

Review Article

Consensus Summary on the Clinical Application of Patient-Controlled Analgesia for Pain Management in China

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Abstract

Patient-controlled analgesia (PCA) is a technique in which healthcare professionals preset the doses and administration parameters of analgesic drugs using a patient-controlled analgesic device according to the patient's pain intensity and physical condition, allowing patients to self-manage pain. PCA suppresses the stress and inflammatory responses caused by surgical trauma and nerve injury, reduces acute pain, alleviates the perioperative suffering of surgical patients, and accelerates postoperative recovery. The implementation of PCA requires specialized PCA pumps, which have undergone continual development and renewal over the past 30 years. With the rapid advancement of computer, network, and intelligent technologies in clinical medicine, China has developed an intelligent PCA (Ai-PCA) analgesic system, which has markedly improved the precision, reliability, and safety of pain management. However, challenges remain because of substantial individual differences in pain perception, the multiplicity of analgesic drug regimens, and suboptimal satisfaction with treatment outcomes. At the invitation of the Chinese Journal of Painology and led by the Anesthesiology Branch of the Chinese Medical Association, experts in anesthesiology and pain medicine were convened to develop this Chinese expert consensus on clinical application practice guidelines for patient-controlled analgesia. A comprehensive literature search was conducted in PubMed, Embase, Web of Science, Chemical Abstracts (USA), Wanfang Database, CNKI, Chinese core journals, Chinese scientific and technological statistical source journals, and EBSCO academic databases, covering PCA technology, clinical application, and perioperative management, from database inception to March 1, 2024. The quality of evidence was graded using the numerical rating scale (NRS), the visual analogue scale (VAS), and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system into four levels (high, moderate, low, and very low), and the strength of recommendations was determined by repeated discussion and revision of the working group and voting of the expert committee via a questionnaire, with consensus categorized as very strong, strong, weak, not reached, or rejected. This consensus provides assessments and recommendations on PCA drug formulation protocols, clinical PCA setting modes, and the management of adverse reactions, covering intravenous PCA (PCIA), epidural PCA (PCEA), subcutaneous PCA (PCSA), Subarachnoid PCA (S-PCA), target-controlled infusion PCA (TCI-PCA), and peripheral nerve block combined with PCA for multimodal analgesia. It applies to pain management in adults but not in children and provides practical guidance for clinical physicians toward the standardized, individualized, and intelligent

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clinical application of PCA.

Keywords

Patient-Controlled Analgesia, Postoperative Pain, Standardization, Expert Consensus

1. Introduction

In 2020, the International Association for the Study of Pain (IASP) revised its definition of pain. The new English wording is: “Pain is an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage” [1]. Pain is always a subjective experience and is simultaneously influenced to varying degrees by biological, psychological, and social-environmental factors. Pain is divided into acute pain and chronic pain. Almost all types of surgical procedures cause tissue and nerve damage and inflammatory responses, which in turn activate nociceptors in the body and produce pain of varying degrees. Pain-related stress may cause a series of disturbances and dysfunctions in respiratory, circulatory, endocrine, and metabolic functions, thereby affecting surgical outcomes and postoperative recovery [2]. Patient-controlled analgesia (PCA) is a treatment technique in which healthcare professionals preset the doses of analgesic drugs using patient-controlled analgesic devices according to the patient's pain level and physical condition, and then the patient is enabled to achieve “self-management” of pain. PCA can suppress the stress and inflammatory responses caused by surgical trauma, thereby alleviating the perioperative suffering of surgical patients and accelerating postoperative recovery [3-10].

2. Overview of PCA

2.1. Origin and Development of PCA

In the early 1970s, Sechzer proposed the principle of on-demand analgesia with PCA, namely, according to the patient's own pain level and analgesic needs, the patient presses the bolus button to self-administer analgesic drugs through a PCA pump configured by medical staff, thereby achieving individualized analgesic medication. With the close integration of computer technology and medicine, the Grasbus Company produced the first PCA pump (The Cardiff Palliator) in 1976 [11].

In 1993, the concept of PCA was introduced to mainland China, and electronic analgesic pumps were adopted in 1994. The PCA pump delivers medication under the control of a microcomputer-controlled infusion pump with a safety control system; anesthesiologists preset the drug administration protocol and dose, and patients self-administer the drug by pressing the administration button when they feel pain. Over the

past 30 years, the development of PCA pumps has continuously progressed through successive generations. With the widespread application of computer technology in clinical medicine, intelligent PCA pumps have emerged, greatly improving the precision, reliability, and safety of PCA treatment [12].

2.2. Definition and Advantages of PCA

2.2.1. Definition of PCA

PCA refers to a technique in which a special computer-controlled micro drug-storage device is connected to the patient through tubing, continuously infusing analgesic drugs into the patient at a specific rate. It is usually equipped with a patient-controlled button; when patients perceive worsening pain, they can press the button themselves to increase the volume of drug delivered. The continuous infusion rate, single bolus dose, and lockout time of the PCA pump are adjusted by anesthesiologists [13].

2.2.2. Types of PCA Pumps

Three types of PCA pumps are commonly used in clinical practice: disposable mechanical infusion pumps, electronic programmable infusion pumps, and network-managed (intelligent) infusion pumps [14].

2.2.3. Advantages of PCA

PCA is mainly used for the treatment and management of acute and chronic pain, such as postoperative pain, labor pain, cancer pain, and analgesia in critically ill adult patients [15-18]. By following the principle of “on-demand analgesia”, PCA addresses the analgesic requirements of different patients at different times and under different pain intensities, serving as an effective means to reduce individual differences in pain and improving patient satisfaction [19].

3. Methods and Evidence Basis for Developing This Consensus

Relevant literature on clinical issues related to PCA was searched in PubMed, Embase, Web of Science, Chemical Ab-

stracts (USA), Wanfang Database, CNKI, Chinese core journals, Chinese scientific and technological statistical source journals, and EBSCO academic databases, covering PCA technology, clinical application, and perioperative management, with the search period from database inception to March 1, 2024. At the invitation of the Chinese Journal of Pain Medicine and led by the Anesthesiology Branch of the Chinese Medical Association, experts in anesthesiology and pain medicine in China were invited. The working group, using evidence-based medicine as the evidence basis and combined with many years of clinical experience, formed this expert consensus after multiple rounds of discussion and revision.

