient and titrate the appropriate dose.

8) CQ: Is it useful to use an antagonist for intravenous sedation?

Recommendation. Use of the specific antagonist flumazenil when awakening is insufficient or slow after using a benzodiazepine or if respiratory depression is prolonged (degree of recommendation: A). Intravenous-

ly inject 0.2 mg; in cases where eye opening, physical movement, and so on are not observed, add 0.1 mg after 1 to 4 minutes and increase by 0.1-mg increments at 1-minute intervals up to a total dose of 0.5 mg (degree of recommendation: B).

Scientific Basis. Intravenously inject an initial dose of 0.2 mg of flumazenil, with additional 0.1-mg doses up to a total dose of 0.5 mg. In case of benzodiazepine overdose, if necessary, administer an intravenous injection up to a total dose of 1.0 to 2.0 mg (level III).^{8,82,83} It is recommended to administer additional doses as needed unless the patient awakens from the 0.2-mg initial dose 4 minutes after administration (level III).⁸³

The antagonistic effect of flumazenil on sedation is rapid, and its efficacy is good (level II).^{82,84} The elimination half-life after intravenous injection is as short as 50 minutes, and the effect duration is short. Resedation (residual sedation) after awakening is not clinically problematic in the case of midazolam (level II).⁸⁴ It has been reported that when flumazenil was administered 18 minutes after administration of midazolam, awakening was observed in all patients after 2 minutes (ie, 20 minutes after administration of midazolam); mild resedation was observed at 40 minutes, although the awakening process was faster than when flumazenil was not administered (level III).⁸⁵ Although there are various opinions on the effects on respiratory depression, it has been reported that antagonism against respiratory depression is favorable in Japanese patients (level III).⁸⁶ It has been reported that, in the case of flumazenil, a higher dose than that needed for overcoming sedation was necessary for recovering a sense of balance (level III).⁸⁷ Sedation regimens that are intended to induce routine reversal of sedatives are not recommended.

Seizure may occur in epileptic patients taking benzodiazepine medications (level IV),⁸⁸ or withdrawal symptoms (e.g. agitation) may rarely develop in patients who regularly receive oral benzodiazepine (level IV).^{82,84} However, it has been reported that patients with severe mental and physical disabilities who received up to 0.5 mg of flumazenil did not experience convulsions or agitation (level III).⁸⁹

9) CQ: Is preparation for oxygen administration necessary during intraoperative management of intravenous sedation?

Recommendation. Intravenous sedation has a risk of respiratory depression, and preparation for the use of

intraoperative oxygen administration is necessary (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

Scientific Basis. During surgical treatment of 20 patients, intravenous sedation with 0.5 mg/kg of pentazocine and 0.2 mg/kg of diazepam was performed, and the respiratory state was observed from arterial blood gas analysis. These results indicated that the mean arterial oxygen partial pressure (PaO₂) was 88.1 ± 14.3 mm Hg after pentazocine and rapidly decreased to 64.2 ± 10.2 mm Hg after administration of diazepam (level IV).⁹⁰

Propofol (6 mg/kg/h) was administered over 10 minutes to 8 adult male volunteers. It was subsequently maintained at 4 mg/kg/h, and a significant decrease in tidal volume was observed from 10 minutes after the start of administration to 5 minutes after discontinuation (level IV).⁹¹

When a sedating dose of diazepam or flunitrazepam was administered to 335 patients between the ages of 20 and 80 years, the rate at which the transcutaneous oxygen saturation level was 93% or less increased with age (an increase was especially noted in patients 60 years or older; level IV).⁹²

In a study investigating amnestic effects and intraoperative respiratory depression in 313 patients who underwent intraoral surgery using midazolam, it was reported that 127 patients (40.6%) had decreased transcutaneous oxygen saturation (93% or less; level IV).⁹³

Guidelines for sedation of the ASA⁸ for nonanesthesiologists (level VI in I) and guidelines for sedation of the ADA⁷ (level VI) state the necessity of preparing for oxygen administration.

The results of an investigation of the presence of complications during endoscopic treatment under sedation in 200 patients with obstructive sleep apnea and 200 controls revealed that oxygen administration was required for obstructive sleep apnea, suggesting that preparation for oxygen administration is indispensable.⁹⁴

Explanation. Since the risk of developing hypoxia in elderly patients, persons with an underlying disease, or persons with individual susceptibility to drugs is possible during intravenous sedation using midazolam or propofol, preparation for oxygen administration using a nasal mask, nasal cannula, and so forth is indispensable.

10) CQ: Does intraoperative sedation management require preparation of emergency equipment?

