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Editorial

It is with great pride and gratitude that we present Volume 49, Issue 1 of the Journal of Southeast Asian Orthopaedics for January to June 2025. This edition reflects the ongoing dedication of researchers, clinicians, and the orthopaedic community to advancing knowledge and improving patient care in the region and beyond.

In this issue, readers will find a diverse collection of original research articles that highlight innovations and evidence-based practices across various subspecialties. From the use of inhaled methoxyflurane as an alternative to intravenous sedation in managing acute shoulder dislocations, to exploring surgical techniques for conditions such as De Quervain's tenosynovitis, this volume captures the breadth of orthopaedic expertise. Other notable studies investigate the outcomes of rotating hinge knee implants in complex revision surgeries and assess the impact of intraoperative techniques in cementless hip arthroplasty.

These studies not only address clinical challenges but also provide actionable insights that can shape future practices. They serve as a testament to the commitment of orthopaedic surgeons to delivering innovative solutions that enhance patient outcomes while fostering a culture of continuous improvement.

The Journal of Southeast Asian Orthopaedics remains dedicated to serving as a platform for knowledge exchange and collaboration among professionals in the region. This achievement would not be possible without the contributions of our authors, the meticulous work of our reviewers, and the tireless efforts of the editorial team. To them, I extend my deepest appreciation.

I hope this issue inspires you to explore new ideas, contribute to the field, and enhance the lives of those we serve.

With warm regards,

Professor. Thanainit Chotanaphuti, MD
Editor-in-Chief, Journal of Southeast Asian Orthopaedics
Past President, Royal College of Orthopaedic Surgeons of Thailand

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The Efficacy of Inhaled Methoxyflurane Versus Intravenous Sedation for the Reduction of Acute Shoulder Dislocation

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Purpose: Anterior shoulder dislocation is one of the most common emergency orthopedic conditions. In general practice, intravenous sedation is the standard treatment to relax patients during shoulder reduction procedures. Sedatives and analgesics are drugs that have side effects after administration, especially when administered intravenously. They can depress neurological function and cause respiratory and cardiovascular system side effects. Self-inhaled methoxyflurane relieves moderate to severe pain. Hospitals may benefit from minimized respiratory and cardiovascular side effects.
Methods: This randomized controlled trial included 50 patients who were randomly assigned to two groups: the inhaled methoxyflurane group (Inh Group) and the intravenous sedation group (IV Group). All patients were assessed for efficacy, procedure duration, pain score during reduction, patient satisfaction, and adverse effects.
Results: Fifty patients satisfied the inclusion requirement: 25 each in the Inh and IV Groups. Reduction was successfully achieved in 92% and 88% of the patients in the Inh and IV Group, respectively. The mean procedural time was 6.4 min and 15.4 min the Inh and IV Group, respectively. Moreover, the mean recovery time was 22.5 min in the Inh Group and 32.4 min in the IV Group.
Conclusions: Inhaled methoxyflurane has better efficacy in reducing acute shoulder dislocation than intravenous sedation alone. Procedural and recovery times were shorter in the Inh Group. Adverse events (hemodynamic instability, desaturation, nausea, vomiting, drowsiness, and dizziness) were more frequent in the IV Group than in the Inh Group.

Keywords: inhaled methoxyflurane, intravenous sedation, acute shoulder dislocation, shoulder reduction

Anterior shoulder dislocation is one of the most common orthopedic emergency conditions caused by sports injuries or road traffic accidents. Patients with traumatic shoulder dislocation present with a gross deformity, limited movement, and severe pain. Physical examination of the shoulder shows abduction and external rotation, flattening of the deltoid muscle contours, and a limited range of motion. Patients are unable to touch the opposite shoulder by crossing an arm in front of the body. This pathognomonic sign is referred to as the Dugar method. Associated injuries include axillary nerve palsy. In suspected cases, shoulder radiography is required to confirm diagnosis.

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In general practice, intravenous sedation is the standard treatment to relax patients during shoulder reduction procedures[1]. Healthcare professsionals must perform intravenous cannulation before administering sedatives. Moderate to deep safety protocols require close monitoring by medical staff. Sedatives and analgesics are drugs that have side effects after administration, particularly when administered intravenously. They can depress neurological function and cause respiretory and cardiovascular system side effects.

