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Suzetrigine in Acute Pain Treatment: A Review of Current Evidence and Future Directions

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ABSTRACT

Introduction: Acute pain is a constant reality in clinical practice. Patients come in because of their pain, surgeons cause it to happen, and a significant part of the care after surgery involves managing this pain. Yet the medications available for treatment are pretty much the same as always, including NSAIDs, paracetamol, local anesthetics, and opioids. There are several limitations when it comes to the use of opioid drugs, such as sedation, vomiting, or dependence. On the other hand, suzetrigine is a completely different method, since it uses a different mechanism of action. It acts on the peripheral part of the pain pathway by blocking sodium channels. *Methods*: A systematic review of the existing literature was conducted, comprising preclinical research and randomized phase II and III clinical trials in the acute postoperative pain setting for suzetrigine. *Results*: The NaV1.8 blocker showed superiority over placebo on the primary endpoint of pain intensity. In contrast to hydrocodone/acetaminophen, the findings were more varied, with some evidence of equivalence in particular operational settings but slightly reduced efficacy in others. Earlier time-to-relief and lower rescue analgesic consumption were also noted compared to placebo. Adverse events were mostly mild and transient. The data we have, however, come from short trials. *Conclusions*: Suzetrigine has been found to be a good potential candidate for an effective acute pain treatment, not being an opioid analgesic. Further research is needed to demonstrate its efficacy across different clinical conditions and patient populations.

Keywords: Suzetrigine; acute pain; NaV1.8; non-opioid analgesics; sodium channel inhibitors

1. INTRODUCTION

Pain that comes on suddenly and lasts no more than a few weeks is what we typically call acute. After that, the label changes — from subacute to chronic — but the dividing lines are based on clinical conventions, not biology. The important factor is the degree of intensity. Pain at moderate or severe levels disturbs sleep and hinders recovery processes, among other effects, and its effects are often undervalued in the literature (Nikitin et al., 2025; Medhat et al., 2026). The main problem here is to determine a pharmaceutical preparation that provides the necessary relief without causing additional side effects. Despite being helpful in many cases, NSAIDs do not provide an absolute solution because of their limited effectiveness and applicability in general. The benefits of paracetamol are clear, but it often requires additional medications. Local anesthetics and NMDA receptor blockers also offer some benefits, but are used in conjunction with other pain management modalities. However, analgesia attempts to integrate all these benefits, but opioids fill the void for moderate-to-severe pain (Hang Kong et al., 2024). Despite the numerous risks involved in taking opioids, these drugs have always been used in managing acute pain (McCoun et al., 2025; Wu and Lu, 2026). Despite their efficiency in managing pain, opioids pose a number of side effects such as dizziness, nausea, vomiting, constipation, confusion, and reduced respiration. Over time, one develops a tolerance for these drugs, leading to physical dependence (Nikitin et al., 2025; Divito et al., 2026). Patients can sometimes abuse these drugs, leading to very difficult withdrawal problems. While all these issues are known, they provide good reasons why pain medicines have received much emphasis in the last few decades (Sibomana et al., 2025; Medhat et al., 2026). Adverse effects, along with insufficient pain relief, have led to the quest for alternative treatments that are less dangerous but more effective (Xie et al., 2026; Hang Kong et al., 2024).

One of the most popular targets of research has become sodium channels. Without them, nociceptors are unable to generate action potentials in the first place — and crucially, not every subtype carries the same liability. NaV1.7 and NaV1.8 are predominantly expressed in the peripheral sensory neurons involved in pain transmission, raising the possibility of an analgesic that would never need to engage the central nervous system at all (Xie et al., 2026; Divito et al., 2026). Suzetrigine is the first drug to make that idea work in practice. The medication is FDA-approved, having been approved on January 30, 2025, under the trade name JOURNAVX™. The drug works on NaV1.8 channels in their nonconducting conformation and is used to treat acute pain in adults (Nikitin et al., 2025; Medhat et al., 2026).