Meanwhile, with reference to the numerical rating scale (NRS) [20], the visual analogue scale (VAS) [21], and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) evidence grading standard [22] (see Table 1), and in combination with existing domestic and international diagnosis and treatment guidelines and consensus statements. A modified-Delphi procedure was adopted for consensus development. The expert panel included multidisciplinary clinicians specializing in anesthesiology and pain medicine.

Consensus agreement criteria were predefined as described above. Multiple rounds of group discussion and questionnaire voting were performed. When disagreements emerged among panel members, further group deliberation followed by repeated voting was undertaken to resolve divergent views prior to finalizing each recommendation. This Expert Consensus on Clinical Application Standardization of Patient-Controlled Analgesia was compiled. The quality of evidence was classified into four levels: high (A), moderate (B), low (C), and very low (D); the strength of recommendations was divided into strong and weak recommendations (Table 1). The consensus strength of recommendations was determined by voting among the expert committee using a Tencent QR-code questionnaire (a support rate of 100% indicated a “very strong” consensus; $\geq 80\%$ indicated a “strong” consensus; $\leq 60\%$ indicated that “no consensus” was reached; values between these thresholds indicated a “weak” consensus; and a support rate of 0% indicated a “rejected” recommendation). This article only evaluates and provides recommendations on PCA drug formulation protocols, clinical PCA setting modes, and the management of adverse reactions.

Table 1. Grading of evidence quality using NRS/VAS and GRADE.

Item	Specific description	Study type
Evidence grading		
High (A)	Very confident that the true effect lies close to the estimate of the effect	Randomized controlled trial (RCT)
Moderate (B)	Moderate confidence in the effect estimate; the true value is likely to be close to the estimate, but there remains a possibility that they differ	High-quality secondary observational studies / RCTs downgraded by one level
Low (C)	Limited confidence in the effect estimate; the true value may differ from the estimate	Observational studies upgraded by one level / RCTs downgraded by two levels
Very low (D)	Little confidence in the effect estimate; the true value is likely to be substantially different from the estimate	Observational studies / RCTs downgraded by three levels
Strength of recommendation		
Strong recommendation	NRS/VAS score 4–6: moderate pain that affects sleep but still allows sleep; 7–10: severe pain that prevents sleep. Clear evidence that the benefits of the intervention outweigh the harms or vice versa	—
Weak recommendation	NRS/VAS score 0: no pain; 1–3: mild pain that does not affect sleep; the balance of benefits and harms is uncertain, or evidence of all quality levels shows that benefits and harms are comparable	—

Some recommendations within this consensus are supported by empirical clinical evidence assessed via the GRADE framework. Other recommendations address clinical scenarios lacking sufficient high-quality direct research evidence

and are derived mainly from the collective expert-panel experience. All recommendations have inherent evidence-related uncertainties, including limitations from study sample size and population heterogeneity, which clinicians should consider when applying them to individual patients.

4. PCA Pump Parameters and Analgesic Medications

4.1. Parameter Settings of PCA Pumps

- 1) Drug concentration: when preparing PCA analgesic solutions, the concentration of one of the drugs is used as the standard for setting, with the unit being mg/ml or µg/ml.
- 2) Loading dose: the loading dose refers to the initial drug dose administered at the start of PCA.
- 3) Continuous infusion or background infusion rate: continuous drug administration intended to achieve a stable plasma drug concentration and sustained analgesic effect in the patient.
- 4) Bolus dose (also known as incremental dose, demand dose, or rescue/bolus dose): the additional drug dose administered after PCA is started when the patient's pain is not relieved or recurs. In general, the bolus dose is equivalent to 1/10 to 1/15 of the daily dose.
- 5) Lockout time: the interval between two bolus administrations. During the lockout time, the first press is effective, while the second and subsequent presses are referred to as "ineffective presses".
- 6) Maximum dose rate: to prevent overdose and toxicity caused by repeated drug administration, the maximum amount of drug allowed per unit time during PCA is usually limited at intervals of 1 or 4 h.
- 7) Rate of injection: the rate at which each PCA pump drug infusion is delivered into the body can be adjusted according to the drug dose, concentration, and the patient's actual needs. Epidural PCA pumps usually require a faster infusion rate, up to 100 ml/h, while the infusion rates of other types of PCA pumps can be adjusted to 1–15 ml/h.
- 8) Real-time recording parameters of PCA pump use
 - a) Total number of patient presses and actual number of deliveries: the PCA pump records the total number of patient presses (demand) and the actual number of deliveries. The D1/D2 (demand/delivery) ratio can serve as an objective indicator for evaluating the analgesic effect; among patients with a ratio below 2, the excellent/good analgesic efficacy rate ($VAS \leq 3$) was 97%.
 - b) Display on the PCA pump screen: the display on the PCA pump screen can show fault alarms and their causes, and can display at any time the dose of the therapeutic drug delivered into the body (mg or ml) and the total amount of drug delivered, which is helpful for understanding and evaluating the PCA effect.
 - c) Volume of remaining drug solution: after prolonged PCA treatment, the volume of drug solution remaining in the pump reservoir (ml) provides a reference for how much longer PCA can be continued.
 - d) Record clearing (press to totals): when the PCA pump is used for a second case, the data recorded from the

previous patient should be cleared.

- e) Review and printing: during the entire course of PCA treatment, the pump's operation status, treatment parameters, abnormal phenomena, alarm causes, pause time, and restart time can be reviewed and printed.

4.2. Analgesic Medications for PCA

- 1) Opioids: postoperative PCA often requires opioids. The fentanyl-series opioids include fentanyl, sufentanil, remifentanyl, and alfentanil; other opioid analgesics include morphine, hydromorphone, dezocine, oxycodone, pentazocine, butorphanol, buprenorphine, and nalbuphine, among others [23-27].
- 2) Nonsteroidal anti-inflammatory drugs (NSAIDs): NSAIDs are a class of drugs with antipyretic and analgesic effects. Commonly used NSAIDs according to analgesic needs include non-selective COX inhibitors, such as flurbiprofen axetil injection; at present, flurbiprofen axetil injection can be continuously infused via PCA [28, 29]. In addition, ketorolac injection can be placed in a PCA pump for PCIA [30].
- 3) Local anesthetics: commonly used long-acting local anesthetics include ropivacaine, bupivacaine, levobupivacaine, and liposomal bupivacaine; the short-acting local anesthetic is lidocaine. Epidural multimodal analgesia is usually performed with local anesthetics combined with opioids; for peripheral nerve blocks, local anesthetics are generally not combined with opioids [31-36].
- 4) Analgesic adjuvant drugs: commonly used PCA adjuvant drugs include dexmedetomidine, esketamine, dexamethasone, ondansetron, and droperidol, which can be selected in clinical practice; however, antiemetic drugs are not recommended to be placed in the PCA pump [37-39]. In addition, paracetamol, duloxetine, gabapentin, and pregabalin, among others, can only be taken orally by the patient alone for adjunctive analgesia when selected clinically [40-42].

