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Indications, contraindications, and safety aspects of procedural sedation

Maartje van Haperen, Benedikt Preckel, and Susanne Eberl

Purpose of review
There is a steadily increasing demand for procedural sedation outside the operating room, frequently performed in comorbid high-risk adult patients. This review evaluates the feasibility and advantages of sedation vs. general anesthesia for some of these new procedures.

Recent findings
Generally, sedation performed by experienced staff is safe. Although for some endoscopic or transcatheter interventions sedation is feasible, results of the intervention might be improved when performed under general anesthesia. For elected procedures like intra-arterial treatment after acute ischemic stroke, avoiding general anesthesia and sedation at all might be the optimal treatment.

Summary
Anesthesiologists are facing continuously new indications for procedural sedation in sometimes sophisticated diagnostic or therapeutic procedures. Timely availability of anesthesia staff will mainly influence who is performing sedation, anesthesia or nonanesthesia personal. While the number of absolute contraindications for sedation decreased to almost zero, relative contraindications are becoming more relevant and should be tailored to the individual procedure and patient.

Keywords
deep sedation, endobronchial thermoplasty, endoscopic submucosal dissection, intra-arterial stroke treatment, transcatheter aortic valve implantation

INTRODUCTION

Advancements of diagnostic and therapeutic procedures in different medical specialisms are leading to a steadily increasing demand for procedural sedation outside the operating room, frequently performed in comorbid high-risk adult patients. Patients nowadays are well informed and are no longer accepting to undergo painful or stressful stimuli without an adequate form of sedation or analgesia. While diagnostic procedures were frequently performed under mild sedation (assessed by the modified Observer's Assessment of Alertness/Sedation Scale, see Table 1, mild sedation: Score 5–4) provided by nonanesthesiologists, the new, sophisticated minimal invasive surgical and endoscopic therapeutic procedures need deep sedation (Score 2–1), which is normally applied by anesthesia-trained staff. The modified form of the MOAA/S scale is extended with assessment of painful stimuli next to uses of the responsiveness component of the original scale [awake (5)–unresponsive (1)]. As reaction to painful stimuli are still possible at anesthetic levels that block reactions to verbal commands, prodding, or shaking, they can be used to assess deeper sedation levels.

Increasing costs as well as shortage of anesthesiologists led a variety of medical societies to develop own sedation strategies, crafting own protocols to address specialty-specific needs and patient populations, and starting to provide sedation on their own responsibility [1▪]. Adequate availability as well as high quality of deep sedation provided by anesthesia staff for the new indications will therefore be the

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KEY POINTS

- Increasing demand of procedural sedation requires local protocols on topics like by whom and how sedation is performed.
- Cardiac transcatheter interventions might be as good as surgical interventions also in less comorbid patients, thus anesthesiologists will face more frequently these interventions which most likely are better performed under conscious sedation than under general anesthesia.
- For some specific gastroenterological interventions, which could be safely performed under deep sedation, interventional results (completeness of resection, perforation rate) seemed to be better in patients subjected to general anesthesia.
- Moderate-to-deep sedation for advanced bronchoscopic procedures in pulmonary severely compromised patients is challenging, and only sufficiently trained anesthesia personal with extensive experience in airway management should be involved in these treatments.
- For intra-arterial treatment after acute ischemic stroke, avoiding general anesthesia and sedation at all might be the optimal choice of treatment.

cornerstone for safe procedural sedation under supervision of anesthesia staff in the future.

INDICATIONS FOR PROCEDURAL SEDATION

Cardiac procedures

Electrocardioversion for treatment of atrial fibrillation has been performed for long time under mild-to-moderate sedation. Catheter ablation performing pulmonary vein isolation (PVI) is now more frequently offered as first-line treatment in patients with atrial fibrillation [2]. These procedures are long lasting with the need of patient immobilization at specific critical time points. It is well known that catheter ablation is a high-risk procedure, with a reported mortality of 1 : 1000 procedures [3]. Although these procedures might be performed under deep sedation [4], a prospective registration of adverse events during procedural sedation showed that PVI alone or in combination with transesophageal echocardiography (TEE) has a risk of 27.5 and 45.5% of sedation-related adverse events, respectively, with 10 and 40% of these adverse events rated as major [5▪]. PVI was the procedure most complicated by hospital admission and yielded two of the four most critical events and one poor outcome. Therefore, it might be advisable to use general anesthesia instead of deep sedation for these procedures.