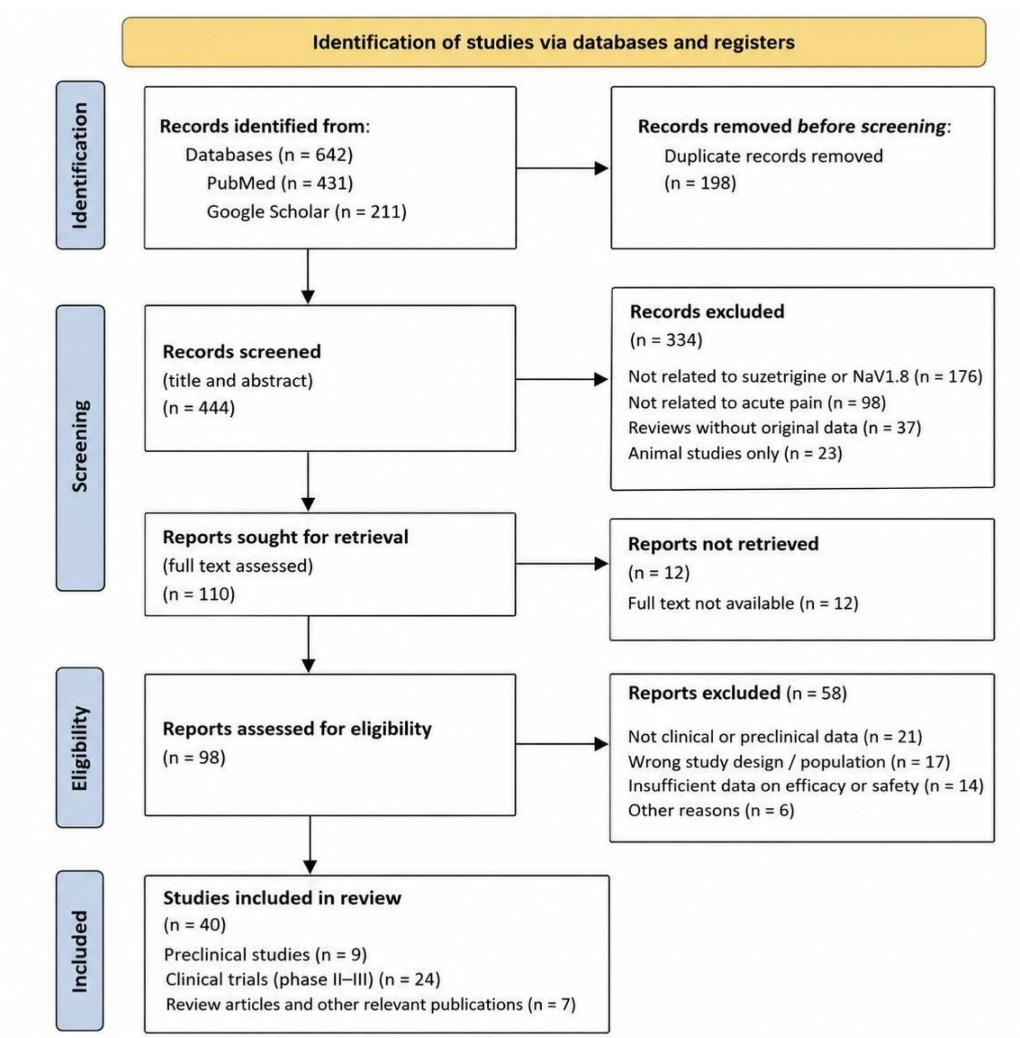

Figure 1. PRISMA flow diagram of the literature search and study selection process.

2. REVIEW METHODS

In this review, a thorough search of the literature on PubMed and Google Scholar was done in order to locate publications written in English within the years January 2020 and February 2026. Such an analysis included a wide variety of publications, including preclinical studies, phase II and phase III clinical trials, reviews, and other academic papers dedicated to the mechanism of action, efficacy, pharmacokinetics, and safety issues related to suzetrigine use for acute pain relief. The selection of sources was based on information in their titles, abstracts, and full-text sections. The article screening process followed the PRISMA guidelines (Figure 1).

3. RESULTS AND DISCUSSION

Mechanism of Action

The simplest way to describe what a sodium channel blocker like suzetrigine does is that it blocks a specific sodium channel, NaV1.8, found almost exclusively on peripheral pain-sensing neurons. NaV1.8 channel inhibition leads to a failure of these neurons to fire and, subsequently, to transmit pain information to the spinal cord. These drugs impacted receptors in several regions of the body like the brain and heart, and hence, caused multiple adverse reactions, such as sedation, respiratory depression, cognitive impairment, and the risk of addiction (Jones et al., 2025; Nahm et al., 2026). Suzetrigine manages to evade all these problems for a simple reason. The fact is that NaV1.8 is not present in large quantities in the CNS; hence, there is no target for the drug here (Peshin et al., 2025). One detail worth noting is the drug's reverse use-dependence. Its inhibitory effect actually weakens when neurons are firing strongly or repeatedly. Rebinding to channels at rest is concentration-dependent, indicating that the drug prefers resting channels over actively firing ones (Pham et al., 2025; Jones et al., 2025; Attal and Barrot, 2025). This implies that only the neurons associated with the pain response are inhibited while the motor and sensory functions remain unaffected, almost unhampered (Rajasingham and Qi, 2025).

