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ORIGINAL RESEARCH

Therapeutic Efficacy of Modified Cocktail Analgesia After Minimally Invasive Chevron Osteotomy for Hallux Valgus: A Retrospective Case Series Study

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Objective: To evaluate the efficacy of modified cocktail analgesia in relieving pain after minimally invasive chevron osteotomy for hallux valgus.

Methods: A retrospective cohort study was conducted to analyze the clinical data of 90 patients with moderate to severe hallux valgus admitted to our hospital from January 2020 to December 2023. Based on the treatment method and the number of affected limbs, the patients were divided into three groups: the modified group (Imp) treated with minimally invasive chevron and Akin (MICA) osteotomy combined with modified cocktail therapy, the traditional group (Tro) treated with MICA osteotomy combined with conventional cocktail therapy, and the control group (NC) treated with MICA osteotomy alone without cocktail therapy. The visual analog scale (VAS) scores for ankle-foot pain from 6 hours preoperatively to 14 days postoperatively, the need for postoperative rescue analgesia, adverse reactions, and complications were observed and compared among the three groups.

Results: There were no significant differences in basic conditions such as age and BMI among the three groups. It is in line with the epidemiological statistics of hallux valgus in terms of gender. The VAS scores at 6 hours and 1 day postoperatively were significantly lower in the modified group [(0.67±0.60), (0.68±0.59) respectively] compared to the traditional group [(0.82±0.50), (0.78±0.90) respectively] ($P < 0.05$). There were no statistically significant differences in VAS scores between groups at 6 hours preoperatively and 7 days and 14 days postoperatively ($P > 0.05$). Five patients (5.56%) in the modified group required postoperative rescue analgesia, which was significantly fewer than the 12 patients (13.33%) in the traditional group ($P < 0.05$).

Conclusion: Based on the comprehensive statistical results and clinical significance, the modified cocktail therapy has certain clinical reference value in the short-term analgesia management after MICA. It is beneficial for the early postoperative rehabilitation functional exercise of patients and has a good safety effect. It can be used as an optional option for early postoperative pain control. However, it is necessary to objectively recognize the timeliness of its therapeutic advantages. Its long-term analgesic effect shows no significant clinical difference from the traditional cocktail therapy and the simple MICA procedure.

Keywords: hallux valgus, cocktail analgesia, minimally osteotomy

Introduction

Hallux valgus is a common forefoot deformity that affects foot morphology and function. Its primary morphological changes include lateral deviation of the hallux and medial displacement of the first metatarsal bone,[1] leading to progressive subluxation of the first metatarsophalangeal joint and impairing forefoot mobility. Traditionally, hallux valgus severity has been classified based on the hallux valgus angle (HVA): mild (15° < HVA < 30°), moderate (30° < HVA < 40°), or severe

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(HVA > 40°).[2] The global prevalence of hallux valgus is 19%,[3] with rates of 12.22% in the 20–60 age group and up to 22.7% in individuals aged 65 and older. Prevalence varies significantly worldwide, with higher rates in Asia and Oceania. Hallux valgus is more prevalent among female patients and is characterized by high heritability and significant impact on patient quality of life. It results in foot deformity and pain, severe cases leading to partial loss of self-care and work capacity, imposing substantial psychological and economic burdens on patients, their families, and society.

Treatment of hallux valgus includes conservative and surgical approaches. Conservative treatment options encompass oral and intravenous analgesics such as opioids and non-steroidal anti-inflammatory drugs, physical therapy, and other modalities including iontophoresis, ultrasound, and electrotherapy.[4,5] When conservative measures fail, surgery becomes the primary solution. The goal of surgical treatment is to restore foot biomechanics and function in patients with hallux valgus. Surgical interventions for hallux valgus are diverse, with over 100 methods currently available.[6,7] Redfern and Vernois first described minimally invasive Chevron and Akin osteotomies in 2015,[8] representing a percutaneous correction technique for hallux valgus. This procedure involves extra-articular osteotomy, stable internal fixation, and correction of severe deformities, now classified as the third-generation surgery (MICA technique).[9] The MICA technique is suitable for all types of hallux valgus deformities,[10] irrespective of severity (mild, moderate, severe), and offers significant advantages including small incisions, aesthetic outcomes, minimal trauma, rapid recovery, reduced postoperative pain, and low complication rates.[11] Its growing acceptance among patients has underscored its importance in clinical practice.[12]