Implantation of rhythm devices, for example, pacemakers or implantable cardioverter defibrillators (ICDs), has also been performed for long time under mild-to-moderate sedation. Testing the function of ICDs includes induction of ventricular fibrillation and is performed under deep sedation, most likely using propofol injections. It has been shown that special trained nonphysician staff can safely perform these sedational procedures [6]. Nowadays, a significant number of devices are implanted prophylactically in young, otherwise healthy patients prone for rhythm disorders due to genetical disposure. Rhythm devices are steadily becoming smaller and leadless devices are often implanted subcutaneously ventral to the heart [7]. These procedures can be painful and often need substantial analgesia and deeper sedation.

In recent years, transcatheter aortic valve implantations (TAVI) led to significant changes in the field of cardiology and cardiac surgery. While transaortic and transapical TAVI still require general anesthesia, the transfemoral approach (TF-TAVI) was performed in the early phase under general anesthesia [8], but is nowadays performed under local anesthesia with or without additional sedation [9▪▪,10▪▪]. It is still a point of discussion whether local or general anesthesia leads to better patient outcome: randomized controlled trials are mostly small, and the available registries are prone to bias due to learning curves of interventionists and anesthesia teams. The most recent data from big registries demonstrate that local analgesia with conscious sedation (LACS) is not inferior to general anesthesia with regard to success of device placement and valve function [9▪▪,10▪▪]. Patients receiving LACS had less major vascular complications, resulting in a lower in-hospital and 30-day all cause mortality [10▪▪]. The development of

Table 1. Modified Observer's Assessment of Alertness/Sedation Scale

Score	Description
5	Responds readily to name spoken in normal tone
4	Maximal lethargic response to name spoken in normal tone
3	Responds only after name is called loudly and/or repeatedly
2	Responds only after mild prodding or shaking
1	Responds only after painful trapezius squeeze
0	No responds after painful trapezius squeeze

smaller introducer sheets, less reliance on TEE during valve employment, and newly designed, repositionable valves without the need for balloon valvuloplasty and rapid ventricular pacing during the procedure [11], will most likely lead to an increasing number of procedures performed under LACS or even under local analgesia without any sedation [12]. In recent years, also transcaval and transcarotid TAVI approaches have been described [13], with the latter showing equal or even better outcome as the transapical or transaortic approaches [14]. While still most of the transcarotid procedures are performed under general anesthesia [15], this procedure can also be performed under LACS [16], and future data will have to show whether this is even beneficial for the long-time outcome of the respective patients.

Percutaneous edge-to-edge mitral valve repair (PMVR) has become an established treatment option for patients with serious degenerative mitral regurgitation not eligible for surgical repair. PMVR still requires guidance of the interventional catheters by two-dimensional or three-dimensional TEE, and is therefore mostly performed under general anesthesia. However, an observational study compared PMVR under general anesthesia with deep sedation, which was found to be safe and feasible [17]. No differences in complications, along with a lower procedure time and less ICU admissions in patients subjected to deep sedation, were described.

Because the transcatheter interventions might be as good as surgical interventions also in less comorbid patients [18▪,19▪], anesthesiologists will face more frequently these interventions, and periprocedural treatment including sedation strategies in these populations should be further optimized.

Gastroenterological procedures

Cancer screening programs including periodic follow-up increase the need for moderate-to-deep sedation [20▪▪]. Gastroenterologic endoscopic technology has extremely improved, with optical high-definition endoscopes using adjuncts, as narrow band imaging or confocal laser [21]. Complex procedures such as endoscopic ultrasound, endoscopic retrograde cholangiopancreatography (ERCP), endoscopic submucosal dissection (ESD), endoscopic mucosal resection, and radiofrequency ablation frequently replace surgical interventions [22]. For accuracy of the procedure, immobility of patients is often required which is mostly achieved by deep sedation or general anesthesia.