With the introduction of methoxyflurane, the treatment method has completely changed from intravenous cannulation to self-inhaled administration. This method has been widely used in Singapore and Australia for procedures such as endoscopic gastroscopy and in prehospital settings[2]. Self-inhaled methoxyflurane relieves moderate to severe pain. Hospitals may benefit from the associated minimized respiratory and cardiovascular side effects. Moreover, the workload can be reduced by changing the procedure to provide more patient-controlled analgesia. With this technique, patients recover faster than with intravenous sedation. Although inhaled methoxyflurane can cause central nervous system depresssion, sedation, hypopnea, and desaturation, the effects last no longer than 25-30 min[3]. Notably, inhaled methoxyflurane has already been approved by the Food and Drug Administration of Thailand; however, its research and usage are still relatively limited. One bottle contains 3 mL methoxyflurane for vaporization. The maximum recommended dosage is 6 mL of methoxyflurane per day and 15 mL per week.

This study primarily aimed to assess the efficacy of inhaled methoxyflurane compared with intravenous sedation in reducing acute shoulder dislocation. Secondary objectives were the duration of the procedure, pain score during reduction, patient satisfaction, and side effects.

METHODS

Study Design: A Randomized Controlled Trial

Design Flow Description

This randomized controlled trial included patients with acute shoulder dislocation admitted to the emergency room of our hospital between November 2021 and December 2023. The inclusion criteria were as follows: (1) traumatic anterior shoulder dislocation; (2) age 18-60 years; and (3) communication in Thai. The exclusion criteria were as follows: (1) recurrent shoulder dislocation; (2) history of methoxyflurane, Morphine, or Midazolam allergy; (3) history of contraindications for methoxyflurane; and (4) multiple organ trauma.

The study design was modified to actively exclude and control confounding variables, including randomization and restrictions. Randomization was performed using a block of four created by the principal investigator. Patient age and exclusion criteria (recurrent shoulder dislocation and multiple organ trauma) were used to restrict the confounding variables. In addition, patient characteristics were analyzed to identify differences. The data were analyzed using a regression model if there were differences.

This study was approved by the local research ethics committee (number 032-2021). All the enrolled participants provided written informed consent.

A total of 145 patients presented to the emergency department with an acute shoulder dislocation. Ninety-five patients with recurrent shoulder dislocations or an associated fracture were excluded from the study. Finally, 50 patients were included in this study, and they were randomly assigned into two groups, as shown in Fig 1: the inhaled methoxyflurane group (Inh Group) and the intravenous sedation group (IV Group). Randomization was performed using a block of four created by the principal investigator.

Patients in the Inh Group were treated with inhaled 3 mL of inhaled methoxyflurane (patients were instructed to inhale intermittently for approximately 6-10 inhalations to achieve adequate analgesia). Patients in the IV Group received midazolam 0.05 mg/kg and morphine 0.05 mg/kg. After patients have received inhaled methoxyflurane or intravenous sedation, the dislocated shoulder was reduced using traction and countertraction techniques by an orthopedic physician. In both Inh and IV Groups, success was confirmed using shoulder radiography. Simultaneously, we

recorded the duration of the procedure, pain score during the reduction, patient satisfaction score (measured using patient satisfaction surveys that enabled patients to rate how happy they were with the investigator on a 1-10 rating scale), and the side effects on the nurse. Vital signs of patients with hypotension were monitored until hemodynamic stabilization was achieved. Patients with oxygen desaturation received oxygen cannula support until they were able to tape off. Medications were not administered for nausea, vomiting, drowsiness, or dizziness, since they are short-term side effects. A patient was diagnosed as having failed shoulder reduction if the patient was unable to succeed within 30 min after infusion of Inh methoxyflurane or IV sedation or if the patient was unable to tolerate pain during shoulder reduction. Patients with unsuccessful reduction underwent closed reduction under general anesthesia.

