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Clinical Applications of Fospropofol Disodium: Current Status, Advances, and Outlook

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Abstract

Fospropofol disodium (FD) is a water-soluble prodrug of propofol. Approved for marketing in China in 2021, it has become a new option for general anesthesia induction. Its key advantage lies in the fact that it does not require a lipid emulsion carrier, thereby avoiding traditional propofol-related adverse reactions such as lipid metabolism disorders and injection pain; at the same time, because the prodrug is slowly hydrolyzed by alkaline phosphatase to release active propofol, hemodynamic fluctuations are more gradual. However, the drug's delayed onset of action (approximately 1-2 minutes slower than propofol), significantly higher incidence of paresthesia and pruritus, and ongoing safety concerns regarding formaldehyde metabolites constitute the main barriers to its clinical adoption. In recent years, with the launch of the Chinese version of FD (HX0507) and the conduct of multiple clinical studies, evidence supporting the use of FD in general anesthesia induction, ICU sedation, and comfort care has continued to accumulate. This article provides a systematic review of the pharmacological characteristics, clinical research evidence, and key unresolved issues regarding FD, aiming to serve as a reference for further research in the field of anesthesiology.

Keywords

Fospropofol Disodium, Propofol, General Anesthesia Induction, Hemodynamics, Sensory Abnormalities

Abbreviations

FD: Fospropofol Disodium; HX0507: Fospropofol Disodium; ICU: Intensive Care Unit

Introduction

Since its introduction, propofol has consistently held a central position among intravenous anesthetics due to its rapid onset of action, complete recovery, and low incidence of postoperative nausea and vomiting. However, issues associated with its lipid emulsion formulation, such as injection pain (with an incidence rate of 30%-70%), lipid metabolism disorders, the risk of bacterial contamination, and propofol infusion syndrome, have long posed challenges in clinical practice [1].

The development of fospropofol disodium phosphate can be traced back to early research by Eisai Co., Ltd. Of

Japan. In 2008, the drug (brand name Lusedra) was approved by the U.S. Food and Drug Administration (FDA) for monitored anesthesia care; however, due to safety concerns regarding formaldehyde accumulation, restrictions on outpatient use, and the requirement that it be administered by an anesthesiologist, it performed poorly in the market and was withdrawn in 2012 [2]. Subsequent studies confirmed that formaldehyde accumulation resulting from short-term use of fospropofol disodium (FD) is limited; after metabolism to formic acid, its concentration is comparable to endogenous levels and does not pose a significant health risk. On May 25, 2021, disodium phospho-propofol for injection (HX0507), independently developed by West China Hospital of Sichuan University in collaboration with Yichang Renfu Pharmaceutical, was approved by the National Medical Products Administration (NMPA) as a Class 1.1 new drug in China, indicated for the induction of general anesthesia in adults [3]. Currently, this drug is in clinical use at numerous hospitals nationwide and has demonstrated unique advantages in areas such as anesthesia for the elderly and intensive care unit (ICU) sedation.

Pharmacological Characteristics

Mechanism of Action:

FD is a phosphate ester prodrug of propofol; its chemical name is disodium 2,6-diisopropylphenol methylacetal phosphate monohydrate. FD itself has no pharmacological activity; after entering the body, it is hydrolyzed by alkaline phosphatase (ALP) in vascular endothelial cells and the liver, releasing active propofol to exert its anesthetic effect. Its neuroinhibitory effects are primarily achieved through two pathways: enhancing the opening of GABAA receptor-mediated chloride channels, thereby promoting the binding of the inhibitory neurotransmitter GABA; and simultaneously inhibiting NMDA receptor-mediated calcium influx in the central nervous system, producing sedative or anesthetic effects [4].

FD's water-soluble nature is its core advantage over traditional propofol. Due to its high lipophilicity, traditional propofol requires a lipid emulsion as a drug delivery vehicle, whereas FD's water solubility eliminates the need for a lipid emulsion carrier, thereby avoiding lipid-related side effects that may result from prolonged infusion [2].

Pharmacokinetic Characteristics:

FD exhibits distinct "prodrug" characteristics. Following intravenous injection, FD is hydrolyzed by alkaline phosphatase to release propofol; this conversion process determines its unique pharmacokinetic profile. Compared with an equal volume of propofol emulsion administered as a bolus, the onset of sedation with FD is significantly delayed (4-8 minutes), and the time to peak plasma concentration of active propofol is typically 8-15 minutes [5]. In healthy subjects, following administration of 10-30 mg/kg of FD, the time to peak plasma concentration of FD itself was 4-5 minutes, while the time to peak concentration of the released active propofol was delayed to 9-15 minutes; the terminal half-life of FD is 27 ± 6 minutes, while that of active propofol is 478 ± 287 minutes, which is significantly longer than the 88 ± 48 minutes observed with standard propofol formulations.

