RESEARCH PAPER

Oral Triclofos in Pediatric Dental and Procedural Sedation: A Comprehensive Review and Comparative Evaluation of Efficacy, Safety, And Clinical Applications

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ABSTRACT
Procedural sedation plays an important role in facilitating diagnostic, therapeutic, and dental procedures in children who are anxious, fearful, or unable to cooperate. Oral triclofos sodium, a chloral hydrate derivative, is widely used because of its ease of administration, favorable safety profile, and effectiveness in producing sedation. However, the available evidence is dispersed across studies conducted in different clinical settings, and recent focused reviews on the efficacy, safety, and clinical applications of oral triclofos are still limited. This review evaluates the efficacy, safety, acceptability, and comparative effectiveness of oral triclofos in pediatric dental and procedural sedation. A literature search was conducted using PubMed, Scopus, Google Scholar, and Web of Science. Studies evaluating oral triclofos in pediatric patients undergoing sedation were identified and reviewed and the findings were synthesized narratively. The available evidence indicates that triclofos usually administered at standard doses of 50–75 mg/kg is an effective sedative for a variety of pediatric procedures, especially electroencephalography, imaging studies, and selected dental procedures. Compared with some commonly used alternatives, triclofos generally provides deeper and more long lasting sedation, although its onset of action is slower. Across studies, it demonstrated a favorable safety profile with mild and self-limiting adverse effects. Its oral route of administration and palatability contribute to good patient acceptance. Oral triclofos remains a useful option for pediatric sedation, particularly for non-interactive procedures requiring sustained sedation and minimal patient movement. Even though newer sedative agents are available, triclofos continues to offer advantages related to safety, ease of administration, and accessibility.

Keywords: *Pediatric Dentistry, Dental Anxiety, Conscious sedation, Triclofos sodium, Procedural sedation.*
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INTRODUCTION

Behavior management remains an essential component of successful pediatric dental practice. However, despite the use of non-pharmacological behavior techniques, some children may remain anxious, fearful, or uncooperative, making dental treatment difficult. In such situations, pharmacological interventions may be required to facilitate treatment, with conscious sedation being one of the most commonly employed approaches.[1]

Conscious sedation is defined as a drug induced depression of consciousness during which patients respond purposefully to verbal commands and are able to maintain a patent airway and protective reflexes. It is often used during diagnostic and minor surgical procedures to relax patients and minimize fear, anxiety and discomfort and in appropriate cases, may be favored over general anesthesia due to its safety and ease of recovery.[2]

The primary goals of conscious sedation are to enhance patient cooperation, reduce apprehension, minimize the negative psychological response towards treatment, maximize amnesia potential and facilitate successful completion of dental procedures. Sedative agents can be administered through several routes, including inhalational, oral, intranasal, submucosal, intramuscular, intravenous, and rectal routes. Among these, the oral route remains one of the most commonly used methods because of its ease of administration and minimal monitoring requirements. A variety of sedative agents have been investigated for procedural sedation, including nitrous oxide, benzodiazepines, chloral hydrate,

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barbiturates, antihistamines, and opioids, either as single agents or in combination.[3-8]

The growing need for safe and effective sedation techniques, particularly by non-anesthetists, has driven the search for an ideal agent that is acceptable to both patients, caregivers and clinicians. While intravenous agents such as ketamine, propofol, midazolam and dexmedetomidine are effective, their use is limited to settings with trained personnel. In contrast, oral sedatives are more suitable for outpatient and small clinical setups due to their simplicity and feasibility. Commonly used oral agents include promethazine, chloral hydrate, melatonin, triclofos, and flunitrazepam; however, no single agent has demonstrated clear superiority.[9]

Among the various oral sedative agents, triclofos has emerged as a commonly used option for procedural sedation in children due to its ease of administration and favorable safety profile. It is a prodrug of chloral hydrate and has been widely used for sedation in children undergoing diagnostic and minor therapeutic procedures. Triclofos is particularly preferred in situations where intravenous access is not feasible and minimal monitoring is desired.