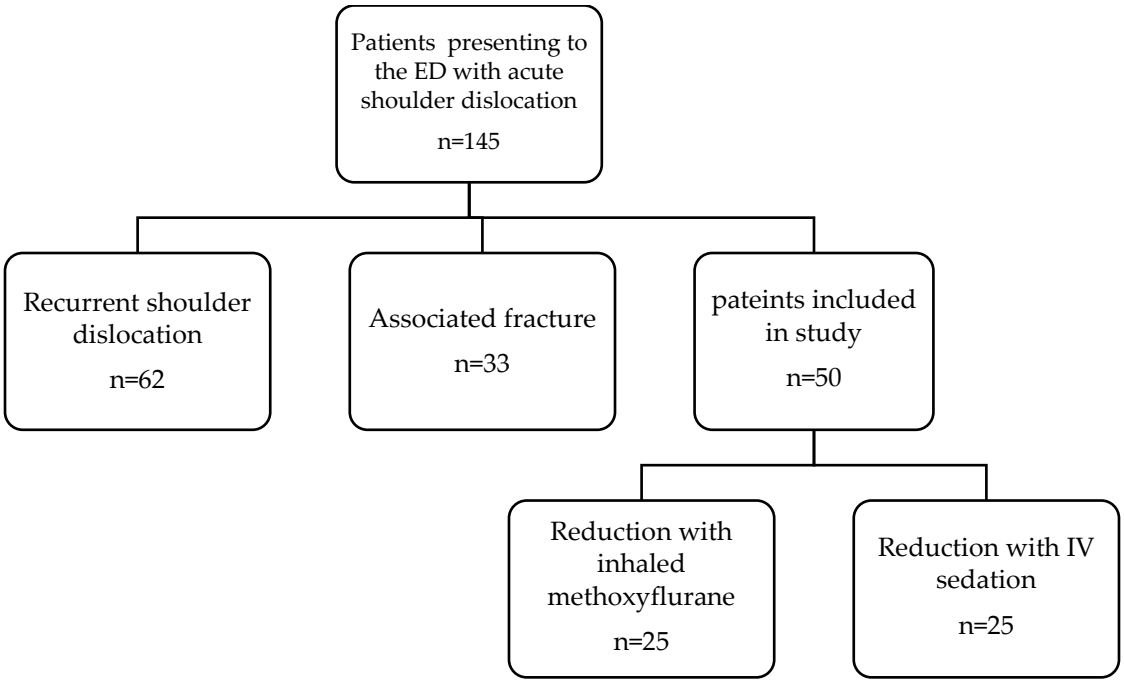

Fig. 1 Flow diagram.

Statistical Analysis

The required sample size was calculated by a binary outcome non-inferiority trial to be 22 in each group when alpha = 0.05 and beta = 0.3, for a ratio of effectiveness of 0.846 in Inh Group and 0.865 in IV Group with a non-inferiority limit (d) of 25%. Assuming a complication rate of 90%, the sample size was determined to be 25 in each group[6,13]. Intention-to-treat and pre-protocol analyses were also performed. Shoulder reduction success was compared between the groups using the chi-square test. Other outcomes were calculated with the t-tests. Statistical significance was set at $p<0.05$.

RESULTS

A total of 50 patients satisfied the inclusion requirement: 25 in the Inh Group and 25 in the IV Group. Participants' mean age was 42.4 and 37.9 years in the Inh and IV Groups, respectively. Table 1 shows patient characteristics and associated variables for both groups.

Inh Group

Successful reduction was achieved in 92% of the patients who received inhaled methoxyflurane. The mean procedural and recovery times were 6.4 min (SD: 3.17) and 22.5 min (SD: 6.28),

respectively. The most common adverse events were dizziness (8.7%) and drowsiness (13.0%).

IV Group

Successful reduction was achieved in 88% of patients who were administered intravenous sedation. The mean procedural and recovery times were 15.4 min (SD: 1.37) and 32.4 minutes (SD 8.27), respectively. Adverse events included dizziness (50%) and drowsiness (54.5%).

The procedural and recovery times were significantly reduced in the Inh Group. Adverse events (hemodynamic instability, desaturation, nausea, vomiting, drowsiness, and dizziness) were significantly more frequent in the IV Group than in the Inh Group. Patient satisfaction was better in the Inh Group (9.65) than in the IV Group (9.31); however, the difference was not statistically significant.

Table 1 Patient characteristics.

Patient characteristics	Inhaled methoxyflurane group	Intravenous sedation group	P-value
Patient (N)	25	25	
Sex (male/female)	17/8	14/11	0.22
Side (right/left)	16/9	15/10	0.68
Dominant side	68%	64%	0.67

Table 2 Study outcome.