Although ERCP procedures require patients in prone position and sometimes repositioning during the procedure, deep sedation using propofol/alfentanil goes along with low anesthesia complication rates [5▪]. Replacing alfentanil by es-ketamine [23] led to a reduced dosage of propofol without a negative effect on recovery time and respiratory or cardiovascular adverse events.

Significantly, although ESD can be safely performed under deep sedation [24▪], interventional results (completeness of resection, perforation rate) seem to be better in patients subjected to general anesthesia [25]. Thus although moderate-to-deep sedation is possible for different procedures, it needs to be evaluated whether this is the optimal anesthetic treatment for the respective procedure.

Pulmonary procedures

The combination of a flexible bronchoscope with brushes, needles, lasersound, cryosound, and ultrasound probes has greatly expanded the diagnostic and therapeutic possibilities of bronchoscopy [26▪▪]. Electromagnetic navigational bronchoscopy and endobronchial ultrasound (EBUS) combined with transbronchial needle aspiration (TBNA) to obtain tissue biopsies from mediastinal and hilar lymph nodes for tumor staging is increasingly replacing surgical mediastinoscopy. The sedation technique (moderate vs. deep sedation) most likely does not influence the diagnostic accuracy of EBUS-TBNA [27]. However, airway manipulation might lead to patient discomfort and the request for deep sedation.

Delivering radiofrequency energy to the bronchial airways during bronchial thermoplasty improves quality of life and reduces symptoms and exacerbation in asthma patients [28,29▪▪]. Moderate-to-deep sedation for these advanced bronchoscopic procedures in pulmonary severely compromised patients is challenging [28], and only sufficiently trained anesthesia personal should be involved in these treatments [29▪▪].

Endoscopic lung volume reduction using endobronchial valves is performed in a select group of patients with severe emphysema. While these procedures can be performed under deep sedation, general anesthesia is recommended as success of the procedure, procedure times and satisfaction of interventionist and patient might be better if the procedure is done under general anesthesia [30▪,31▪].

Interventional radiology and neuroradiology procedures

Interventional radiology uses image guidance to perform minimally invasive, catheter-based

procedures often replacing standard surgical interventions. Procedures include catheter insertions, endovascular stent placement, embolization of tissue, catheter-directed thrombolysis, transjugular intrahepatic porto-systemic shunt procedures, and tumor ablation therapy. Different techniques as chemoembolization, radioembolization, radiofrequency or microwave ablation, and cryoablation are used. Although these techniques are minimally invasive, treatment is sometimes extremely painful making analgesia and moderate or deep sedation necessary. Endovascular treatment of acute stroke is very effective [32▪▪]. Applying sedation instead of general anesthesia not only allows better monitoring of the neurological function of patients, but goes also along with less hemodynamic fluctuations. A periprocedural decrease in the mean arterial pressure during general anesthesia was associated with worse outcome [33]. Data from meta-analyses suggest improved outcome when conscious sedation is used instead of general anesthesia in patients subjected to intra-arterial treatment after acute ischemic stroke [34▪▪,35]. Local anesthesia alone might be even better in these emergency procedures probably due to shorter times between the acute ischemic stroke and the interventional procedure [36,37▪]. Every hour of treatment delay is associated with worsened outcome in this patient population [36,38▪▪]. However, until now, no randomized controlled trial exists investigating directly the influence of anesthesia in patients undergoing intra-arterial treatment, and the previously shown results might be negligible if observational studies are excluded from analysis [39,40▪▪].