Pharmacological Characteristics

Two features really define Suzetrigine pharmacologically. One of them is the target that the drug is directed against - NaV1.8, a peripheral channel. The other one is the drug’s selectivity when acting on that specific target. Combined together, these properties enable the drug to exert analgesic effects without inducing any cardiotoxicity, CNS-related adverse effects, or muscle problems characteristic of non-selective sodium channel blockers. The name of the compound in terms of chemistry is 4-[(2R,3S,4S,5R)-3-(3,4-difluoro-2-methoxyphenyl)-4,5-dimethyl-5-(trifluoromethyl)oxolane-2-amido]pyridine-2-carboxamide. During clinical development, it was reported as VX-548 (Mohiuddin and Ahmed, 2025; Divito et al., 2026). The peripheral restriction of NaV1.8 is also what explains the drug’s low abuse and dependence potential — there is no central reward pathway being engaged (Divito et al., 2026). Favorable oral bioavailability. The half-life of elimination is around 23–24 hours, allowing a once- or twice-daily dosing schedule. Steady state occurs within 3 days due to fecal and urinary elimination. Maximum plasma concentrations are sufficient for NaV1.8 inhibition between dosages (AlDoughaim et al., 2025; Mach et al., 2025; Divito et al., 2026). None of the standard demographic variables — age, sex, body weight, race, mild renal impairment — appear to shift the pharmacokinetics in any clinically important way (Divito et al., 2026). The metabolism of this drug is mainly via hepatic CYP3A enzymes, while about 44% of the parent compound is eliminated via the kidneys. Liver impairment has little effect on CYP3A activity, whereas inhibitors increase suzetrigine and M6-SUZ levels (Mach et al., 2025; Chittoria et al., 2025). Information is scant on its impact on patients with advanced renal impairment (eGFR $<$ 15 mL/min) (AlDoughaim et al., 2025). Thus far, the impact of hepatic dysfunction has been classified based on the Child-Pugh classification scale. For instance, when hepatic dysfunction is classified as mild (Child-Pugh Class A), the concentration of suzetrigine does not differ greatly from that in normal healthy individuals. In moderate hepatic dysfunction (Child-Pugh score B), the increase in AUC values amounts to approximately 1.5-fold, Cmax – 1.3-fold, and M6-SUZ – 1.2-fold. The same is true of patients with severe renal disease — those with eGFR below 15 mL/min were not represented in the trials we have so far (AlDoughaim et al., 2025; Divito et al., 2026).

Clinical Evidence

The clinical case for suzetrigine has been built largely on the back of two trial programs — NAVIGATE-1 and NAVIGATE-2. Both were randomized, double-blind studies that included a placebo and an active comparator, hydrocodone/acetaminophen. Two suitable models for testing an analgesic in terms of their postoperative pain profiles include bunionectomy and abdominoplasty (Table 1), (Peshin et al., 2025; Khan et al., 2025). Before any of this reached patient, the drug underwent the usual preclinical battery of tests in rats and monkeys. The results from those studies were unremarkable in the best sense. Animals showed no sedation, no stimulant behavior, and no signs of physical dependence on discontinuation — even at exposures well above what would later be used clinically. There were no CNS-related toxicities seen even after prolonged toxicity testing, and there were no clinical findings regarding cardiovascular or respiratory function (Rejeev et al., 2025).

In the Phase III clinical trial, 577 participants aged 18 to 75 years were enrolled. Out of these participants, 274 patients underwent bunionectomy operation, and 303 underwent abdominoplasty surgery. Pain intensity difference over 48 hours, measured by NPRS, constitutes the primary efficacy outcome measure, SPID48. Other criteria included SPID24 and the percentage of patients who experienced a 30%, 50%, and 70% reduction in pain over 48 hours (Hang Kong et al., 2024). Participants had to have moderate or severe pain (NPRS ≥ 4). The subjects were then randomized to one of three groups: suzetrigine (100 mg loading dose followed by 50 mg BID), HB/APAP (5 mg/325 mg Q6h), or placebo (Karri et al., 2025; Rejeev et al., 2025). The SPID48 difference came out at 48.4 in the abdominoplasty model (95% CI 33.6–63.1; p<0.0001) and 29.3 in the bunionectomy model (95% CI 14.0–44.6; p=0.0002) (Jones et al., 2023; Bertoch et al., 2025). There was a reduction of 52% (p=0.003) in rescue analgesics taken compared to placebo (Bertoch et al., 2025). 240 minutes for bunionectomy patients, compared with 480 minutes for the placebo. As compared to the opioid drug combination, it did not perform as well (Jones et al., 2023; Rejeev et al., 2025). Compared to the hydrocodone/acetaminophen combination, the outcomes were not as favorable: similar after abdominoplasty but slightly inferior after bunionectomy compared to the opioid group (Peshin et al., 2025; Hang Kong et al., 2024). Based on the analysis, the following conclusion can be drawn (Augoustides et al., 2025; McCoun et al., 2025).