Results	Inhaled methoxyflurane group	Intravenous sedation group	P-value
Success rate	23/25 (92%)	22/25 (88%)	0.54
Procedural time	6.4 (3.17)	15.4 (1.37)	<0.01
Recovery time	22.5 (6.28)	32.4 (8.27)	<0.01
VAS score			
Pre-med	9.92 (0.4)	9.76 (0.66)	0.30
At 3 min	2.92 (0.91)	2.8 (0.91)	0.64
At 5 min	2.36 (0.64)	2.48 (0.77)	0.55
Post reduction	1.21 (0.67)	1.27 (0.63)	0.78
Pre dischage	1.13 (0.69)	1 (0.69)	0.53
Patient satisfaction scores	9.65 (0.71)	9.31 (0.94)	0.19
Side effects			
Hemodynamic unstable	0	6/22 (27.27)	<0.01
Desaturation	0	6/22 (27.27)	<0.01
Nausea	0	6/22 (27.27)	<0.01
Vomiting	0	6/22 (27.27)	<0.01
Drowsiness	3/23 (13%)	12/22 (54.54)	<0.01
Coughing	0	0	NA
Dizziness	2/23 (8.7%)	11/22 (50)	<0.01
Amnesia	0	0	NA
Fever	0	0	NA

DISCUSSION

Although statistically significant, our randomized controlled trial showed a better efficacy for inhaled methoxyflurane than intravenous sedation in reducing acute shoulder dislocation. Regarding secondary outcomes, the procedure duration and recovery time were better in the Inh Group. Adverse events (hemodynamic instability, desaturation, nausea, vomiting, drowsiness, and dizziness) were more frequent in the IV Group than in the Inh Group. However, the study did not include blinding, which may have biased the results.

When compared with previous reports that were retrospective reviews and case series, we found the same results as those reported by the Young L study: methoxyflurane can be used to reduce acute anterior shoulder dislocation with the same efficacy as the gold standard technique. Adverse events (hemodynamic instability, desaturation, nausea, vomiting, drowsiness, and dizziness) were more frequent in the IV Group than in the Inh Group, similar to the results of the Mir-Kohler study. However, the current cost of inhaled methoxyflurane is more than five times higher than that of intravenous sedation.

Although, inhaled methoxyflurane is approximately five times more expensive than traditional intravenous sedation, it requires fewer health care providers because it does not require nurses of nursing assistants for intravenous drug administration or drug preparations like traditional intravenous sedation.

This study has some limitations. First, the study population had a first-time shoulder dislocation; however, in a real situation in the emergency department, we found that half of the patients had recurrent dislocations. Second, patients with associated fractures were excluded; however, in real-life situations, shoulder fracture-dislocation requires reduction. Another limitation of this study is the mean recovery time, which was superior in the Inh Group, approximately 9.9 min when compared with the IV Group. This difference may have been due to adverse events; therefore, the patient was not discharged.

Our study showed statistically significant adverse events in the IV Group compared to the Inh Group. Since the adverse events of analgesic and sedative drugs were dose-related, we administered the medications to patients in the IV Group as a single dose. Therefore, adverse events may decrease if the dosage of IV sedation is separated into sedative and visual analog scale scores.

For future research, the inclusion criteria should be expanded to include all directions of shoulder dislocation, fracture-dislocation of the shoulder that needs to be reduced, and young and older age patient groups. Future studies may require two doctors to conduct blinding studies to minimize bias, with the first doctor selecting a group and administering medication and another doctor performing the shoulder reduction. Cost-benefit analysis is a good project that provides a clearer picture of economic implications. Future research also needs to repeat intravenous sedation until the maximum dosage is reached to assess the patient's hemodynamic stability and sedation score. Finally, patients should be monitored for a long time for factors that may occur, such as the rate of recurrent shoulder dislocation or long-term side effects of medications.

CONCLUSIONS

The efficacy of self-inhaled methoxyflurane in reducing acute shoulder dislocation was better than that of intravenous sedation; however, the difference was not statistically significant. The procedure duration and recovery time were shorter in the Inh Group. Fewer adverse events (hemodynamic instability, desaturation, nausea, vomiting, drowsiness, and dizziness) were observed in the Inh Group.