Despite advances in surgical interventions, up to one-third of patients continue to experience pain following hallux valgus surgery.[13] Pain at the metatarsal head in hallux valgus deformity results from increased pressure and load transferred to the lateral metatarsal region.[14] Even after minimally invasive chevron osteotomy for hallux valgus,[15] some patients experience residual pain during postoperative rehabilitation, potentially related to muscle fatigue around the surgical area, overuse, heat injury, and osteotomy ends. Therefore, significantly reducing or eliminating both pre- and postoperative pain for patients has become a critical issue in current hallux valgus surgical treatment.

Currently, intraoperative cocktail therapy for analgesia has been widely applied in spinal and ankle joint surgeries and has garnered significant attention from scholars both domestically and internationally.[16] The modified cocktail (morphine, dexamethasone, ropivacaine, saline) used in the previous work of Li Shaopeng et al has shown significant pain control effects in patients undergoing total hip arthroplasty, reducing the use of opioids and non-steroidal anti-inflammatory drugs postoperatively, promoting early recovery of hip joint function, and demonstrating good safety.[17] This modified cocktail regimen has not been previously applied in the treatment of patients with hallux valgus; therefore, since 2021, we have implemented it in minimally invasive hallux valgus surgery at our hospital. The modified cocktail consisted of 10 mg of morphine hydrochloride injection (Shenyang First Pharmaceutical Co.,Ltd.,Northeast Pharmaceutical Group; Batch number: H21022436;1mL:10mg), 5 mg of dexamethasone sodium phosphate injection (HeNan RunHong Pharmaceutical Co., Ltd.;Batch number: H41020330;1mL:5mg), and 300 mg of ropivacaine hydrochloride injection (QiLu Pharmaceutical Co., Ltd.; Batch number: H20153780;10mL:100mg), mixed with 64 mL of 0.9% sodium chloride injection (HuaRen Pharmaceutical Co., Ltd.;Batch number:H20023446;100mL:0.9g).Prior to closing the incision, a 20 mL cocktail mixture was administered via multiple infiltration injections into the periosteum of the metatarsal osteotomy and surrounding nerves, including the medial branch of the deep fibular nerve, the dorsal branch of the superficial fibular nerve, and the plantar nerve, as illustrated in Figure 1. This study retrospectively reviewed 150 patients with moderate to severe hallux valgus treated at our hospital from January 2020 to December 2023, who were respectively treated with MICA combined with the modified cocktail, MICA combined with traditional cocktail, and pure MICA technique. By evaluating postoperative visual analog scale (VAS) scores, need for rescue medication, adverse reactions, etc., we compared the analgesic effects and clinical outcomes of the two cocktail surgery protocols, aiming to provide solutions for alleviating pain in future hallux valgus patients.

Materials and Methods

Inclusion Criteria and Exclusion Criteria

Inclusion criteria: (1) Moderate to severe hallux valgus deformity;[18] (2) American Society of Anesthesiologists (ASA) grade I–II; (3) Presence of medial pain at the first metatarsophalangeal joint, or concurrent pain at the second and third