Recommendation. Drugs used in intravenous sedation have a risk of causing respiratory arrest and cardiac

arrest depending on the patient's susceptibility, dosage, administration rate, and underlying diseases of the patient, and preparation of emergency equipment necessary for basic life support is essential (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

Scientific Basis. A questionnaire survey of intravenous sedation regimens conducted at 77 institutions (eg, a dental university, dental school in a university, oral surgery department in a medical school) revealed that respiratory depression and glossoptosis occurred in 37 facilities, respiratory arrest in 8, and cardiac arrest in 4. Thus, the need for emergency equipment is valid (level IV).⁵ In a questionnaire survey administered to 29 dental universities and dental school anesthesiology departments across Japan, an intubation instrument was required in 5 facilities (level IV).²⁹ An investigation of intravenous sedation methods using propofol and fentanyl in 785 patients revealed that emergency responses were necessary in some cases (respiratory depression in 22 patients, hypotension in 3, bradycardia in 1, and postoperative angina pectoris in 1; level IV).⁹⁵

There was 1 patient who underwent intravenous sedation and developed neurologic shock; artificial respiration with atropine and 100% oxygen and administration of dopamine were necessary (level V).³⁷ There was also a case in which cardiac arrest occurred when the patient's vein was accessed during intravenous sedation, and it was necessary to perform precordial thump and administer atropine and ephedrine (level V).⁹⁶

In the "Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists" of the ASA⁵ (level VI in I) and "Guidelines for the Use of Sedation and General Anesthesia by Dentists" of the ADA⁷ (level VI), the necessity for acquiring basic life support skills is noted.

Explanation. When performing intravenous sedation, there is a risk that symptoms of respiratory and cardiovascular suppression will arise, and it is indispensable to acquire the knowledge and skill for using emergency instruments, such as auxiliary instruments for airway management.

11) CQ: Does intraoperative management of intravenous sedation require acquisition of airway management and resuscitation skills?

Recommendation. When using intravenous sedation, there is a risk of glossoptosis and respiratory depression, and acquisition of airway management and resuscitation techniques is essential (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

Scientific Basis. When midazolam (0.068 ± 0.004 mg/kg) was administered to 14 male volunteers, occlusion pressure of -8.2 ± 1.4 cmH₂O, upper airway resistance of 21.0 ± 2.0 cmH₂O/L/s, and suppression of respiration were observed (level IV).⁹⁷

In a study investigating oral cavity water retention ability in the sedated state, propofol (target blood concentration of 2.2 µg/mL) or midazolam (0.07 mg/kg) was administered to 14 male volunteers; 1 patient with midazolam could not hold water in the oral cavity and swallowed, and 1 patient choked and spit the liquid out. Thus, while the risk of aspiration was low, it was not completely absent (level III).⁶⁸

Among the 804 patients who received intravenous sedation with midazolam, 22 had an increase in blood pressure of 30% or higher, 19 had a decrease, 26 had an increase in pulse rate, 5 had a decrease, 8 had arrhythmia, 23 had respiratory depression, 30 had a SpO₂ decrease of 7% or more, and 4 had an allergic reaction.³⁸ Among the 1134 patients who received intravenous sedation with propofol, 18 had an increase in blood pressure of more than 30%, 115 had a decrease, 75 had an increase in pulse rate, 16 had a decrease, 2 had arrhythmia, 49 had respiratory depression, 32 had an SpO₂ decrease of 7% or more, and 2 had an allergic-like reaction (level IV).³⁸

When intravenous sedation using diazepam (2.5–7.5 mg) was performed in four men (aged 65 to 87 years) with complicated cardiac disease, glossoptosis was caused by administration of 7.5 mg of diazepam in one 65-year-old man, and airway management was required (level V).⁹⁸

When 1 to 2 mg of midazolam was administered to patients with Sheehan syndrome, unresponsiveness continued for 2 to 3 hours (level V).⁹⁹ An investigation of intraoperative and postoperative complications of 304 patients aged 65 years and older in whom intravenous sedation was performed revealed decreased SpO₂ intraoperatively in 43 patients, aspiration in 11, glossoptosis in 4, and hypotension in 1; postoperatively, snoring due to upper airway obstruction and decreased SpO₂ were observed in 74 patients (level IV).¹⁰⁰

The necessity to acquire basic life support techniques is mentioned in both the “Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists” of the ASA⁸ and the sedation guidelines of the ADA.⁷

Intraoperative accidents occurred in 18.4% of 1309 cases of intravenous sedation performed at a university hospital, and respiratory depression was the most frequent type.³

Explanation. Intravenous sedation using midazolam and propofol may result in upper airway obstruction and aspiration. Therefore, it is essential for the person performing sedation to prepare various airway-securing

devices and study practical techniques and cardiopulmonary resuscitation.

POSTOPERATIVE MANAGEMENT

1) CQ: How can recovery from intravenous sedation be evaluated?