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A Randomized Prospective Study of Short-Term Complications Between Simple Release and Extensor Retinaculum Reconstruction in De Quervain's Tenosynovitis

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Purpose: To study and compare the postoperative complications of De Quervain's tenosynovitis treatment using two methods: simple release and extensor retinaculum reconstruction.
Methods: This randomized controlled trial included 24 patients divided into two groups: Group 1 (simple release) and Group 2 (extensor retinaculum reconstruction), with 12 patients in each group.
Results: The mean age of the participants was 51.75 and 49.25 years for Groups 1 and 2, respectively. The study participants included three males and 21 females. Intraoperatively, subcompartments were observed in two patients in Group 1 and six patients in Group 2. Additionally, a ganglion cyst in the tendon was found in one patient per group. The mean preoperative visual analog scale (VAS) and Disabilities of the Arm, Shoulder and Hand (DASH) scores for Group 1 were 7.83 and 61.44, respectively, whereas those for Group 2 were 8.17 and 66.52, respectively. Postoperatively, the VAS and DASH scores for Group 1 changed to 2.17 and 15.47, respectively, whereas those for Group 2 changed to 2.67 and 16.33, respectively ($p = 0.843$ and 0.63, respectively). Tendon subluxation was observed in two patients in Group 1, with none in patients in Group 2 ($p = 0.14$).
Conclusions: No significant tendon subluxation was observed in either surgery type, with no significant differences in the treatment outcomes.

Keywords: De Quervain's tenosynovitis, simple release, extensor retinaculum reconstruction

De Quervain's tenosynovitis is a condition commonly encountered in working-age individuals and is often attributed to wrist overuse. Non-operative management typically involves administering local injections 2–3 times; however, if symptoms persist despite this method, surgical intervention may become necessary[1–3]. The primary surgical approach involves simple release (SR) of the extensor retinaculum. However, some studies have reported tendon subluxation-induced discomfort during use[4–6]. Consequently, an alternative surgical method involving extensor retinaculum reconstruction (ERR) has been employed to mitigate this complication.

This research aimed to investigate tendon subluxation-related complications following surgery for De Quervain's tenosynovitis. We hypothesized that ERR results in fewer complications than SR.

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MATERIALS AND METHODS

This study was approved by our institute and was conducted between March 2021 and October 2023. Inclusion criteria included participants aged >18 years who underwent a physical examination for De Quervain's tenosynovitis, with tenderness at the 1st dorsal compartment, and a positive Finkelstein's test was observed. Eligible patients received local corticosteroid injections two or more times without improvement or experienced symptom recurrence. Exclusion criteria encompassed individuals with underlying conditions such as rheumatoid arthritis, osteoarthritis of the 1st carpometacarpal joint, and median carpal tunnel syndrome.

The sample size was calculated using the N4studies version 1.4.2 program. Values were represented with reference to the research by Kim et al.[7] as follows (using standard deviation values from complications in this study). Twenty-six patients participated in the study after providing informed consent and were categorized into two groups: participants in Group 1 underwent SR, and those in Group 2 underwent release with ERR. The participants were evenly distributed, with each group comprising 13 patients using computer-generated randomization. All surgeries were performed by a single surgeon at our institute. Postoperatively, one patient from each group was lost to follow-up, resulting in a final cohort of 12 patients per group. Pain and functional outcomes were assessed using the visual analog scale (VAS) and Disabilities of the Arm, Shoulder and Hand (DASH) scores preoperatively and 3 months postoperatively. Additionally, data on complications, such as tendon subluxation, wound infections, and injuries to the veins, tendons, and nerves were recorded. For postoperative tendon subluxation, the assessor measured the mobility of the tendon on the patient's skin around the wrist while it was flexed and extended (Fig. 4).

Demographic data were analyzed using means, medians, and percentage values. The chi-square test was employed for the complication analysis. The assessment of VAS and DASH scores preoperatively and 3 months postoperatively employed the Mann-Whitney U test. Statistical analyses were performed using SPSS for Windows version 28.0.1.0, and the level of significance was set at $p < 0.05$.