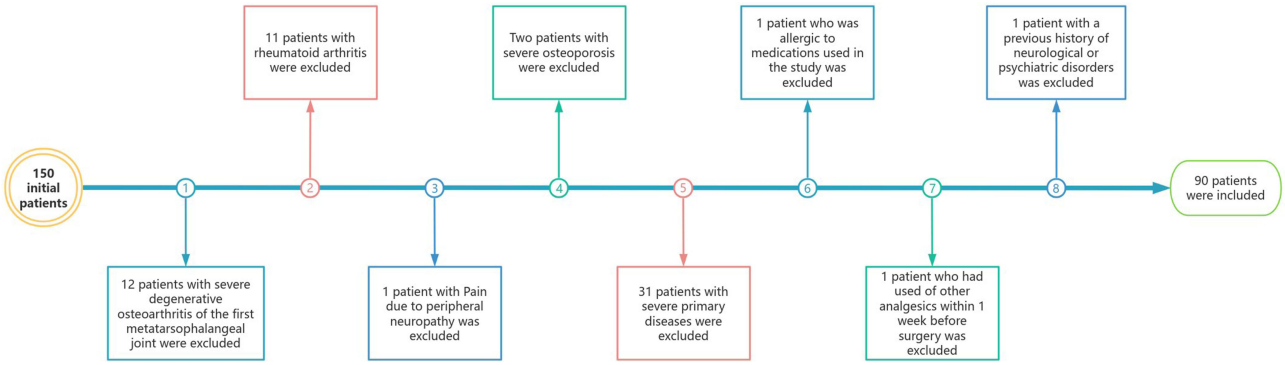

Figure 1 Flow chart of patient screening. A total of 150 patients were initially enrolled in this study, and subsequent screening was conducted in sequence according to the predefined exclusion criteria. The screening process and results were as follows. Among them, 0 people with skin ulceration and infection at the ankles were not included in Figure 1. Finally, 90 eligible patients were included in the formal study. All exclusion criteria were formulated based on the study protocol, and the screening data were extracted from the electronic medical records and case report forms, ensuring the accuracy and traceability of the data.

metatarsophalangeal joints with corns; (4) Patients undergoing minimally invasive chevron and Akin (MICA) procedure; (5) Ineffective conservative treatment and X-ray evidence of poor joint mobility or (sub)luxation; (6) Complete imaging data and follow-up questionnaire scores at >12 months postoperatively.

Exclusion criteria (Figure 2): (1) Severe degenerative osteoarthritis of the first metatarsophalangeal joint; (2) Rheumatoid arthritis; (3) Pain due to peripheral neuropathy; (4) Foot or ankle skin breakdown, infection; (5) Severe osteoporosis; (6) Patients with severe primary diseases such as coronary heart disease, diabetes; (7) Allergy to medications used in the study; (8) Use of other analgesics within 1 week before surgery; (9) History of neurological or psychiatric disorders affecting compliance with treatment.

General Information

Ninety patients (180 feet in total) with moderate to severe hallux valgus treated with the minimally invasive chevron and Akin (MICA) procedure at our hospital from January 2021 to December 2023 were included in the study. Patients were allocated into two groups based on treatment method: the Modified group (MICA combined with modified cocktail) and the Traditional group (MICA combined with traditional cocktail), denoted as Modified (Imp) with 27 patients and Traditional

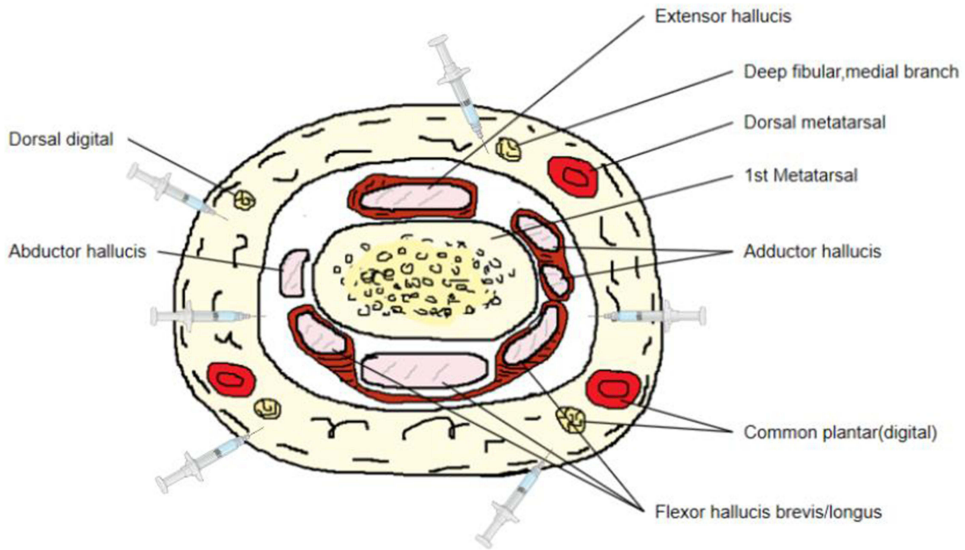

Figure 2 Schematic Diagram of Injection Sites for the Cocktail Mixture. We performed multiple injections around the first metatarsal. The selected injection sites included six locations: injections were administered horizontally at the periosteum, beneath the deep peroneal nerve, and beneath the plantar digital nerve.