Table 1. Summary of clinical studies on suzetrigine.

Name of study	Study design	Participants characteristics	Study phases	Total participants
NAVIGATE-1	Randomized, double-blind trials with both placebo and active comparators	Patients experiencing acute postoperative pain after abdominoplasty or bunion surgery	I-III	2447
NAVIGATE-2	Two randomized, double-blind trials including placebo and active control groups	Patients with acute pain after abdominoplasty or bunionectomy	I-III	1000

Safety Profile and Adverse Effects

Tolerability has been a strong point for suzetrigine. Most adverse events recorded during the trials were mild to moderate, and the symptom list included itching, muscle spasm, headache, and nausea (Jones et al., 2023; Hu et al., 2025). It is clear that a pattern exists in the data presented here. Adverse effects were recorded in 1,010 subjects under suzetrigine therapy, 574 under placebo therapy, and 1,015 under hydrocodone/acetaminophen (HB/APAP) treatment. Vomiting is the best example of this observation; it was observed in 19 of 1,010 subjects taking aripiprazole (Bansal et al., 2026; Jones et al., 2023). Pharmacologically, Suzetrigine is a CYP3A inducer, which decreases the bioavailability of co-administered drugs that are metabolized via the same pathway. This means that CYP3A4 strong and moderate inhibitors might increase plasma concentrations of suzetrigine and M6-SUZ. A frequent criticism raised in the scientific literature is that suzetrigine lacks a proven greater analgesic potency compared to opioids when compared on an equal basis in empirical terms. While true on its face value, this argument misses out on one very important aspect about the two classes of drugs and how they work (Robinson et al., 2025). The opioids work for systemic analgesia through central actions, while the analgesia produced by Suzetrigine is peripheral. No direct comparison can be drawn between the two drugs. The former reaches its maximum blood concentration in 1–2 hours, whereas the latter takes 4–6 hours (Jones et al., 2023; Robinson et al., 2025). The trade-off continues to be significant.

The exclusion of any impact on the central nervous system means that one class of risks is completely taken off the table – sedation, breathing difficulty, and dependency (Peshin et al., 2025). An important limitation in the current state of affairs is the length of time for which data are available; the studies carried out have taken place over a few weeks rather than months (Nikitin et al., 2025; Nahm et al., 2026; Divito et al., 2026).

Future Perspectives

The current data are encouraging, but they are also early. Trials have been relatively short, and the patient populations have been relatively narrow — mostly otherwise healthy adults undergoing elective surgery. Long-term safety, the full drug–drug interaction profile, and the drug's economics are also still open questions. Some of these answers will only come through post-marketing surveillance, which will be essential for detecting rare or late-onset events that randomized trials are simply not large enough to detect. The bigger hope — and it is a meaningful one — is that Suetrigine ends up reducing. The share of acute pain managed with opioids, with all that this implies for population-level harm. A number of trials are already underway. One NCT06628908 is a randomized, double-blind phase III study running suzetrigine against pregabalin and placebo for 12 weeks in patients aged 18–80 with painful diabetic peripheral neuropathy. NCT06696443, an open-label extension, is following patients from that program for longer-term safety and effectiveness data. The rationale here is that NaV1.8 is also involved in the disordered signaling that drives neuropathic pain, and the phase II results have been given some early grounds for optimism.

Another active study, NCT06887959, a phase IV, single-arm, open-label trial, is looking at suzetrigine as part of multimodal analgesia after laparoscopic aesthetic and reconstructive procedures. Alongside these studies, other studies involve kidney and liver patients, examine the effects on CYP3A enzymes, assess its safety for heart patients, and address the broader issue of its effects on minority patient populations that did not participate in the first round of studies.

4. CONCLUSION

The use of suzetrigine could represent an advance over the treatment of moderate-to-severe acute pain by providing analgesic relief through the specific peripheral blocking of NaV1.8 sodium channels. In clinical studies, suzetrigine has been shown to be as effective as a placebo and at least equivalent to standard (opioid) therapies for pain relief. The drug was also found to have a good safety record and fewer adverse side effects associated with the CNS than other analgesics. However, the current evidence is largely limited to short-term studies, and additional research is required to establish its long-term safety, efficacy, and broader clinical effectiveness. Such Studies will be essential to confirm its place in clinical practice and its prospective impact on public health.

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Informed consent

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Ethical approval

Not applicable. This article does not contain any studies with human participants or animals performed by any of the authors.

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Conflict of interest

The authors declare that they have no conflicts of interest, competing financial interests or personal relationships that could have influenced the work reported in this paper.

Data and materials availability

All data associated with this study will be available based on the reasonable request to corresponding author.

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