Recommendation. Consideration for psychomotor and balance functioning, which are indicated to have the most delayed recovery, is necessary (degree of recommendation: A evaluated by the Working Group on Guidelines Development). When determining the success of recovery, appropriate recovery evaluation criteria and evaluation methods should be selected according to the purpose of the determination (degree of recommendation: A). In daily clinical practice, a simple method of determination should be used (degree of recommendation: B).

Scientific Basis. It has been reported that recovery after intravenous sedation for cognitive and psychomotor functions is most delayed (level II and level III),^{101,102} balance (level II and level III),^{103,104} or both equivalently (level II and level III).^{66,105} It has also been reported that, in the case of propofol, recovery of the sensory feeling of lightheadedness while walking is more delayed than psychomotor and balance functions (level II).¹⁰⁵

Evaluation of psychomotor function was originally thought to be the most important metric in evaluating recovery from general anesthesia and intravenous sedation; although psychomotor function tests that have been reported in the past are highly useful for research, they are difficult to use in clinical practice because of the complexity of implementation (level VI in I).¹⁰⁶ Equilibrium testing using specialized equipment is similarly difficult to use in clinical practice (level III).⁶⁶

Explanation. Metrics to be evaluated immediately after intravenous sedation, which are also intraoperative monitoring metrics, are consciousness, oxygenation, airway/ventilation, and circulation. An evidence-based gold standard has not been established for simple determination of the recovery process in daily clinical practice.

2) CQ: What are the indications for allowing the patient to be discharged home after intravenous sedation?

(1) What are the indications for allowing the patient to travel by car or taxi with an attendant after being discharged?

Recommendation. The following must be confirmed: (a) vital signs are stable; (b) the basic psychomotor

ability to recognize people, places, time, and so forth has recovered; and (c) independent and stable walking at normal speed is possible, or basic equilibrium function is restored, such as being able to remain standing for 30 seconds during the bipedal stance test with eyes closed (degree of recommendation: A evaluated by the Working Group on Guidelines Development). Furthermore, it is also necessary to confirm that there is no need for treatment of (d) postoperative hemorrhage, (e) pain, or (f) nausea or vomiting (degree of recommendation: A evaluated by the Working Group on Guidelines Development). (g) Postoperative instructions and printout with contact information must be given when returning home (degree of recommendation: A evaluated by the Working Group on Guidelines Development).

It is desirable to confirm that there are no complaints or abnormalities by telephone call after return home (degree of recommendation: C). The ability to drink water is not a necessary condition of the criteria for permission to return home, and this condition should be left up to the patient (degree of recommendation: A).

Scientific Basis. The success of outpatient surgery depends on whether the patient who undergoes general anesthesia or sedation can return home at the appropriate time based on correct evaluation, and criteria for safe home return have been indicated (level VI).¹⁰⁷ In a systematic review, a clinical scoring system useful for determining when to give a patient permission to return home was presented (level VI in I).¹⁰⁶ The ASA also proposed guidelines for postoperative management, which can be applied to general anesthesia, local anesthesia, and moderate or deep sedation, and the criteria permitting return home are indicated in the guidelines (level VI in I).¹⁰⁸ There is also a summary of the conditions permitting return home after intravenous sedation written in Japanese (level VI).⁵

Postoperative instructions and a printout with contact information must be distributed to patients returning home (level VI, level VI in I, level VI in I).^{106–108}

In recent years, confirmation of an ability to drink water and urinate has been excluded from the essential items allowing permission to return home (level VI in I, level VI in I, level II [concerning drinking of water]).^{106,108,109}

Explanation. There are no reports of randomized controlled trials that have used the criteria for returning home after administering general anesthesia or sedation and the presence of adverse events as endpoints. The guidelines to date have been summarized with reference to opinions from expert committees and guidelines frequently used in daily clinical practice. The criteria used for giving permission to be discharged home in this

article were also created based on the above 4 guidelines.^{5,109–111}

(2) What are the indications for allowing patients to be discharged home by walking?

Recommendation. To evaluate a patient's ability to walk home, it is desirable to perform a dynamic equilibrium function evaluation. For example, an evaluator has the patient quickly perform an Up & Go test (ie, stand up from a chair, walk forward 3–5 m, and sit back in the chair again), confirm subjective and objective dizziness (degree of recommendation: C), or measure the required time for completion of the test (Timed Up and Go test; degree of recommendation: B).

Scientific Basis. Posturography (a term describing techniques used to quantify postural control in upright stance in either static or dynamic conditions) testing should be performed. The Timed Up and Go test is a reliable and simple dynamic balance test, well correlated with precise computerized dynamic posturography (level III).⁶⁶ A significant difference in Timed Up and Go test values between community-dwelling old persons with a history of fall or no fall has been demonstrated (level III).¹¹⁰

Explanation. If recovery of equilibrium function and muscular strength is insufficient after sedation, there is a possibility of a fall; caution is needed, especially in elderly patients, because a decline in equilibrium function is observed at baseline, before undergoing sedation.