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(Tro) with 31 patients. As controls (NC group), we included 32 patients who underwent minimally invasive chevron osteotomy for hallux valgus without cocktail therapy during 2020 due to technical reasons. There are no significant differences in the general information such as the age, disease course and condition of the above-mentioned patients. The gender data is in line with the epidemiological statistics of hallux valgus. All patients underwent comprehensive medical history collection and preoperative physical examinations. They received detailed explanations of the Visual Analog Scale (VAS) scoring criteria and the appropriate use of analgesics. One day after the operation, the patient walked on the ground wearing specially designed non-weight-bearing shoes for the forefoot. From the seventh day after the operation, under the guidance of the rehabilitation department of our hospital, appropriate functional exercises such as hallux flexion and extension activities were carried out. Uniform preoperative preparations were provided to prevent infections and stress ulcers. The study was terminated in cases of severe infection, any anesthesia-related accidents, arrhythmias, or other potentially life-threatening complications.This study has obtained informed consent from all patients and relevant personnel and this research has been approved by the authors' affiliated institutions.

Surgical Procedures

After general anesthesia induction, the patient was placed in supine position. The surgical site was routinely disinfected, draped, and a 0.5 cm incision was made on the dorsolateral aspect of the affected side's first metatarsophalangeal joint. The oblique head and transverse head of the adductor hallucis, lateral joint capsule, and sesamoid suspensory ligament were released to relax the metatarsophalangeal joint. After improving the range of motion of the hallux valgus deformity, approximately 0.5 cm incisions were made at the upper and lower edges of the medial side of the first metatarsophalangeal joint and sesamoid capsule. The capsule was stripped from the bone prominence, and the inner and dorsal bone prominences of the first metatarsal head were removed by grinding and drilling. A chevron osteotomy was performed at the distal end of the first metatarsal bone, shifting the distal end of the first metatarsal bone outward. Two Kirschner wires were inserted to secure fixation once satisfactory correction of the hallux valgus deformity was achieved under C-arm fluoroscopy. The osteotomy ends were well-aligned, and the correction of hallux valgus deformity was satisfactory upon re-examination of fixation efficacy. Sterile dressing was applied.The procedure on the contralateral side followed the same method.

Modified Group: The modified cocktail was injected into the periosteum of the metatarsal osteotomy and surrounding nerves, including the medial branch of the deep fibular nerve, the dorsal branch of the superficial fibular nerve, and the plantar nerve before the incision was closed. Patients were observed in a supine position for 30 minutes without adverse reactions before concluding treatment.

Traditional Group: The pre-prepared cocktail mixture (200 mg of ropivacaine hydrochloride and 0.25 mg of adrenaline (Grand Pharmaceutical Group;Batch number:H42021700;1 mL corresponds to 1 mg based on $C_9H_{13}NO_3$)., mixed with 64 mL of 0.9% sodium chloride injection) was administered using the same method as in the Modified Group. All surgeries and cocktail injections were performed by the same group of physicians.

Control group: Before closing the incision, 20 mL of normal saline was injected into the same sites. All other surgical procedures were identical to those described above for the two groups.

Postoperative Management

On the day of surgery, patients were encouraged to ambulate using custom arch support slippers provided by our hospital. On the first postoperative day, bilateral weight-bearing anteroposterior X-rays were taken to assess the fixation of Kirschner wires and changes in the hallux metatarsophalangeal joint alignment. Dressings were changed weekly postoperatively to monitor wound healing progress and assess pain levels in patients.

Evaluated Parameters

Patient demographic data, including age, gender, and body mass index (BMI), were recorded. The Visual Analog Scale (VAS) for foot and ankle pain was used to assess pain levels from 6 hours preoperatively to 14 days postoperatively. The effectiveness of pain relief following cocktail administration was evaluated based on the usage of rescue analgesics within 14 days postoperatively.

Statistical Analysis

Data were analyzed using SPSS version 26.0 statistical software.Quantitative judgment is made through the Shapiro–Wilk test to determine whether the data conform to a normal distribution. Continuous data are presented as mean ± standard deviation. For normally distributed data, independent sample *t*-tests were used to compare between groups, and within-group comparisons at different time points were conducted using one-way analysis of variance (ANOVA) with LSD post-hoc tests. For non-normally distributed data, non-parametric tests were employed. Statistical significance was set at $P < 0.05$.