The fundamental reason for the slower onset of action is that FD must first be hydrolyzed by ALP before it can cross the blood-brain barrier, and the activity of this enzyme varies among individuals. The higher the ALP level, the faster the onset of action, but the incidence of hypotension during the induction phase also increases accordingly. This pharmacokinetic characteristic of "slow onset and long duration" serves as both the biological basis for FD's more stable hemodynamics and a critical timing consideration in its clinical application.

Differences Between Chinese and U.S. Formulations:

It should be noted that the U.S. version of FD (Lusedra) and the Chinese version of FD (HX0507) differ in excipients and molecular weight. Lusedra contains 0.25% dihydroxypropylthiol and 0.12% aminobutyltriol as excipients; in contrast, HX0507 uses mannitol as an excipient, has a molecular weight of 350.26 g/mol, and contains 500 mg of lyophilized powder per vial, which is reconstituted with saline or water for injection prior to use. These formulation differences may affect the drug's dissolution characteristics, stability, and adverse reaction profile

and must be distinguished when comparing across studies [2].

Current Status of Clinical Application Research

General Anesthesia Induction:

Induction Success Rate and Efficacy:

Multiple clinical studies have confirmed that FD is effective for general anesthesia induction. A multicenter, randomized, double-blind, dual-simulation Phase III non-inferiority clinical trial found that fospropofol disodium phosphate (20 mg/kg) was non-inferior to propofol medium- to long-chain fatty acid emulsion (2 mg/kg) in terms of the induction success rate for general anesthesia in adults, and neither drug was associated with delayed emergence or cognitive impairment. A Phase III trial by Wu et al. (2021) further confirmed that FD 20 mg/kg was non-inferior to propofol in terms of sedation during general anesthesia induction, and no serious adverse events were reported in either group [3].

The latest systematic review and meta-analysis (2026) indicated that the induction success rate of high-dose disodium phospho-propofol was comparable to that of propofol, and it offered clear advantages in reducing injection pain and bradycardia [6].

Onset of Action and Combination Therapy:

The main limitation of FD is its slow onset of action. Previous studies have shown that the onset of action of FD is significantly slower than that of propofol [3,6]. To address this issue, a randomized controlled trial conducted by Li et al. (2025) found that combining FD with sufentanil during general anesthesia induction in elderly patients significantly shortened the time to loss of consciousness, improved the sedation success rate, and reduced the incidence of adverse reactions [7]. This study was the first to evaluate the clinical value of combining sufentanil with FD for general anesthesia induction in elderly patients, providing important guidance for optimizing FD induction protocols.

Hemodynamic Stability:

Hemodynamic stability is one of the core advantages of FD. A dose-exploration study by Cheng et al. (2025) found that the combination of FD and sufentanil modulates the cardiovascular response induced by endotracheal intubation [8]. A randomized controlled trial by Sun et al. (2026) further confirmed that, in patients undergoing supratentorial tumor resection, FD had a more favorable effect on intraoperative hemodynamics than propofol [9]. Compared with conventional propofol, FD is associated with a lower incidence of hypotension during the induction phase and more gradual hemodynamic fluctuations [2]. This characteristic makes FD particularly suitable for elderly patients and critically ill patients with reduced cardiovascular reserve.

Anesthesia in Elderly Patients:

Due to reduced cardiovascular compensatory capacity, elderly patients are more sensitive to the hemodynamic effects of anesthetic agents. The use of FD in elderly patients is one of the current research hotspots.

Several studies have evaluated the clinical value of FD in elderly patients undergoing total hip arthroplasty. A retrospective study by Ding et al. (2025) demonstrated that FD and propofol produced similar outcomes regarding the quality of postoperative recovery in elderly patients undergoing total hip arthroplasty [10]. Zhu et al. (2025) further compared the effects of FD and propofol on perioperative neurocognitive function in elderly patients undergoing total hip arthroplasty, finding that FD was non-inferior in preventing perioperative neurocognitive impairment and was associated with fewer adverse reactions [11]. A study by Wu et al. (2026) also confirmed that FD can be safely and effectively used for anesthetic induction in elderly patients undergoing hip surgery [12].

In China, several dose-exploration studies have been conducted on the sedative effects of FD during general anesthesia induction in elderly patients. Additionally, comparative studies between FD and etomidate for general anesthesia induction during percutaneous nephrolithotomy in elderly patients are currently underway. Overall, FD demonstrates the advantage of more stable hemodynamics in elderly patients and is particularly suitable for elderly populations with relatively fragile cardiovascular systems. However, it

should be noted that there is currently limited clinical experience with fospropofol disodium for injection in patients aged 65 years and older; it is recommended to start with a low dose and administer it slowly in patients of this age group [12].