Despite its widespread use, studies have reported variability in the efficacy, onset of action and safety profile of oral triclofos across a range of pediatric medical and dental procedures. In addition, comparisons with commonly used sedative agents such as midazolam and dexmedetomidine have yielded variable findings with regard to sedation depth, clinical performance, and adverse effects. **Although individual studies have evaluated oral triclofos across dental, neurodiagnostic, imaging, and surgical settings, a consolidated evaluation of its efficacy, safety, and comparative performance with contemporary sedative agents remains limited.** This narrative review aims to provide a comprehensive overview of the pharmacological profile, clinical applications, efficacy, safety, and comparative effectiveness of oral triclofos in pediatric procedural sedation.

PHARMACOLOGY OF TRICLOFOS IN PEDIATRIC SEDATION

Triclofos is a phosphorylated derivative and active metabolite of chloral hydrate and has been widely used as a sedative in pediatric practice. It is available as triclofos sodium (monosodium trichloroethyl phosphate), a phosphate ester form that is metabolized in the liver to trichloroethanol, the pharmacologically active compound responsible for its central nervous system depressant effects and reduction in sleep onset time.[1,10, 11]

It is a non-barbiturate sedative hypnotic agent and has been one of the most popular agents in this class for pediatric use. Although commonly employed for short procedures in children, it has not been extensively utilized as a pre-medicant and its efficacy has been reported to be variable. Triclofos produces good anxiolysis and facilitates smooth induction of anesthesia, particularly in children under 5 years of age, and also exhibits an ant sialagogue effect.[12,13,14,10] Following oral administration, triclofos is well absorbed and typically produces its effect within 30–45 minutes. Commonly used doses range from 50–75 mg/kg, with 70 mg/kg reported to provide satisfactory sedation.[15]

The drug induces a hypnotic effect lasting approximately 6–8 hours; however, the duration of sedation may be highly variable and can extend up to 24 hours,[16] possibly due to erratic gastric absorption and an unclear mechanism of action. Compared to chloral hydrate, triclofos demonstrates improved palatability, causes less gastric irritation, and is available as a palatable syrup formulation, making it more acceptable for pediatric use while maintaining equivalent hypnotic potency.[17,18]

METHODOLOGY

A comprehensive literature search was conducted to evaluate the role of oral triclofos in pediatric procedural sedation. Relevant articles were identified through searches of PubMed, Scopus, Google Scholar, and Web of Science using combinations of the terms oral triclofos, conscious sedation, premedication, behavior management, electroencephalography and procedural sedation. Reference lists of relevant articles were also screened to identify additional studies.

Studies were included if they evaluated oral triclofos as a standalone sedative or compared it with other sedative agents in pediatric patients undergoing dental, diagnostic, therapeutic, or procedural sedation. Randomized controlled trials, prospective and retrospective clinical studies, and observational studies were considered for inclusion. Case reports, review articles and other articles lacking original clinical data were excluded.

The selected studies were reviewed in detail and findings were synthesized narratively to provide an overview of the pharmacological profile, clinical applications, efficacy, safety and comparative effectiveness of triclofos in pediatric sedation.

DISCUSSION

This review summarizes the available evidence on oral triclofos for pediatric sedation, focusing on its efficacy, safety, and performance against alternative sedatives. The included literature comprised randomized controlled trials, crossover studies, observational studies, retrospective analyses and prospective clinical studies conducted across dental, surgical, imaging and neurodiagnostic settings. Most studies were published between 2016 and 2025, providing relatively recent evidence on the efficacy, safety, and behavioral outcomes. The diversity of clinical settings strengthens the relevance of the findings across a broad range of pediatric procedures. The characteristics of the included studies, including study design, patient population, interventions, and principal findings, are summarized in **Table 1**.