(3) Concerning the necessity of an attendant

Recommendation. After undergoing sedation, the patient should always be accompanied by an attendant when being discharged home (degree of recommendation: A evaluated by the Working Group on Guidelines Development). If it is unavoidable for the patient to return home alone, measures, such as delaying the patient's return home, should be taken (degree of recommendation: A evaluated by the Working Group on Guidelines Development). In such a case, the use of propofol is preferable (degree of recommendation: A). It is essential for the patient to return home with an attendant when using diazepam or flunitrazepam (degree of recommendation: A).

Scientific Basis. According to the ADA Sedation Guidelines (level VI),⁷ the ASA Guidelines on Post-anesthesia Care (level VI in I),¹⁰⁸ and the ASA "Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists" (level VI in I),⁸ the presence of an attendant is always required for the patient to return home after undergoing intravenous sedation.

The recovery time of psychomotor function, memory ability, and equilibrium function after intravenous sedation with propofol in long cases is 60 minutes by flicker fusion test (level II),¹¹¹ 30 minutes by a memory test using several pictures and cards (level II),⁶⁴ and 40 minutes by dynamic balance test (level III),⁶⁶ respectively.

Even 7 hours after intravenous administration of diazepam (0.3 mg/kg), the fluctuation value in precise computerized posturography was twice the preadministration value (level II).¹⁰³ After intravenous administration of diazepam (0.3 mg/kg), psychomotor function tests, such as a coordination test and critical flicker fusion test, revealed that functioning did not recover by 6 hours but did after 8 hours (level II).¹⁰¹ Even 10 hours after intravenous administration of flunitrazepam (0.02 mg/kg), psychomotor function tests, such as the hand-eye coordination test, revealed that functioning did not recover. Therefore, if more than 0.02 mg/kg of flunitrazepam is used, the patient is not indicated to return home on the same day (level II).¹¹²

- (4) Permission for driving of an automobile or performing work requiring important judgment

Recommendation. After undergoing intravenous sedation, driving of an automobile or performing work that requires important judgment on the same day must be avoided (degree of recommendation: A).

Scientific Basis. Based on psychomotor function testing, operation of an automobile or machinery must be avoided for 6 hours after a 0.15-mg/kg dose and 10 hours after a 0.3-mg/kg dose of intravenous diazepam (level II).¹⁰¹

Results from multiple sleep latency tests suggested that operation of an automobile or heavy machinery should be avoided 8 hours after administration of midazolam and fentanyl, and the main cause of the recovery delay was midazolam rather than fentanyl (level II).¹¹³

Explanation. The time required for complete recovery of psychomotor function is never brief. Furthermore, it has been reported that recovery after intravenous propofol was noted after 2 hours using a driving simulator.¹¹⁴ However, it is debatable whether recovery in a driving simulator test is an indicator of safe implementation in practice, and considering the seriousness of an automobile accident, it seems reasonable to allow a sufficient margin of safety.

3) CQ: How should postoperative complications be monitored?

Recommendation. In the recovery room, SpO₂ should be monitored in order to prevent hypoxia (degree of

recommendation: A). It is also desirable to monitor blood pressure and pulse rate (degree of recommendation: B evaluated by the Working Group on Guidelines Development).

Criteria for airway narrowing and respiratory depression are glossoptosis, paradoxical respiration, decreased SpO₂, and so forth, and the criterion for hypoxemia requiring treatment is a SpO₂ less than 93% in room air (degree of recommendation: A). The criterion for determination of abnormal circulatory dynamics is a persistent increase or decrease of 30% or more in preoperative blood pressure and pulse rate values (degree of recommendation: B evaluated by the Working Group on Guidelines Development).

Scientific Basis. Pulse oximetry detected postoperative hypoxemia and associated unforeseeable events, but no difference was found in the incidence of postoperative complications with or without pulse oximetry (level I).¹¹⁵

In the guidelines for sedation in dentistry (level VI, level VI in I),^{7,116} the “Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists” created by the ASA (level VI in I),⁸ and the guidelines for postanesthetic care by an anesthesiologist (level VI in I),¹⁰⁸ it is stated that monitoring should be continued in the recovery room after performing intravenous sedation.

Patients who had an SpO₂ reading less than 93% when entering the recovery room following surgery received further treatment for hypoxemia during their stay in the recovery room regardless of the subsequent presence or absence of oxygen administration or the administration method (level II).¹¹⁷

Explanation. The consultants of the ASA’s task force report stated, “There is no literature clearly indicating that postoperative monitoring effects have contributed to patient outcomes, but postoperative monitoring is necessary.”⁸ Other key guidelines also lack consistency with the evidence but advocate the need for postoperative monitoring.

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