Intensive Care Unit (ICU) Sedation:

Long-term sedation of mechanically ventilated patients in the intensive care unit (ICU) is another important potential application area for FD. Multiple studies are currently exploring the efficacy and safety of FD in ICU sedation. Current clinical guidelines emphasize the standardized use of sedative-analgesic medications during continuous neuromuscular blockade [13], and as a novel sedative, it is worth examining whether FD aligns with these guidelines.

A dose-finding study by Gao et al. (2024) provided preliminary dosage references for the use of FD in sedating postoperative ICU patients [14]. Their subsequent randomized clinical trial further compared the efficacy of FD with propofol for long-term sedation in patients undergoing invasive mechanical ventilation; the results showed no significant difference between the two groups in the percentage of time spent within the target sedation range (median of 83.33% for both groups), indicating that FD is a feasible, effective, and safe agent for long-term sedation [15]. Another randomized controlled trial by Gao et al. (2025) also demonstrated that FD is comparable to propofol in achieving deep sedation in critically ill patients [16].

A prospective, open-label, randomized controlled trial by Feng et al. (2026) is comparing the efficacy of FD, propofol, and midazolam for goal-directed sedation in mechanically ventilated ICU patients [17]. Wang et al. (2025) evaluated the safety of FD in patients with hepatic impairment from a pharmacokinetic perspective [18], providing data to support the use of FD in patients with liver disease [2].

Regarding the dosage of continuous FD infusion, studies suggest that continuous intravenous infusion at a rate of 3.0-3.5 mg/kg/h can provide mild-to-moderate sedation for postoperative mechanically ventilated patients in the ICU [14,15]. The advantages of FD in ICU sedation include the avoidance of lipid-related complications, such as hypertriglyceridemia, a reduced risk of bacterial contamination, and more stable hemodynamic performance.

Comfort Care and Endoscopy:

FD has also shown potential for use in comfort care settings, such as outpatient minor surgeries and endoscopic procedures. Yue et al. (2025) investigated the anesthetic effects of different doses of FD for painless colonoscopy [19]. Zhao et al. (2024) reported a protocol for an ongoing randomized, double-blind, non-inferiority trial of FD sedation for same-day bidirectional endoscopy in elderly patients [20].

In addition, the application of FD in specialized surgical settings continues to expand, including cardiopulmonary bypass surgery, laparoscopic surgery, endoscopic retrograde cholangiopancreatography (ERCP), and hysteroscopy.

Safety and Adverse Reactions

Common Adverse Reactions:

The most common adverse reactions to FD are paresthesia and pruritus. In a Phase III study of colonoscopy sedation, the incidence of paresthesia in the 6.5 mg/kg FD group was 68%, and the incidence of pruritus was 16%. These adverse reactions typically manifest as burning, stinging, or itching sensations in the perineal region, usually occurring within 5 minutes of administration. They are generally transient and self-limiting, with mild-to-moderate severity [2,21].

Domestic Phase III clinical trials have also confirmed that sensory abnormalities are the most common adverse reaction in the FD group [3]. This adverse reaction is believed to be related to the mechanism by which FD releases phosphate through hydrolysis by alkaline phosphatase, similar to the sensory abnormalities caused by the injection of other phosphate esters, such as dexamethasone phosphate.

To mitigate this adverse reaction, Jiao et al. (2026) conducted preclinical studies and randomized controlled trials to evaluate the safety and clinical efficacy of a premixed solution of FD and lidocaine, providing a new approach for clinically alleviating FD-related paresthesia [21].

Safety Concerns Regarding Formaldehyde Metabolites:

Formaldehyde released during the hydrolysis of FD is at the center of the safety controversy. One of the main reasons for the 2012 market withdrawal of the U.S. version of FD (Lusedra) was safety concerns regarding formaldehyde accumulation. However, subsequent studies have found that short-term use of FD results in only limited formaldehyde accumulation; this formaldehyde is subsequently metabolized into formic acid, whose levels are comparable to endogenous concentrations and do not pose a significant health risk. Nevertheless, the safety of formaldehyde metabolites associated with long-term use of FD still requires validation through larger-scale, longer-term studies [2].

Safety Comparison with Conventional Propofol:

Compared with conventional propofol, FD's safety advantages are primarily reflected in the following aspects:

Injection Pain: FD is a water-soluble formulation with an extremely low incidence of injection pain, whereas the incidence of injection pain with conventional propofol can reach 30%-70% [1].

Lipid Metabolism: FD does not contain a lipid emulsion carrier, thereby avoiding lipid-related complications such as hyperlipidemia and pancreatitis.