5. Common Clinical Routes of PCA

5.1. Intravenous PCA

5.1.1. Commonly Used Opioid Analgesics for Intravenous PCA (PCIA)

Drug selection for PCIA is generally based on potent opioids, supplemented by NSAIDs, ketamine, and antiemetics. There are many commonly used analgesic drugs at present, with the following relative analgesic potency ratios among them: morphine 10 mg $\approx$ fentanyl 0.1 mg $\approx$ sufentanil 0.01 mg $\approx$ hydromorphone 1 mg $\approx$ tramadol 100 mg $\approx$ pethidine 100 mg $\approx$ butorphanol 2 mg $\approx$ oxycodone 10 mg $\approx$ dezocine 10 mg. The differences in pharmacokinetics and pharmacodynamics among different PCIA drugs determine that parameter settings

such as bolus dose and lockout time differ accordingly [18, 20, 23, 27, 44-51]. Postoperative PCIA may use a multimodal approach, including pre-emptive analgesia and preventive analgesia [52]. This medication model is consistent with the concept of enhanced recovery after surgery (ERAS), promoting the development of traditional PCA [53].

5.1.2. Indications for PCIA

PCIA can be used for moderate to severe postoperative pain, especially in patients who cannot tolerate oral medication, and is suitable for analgesia of all parts of the body. PCIA is indicated for: adults of ASA class I–III and children (age ≥ 0.6 years) without preoperative cough and sputum production and without severe abnormalities in cardiac, pulmonary, hepatic, or renal function; maintenance treatment of severe cancer pain and refractory cancer pain; and effective control of breakthrough pain [18, 20, 23, 27, 44-51].

5.1.3. Absolute Contraindications to PCIA

- 1) Coma or impaired consciousness;
- 2) cognitive dysfunction, with inability to correctly understand and use PCA technology;
- 3) patients with severe sleep apnea syndrome; (iv) patient refusal [17, 54].

5.1.4. Relative Contraindications to PCIA

- 1) Presence of systemic infection, cardiopulmonary failure, coagulation abnormalities, severe hepatic or renal insufficiency, etc.;
- 2) patients with acute upper gastrointestinal bleeding or obstruction that can readily cause regurgitation and aspiration;
- 3) patients who are conscious but, owing to their own disabilities, cannot operate the “self-controlled button”;
- 4) psychiatric disorders, including sleep apnea, etc. [55].

5.1.5. Advantages of PCIA

Intravenous PCA has broad indications, is suitable for adults and children, and is suitable for analgesia of all parts of the body, with a high rate of clinical application. PCA treatment usually selects potent μ -opioid receptor agonists as well as partial opioid receptor agonists and agonist-antagonists [55]. Pethidine is not recommended for analgesic treatment of PCIA patients because its metabolites are highly toxic, it has high addictive potential, and it cannot be antagonized by naloxone [56].

5.1.6. Disadvantages of PCIA

The analgesic effect varies considerably among different individuals, and after increasing the PCIA drug dose, adverse reactions increase, such as nausea and vomiting, dizziness, pruritus, excessive sedation, respiratory depression, and hypotension.

5.1.7. Methods for Evaluating the Analgesic Effect of PCIA

The numerical rating scale (NRS), visual analogue scale (VAS), verbal rating scale (VRS), and Wong-Baker face pain rating scale can be used; the Bruggemann comfort scale (BCS) is used to assess the comfort level, and the Ramsay score is used for sedation status assessment. The McGill Pain Questionnaire is also commonly used, as is the patient comfort index (AQI) score of intelligent PCA. Adverse reactions such as nausea and vomiting, pruritus, and dizziness are assessed and recorded during routine follow-up.

5.2. Epidural PCA

5.2.1. Anesthetic Drugs for Epidural PCA (PCEA)

Combined analgesia with opioids and long-acting local anesthetics is usually required. The combined application of local anesthetics and opioids in the epidural space produces a synergistic analgesic effect, allowing lower concentrations of local anesthetics and reduced doses of opioids. Because opioids act directly on opioid receptors in the spinal cord to produce analgesia, epidural administration can reduce opioid-related adverse reactions and potential risks compared with intravenous and oral administration [20, 57-59]. PCEA can provide effective, prolonged segmental analgesia [60, 61].

5.2.2. Indications for PCEA

- 1) All patients undergoing epidural anesthesia can receive postoperative PCEA; guidelines recommend PCEA after open thoracic and open abdominal surgery.
- 2) Trauma patients: it can be used for analgesia in trauma patients who do not require surgery, such as rib fractures; epidural analgesia can help relieve pain caused by respiratory movement, thereby potentially reducing the occurrence of atelectasis and pulmonary inflammation.
- 3) Patients with pain syndromes [62].

5.2.3. Contraindications to Epidural PCA

- 1) Patient refusal;
- 2) patients with coagulopathy or those currently receiving or preparing to receive anticoagulant therapy;
- 3) patients with bacteremia or local infection at the epidural puncture site;
- 4) patients with impaired consciousness or psychiatric disorders;
- 5) patients with spinal deformity or diseases of the spine or spinal cord (relative contraindication);
- 6) patients with increased intracranial pressure or central nervous system diseases;
- 7) patients in shock with severely impaired cardiovascular function;
- 8) lack of qualified acute pain service staff.

5.2.4. Advantages of PCEA

- 1) It facilitates early mobilization of patients;
- 2) reduces pulmonary complications;
- 3) reduces the incidence of deep vein thrombosis;
- 4) shortens the time to recovery of gastrointestinal function;
- 5) reduces pain-induced stress responses and the occurrence of myocardial ischemia;
- 6) is beneficial to the survival of transplanted tissue after lower limb vascular surgery; (vii) reduces bladder spasm after prostatic surgery and hypospadias surgery; (viii) using a spiral-reinforced steel-wire catheter for epidural puncture and retaining the steel-wire catheter for PCEA helps reduce complications such as catheter breakage and nerve injury [63].