Surgical Technique

The patient was placed in the supine position, and 2% xylocaine with adrenaline was injected approximately 1 cm proximal to the radial styloid. A 2–3 cm oblique skin incision was made over the 1st compartment. The superficial radial nerve was identified and protected. Similarly, the 1st dorsal compartment, along with the abductor pollicis longus and extensor pollicis brevis tendons, was identified (Fig. 1). Simple longitudinal release of the extensor retinaculum was performed in the control group. In the study group, ERR was performed using the Takagi technique. The first extensor retinaculum was cut in a step-cut manner, with the ends defined as the distal ulnar and proximal radial bases (Fig. 2). The extensor pollicis brevis and abductor pollicis longus tendons were explored, the subcompartmental septum and ganglion cyst were identified, and if present, the cyst was addressed and excised. In the study group, the distal and proximal retinacula were sutured together without tension (Fig. 3). Tendon movement toward the wrist was assessed in both groups by gently flexing and extending the wrist to observe volar subluxation. Postoperatively, patients were advised to move their wrists gently.

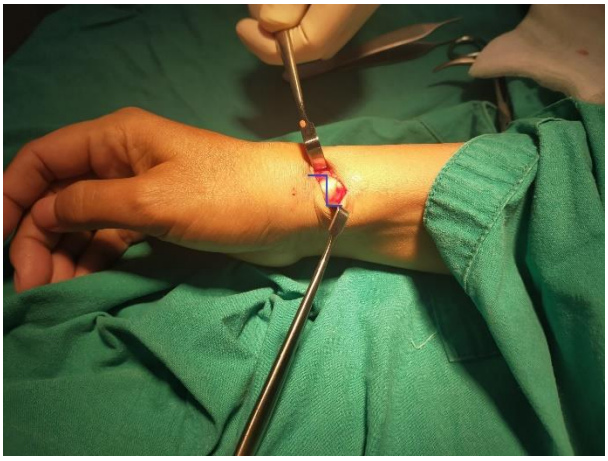

Fig. 1 Identifying the 1st dorsal compartment and planning the step-cut incision.

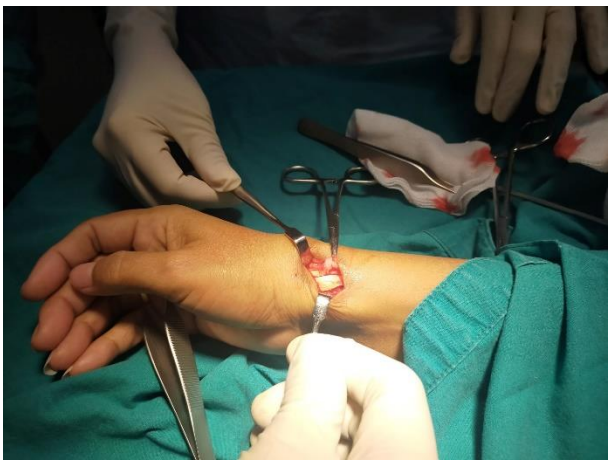

Fig. 2 The 1st extensor retinaculum is cut in a step cut, with the ends defined as the distal ulnar and proximal radial bases.

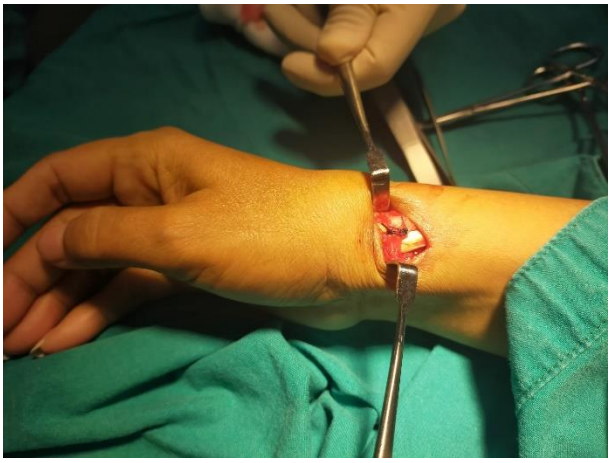

Fig. 3 The distal and proximal bases were sutured together without tension.

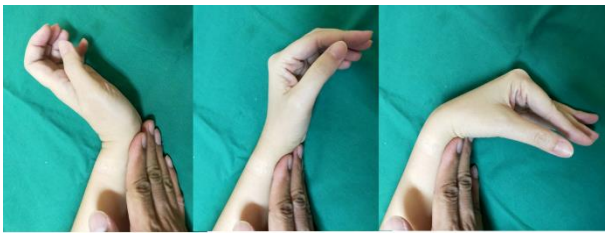

Fig. 4 Demonstration of physical examination of tendon subluxation. The examiner places their hand on the volar side of the patient's wrist while the wrist is extended. Then, the patient is asked to bend their wrist down slowly. Tendon subluxation can be detected during this examination.