Table 1: Comparative Evaluation of Included Clinical Studies

Sl. No.	Study (Year)	Study Design & Population	Intervention and Dosing Protocols	Key outcomes and statistical Highlights	Clinical implication
1	Sardesai et al. [29] (2025)	Single-blind RCT; n = 60 children (aged 2–11 years), ASA I–II	Intranasal dexmedetomidine (2 mcg/kg) vs. Oral triclofos sodium (50 mg/kg)	Dexmedetomidine provided more effective sedation, higher sedation scores, lower wake-up behavior scores, and superior radiologist satisfaction.	Intranasal dexmedetomidine is superior to oral triclofos for non-operating room pediatric imaging sedation.
2	Bharathi et al. [20] (2025)	RCT; n = 184 children (aged 6 months to 5 years) requiring sleep EEG	Oral hydroxyzine vs. Oral triclofos (1:1 ratio)	Successful EEG completion reached in 90.2% of the triclofos arm vs. 82.6% in the hydroxyzine arm (P=0.092). Time to sleep, adverse profiles, and motion artifacts were comparable.	Hydroxyzine is a safe, acceptable, and efficacious alternative sedative agent to triclofos for pediatric EEG recording.
3	Chandrasekar et al.[30] (2023)	Open-label, three-arm RCT; n = 195 children scheduled for MRI	Oral triclofos vs. Intranasal midazolam (INM) vs. Intranasal dexmedetomidine (IND)	IND was superior in achieving successful sedation. INM had shorter onset but 88.3% failure rate. Odds of sedation increased 2.26 times changing from INM to Triclofos ($p<0.01$).	IND is the most efficacious for pediatric MRI, but oral triclofos significantly outperformed intranasal midazolam.
4	Agarwal et al.[23] (2023)	Prospective, double-blind RCT; n = 50 children (aged 1–10 years), ASA I	Oral midazolam (0.5 mg/kg) vs. Oral triclofos (75 mg/kg)	At 30 minutes, 90% in the triclofos group were asleep vs. 18% in the midazolam group ($p = 0.000$); however, midazolam yielded better face mask acceptance ($p = 0.014$).	Triclofos has a more potent sedative premedication effect (inducing sleep), while midazolam provides superior face mask acceptance.
5	Ghosh et al.[28] (2022)	Prospective, single-blind RCT; n = 60 patients (aged 2–8 years)	Oral midazolam (0.5 mg/kg) vs. Oral triclofos sodium (75 mg/kg)	No significant differences found in hemodynamics; triclofos demonstrated better palatability, but midazolam showed better sedative and anxiolytic properties.	Oral midazolam is preferred due to a more rapid, effective sedative effect and superior anxiolysis.
6	Chakraborty & Bandyopadhyay[21] (2021)	Comparative clinical study; n = 50 children (aged 7–13 years)	Oral triclofos sedation (administered 30 mins prior) vs. No sedation control	Children given triclofos were significantly more cooperative during tooth extraction (VAS; $p = 0.003$) and required less procedural time.	Oral triclofos improves patient cooperation and reduces extraction procedural times.
7	Matta & Peddisetty[19] (2019)	Retrospective study; n = 384 children (aged 6 months–5 years)	Oral triclofos for sleep EEG induction	Successful sleep EEG achieved in 96.8% of cases (85.6% single dose, 14.4% second dose); mean onset latency was 36 mins; mean sleep duration was 84 mins.	Oral triclofos is highly effective for pediatric sleep EEGs, though patients with neurological sequelae frequently

					require redosing.
8	Mytily & Sathya[24] (2019)	Double-blind RCT; n = 150 children, ASA I	Oral midazolam (0.5 mg/kg) vs. Oral triclofos (75 mg/kg)	Triclofos was more palatable, better accepted, and produced excellent sedation at 45 mins with better mask acceptance and postoperative recovery scores.	Oral triclofos is superior to oral midazolam as a sedative premedicant for pediatric day-care surgeries.
9	Sharma et al.[25] (2018)	Open-label parallel group prospective RCT; n = 200 children (aged 3 months–5 years)	Oral triclofos sodium (50 mg/kg) vs. Intranasal midazolam spray (0.2 mg/kg)	Adequate sedation (Ramsay 3–4) was obtained in 86% of children for midazolam vs. 80% in triclofos group (p = 0.138); mean onset was significantly faster with midazolam (12 mins vs. 20 mins).	Both agents achieve comparable sedation rates, but intranasal midazolam acts significantly faster.
10	Geetha & Sunitha[26] (2018)	Randomized comparative study; pediatric patients (aged 1–12 years, <25 kg), ASA I–II	Oral triclofos (70 mg/kg) vs. Oral midazolam (0.5 mg/kg in honey)	100% in midazolam group vs. 86.7% in triclofos group were sedated after 30 and 45 mins, respectively; midazolam showed superior anxiolysis and IV cannulation scores.	Both drugs are safe and effective, but oral midazolam achieves satisfactory sedation and anxiolysis much faster.
11	Subramaniam et al.[22] (2017)	Randomized clinical study; n = 60 anxious children (aged 5–10 years)	40% nitrous oxide/60% oxygen inhalation vs. oral triclofos sodium (70 mg/kg)	Overall Houpt behavior scores were similar; however, triclofos caused significantly more drowsiness/disorientation, and oral route acceptance was superior.	Both modalities are safe and effective; oral triclofos is a highly accepted alternative to inhalation sedation.
12	Jain et al.[10] (2016)	Prospective observational study; n = 160 children (aged 6 months–5 years)	Oral triclofos for sleep EEG induction	EEGs were successfully recorded in 93.1% of children; median sleep onset latency was 30 mins, and median sleep duration was 90 mins.	Oral triclofos is a reliable, safe sedative agent for sleep EEGs with minimal, self-limiting adverse effects.
13	Bhatnagar et al.[31] (2012)	Comparative in vivo study; n = 60 anxious pediatric patients	Oral midazolam vs. Oral tramadol vs. Oral triclofos vs. Oral zolpidem	Statistically significant differences were recorded in sedation levels (p < 0.001); midazolam achieved the optimal sedation plane, followed by tramadol and triclofos.	Oral midazolam remains the most effective drug among those compared for pediatric conscious sedation.
14	Shabbir et al.[27] (2011)	Cross-over study; n = 12 children (aged 3–9 years) with Frankl scale 2 behavior	Oral midazolam (0.5 mg/kg) vs. Oral triclofos (70 mg/kg)	Both drugs significantly improved Houpt behavior scores compared to baseline; midazolam achieved significantly higher scores than triclofos.	Oral midazolam is more effective at regulating patient behavior during dental treatment than triclofos.