Respiratory Depression: FD causes milder respiratory depression than propofol, and when it occurs, it is typically transient and self-limiting.

Allergic Reactions: FD does not contain allergens such as lecithin found in propofol emulsions, resulting in a lower risk of allergic reactions.

Safety in Special Populations:

In patients with hepatic impairment, a prospective cohort study by Wang et al. (2025) evaluated the pharmacokinetics and safety of FD in subjects with impaired liver function, providing important guidance for the clinical use of FD in patients with liver disease [18]. Wang et al. (2026) also reported a case series on the use of FD for anesthetic induction in liver transplant recipients [22]. In patients with hyperlipidemia, a randomized trial by Yang et al. (2025) investigated the effects of FD on lipid metabolism and inflammatory responses [23].

Outstanding Issues and Research Prospects

Optimization Strategies for Delayed Onset:

The slow onset of action of FD, approximately 1-2 minutes later than propofol, is one of the main limitations to its clinical application. It is currently known that combination with sufentanil can shorten the time to loss of consciousness [7], but the optimal combination regimen, dosing, and administration sequence require further study. Additionally, more evidence-based data are needed regarding the applicability of FD in scenarios requiring rapid attainment of anesthetic depth, such as rapid induction and intubation.

Pathogenesis and Management of Sensory Abnormalities:

Sensory abnormalities are the most common adverse reaction associated with FD, with an incidence rate as high as 68% [2,21]. Although the mechanism is believed to be related to phosphate release, the exact molecular mechanism remains unclear. Whether premixing FD with lidocaine can effectively reduce the incidence of sensory abnormalities [21], and whether there are optimal prevention and treatment strategies, remain to be investigated in depth.

Safety of Long-Term Use:

Although formaldehyde accumulation from short-term use of FD is not considered to pose a significant health risk, there is a lack of sufficient safety data regarding the cumulative effects of formaldehyde and its metabolites during long-term use of FD, such as prolonged sedation in the ICU. A review by Zou et al. (2025) clearly states that larger-scale, more rigorous clinical trials are still needed to validate the efficacy of long-term FD use [2].

Evidence on Use in High-Risk Populations:

Current experience with FD in elderly patients remains limited [12], and data on its safety and efficacy

in high-risk populations, such as children, pregnant women, patients with severe hepatic or renal impairment, and those classified as American Society of Anesthesiologists (ASA) Class III or higher, are even scarcer [18,22]. Dosage regimens, dosage adjustment principles, and risk management strategies for these populations are all important areas for future research.

Feasibility of Administration by Non-Anesthesiology Healthcare Personnel:

One of the reasons for the withdrawal of the U.S. version of FD from the market was the requirement that it be administered by an anesthesiologist [2]. Whether the Chinese version of FD can be used in comfort care settings, such as sedation for gastrointestinal endoscopy, under the supervision of non-anesthesiology healthcare professionals involves multifaceted issues related to patient safety, healthcare quality management, and legal regulations and requires systematic evaluation.

Pharmacoeconomic Evaluation:

As a Class 1.1 new drug, FD is priced higher than traditional propofol. Against the backdrop of healthcare cost containment, a systematic pharmacoeconomic evaluation is needed to determine whether FD's clinical advantages can translate into cost-effectiveness advantages. Furthermore, head-to-head comparisons between FD and novel intravenous anesthetics such as cyclopropanol, as well as the development of new propofol analogs, such as dihydrobenzofuran derivatives [24], represent important directions for future research. It is worth noting that conventional propofol has demonstrated antitumor activity in in vitro studies, such as promoting ferroptosis in triple-negative breast cancer cells [25], whereas it remains unknown whether FD possesses similar effects; this also provides a new perspective for future exploration.

Conclusion

As a Class 1.1 water-soluble propofol prodrug independently developed in China, fospropofol disodium offers new options for clinical anesthesia due to its unique advantages, such as the absence of a lipid carrier, minimal injection pain, and hemodynamic stability [2]. Current evidence indicates that FD is non-inferior to propofol in the induction of general anesthesia [3,6] and shows promising prospects for use in anesthesia for elderly patients [10,11,22] and ICU sedation [14-17]. However, issues such as delayed onset of action, a high incidence of sensory abnormalities, insufficient long-term safety data, and a lack of evidence regarding its use in high-risk populations remain the primary barriers to its widespread clinical application [2,7,21]. Future research requires more rigorously designed, adequately powered randomized controlled trials to further identify the optimal patient population for FD, optimize dosing regimens, verify long-term safety, and establish standardized clinical practice guidelines.

Conflict of Interest

The author has read and approved the final version of the manuscript. The author declares no conflicts of interest.

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