5.2.5. Disadvantages of PCEA

Some of the adverse reactions and complications caused by PCEA are related to procedures such as epidural puncture and catheter placement, including epidural hematoma, neuraxial infection, and post-dural puncture headache (PDPH); others are related to the use of the analgesic drug solution (opioids and local anesthetics) [64]. Currently, most surgeries are minimally invasive with reduced pain intensity, and the popularity of PCEA in thoracic and abdominal surgery is not high. Recent literature suggests that PCEA prolongs hospital stay in patients undergoing thoracic surgery, whereas patients undergoing abdominal surgery benefit from PCEA [65].

5.2.6. Methods for Evaluating the Analgesic Effect of PCEA

The objective pain assessment method is the same as that for PCIA [34]. In addition, the modified Bromage scale is used to assess the degree of motor block, and the Frankel grading system is used to assess the degree of spinal cord injury; AQI is used to assess patient analgesic comfort [36, 37].

5.3. Other Routes of PCA Use

5.3.1. Subcutaneous PCA

Subcutaneous PCA (PCSA) involves placing a thin catheter under the skin at a site on the patient, filling the pump with opioids, and setting the PCA infusion mode to perform PCSA. In this method, the drug is absorbed slowly from the subcutaneous tissue and requires a long time to take effect. Its advantages are relative safety and mild adverse reactions; its disadvantage is slow onset of action.

5.3.2. Subarachnoid PCA

Subarachnoid PCA (S-PCA) is the placement of a special catheter directly in the subarachnoid space after spinal puncture and drug injection to perform S-PCA [9]. S-PCA has two forms: (1) A dedicated catheter is placed directly in the subarachnoid space to perform S-PCA, with a catheter retention

time of ≤ 48 h, suitable for special lower limb or lower abdominal pain; for this form of S-PCA, the catheter retention time must not exceed 48 h, otherwise the patient may develop spinal cord irritative high fever, and prompt removal of the catheter eliminates the high fever. (2) A novel TPU catheter is placed in the subarachnoid space, with the drug reservoir buried subcutaneously; the PCA pump injects the drug into the reservoir through a needle, and S-PCA is performed in CP mode, with a retention time of 1–3 years, suitable for long-term analgesia in patients with cancer. The advantages of S-PCA are rapid onset and strong analgesic effect; its disadvantages are the high risk of infection and the danger once infection occurs. Strict aseptic technique must be maintained throughout the entire process to avoid infection.

5.3.3. Epidural Catheter Analgesia After Subarachnoid Puncture and Drug Administration (PCEA)

Because during combined spinal-epidural anesthesia the puncture needle has already pierced the dura mater, leaving a small hole through which part of the drug solution can penetrate into the subarachnoid space, PCEA remains safe and effective in this setting [66, 67].

5.3.4. Target-Controlled Infusion PCA

Target-controlled infusion (TCI) combined with PCA is termed TCI-PCA. For example, with remifentanyl, after the patient presses the bolus button, an intelligent intravenous infusion delivery system that semi-automatically adjusts the target drug concentration can rapidly achieve the preset target concentration in the plasma or effect-site compartment. The advantage of TCI-PCA analgesia is rapid onset; however, the duration of maintenance is short. One study reported that intravenous remifentanyl TCI-PCA is effective for labor analgesia [68].

5.3.5. Peripheral Nerve Block PCA

Ultrasound-guided PNB and continuous peripheral nerve block (CPNB) are performed by infusing local anesthetic solutions, intermittent bolus injection, or indwelling catheter placement for PCNA. PCNA is used not only to control pain in patients undergoing major upper and lower limb surgery, but also provides perioperative analgesia for patients undergoing abdominal, plastic, urological, gynecological, thoracic, and trauma surgery [69].

5.3.6. Multimodal Analgesia with PCA in Combination with Other Drugs

- 1) PCA delivery modes
 - a) LCP mode: loading dose + continuous dose + PCA (abbreviated as LCP). A loading dose is given first, followed by a continuous dose, and the patient presses the PCA start button when feeling pain.
 - b) CP mode: continuous infusion + PCA. A certain dose

of the basal drug is given by continuous infusion, and the patient presses the bolus self-control button when feeling pain.

- c) P mode: during the entire analgesia period, the patient relies purely on PCA self-control, pressing the self-control button when feeling pain. The use of a loading dose helps maintain the minimal effective analgesic concentration (MEAC) required by the patient. As long as appropriate loading and continuous doses are selected, the plasma drug concentration can be more easily maintained within the MEAC, and no drug overdose occurs in any age group. When the analgesic pump is prepared with equipotent doses, the analgesic effect of long-acting opioid PCA without a background dose shows no statistically significant difference from LCP-mode medication, but the duration of maintenance differs; drug selection should be based on the surgical trauma, which is conducive to standardized management [70].

2) PNB + PCIA multimodal delivery

Before or at the end of surgery, the long-acting local anesthetic ropivacaine can be used for PNB, followed by the PNB + PCIA mode. This can markedly reduce the dosage of analgesic drugs. Ultrasound-guided PNB with liposomal bupivacaine provides more complete and durable analgesic effects for postoperative PCIA, facilitating early functional exercise and rapid postoperative recovery of patients [71].

6. Pre-PCA Patient Assessment, Education and Intelligent PCA System

6.1. Pre-PCA Patient Assessment and Education for Patients and Caregivers

6.1.1. Preoperative Assessment

The safe and effective management of PCA requires an interdisciplinary acute pain service (APS) team composed of physicians, pharmacists, and nurses. Before PCA, physicians should understand the patient's ASA classification, BMI, type of surgery, blood transfusion, correct assessment of the postoperative pain score (NRS), the selection of the analgesic pump type, and the factors influencing the postoperative patient-controlled analgesia effect. Physicians issue orders, nurses execute orders, the APS prepares drugs correctly, continuously evaluates the analgesic effect, and dynamically monitors adverse reactions. APS team members need to be familiar with the PCA management process, including patient screening, comprehensive identification and assessment of high-risk patients, formulation of the PCA drug regimen, dose adjustment during use, and monitoring and management of adverse reactions; they should communicate with one another to achieve the best pain control outcome and avoid complications [72, 73].