CONTRAINDICATIONS FOR PROCEDURAL SEDATION

Basically, there are no *absolute* contraindications for procedural sedation. Formerly, a 6-h preprocedural fasting period for solid food and 2-h for clear liquids was requested. However, recent data show that aspiration rate during elective sedation procedures is extremely rare [5▪,41]. Green *et al.* [41] identified 292 instances of aspiration mostly in serious ill adults undergoing gastrointestinal endoscopic procedures, finally resulting in eight deaths during/after sedation. It remains unclear whether these deaths were related to the sedation procedure, or the underlying diseases. Following the American Society of Anesthesiologists (ASA) guideline, although if complete gastric emptying is not achievable, urgent or emergent procedures should not be delayed if only mild or moderate sedation is required [42▪▪]. However, unscheduled, time-sensitive procedural sedation protocols might differ significantly from scheduled, elective procedural sedation [43]. This has to be organized and documented on in a local protocol.

Adequate preprocedural risk-assessment is required to balance benefits against risks when to decide whether deep sedation or general anesthesia is indicated. This should include special details and location of the procedure (e.g., invasiveness, complexity, length, needed level of sedation), patient comorbidities as well as sedation practitioner experience. Postprocedure recovery facilities are also needed.

Relative contraindication may be related to the patient conditions: for example, an ASA physical status 4, cardiorespiratory-decompensated patient with chronic global obstructive lung disease four scheduled for a TAVI, who is not able to lie flat for the procedure, might not be suitable for sedation. However, using humidified high-flow nasal cannula oxygen therapy and after hemodynamic stabilization by an experienced anesthesiologist, it is reasonable to start the procedure under local anesthesia with/without sedation, switching to general anesthesia only if necessary.

SAFETY OF PROCEDURAL SEDATION

Sedation-related complications are generally low: in over 300 000 gastro-endoscopic patients low rates of minor (0.3%) or major complications (0.01%) and mortality (0.004%) were observed [44]. Significant differences between sedation standards, registration, definition, and interpretation of complications make it difficult to compare available studies. Using the Adverse Event Reporting Tool [45] or the Tracking and Reporting Outcomes of Procedural Sedation Tool [46] would allow to uniformly record sedation-related complications.

Although rare, respiratory and cardiovascular complications can be severe and life-threatening, needing immediate adequate treatment [5▪]. This should be taken into account when discussing the question: who is performing the moderate-to-deep sedation, including use of propofol. Financial compensation of sedation service varies in the individual countries. Increasing costs and unavailability of trained anesthesia staff resulted in attempts of non-anesthesia specialties to perform sedation under supervision of the interventionist [47]. Commonly accepted are minimum requirements for patient screening, location of sedation, preprocedural preparation, necessary material, and skills and knowledge of the multidisciplinary team, including sedation providers [48].

Screening includes medical and surgical history, as well as previous sedation procedures. The screening needs to be completed by a short physical examination: assessment of global neurological, cardiac, and pulmonary function including auscultation of heart and pulmonary sounds. The airway needs to be examined for possible problems concerning mask ventilation and intubation, allowing risk assessment of possible difficult airway in case respiratory problems occur.

During moderate-to-deep sedation, monitoring should include an electrocardiogram to determine heart rate and rhythm, measurement of noninvasive blood pressure and peripheral oxygen saturation, and determination of respiratory rate [49▪▪]. Local protocols for postprocedural discharge should state which criteria have to be fulfilled before patients go home after having had sedation. A frequently used recovery scale is the ALDRETE score, which should be at least 9 or similar to the preprocedural score before patients are discharged home. A period of at least 30 min after stopping sedation seems to be appropriate for postprocedural observation before discharging the patient [49▪▪].

Previously, guidelines on sedation were developed by either anesthesia societies, or nonanesthesia societies, mostly without interdisciplinary collaborations. The new guidelines from the ASA on nonanesthetist provided sedation were grafted with the input and endorsement of at least five other specialisms, focusing on patient safety in mild-to-moderate sedation [42▪▪]. However, deep sedation and medication 'intended for general anesthesia' as for example, propofol are not included. Recently, the British Society of Gastroenterology together with the Royal College of Anaesthetists endorsed a joint position statement with the focus on anesthetist-led deep sedation [48]. Moreover, the European Society of Anaesthesiologists (ESA) established new guidelines for procedural sedation and analgesia in adults [49▪▪]. The role of the anesthesiologist is seen as a coordinator and supervisor for procedural sedation even if performed by nonanesthesiologist [49▪▪]. The highest level of patient safety should be achieved by setting a high, evidence-based safety standard to reach zero preventable complications. On the contrary, like for the guideline from the Gastroenterology Society, there was limited interdisciplinary collaboration while developing the ESA guideline [49▪▪].