Result

General Demographic Results

There were no statistically significant differences in age distribution and BMI among the three groups ($P > 0.05$). The gender distribution was consistent with the epidemiological characteristics of hallux valgus, indicating a higher incidence of this deformity in female patients ($P < 0.05$). (Table 1).

Comparison of VAS Scores

Compared to the control group, there was no significant difference in VAS scores between the Modified and Traditional groups at 6 hours preoperatively ($P > 0.05$). At 6 hours and 1 day postoperatively, VAS scores in the Modified and Traditional groups were significantly lower than those in the control group, showing statistical significance ($P < 0.05$). However, at 7 days and 14 days postoperatively, there was no significant difference in VAS scores between the Modified and Traditional groups ($P > 0.05$), although both scores were lower than those in the control group (Table 2, Figure 3).

Non-Steroidal Anti-Inflammatory Drug (NSAID) Rescue Usage

Regarding postoperative rescue analgesic requirements among patients, statistically significant differences were noted at 6 hours (P=0.018), 6 hours to 1 day (P=0.032), and 1 to 7 days postoperatively (all $P < 0.05$), while no statistically significant difference was observed at 7 to 14 days postoperatively (P=0.786). Furthermore, the P-value for the distribution of patients who did not require rescue analgesia was 0.003, indicating a highly significant difference in this distribution among the three groups (Table 3).

Table 1 The Comparison of General Patient Characteristics Among Groups

Group	Male/Female	Age (Years)	BMI (kg/m^2)
NC group (n=32)	7/25	53.75±6.59	25.29±1.85
Tro group (n=31)	5/26	50.52±7.28	26.39±1.89
Imp group (n=27)	4/23	51.05±8.16	26.27±1.79

Table 2 The VAS Scores of Patients in Each Group (x ±s, Points)

Project	Time	NC Group (n=32)	Tro Group (n=31)	Imp Group (n=27)
VAS score	Pre-6h	4.21±1.20	4.30±1.50	4.30±1.40
	Post-6h	1.10±1.10	0.82±0.50	0.67±0.60
	Post-1d	1.20±0.98	0.78±0.90	0.68±0.59
	Post-7d	1.15±0.92	1.10±0.87	0.92±0.61
	Post-14d	1.17±0.93	1.07±0.77	1.00±0.70

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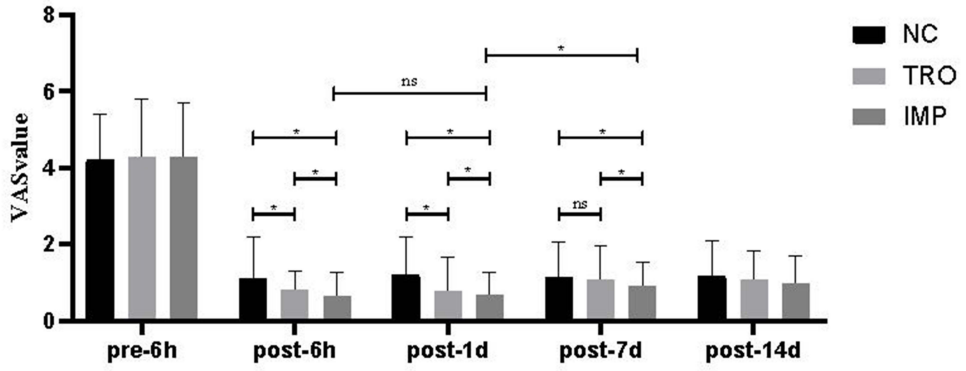

Figure 3 The VAS scores of patients in each group. The three groups of patients underwent VAS scoring at the time points of 6 hours before surgery, 6 hours after surgery, 1 day after surgery, 7 days after surgery, and 14 days after surgery.* (P<0.05);ns (P≥0.05).