6.1.2. Preoperative Education

Preoperatively, the patient is conscious and can correctly understand the education provided by healthcare professionals to the patient and family members; repeated preoperative education by healthcare professionals deepens the patient's memory. The contents of education include: (1) explaining to the patient the importance of postoperative pain relief; (2) introducing the principles and safety of the PCA pump to the patient; (3) explaining the key points of use to the patient. Physician education of the patient about PCA, and the understanding of PCA by the patient and family members, are very important for the safety of PCA. Before applying PCA analgesia, communication with the patient and family members is needed; according to the different occupations and educational levels of the patient and family members, the advantages of the PCA pump and the importance of safe use should be introduced in detail. Patients and family members should be trained and educated on how to use the device correctly, and it should be emphasized that patients and family members are prohibited from adjusting the various parameters of the PCA pump on their own; in particular, it should be emphasized that only the patient himself/herself or an authorized person is allowed to press the PCA button, to avoid accidental injury [74].

6.2. Structure of Intelligent PCA

The intelligent PCA (artificial intelligence PCA, Ai-PCA) technical system is an analgesic pump that combines the Internet of Things and artificial intelligence, and was approved for registration by the State Food and Drug Administration in May 2011. Ai-PCA consists of the intelligent analgesic terminal (the intelligent analgesic pump, including the intelligent infusion driving device and the disposable dedicated drug reservoir), the base station (the basic equipment for data transmission), and the central analgesia monitoring station (computers, pads, and mobile phones installed with analgesia management software) [43, 75].

6.2.1. Base Station

The base station is the basic equipment for network establishment and data reception and transmission. It is equipped with a wireless module inside, an RS232 serial port at the bottom, a rubber-rod antenna on the right side of the housing, and a status indicator light on the front of the housing. The base station is a plug-and-play device. As the basic component of the communication network of the analgesia information system, the base station collects the information sent by the intelligent analgesic terminal devices and transmits it to the central analgesia monitoring station [76].

6.2.2. Central Analgesia Monitoring Station

The central analgesia monitoring station is the equipment

for analyzing and processing the information uploaded by analgesic terminals. Operators can monitor the use of the analgesic terminals through the central analgesia monitoring station, which automatically generates postoperative follow-up and patient-controlled analgesia (PCA) record sheets. Hospitals must implement the announcement on the Catalog of Medical Device Classification (No. 104 of 2017) issued by the China Food and Drug Administration (CFDA), and departments need to follow the national requirement that “the infusion information collection system for analgesic drugs must be registered as Class III” [77].

7. Standardized PCA Management System

7.1. Standardized PCA Operation Management

The management model of the “pain cloud ward” or the “virtual pain unit (VPU)” in the department of anesthesiology should be implemented, following a system of all-staff participation, whole-process control, and comprehensive quality control [78]. Physicians of the acute pain service (APS) should inform patients of pain-related content during the preoperative visit [79]. According to the Notice on Strengthening the Management of Narcotic Drugs and First-Class Psychotropic Substances in Medical Institutions (Guoweyifa [2020] No. 13), anesthesiologists cannot handle drugs alone; in accordance with the Law of the People's Republic of China on Physicians, the department of anesthesiology must establish a physician order system. APS physicians issue electronic orders, nurses prepare the analgesic drugs, and the preparation process must be subject to relevant supervision; the order parameters are automatically written into the infusion pump through the intelligent order system to improve efficiency and prevent the risk of manual error in setting [80]. Owing to the diversity and complexity of PCA formulations, a double-check system should be adopted clinically, AQI should be strengthened, and the overall effectiveness of PCA should be improved.

An APS 24 h × 7 d responsibility system is adopted, and all patients receiving pain treatment are managed by the APS physician on duty, who handles alarms and other problems. The APS has dedicated application forms, registration forms, and routine nursing record sheets. APS physicians make scheduled rounds 1–3 times a day; during rounds, VAS scores, BCS comfort scores, and sedation scores are assessed, the patient's SpO₂ is monitored, and the operation of the PCA pump is checked. Dedicated anesthesiologists and nurses make rounds every afternoon to evaluate the analgesic effect of patients using analgesic pumps, check for adverse reactions, and answer questions about analgesia. During rounds, a VAS score ≤ 3 indicates good analgesia; if the VAS score is ≥ 4 and/or adverse reactions occur, timely symptomatic treatment is required to promote patient ERAS [82].

7.2. Quality Control Management of the Intelligent Analgesia System

An integrated platform for multimodal evaluation, recording, and query operations has been established, realizing remote real-time management and monitoring of analgesic terminals. After removing the catheter and withdrawing the pump, APS nurses place the intelligent analgesic pump into an intelligent residual-volume verification robot, which performs intelligent registration, disposal, and verification of the residual volume, followed by disinfection [83].

1) Standardization of PCA data collection

Postoperative follow-up and patient PCA record sheets are an important component of the medical record system for surgical patients. During the patient's analgesia process, medical data are collected at the source in a unified format to achieve comprehensiveness and accuracy, ensuring consistency in the collection, storage, organization, analysis, retrieval, and application of the data.

2) Standardization of real-time PCA tracking

The system automatically collects the analgesia information of postoperative patients and automatically records and generates medical documents, achieving quality control and real-time tracking of the patient throughout the entire analgesic process. This not only records the changes in the patient's condition more objectively and prevents anesthesiologists from missing important information that affects analysis and judgment because they are busy recording, but also avoids errors when physicians retrospectively write records after events have been handled, thereby improving efficiency.

3) Digitization of PCA information storage

Computer database storage technology is used to record, process, and preserve information related to the patient's analgesic process. The intelligent analgesia system can realize on-demand retrieval of medical-related data under combined conditions. The information can be transferred to data-mining software such as SPSS and SAS for macroscopic analysis and scientific research, providing strong support for the management of medical behaviors in patient analgesia, reproducing the PCA process, and analyzing the analgesic effect.

4) Intelligent PCA quality control

The pain operation management model of the department of anesthesiology is implemented, with all-staff participation, whole-process control, and comprehensive quality control. The AQI software is used to analyze the frequency of self-control button presses, evaluation rates, the incidence of various alarms, the handling time of important alarms, the drug solution utilization rate, and the completeness of patient information, comprehensively reflecting the level of analgesic skills of healthcare professionals, the meticulousness of patient assessment, the precision of physician orders, and the standardization of management. Departments usually choose to display the 24-h AQI to intuitively reflect analgesia quality, and use the PDCA cycle for continuous improvement of the

problems shown by the AQI; AQI values of different departments and different hospitals are analyzed and compared to evaluate the level of analgesia quality and promote continuous quality improvement [84].