Interdisciplinary in-situ simulation training (SST) is useful to train the whole team acting adequately in clinical emergency situations. In-situ simulation training is integrated into the clinical workflow, using high-fidelity simulation mannequins in the clinical departments where sedation is provided. Basic knowledge and skill-sets in a multidisciplinary team differ significantly. Performance of tasks related to patient safety (preprocedural patient evaluation, rescue preparation, and equipment checks) improved with SST [50].

Personal skills training can be combined with SST, for example, using individual self-learning modules in combination with an airway skills training course before SST [51]. Fehr *et al.* [52] concluded that 'simulation is integral in enhancing patient safety: initial training can be provided, baseline competency can be assessed, and preliminary steps toward mastery can be achieved, without placing any patients at risk'. If this is done in multidisciplinary teams, following multidisciplinary guidelines, patient safety in sedation procedures will be further improved.

CONCLUSION

There are continuously new indications for procedural sedation, and the number of absolute contraindications decreased to almost zero. Relative contraindications, tailored to the individual procedure and patient, are becoming more relevant. National and international interdisciplinary guidelines should be used to implement local sedation protocols. In-situ simulation training can help to further develop the competence and compliance of all stakeholders involved in procedural sedation, thereby maintaining and further improving patient safety.

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Conflicts of interest

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- ■■ of outstanding interest

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The complication rate during sedation performed by specially trained sedation providers is low. To compare the severity of the various complications and therefore improve safety, it is important to standardize the definitions for sedation-related adverse events.

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The trial showed that local anesthesia with conscious sedation (LACS) is not inferior to general anesthesia, underlining the safety and efficacy of LACS. This conclusion is based on a total of 16 543 patients from the German Aortic Valve Registry from 2011 to 2014, demonstrating a clear benefit of LACS versus general anesthesia in terms of 30 day mortality. The rate of permanent pacemaker implantation, device malposition, or paravalvular leakage did not differ in both groups.

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Data from 11 006 patients undergoing transfemoral transcatheter aortic valve replacement (TF-TAVR) between January 2014 and June 2016 were analyzed and show that LACS is not inferior to general anesthesia in these procedures. LACS does not compromise procedural outcomes, and was associated with reduced length of ICU and hospital stay, increased rates of discharges to home instead of a nursing facility, and reduced in-hospital and 30-day mortality. These findings support the conclusion that in time LACS may ultimately become the default strategy for performing TF-TAVR. The use of general anesthesia, if possible with transesophageal echocardiography during and after the valve placement, can be taken into account rather than being mandatory.

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Transcatheter interventions might be as good as surgical interventions also in less comorbid patients. Therefore, anesthesiologists should optimize periprocedural treatment including sedation strategies in these populations.

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The ASGE guideline is based on the practice guideline for nonanesthesiologists providing sedation of the ASA Committee for Sedation and Analgesia by Non-Anesthesiologists and recommends that all patients undergoing endoscopic procedures should be evaluated to assess their risk of sedation related to preexisting medical conditions, routine monitoring during the procedure with additional capnography during deep sedation, supplemental oxygen supply should be considered for moderate sedation and should be administered during deep sedation. Anesthesia provider-administered sedation should be considered for complex endoscopic procedures, patients with multiple medical comorbidities, patients at risk for airway compromise, or when it is expected to improve patient safety, comfort, procedural efficiency, and/or successful procedure completion. Special emphasize is on specific training for sedation providers to diagnose and manage sedation-related adverse events.