Sedation efficacy and success rates

Across the included studies, oral triclofos demonstrated consistent effectiveness in pediatric patients undergoing dental, diagnostic and minor surgical procedures. High success rates were observed in EEG-based studies, with Jain et al.[10] reporting successful sedation in 93.1% of children and Matta and Peddisetty[19] reporting 96.8% success, with only 3.2% requiring rescheduling. More recently, Bharathi et al.[20] reported successful EEG completion rates of over 90% with triclofos, compared to 82.6% with hydroxyzine.

In dental settings, Chakraborty and Bandyopadhyay[21] observed improved cooperation and reduced procedural time, while Subramaniam et al.[22] reported behavioral outcomes comparable to nitrous oxide, although triclofos produced greater drowsiness and disorientation, suggesting a deeper level of sedation. Studies by Agarwal et al.[23] and Mytily **and Sathya**[24] demonstrated superior sedation scores and improved postoperative recovery profiles with triclofos when compared to oral midazolam.

A consistent finding across multiple randomized controlled trials is that triclofos produces deeper levels of sedation, often resulting in children being asleep or drowsy during procedures which may be particularly advantageous in procedures requiring minimal patient movement, such as imaging or electroencephalography (EEG). The clinical applications of oral triclofos across different pediatric procedures are summarized in **Table 2**.

Table 2: Clinical Applications and Efficacy of Oral Triclofos

Clinical Application	Supporting Literature	Age Group	Specific Sedation Objective	Clinical Outcomes
Pediatric Dentistry	Shabbir et al.[27], Chakraborty & Bandyopadhyay[21], Subramaniam et al.[22], Bhatnagar et al.[31]	3–13 years	Behavior management, anxiety control, facilitating extractions and restorations.	Significantly improves child cooperation ($p = 0.003$), reduces chair-side procedural time, and matches nitrous oxide efficacy, though it causes more drowsiness.
Preoperative Premedication	Agarwal et al. [23], Ghosh et al.[28], Mytily & Sathya[24], Geetha & Sunitha[26]	1–12 years	Allying preoperative anxiety, facilitating smooth parental separation, improving face mask acceptance.	Highly effective premedicant; induces deep sleep (up to 90% of cases at 30 mins) and calm parent separation, though onset is consistently slower than midazolam.
Neurodiagnostic Studies (Sleep EEG)	Jain et al. [10] Matta & Peddisetty[19] Bharathi et al.[20]	6 months–5 years	Inducing rapid and sustained sleep to allow artifact-free EEG recording.	High EEG completion rates (90.2%–96.8%) with stable sedation and acceptable safety. Hydroxyzine showed comparable efficacy, although triclofos achieved slightly higher EEG completion rates.
Medical Diagnostics (MRI / CT Imaging)	Sardesai et al.[29] Chandrasekar et al.[30]	2–11 years	Facilitating successful MRI/CT imaging by minimizing patient movement	Provides effective sedation for MRI and CT imaging. Although intranasal dexmedetomidine demonstrated superior sedation success, triclofos performed better than intranasal midazolam while maintaining a favorable safety profile.