Postoperative Adverse Reactions and Complications

Postoperatively, symptoms of nausea and vomiting occurred in 1 case in the Modified group, 2 cases in the Traditional group, and 1 case in the control group, with no statistically significant differences among the three groups (P = 0.519). None of the patients in any group experienced dizziness, itching, drowsiness, urinary retention, or cardiovascular complications. During follow-up, no patients experienced ankle pain, insufficient correction or recurrence of deformity, overcorrection, medial deviation, degenerative arthritis, internal fixation instability, or delayed healing.

Discussion

This study, as a retrospective analysis, aims to compare the efficacy of modified cocktail therapy in relieving pain after minimally invasive chevron osteotomy for hallux valgus. The study results demonstrated that the Visual Analog Scale (VAS) scores for foot and ankle pain in the modified cocktail group were significantly lower than those in the traditional cocktail group and control group at 6 hours and 1 day postoperatively, indicating effective pain relief. However, at 7 days and 14 days postoperatively, there was no statistically significant difference in VAS scores between the modified group and the traditional group or control group (P > 0.05), although scores were consistently lower in the modified group compared to the traditional and control groups. These results suggest that modified cocktail therapy is superior to traditional cocktail therapy in controlling postoperative pain, with both groups showing significant benefits within the first 7 days. The VAS scores gradually approached those of the control group by 7 days postoperatively, and these results also indicate that cocktail therapy exerts short-term efficacy in postoperative pain management. There were no significant differences in long-term analgesic efficacy between the two groups (modified vs traditional cocktail groups), but the modified cocktail therapy exerted a more effective analgesic effect in the early postoperative period, facilitating patients' early rehabilitation exercises. Regarding the VAS scores at 6 hours and 1 day postoperatively, although the numerical

Table 3 The Number of Patients Requiring Analgesic Medication Postoperatively. (Umber (X%))

Time	NC Group	Tro Group	Imp Group	p-values
Post-6h	8 (25.00%)	4 (12.90%)	2 (7.41%)	0.018
Post 6h-1d	7 (21.88%)	4 (12.90%)	2 (7.41%)	0.032
Post 1d-7d	4 (12.50%)	3 (9.68%)	1 (3.70%)	0.045
Post 7d-14d	1 (3.13%)	1 (3.23%)	0	0.786
Never	12 (37.50%)	19 (61.29%)	22 (81.48%)	0.003
Total	32	31	27	

differences were modest, they remained statistically significant. Additionally, patients reported a noticeable improvement in subjective pain perception and a substantial enhancement in surgical satisfaction. Furthermore, analysis of patients requiring additional analgesic medications postoperatively revealed significantly fewer patients in both the modified and traditional cocktail groups compared to the control group, with significantly fewer patients in the modified group than in the traditional cocktail group ($P < 0.05$), further confirming its superiority and effectiveness in pain management.There was no statistically significant difference in the use of other analgesic drugs among patients 7 to 14 days after the operation (P=0.786), which was in line with the clinical rule of natural relief of postoperative pain and disappearance of differences between groups.

The application of cocktail therapy has introduced new perspectives in pain management, especially with the attention garnered by modified cocktail regimens in this field. The modified cocktail we used includes morphine, dexamethasone, ropivacaine, and saline solution. Morphine acts as an analgesic by alleviating pain through its action on the central nervous system.[19] Dexamethasone, a synthetic glucocorticoid, exhibits potent local anti-inflammatory effects, with a potency of 25–300 times that of cortisol. It has anti-inflammatory and anti-allergic properties, indirectly reducing inflammation and providing analgesic relief.[20] Relevant studies have shown that low-dose (physiological dose) corticosteroid hormones have no inhibitory effect on fracture healing. Instead, they are crucial for fracture repair by precisely regulating inflammatory responses, promoting osteogenic differentiation and bone transformation.[21] Ropivacaine is a long-acting local anesthetic that blocks pain signal transmission by inhibiting sodium ion channels. It selectively blocks sensory without affecting motor function, offering significant analgesic and sedative effects.[22] Cefuroxime sodium may be added postoperatively for infection prophylaxis. These drugs are combined to form a cocktail injection, administered locally to the forefoot, to block the action of pain mediators produced by surrounding tissue damage on sensory nerve endings.[23] This approach effectively provides pain relief, anti-inflammatory benefits, and infection prevention, thereby alleviating postoperative pain.The three factors worked together to achieve the advantage of a "window period" for analgesia from 6 hours to 1 day after the operation. Although the effect of this early analgesia is only comparable in VAS scores and does not reach the threshold of significant clinical significance, when combined with the subjective feelings of patients and clinical practice, its value lies in creating conditions for early postoperative rehabilitation. Patients can perform toe flexion and extension and weight-bearing training as early as possible in a low-pain state, reducing the risk of joint adhesion and muscle atrophy caused by long-term immobilization. This is highly consistent with the concept of "rapid recovery" in minimally invasive osteotomy for hallux valgus. The result of the convergence of VAS scores among groups 7 days after the operation is, on the one hand, due to the natural attenuation of the drug's effect duration, and on the other hand, it also reflects the self-limiting nature of postoperative pain. This suggests that the core value of the modified cocktail therapy lies in optimizing the management of acute postoperative pain.