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Bronchial thermoplasty reduces airway smooth muscle mass in patients with severe uncontrolled asthma. The procedure is associated with a higher change of postprocedural respiratory complications, as laryngospasm and bronchospasm. Patients undergoing bronchial thermoplasty are therefore at increased risk for procedure-related airway complications and present unique anesthetic and airway challenges for an anesthesiologist. This article emphasize the importance of a well trained and experienced perioperative care team (consisting of at least an attending anesthesiologist, pulmonologist, and a pulmonology-trained registered nurse) to ensure patient safety during these high-risk procedures.

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Endoscopic lung volume reduction can be performed under deep sedation, but general anesthesia is recommended as success of the procedure, length of procedure time and satisfaction of interventionist and patient might be better.

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The guideline presents an overview on the recommendations consisting of the prehospital care, initial evaluation and treatment, emergency treatment and supportive care, and in hospital management in patients with acute ischemic stroke. There is strong evidence for the selection of an anesthetic technique during mechanical thrombectomy based on individualized assessment of patient risk factors, technical performance of the procedure, and other clinical characteristics. A post-hoc analysis of the MR CLEAN trial showed a 51% decrease in treatment effect when general anesthesia was applied compared with conscious sedation, and several retrospective studies suggest that general anesthesia produces worsening of functional outcomes after stroke. Other studies did not find an impact of general anesthesia or conscious sedation on outcome.

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The study assessed functional outcome in ischemic stroke patients undergoing endovascular thrombectomy under general anesthesia vs. thrombectomy not under general anesthesia (with or without sedation) vs. standard care (i.e., no thrombectomy). They concluded that the use of general anesthesia for thrombectomy is associated with worse outcomes compared with the avoidance of general anesthesia during thrombectomy, independent of patient comorbidities. Thrombectomy is superior compared with standard care even when using general anesthesia, as long as the procedure isn't delayed due to a logistical time component providing general anesthesia. Therefore, general anesthesia necessary due to airway compromise or patient agitation should not withhold clinicians from pursuing endovascular thrombectomy.

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Randomized clinical trials in selected acute ischemic stroke patients reported diminishing chances of functional independence by up to 3.4% for every hour delay in endovascular treatment. This study aimed to establish an association of time to endovascular treatment with functional outcome in patients with an acute ischemic stroke. More important than different anesthetic strategies is the short time to treatment onset.

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Currently the impact of anesthesia strategies on the outcomes of acute ischemic stroke patients undergoing endovascular treatment remains discussable. This meta-analysis indicated a worse functional outcome and an increased mortality rate for endovascular treatment under general anesthesia compared with conscious sedation. Nevertheless, a randomized controlled trial subgroup analysis could not show a difference in outcome between general anesthesia and conscious sedation groups; probably because findings on a worsened outcome in the general anesthesia group are based on retrospective studies without randomization of patients by anesthesia type.

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The guideline is developed by a multidisciplinary task force of physicians from several medical and dental specialty organizations to address moderate procedural sedation independent of the specialty of the provider. It only focus on mild-to-moderate sedation. Therefore, it does not address deep sedation and the educational, training, or certification requirements for providers of deep procedural sedation. Next to thorough preassessment and preparation of the patient, continual monitoring of ventilatory function with capnography, adequate recovery care, the implementation of a Plan Do Check Act cycle or other quality improvement processes and knowledge of the medication used for sedation and general anesthesia are recommended. The presence of an individual in the procedure room with the knowledge and skills to recognize and treat airway complications without participating in the procedure is requested.

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The guideline can be used as a basis for national societies of anesthesia for building their medico-legal frame and decisions on how professionals can deliver procedural sedation in the safest way possible according the Helsinki Declaration on Patient Safety in Anaesthesiology. Healthcare providers involved in procedural sedation and analgesia (PSA) need specific training and advanced skills in managing the airway and administering emergency drugs in case this should be necessary. It is still open for discussion whether the PSA management should be performed by the anesthesia department. To maintain the highest level of safety, coordination, supervision and training of PSA activities should be the role of the anesthesiologist.

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