8. Typical PCA Regimens

8.1. Recommendations for PCIA in Postoperative Patients

- 1) Recommended opioids for PCIA [85-88]: for PCIA, the strong opioids morphine, sufentanil, and hydromorphone are recommended (evidence level: B; strength of recommendation: very strong; consensus: 100.0%).
- 2) Recommended μ -opioid receptor partial agonist-antagonists for PCIA [89-91]: μ -opioid receptor partial agonist-antagonists are recommended (evidence level: B; strength of recommendation: strong; consensus: 80%).
- 3) Fentanyl for PCIA [92]: fentanyl is recommended for PCIA (evidence level: C; strength of recommendation: weak; consensus: 37.2%).
- 4) Oxycodone for PCIA [50, 93, 94]: oxycodone is recommended for PCIA (evidence level: C; strength of recommendation: weak; consensus: 60.0%).
- 5) NSAIDs for PCIA [95]: the analgesic adjuvant drug flurbiprofen axetil is recommended during PCIA (evidence level: B; strength of recommendation: strong; consensus: 86%).
- 6) Analgesic adjuvant drugs for PCIA [96, 97]: analgesic adjuvant drugs such as dexmedetomidine and esketamine are recommended during PCIA (evidence level: B; strength of recommendation: strong; consensus: 97.7%) [4, 19, 23, 50, 57, 58, 83-112].
- 7) Adjuvant drugs combined with PCIA [4, 23, 142]: adjuvant drugs such as dexamethasone, droperidol, ondansetron, azasetron, and tropisetron are recommended during PCIA to prevent adverse reactions such as nausea and vomiting caused by opioids (evidence level: B; strength of recommendation: strong; consensus: 93.0%).
- 8) Adjuvant drugs for PCIA [98]: the adjuvant drugs gabapentin and pregabalin are recommended during PCIA (evidence level: C; strength of recommendation: weak; consensus: 16.3%).

8.2. Recommendations for PCEA in Postoperative Patients

- 1) Single-pump PCEA analgesia [57, 58, 99-111]

Using the LCP mode (initial infusion + continuous fixed-rate infusion + patient-controlled infusion) for strong opioids, i.e., a loading (titration) dose of 5 ml per administration + a continuous dose of 0.5 ml + a PCA bolus of 1 ml per administration, with a lockout time of 10–15 min and a safety-limited maximum dose of 15 ml per 1-h unit time. For PCEA, the

strong opioids sufentanil and hydromorphone and the long-acting local anesthetics 0.2% ropivacaine and 0.2% levobupivacaine are recommended (evidence level: B; strength of recommendation: very strong; consensus: 100%).

2) Dual-pump PCEA analgesia

Foreign countries recommend a dual-pump analgesia method: pump A delivers continuous infusion of 0.2% ropivacaine at 8–12 ml/h; when the analgesic effect of continuous local anesthetic infusion is insufficient, pump B is connected to the intravenous catheter through a three-way connector for PCIA with 0.1% morphine [112-114]. In China, a dual-pump analgesia method is recommended: pump A delivers continuous infusion of 0.2% ropivacaine at 4–6 ml/h; when the analgesic effect of continuous local anesthetic infusion is insufficient, the patient can press the self-control button, and pump B is connected to the epidural catheter through a three-way connector for PCEA with 0.01% morphine, administered in LP mode, i.e., a loading (titration) dose of 5 ml per administration + a PCA bolus of 1–2 ml per administration, with a lock-out time of 15–20 min, to enhance the analgesic effect [62, 115, 116]. However, when the local anesthetic exceeds 8 ml/h, after 6 h of infusion patients develop obvious numbness in both lower limbs; Chinese patients consider this numbness more intolerable than pain and request cessation of pump infusion, so the dose recommended in China is markedly lower than that abroad. Dual-pump analgesia is used for postoperative patients for whom it is indicated (evidence level: C; NRS/VAS score 4–10; weak; consensus: 60%).

- 3) PNB + PCEA [117-119]: used for analgesia in postoperative patients (evidence level: C; NRS/VAS score 4–10; strength of recommendation: strong; consensus: 95.3%).

8.3. Recommendations for Different Routes of Labor Analgesia

- 1) PCIA [47]: for parturients receiving labor analgesia (evidence level: C; NRS/VAS score 4–10; strength of recommendation: weak; consensus: 16.3%).
- 2) PCEA [81, 120]: for parturients receiving labor analgesia (evidence level: A; NRS/VAS score 4–10; strength of recommendation: very strong; consensus: 100%).
- 3) TCI-PCA [121]: for parturients receiving labor analgesia (evidence level: C; NRS/VAS score 4–10; strength of recommendation: weak; consensus: 18.6%).

8.4. Recommendations for Different Routes for Angina Pectoris in Internal Medicine

- 1) PCIA [48]: for patients with angina pectoris in internal medicine (evidence level: C; NRS/VAS score 4–10; strength of recommendation: weak; consensus: 74.4%).
- 2) PCEA [122, 123]: for patients with angina pectoris in internal medicine, PCEA (T5–6) can markedly relieve the paroxysmal chest pain or chest discomfort in patients caused by coronary insufficiency and acute, transient

myocardial ischemia and hypoxia (evidence level: B; NRS/VAS score 6–10: strength of recommendation: strong; consensus: 86.0%).