Table 1 Demographic distribution and intraoperative pathology.

		Group 1: SR	Group 2: ERR	P-value
Mean age (years)		51.75	49.25	0.422
Sex	Female	11 (91.67%)	10 (83.33%)	0.537
	Male	1 (8.33%)	2 (16.67%)	0.537
Subcompartmental		2 (16.67%)	6 (50%)	0.083
Ganglion cyst		1 (8.33%)	1 (8.33%)	1

SR, simple release; ERR, extensor retinaculum reconstruction

Table 2 Preoperative and Postoperative Scores.

Functional scores	Group 1: SR	Group 2: ERR	P-value
Preoperative VAS	7.83	8.17	0.887
Preoperative DASH	61.44	66.52	0.59
Postoperative VAS	2.17	2.67	0.843
Postoperative DASH	15.47	16.33	0.63

SR, simple release; ERR, extensor retinaculum reconstruction; VAS, visual analog scale; DASH, Disabilities of the Arm, Shoulder and Hand

Table 3 Prevalence of complications between Groups 1 and 2.

Complication	Group 1: SR	Group 2: ERR	P-value
Tendon subluxation	2 (16.67%)	0	0.14
Infection	2 (16.67%)	1 (8.33%)	0.537
Nerve injury	1 (8.33%)	2 (16.67%)	0.537

SR, simple release; ERR, extensor retinaculum reconstruction

RESULTS

This study included 26 patients, two of whom were lost to follow-up. Consequently, each group had 12 patients available for follow-up of the treatment outcomes. In Group 1, the mean age was 51.75 years, whereas in Group 2, it was 49.25 years. The sex distribution of the study participants included three males and 21 females, with 62.5% of cases affecting the dominant wrist. Intraoperatively, subcompartments separating the abductor pollicis longus and extensor pollicis brevis were identified in 33.33% of the cases (eight patients), with two patients in Group 1 and six in Group 2. Intratendinous ganglion cysts were observed in 8.33% of the cases (two patients), with one patient in each group, as detailed in Table 1. The mean preoperative VAS and DASH scores for Group 1 were 7.83 and 61.44, respectively, and those for Group 2 were 8.17 and 66.52, respectively ($p = 0.887$ and 0.59, respectively). Three months postopera-

tively, the VAS and DASH scores for Group 1 changed to 2.17 and 15.47, respectively, whereas those for Group 2 changed to 2.67 and 16.33, respectively (p = 0.843 and 0.63, respectively) (Table 2). Complications, including tendon subluxation, were observed in two patients in Group 1, with none in Group 2 (p = 0.14). All infections were superficial, with two cases in Group 1 and one case in Group 2, and were managed with oral antibiotics for 1–2 weeks. All nerve injuries were neurapraxic and were found in one and two patients in Groups 1 and 2, respectively. The additional complications are detailed in Table 3.

DISCUSSION

De Quervain's tenosynovitis is a common disease that often results from excessive wrist use. When non-operative treatments prove ineffective, surgery is the next viable option. The initial surgery introduced by Dr. Fritz De Quervain[8] involved a transverse incision[9], which was later associated with an increased risk of superficial radial nerve injury. Subsequently, a longitudinal incision was proposed[10], proving to be a safer approach with favorable treatment outcomes. Other alternatives, such as a lazy S or oblique incision[11], have also been explored. A comparative study of longitudinal and transverse incisions revealed a higher likelyhood of hypertrophic scarring and superficial radial nerve injury with transverse incisions. For this study, an oblique incision was selected because it demonstrated no nerve injury and resulted in the absence of hypertrophic scars[12].

The pain and functional outcomes in this study were not significantly different between the two surgery types. Tendon subluxation, a common complication associated with substantial functional impairment and potential nerve injury on the volar and dorsal sides[13], can lead to wrist pain. To address this issue, various surgical methods have been devised, including brachioradialis flap[14] and ERR. Different techniques, as described by many authors[15-17], aim to correct tendon subluxations. The Bakhach method involves cutting the periosteal area in front of the radial styloid into an omega shape, creating additional space for tendon movement without disturbing the pulley. Van de Wijk's approach includes a diagonal cut to the pulley, a cut to the base of the bone, suturing, space enhancement, and prevention of tendon subluxation. In this study, Takagi's method was used, employing step-cut and restoration sutures. Two cases of tendon subluxation occurred in the SR group, whereas none were reported in the ERR group; however, the difference was not statistically significant.