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Minimally Invasive Outpatient Care	Sharma et al. [25]	3 months–5 years	Short procedural conscious sedation.	Achieves adequate Ramsay sedation scores (levels 3–4) in approximately 80% of children and demonstrates efficacy comparable to intranasal midazolam despite a slower onset.

Onset time and duration of sedation

Triclofos consistently demonstrated a slower onset of action compared to other sedative agents. Sharma et al.[25] reported a mean onset time of 20 ± 5.4 minutes, for triclofos, significantly slower than intranasal midazolam (**12 ± 4.5 minutes**). Similar findings were reported by Geetha and Sunitha[26], who observed a more rapid onset of sedation with midazolam. EEG studies by Matta and Peddisetty[19] and Jain et al.[10] reported sleep onset latencies of 36 minutes and 30 minutes, respectively, indicating a relatively delayed onset of sedation with triclofos when compared to benzodiazepines.

Despite the slower onset, triclofos provided adequate sleep duration, with mean durations ranging from 84 to 90 minutes. This delayed onset is likely related to the metabolic conversion of triclofos to its active metabolite, trichloroethanol, which also contributes to a prolonged and stable sedation, making the agent particularly suitable for longer procedures. Clinically, this necessitates appropriate timing of drug administration to align peak sedation with the start of the procedure.

Behavioral outcomes and sedation depth

Several studies have evaluated the behavioral responses using standardized assessment scales showing overall behavioral improvement with triclofos across different procedural settings. Shabbir et al.[27] found that both triclofos and midazolam significantly improved behavior compared with no sedation; however, midazolam demonstrated higher behavior scores. Similarly, **Ghosh et al.[28]** found that although triclofos had **better acceptability**, **midazolam demonstrated superior sedative and anxiolytic effects**.

In contrast, **Mytily and Sathya[24]** observed that triclofos produced **excellent sedation at 45 minutes**, along with **better mask acceptance and postoperative recovery**, suggesting its effectiveness as a premedicant. **Agarwal et al.[23]** reported that **90% of children in the triclofos group were asleep at 30 minutes**, compared with **18% in the midazolam group**, indicating **deeper sedation with triclofos**, although face mask acceptance was better with midazolam. These findings highlight an important distinction between depth of sedation and anxiolysis. Triclofos tends to produce deeper sedation, often resulting in sleep, whereas agents like midazolam provide more effective anxiety reduction and behavioral control.

When evaluated against newer sedatives, Sardesai et al.[29] found that intranasal dexmedetomidine produced superior sedation and higher procedural satisfaction compared to oral triclofos in imaging procedures, although both drugs showed similar safety profiles. Chandrasekar et al.[30] compared oral triclofos, intranasal midazolam, and intranasal dexmedetomidine for MRI sedation and found dexmedetomidine to be the most effective agent. However, triclofos achieved higher sedation success than midazolam and maintained a favorable safety profile. Additionally, Bhatnagar et al.[31] found that triclofos was less effective than midazolam and tramadol in achieving optimal sedation, ranking lower among the compared agents. This difference is clinically significant, as deeper sedation does not necessarily equate to better cooperation, particularly in anxiety-driven pediatric dental settings where individualized drug selection is important.

Safety and adverse effects

From a safety perspective, triclofos showed a favorable safety profile across studies. Jain et al.[10] and Matta et al.[19] reported only mild and self-limiting adverse effects such as irritability, vomiting and dizziness whereas **Sardesai et al.[29]** observed **no significant adverse effects** during procedural sedation. Comparative studies such as Ghosh et al.[28] reported no major hemodynamic instability, supporting the cardiorespiratory safety of triclofos during sedation. Chandrasekar et al.[30] also found that oral triclofos did not cause the side effects seen with other drugs, such as the nasal discomfort from intranasal midazolam (18.3%) or mild hypotension (10.8%) and tachycardia (4.6%) seen with intranasal dexmedetomidine.