8.5. Recommendations for Different Routes in Patients with Cancer Pain

- 1) PCIA [19, 110, 111, 124-126]: for patients with moderate cancer pain, a simple PCA on-demand delivery mode is recommended (evidence level: B; strength of recommendation: strong; consensus: 95.3%).
- 2) Pethidine via PCIA [127]: pethidine is not recommended for the treatment of cancer pain via PCIA (evidence level: C; strength of recommendation: rejected; consensus: 0%).
- 3) PCEA [128]: for patients with severe cancer pain, patients should undergo multidimensional assessment before applying PCA. After PCA titration with a potent μ -opioid receptor agonist is completed, informed consent should be obtained from the patient; according to the patient's individual condition, treatment should be started with a small dose, and during titration the efficacy and adverse reactions should be dynamically assessed and parameters adjusted in a timely manner (evidence level: B; strength of recommendation: strong; consensus: 86%).
- 4) S-PCA [129]: for patients with extremely refractory cancer pain in the lower abdomen and lower limbs who are unable to lie flat to sleep, suffer unbearable pain, and have a strong desire [for relief], with the patient's informed consent, long-acting local anesthetics can be used for PCSA (evidence level: C; strength of recommendation: strong; consensus: 95.3%).
- 5) PCSA [130]: for patients with refractory moderate cancer pain, potent μ -opioid receptor agonists are used via PCNA (evidence level: C; NRS/VAS score 4–10: strength of recommendation: weak; consensus: 58.1%).
- 6) PNB + PCIA [131, 132]: used for patients undergoing indicated surgery (evidence level: C; NRS/VAS score 4–10: strength of recommendation: strong; consensus: 97.7%).

8.6. Recommendations for Different Routes in Adult Patients with Severe Pain

- 1) PCIA [24]: for adult patients with severe pain, when patients with acute myocardial infarction develop severe chest pain (evidence level: B; NRS/VAS score 4–10: strength of recommendation: weak; consensus: 60.5%).
- 2) PCIA [133]: for adult patients with severe pain, when patients with acute myocardial infarction develop severe chest pain, NSAIDs are recommended for analgesia (evidence level: B; NRS/VAS score 4–10: strength of recommendation: weak; consensus: 16.3%).
- 3) PCIA [134]: morphine is recommended for patients with pain in shock (evidence level: C; NRS/VAS score 4–10:

strength of recommendation: weak; consensus: 32.6%).

- 4) PCIA [135]: for patients with acute abdomen of moderate to severe pain intensity and a confirmed diagnosis, on-demand analgesic treatment is recommended (evidence level: B; NRS/VAS score 4–10: strength of recommendation: strong; consensus: 95.3%).
- 5) PCEA [136]: for patients with acute abdomen of severe pain intensity and a confirmed diagnosis, analgesic treatment is recommended (evidence level: B; NRS/VAS score 4–10: strength of recommendation: strong; consensus: 81.4%).
- 6) PCEA [137]: for patients with pain due to acute severe pancreatitis, opioids are recommended for analgesia (evidence level: B; NRS/VAS score 4–10: strength of recommendation: strong; consensus: 90.7%).
- 7) PCIA/PCEA [138, 139]: for postoperative patients with severe pain, opioid analgesic treatment should be routinely selected (evidence level: B; NRS/VAS score 4–10: strength of recommendation: strong; consensus: 97.7%).
- 8) PCIA [140, 141]: for patients with pain after craniocerebral surgery (evidence level: C; NRS/VAS score 4–10: strength of recommendation: weak; consensus: 62.8%).

8.7. Precautions for PCA Formulations

Before selecting drugs for combined analgesia with postoperative PCA, a thorough assessment of the pain patient should be performed. Because patients differ in ASA classification and type of surgery, the nature of postoperative pain differs, the pharmacological effects of the various drugs selected differ, and there are differences in drug combination protocols, analgesic pump types, analgesic routes, and delivery modes, the PCA effect differs accordingly. A uniform analgesic method is not appropriate; the multimodal analgesic regimen should be determined objectively and individually, adapted to the specific patient and situation [20, 27].

9. Monitoring and Management of PCA Adverse Reactions

9.1. Adverse Reactions to PCIA and Their Monitoring

9.1.1. Adverse Reactions to PCIA

The adverse reactions of postoperative PCA have a certain impact on the satisfaction of patients with pain. The adverse reactions of intravenous patient-controlled analgesia mainly arise from the adverse effects of the drugs, including excessive sedation, respiratory depression, nausea and vomiting, and constipation; a few patients may develop pruritus and urinary retention [23]. PCIA can optimize the delivery mode of opioid

analgesics, minimizing the impact of differences in pharmacokinetics and pharmacodynamics among individuals. Respiratory rate is used as a routine indicator for observing respiratory depression, and pulse oxygen saturation (SpO₂) monitoring should be used as much as possible.

9.1.2. Adverse Reactions to PCEA

Some of the complications and adverse reactions caused by epidural analgesia are related to procedures such as epidural puncture and catheter placement; the adverse reactions include respiratory depression, excessive sedation, hypotension, nerve injury, unilateral lower limb numbness occasionally accompanied by weakness or lower limb motor dysfunction, and other adverse reactions such as postoperative nausea and vomiting (PONV), skin pruritus, somnolence, vertigo, and urinary retention [143].

9.1.3. Adverse Reactions Related to PCA Equipment or Operation

Standard puncture procedures and equipment use rarely cause adverse reactions such as bleeding and infection. Analgesic pump programming errors, equipment failure, tampering with parameters, and family members pressing the PCA button on behalf of the patient can lead to drug overdose and serious adverse reactions such as respiratory depression. Therefore, during the first 24 h after initiation of PCA or after adjustment of delivery parameters, the patient's vital signs should be closely monitored, with particular attention to the presence of respiratory depression and changes in the level of consciousness [144].

9.1.4. Adverse Reactions of Ultrasound-Guided Nerve Block + PCA

Ultrasound-guided nerve block (PNB) can provide safe and effective analgesia for postoperative patients. However, nerve block still carries risks of bleeding, infection, and nerve injury [20, 27].

9.2. Management of Adverse Reactions

9.2.1. Respiratory Depression

Respiratory depression is the most life-threatening. When the respiratory rate is < 8 breaths/min, the patient's condition and skin color, as well as the patency of the airway, should be checked immediately; for somnolent patients, the characteristics of respiration should be observed, and naloxone 0.1–0.4 mg should be given intravenously. When there is mild airway obstruction and the patient is easily arousable, the patient should be encouraged to choose an optimal position to maintain airway patency [145].

9.2.2. Shivering

Postoperatively, muscle tremor can occur as a side effect of

morphine. The local use of hot water bottles should be avoided. After shivering, check whether body temperature has risen, and pay attention to differentiating it from postoperative fever and infusion reactions [146].

9.2.3. Lower Limb Numbness with Weakness

This is a side effect after the use of local anesthetics, caused by migration of the tip of the epidural catheter to a nerve root, an excessive dose of the analgesic drug, or deviation of the epidural catheter to one side resulting in failure of the local anesthetic to spread; slowing the infusion rate can provide some relief [147]. The numbness of the limbs disappears quickly after catheter removal and requires no special treatment. During the period of indwelling analgesic pump use, education and nursing measures for fall prevention should be provided.