Postoperative pain following hallux valgus surgery mainly originates from two aspects: (1) Incision-related pain: This type of pain is caused by the skin incision, transmitted through nociceptors to the spinal dorsal horn cells, and finally reaching the cerebral cortex, manifesting as superficial sensory pain characterized by sharpness and urgency. (2) Foot pain: Surgery around the forefoot and midfoot causes incisions, leading to bleeding, clot formation, tissue swelling, and other stimuli to proprioceptors. Pain signals are transmitted via the spinothalamic tract to the thalamus, presenting as subjective sensations of swelling pain.[4,24] It is noteworthy that postoperative pain due to joint capsule adhesions[25,26] and inflammation caused by vigorous contact of Kirschner wires during patient activity[27] currently lack effective preventive measures. In our study, the specific therapeutic effects of cocktails were primarily observed within 7 days postoperatively. Long-term results did not show significant differences in efficacy between modified and traditional cocktails. Our study included a total of 90 cases, with a predominance of female patients, which may have been influenced by incidental factors. This technology will be applied to all metatars osteotomy for example friberg, bunionette, etc. in the future. To expand the scope of our research and improve the long-term efficacy and safety of the cocktail injection still need to be verified through further large-sample prospective clinical studies.In recent years, local analgesic injection has drawn attention from orthopedic surgeons. Ankle nerve block techniques require surgeons to have a thorough understanding of the anatomical structure of the foot and ankle nerves.[28] Despite the relative complexity of ankle nerve blocks and the potential for transient nerve paralysis in some patients, this technique offers foot and ankle surgeons a convenient and effective method for pain management.[29] Effective postoperative pain relief not only helps reduce postoperative stress responses and cardiovascular load but also provides favorable conditions for postoperative recovery and joint function restoration.

This study, as a retrospective cohort study, relied on previous medical records from January 2020 to December 2023 for data collection. Due to the inherent limitations of the content of routine clinical diagnosis and treatment records, some baseline characteristic data that might affect the postoperative analgesic effect and rehabilitation process were not fully obtained, specifically including: Quantitative assessment indicators of bone quality (such as bone density test results), the actual weight of the patient (in this study, only the body mass index BMI was recorded), smoking history (including smoking years and daily smoking volume), etc. In response to this limitation, future studies will adopt a prospective cohort design, pre-standardizing the collection dimensions of baseline data in the research protocol, thereby more comprehensively controlling confounding factors and enhancing the robustness and clinical reference value of the research conclusions.

Conclusion

These drugs are combined to form a cocktail injection, administered locally to the forefoot, to block the action of pain mediators produced by surrounding tissue damage on sensory nerve endings. This study demonstrates that the modified cocktail has certain clinical reference value in the management of short-term postoperative analgesia, which is conducive to early postoperative rehabilitation functional exercises for patients. This technique is not only easy to operate but also can reduce the use of analgesic drugs, and has high safety and economy. It can be used as an optional option for early postoperative pain control.

Ethics Declaration

This study was conducted in strict accordance with the Declaration of Helsinki. The protocol of this study was reviewed and approved by the Affiliated Zhongshan Hospital of Dalian University Ethics Committee. The approval number for this study is KYS2023-021-1. The experiment was completed in the Orthopedic Laboratory of Zhongshan Hospital Affiliated to Dalian University.

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Disclosure

Jiahe Liu and Tao Zhang contributed equally to this work and should be considered co-first authors. The authors report no conflicts of interest in this work.

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