The overall absence of serious complications suggests that triclofos is a safe sedative when used within recommended dosages. This supports its continued use in pediatric sedation, particularly in settings where advanced monitoring resources may be limited. The key components of pre-sedation assessment relevant to oral triclofos administration are summarized in **Figure 1**. A comparative summary of the safety profile and adverse effects of oral triclofos are summarized in **Table 3**.

Figure 1: Pre-Sedation Assessment

Table 3: Comparative Safety and Adverse Effects

Evaluated Parameter	Findings for Oral Triclofos	Findings for Evaluated Comparator Agents	Supporting Studies
Hemodynamic Stability	Maintains stable systolic/diastolic blood pressure, heart rate, respiratory rate, and oxygen saturation throughout sedation.	Highly stable vital signs matching baseline across all comparators.	Ghosh et al. [28], Mytily & Sathya[24] , Geetha & Sunitha[26]
Common Side Effects	Mild, self-limiting adverse effects including irritability, vomiting, and dizziness.	Mild adverse effects reported across comparator groups; transient nasal discomfort with intranasal midazolam and transient hypotension or tachycardia with intranasal dexmedetomidine.	Jain et al. [10] Matta & Peddisetty[19], Sharma et al. [25] Bharathi et al.[20] Chandrasekar et al.[30]
Sedation Depth / Drowsiness	Induces significantly deeper sedation, with a high proportion of children falling completely asleep.	Midazolam produces a lighter, awake-but-calm anxiolytic state; dexmedetomidine induces deeper natural sleep.	Agarwal et al. [23] Subramaniam et al. [22] Sardesai et al. [29] Chandrasekar et al.[30]
Onset and Speed of Action	Significantly slower onset of action; requires 20 to 45 minutes to achieve satisfactory clinical sedation.	Rapid onset; intranasal midazolam takes 12 mins; oral midazolam takes 30 mins.	Sharma et al. [25], Geetha & Sunitha[26]
Need for Rescue / Redosing	14.4% of patients required a secondary dose if sleep is not successfully achieved within 60 minutes.	Secondary dosing is rarely reported for standard comparative settings.	Matta & Peddisetty[19] Bharathi et al.[20]

Drug acceptability and cooperation

Triclofos showed high acceptability, primarily due to its oral route and palatability. Ghosh et al.[28] and Mytily and Sathya[24] both noted higher acceptance rates with triclofos syrup compared to midazolam which is bitter, while Subramaniam et al.[22] observed greater acceptance of oral sedation over inhalational methods. Improved cooperation was also observed in several studies, particularly in dental settings, contributing to procedural success. The ease of oral administration is a significant clinical advantage, especially in pediatric patients who may resist invasive or unfamiliar drug delivery methods. This facilitates smoother pre-procedural preparation and may improve overall treatment compliance.

Although newer agents such as dexmedetomidine may provide superior sedation quality and clinician satisfaction, as reported by Sardesai et al.[29] factors such as ease of administration, availability, low cost, and high patient acceptance strongly justify the continued use of triclofos in routine pediatric practice, particularly in resource-limited settings.

CLINICAL IMPLICATIONS

The available evidence suggests that oral triclofos is most useful in situations requiring prolonged and deeper sedation, particularly for non-interactive procedures such as electroencephalography and imaging, where immobility is essential. In contrast, for procedures where patient cooperation, communication, and anxiety reduction are important, agents such as midazolam or dexmedetomidine may be preferable because of their superior anxiolytic and behavior-modifying effects. These comparisons underscore that no single agent is universally superior; rather, each offers distinct advantages depending on the clinical situation. While triclofos is highly effective for achieving sustained sedation, midazolam and dexmedetomidine excel when rapid onset and anxiolysis are the primary objectives. This reinforces the need to choose a sedative based on the specific requirements of the procedure and the behavioral needs of the child.

LIMITATIONS AND FUTURE DIRECTIONS

Despite the valuable insights and encouraging findings provided by the available literature, certain limitations must be noted. The included studies varied in study design, differences in dosing protocols, relatively small sample sizes and variability in sedation assessment scales, which limits direct comparison across trials. Additionally, some studies also lacked blinding or were observational in nature, introducing a risk of bias. Therefore, while the overall evidence supports the efficacy and safety of oral triclofos, further well-designed randomized controlled trials are needed to establish standardized protocols and strengthen the evidence base.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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