9.2.4. Urinary Retention

Urinary retention is an adverse reaction of morphine-type analgesics. Most patients using a PCA pump after surgery have an indwelling urinary catheter; it is recommended that the timing of urinary catheter removal be after discontinuation of the analgesic pump [148].

9.2.5. Somnolence

Some patients using a PCA pump may develop somnolence. Somnolent patients can be aroused when called; nurses should frequently wake the patient, closely observe the respiratory rate, rhythm, and depth, as well as the color of the skin, lips, and nail beds, and remind the anesthesiologist whether the dose of the analgesic should be reduced [149]. While the patient is somnolent, nurses should strengthen rounds, raise the bed rails, and provide safety education to caregivers to prevent accidents such as falling out of bed, self-removal of the catheter, and burns.

9.2.6. Hypotension

Hypotension may be related to changes in body position, hypovolemia, or peripheral vasodilation caused by anesthetic drugs. If necessary, the PCA pump should be paused. Blood volume should be replenished, and vasoactive drugs can be used to raise blood pressure when necessary [150].

9.2.7. Skin Pruritus

Pruritus is an adverse reaction caused by morphine-induced histamine release. Pruritus is mostly confined to the head and neck but may also spread over the trunk. Mild pruritus may resolve spontaneously within 1–2 days; for more severe cases, patients should be instructed to avoid scratching the skin, and antihistamine drugs such as diphenhydramine and promethazine should be given; nalmefene can be used for pruritus prevention [150].

9.2.8. Inhibition of Intestinal Motility

Because the analgesics used in the PCA pump are generally opioids such as morphine and fentanyl, these drugs have the side effect of inhibiting intestinal motility. Nurses should pay attention to observing the patient's intestinal motility, including bowel sounds, passage of flatus, and defecation; especially patients undergoing abdominal surgery may experience abdominal distension, prolonged time to flatus, and postoperative nausea and vomiting [151]. For patients with abdominal distension who have not passed flatus by 3 days after surgery, nurses should instruct them, if their condition permits, to increase activity, such as increasing the frequency of turning over or bedside activity, and applying warm compresses to the abdomen to promote intestinal motility; for patients with severe abdominal distension, continuous gastrointestinal decompression or anal tube decompression can be performed as ordered [85]. Patients who can eat may be encouraged to eat more vegetables and fruits, such as bananas, which facilitate defecation.

9.2.9. Chronic Postsurgical Pain

If acute postoperative pain is not effectively controlled, patients are prone to chronic postsurgical pain (CPSP). Patients who have acute critical illness or coronavirus disease 2019 (COVID-19) before surgery are even more prone to CPSP after surgery. One study was the first to clarify that acute-phase critical illness and the presence of post-COVID-19 condition (long COVID) after surgery were associated with a trend toward an increased incidence of CPSP in patients with preoperative COVID-19 [152].

9.2.10. Psychological Care

PCA treatment combined with psychological care can achieve the best analgesic effect. Healthcare professionals should provide more comfort and encouragement to patients to strengthen their confidence in overcoming pain. Patients should be helped to learn to relax, divert attention, and adjust their mood, and to actively cooperate with pharmacological pain control using integrated traditional Chinese and Western medicine approaches [153].

9.3. Recommendations for the Management of Adverse Reactions

During the application of PCA, close monitoring should be performed, combined with psychological care; patients should learn to relax, and acupuncture and integrated traditional Chinese and Western medicine methods should be used in a timely manner [154]. Recommendations for the management of adverse reactions (evidence level: B; strength of recommendation: very strong; consensus: 100%).

10. Prospects

Important evidence gaps persist for PCA practice in China,

such as the shortage of large-scale prospective domestic clinical data to guide clinical decision-making. Implementation of these standardized recommendations may face real-world barriers including uneven equipment availability and inconsistent staff training across institutions. These consensus statements are not universally applicable and require individualized clinical judgment, especially in resource-limited environments or for special patient subgroups.

The development of PCA for pain treatment is a microcosm of the rapid development of clinical medicine in China. From introduction to independent innovation, Ai-PCA has further improved the precision, reliability, and safety of pain treatment [155]. At present, artificial intelligence is developing extremely rapidly; in 2024, Sora appeared on the basis of ChatGPT 4.0. Therefore, PCA technology should continue to keep pace with the development of the times and intensify the innovation and improvement of intelligence. Future digital-intelligent healthcare should provide more standardized, safer, more effective, broader, higher-quality, and more precise analgesic treatment services, and patient-controlled analgesia should develop in a standardized and high-quality manner toward digital-intelligent healthcare [137, 155-158], thereby promoting the standardized and high-quality development of PCA technology in anesthesiology and pain medicine toward digital-intelligent healthcare [158].

Abbreviations

PCA	Patient-Controlled Analgesia
PCIA	Patient-Controlled Intravenous Analgesia
PCEA	Patient-Controlled Epidural Analgesia
PCSA	Patient-Controlled Subcutaneous Analgesia
S-PCA	Subarachnoid Patient-Controlled Analgesia
TCI	Target-Controlled Infusion
TCI-PCA	Target-Controlled Infusion Patient-Controlled Analgesia
PNB	Peripheral Nerve Block
CPNB	Continuous Peripheral Nerve Block
Ai-PCA	Artificial Intelligence Patient-Controlled Analgesia
IASP	International Association for the Study of Pain
NRS	Numerical Rating Scale
VAS	Visual Analogue Scale
VRS	Verbal Rating Scale
GRADE	Grading of Recommendations Assessment, Development and Evaluation
RCT	Randomized Controlled Trial
MEAC	Minimal Effective Analgesic Concentration
ERAS	Enhanced Recovery After Surgery
APS	Acute Pain Service
ASA	American Society of Anesthesiologists
BCS	Bruggermann Comfort Scale
AQI	Analgesia Quality Index (Patient Comfort Index in this article)
PDPH	Post-Dural Puncture Headache
PONV	Postoperative Nausea and Vomiting

CPSP	Chronic Postsurgical Pain
SpO ₂	Pulse Oxygen Saturation
VPU	Virtual Pain Unit
CFDA	China Food and Drug Administration
PDCA	Plan-Do-Check-Act

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Conflicts of Interest

The authors declare no conflict of interest.

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