The primary limitation of this study is its relatively small sample size. Future research should include a larger number of patients to enhance the statistical power of this study. Additionally, the various types of tendon reconstruction surgeries were not compared in this study. Focusing solely on short-term results may not provide a comprehensive understanding of the longevity of complications, suggesting the need for further investigation with extended follow-up periods.

CONCLUSIONS

Surgery for De Quervain's tenosynovitis, whether through SR or ERR, has proven to be effective. However, the likelihood of postoperative pain and tendon subluxation was higher in the SR group.

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Outcomes of the Rotating Hinge Knee in Revision Total Knee Arthroplasty: A Short-term Report with a Median Follow-up of 2.75 Years in a Large Asian Institute

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Purpose: Revision total knee arthroplasty (TKA) is often necessary because of infection and malalignment and represents significantly greater challenges. Rotating-hinge knee (RHK) play an important role in complex situations, with survival rates varying from 73% to 97.2% over 5 to 10 years. However, most knee arthroplasty concepts are primarily tailored to suit Caucasians, potentially raising concerns about their suitability for Asian populations. The purpose of our research was to determine the rates of survival and complications, as well as to review the factors that contribute to failed RHK revisions in our large Asian institute.

Methods: This retrospective study included all revisions with RHKs performed between January 2013 and December 2021 while excluding those who underwent primary RHK procedures. Data collection included revision diagnoses and reasons for RHK implant failure. Implant survivorship was calculated from the date of surgery to the time of re-revision surgery.

Results: This study included 37 patients, consisting of four men and 33 women participants, with an average age of 75 years. The mean follow-up was 2.75 years. The main causes of revision to RHK were prosthetic joint infection and instability, both accounting for 29.7% of cases, followed by aseptic loosening at 21.6%. The 2-year survival rate was 91.67%. The mean survival time was 2.08 years, with an overall failure rate of 5.4% due to infection.

Conclusions: RHK implants are essential in revision knee arthroplasty under specific conditions. Our large Asian institution has shown a 2-year survival rate of 91.67% and a recurrence-free survival rate of 94.6%.

Keywords: Rotating hinge knee, Revision knee arthroplasty, Survival rate, Complication

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Revision total knee arthroplasty (TKA) is typically required after failure of primary TKA due to prosthetic joint infection (PJI), periprosthetic fracture, aseptic loosening, polyethylene wear, and instability [(1)]. Although a CR or PS prosthesis can resolve most causes for revision, in complex cases involving collateral ligament insufficiency, severe varus or valgus deformity (>20°) accompanied by

significant soft-tissue release and bone loss, compromised collateral ligament insertions, gross flexion-extension gap imbalance, ankylosis, and hyperlaxity [2], the rotating-hinge knee (RHK) is the only remaining implant option.

Survival rates for RHK, as reported in several studies [3-6], range from 73% to 84.5% for 5-year survival and from 51% to 97.2% for 10-year survival. The potential causes of RHK implant failure include infection, instability, aseptic loosening, arthrofibrosis, and periprosthetic fractures.

Notably, most TKA prostheses are based on the typical characteristics of Caucasian populations [7]. Due to distinct anatomical features, such as a higher degree of tibial torsion and lesser varus knee in the Japanese population, a mismatch in the femoral aspect ratio (mediolateral/anteroposterior), and the requirement for greater degrees of motion for traditional activities compared to that in Caucasians [2], reports [8] suggest potential incompatibilities for Asian populations.

The main objectives of our study were to evaluate the survival rates of RHK implants, analyze the complication rates within our large high-standard Asian institution, and investigate the reasons for implant failure.

MATERIALS AND METHODS

A retrospective analysis was conducted using data from our institute between January 1, 2013, and December 31, 2021, and was approved by the Institutional Review Board. This study included patients who underwent revision knee arthroplasty using RHK. The indications for RHK revision included severe instability, significant bone loss, infection, aseptic loosening, and periprosthetic fractures. Patients who underwent RHK as primary surgery and those with incomplete data were excluded. The specific models of RHK used in this study were the S-ROM™ NOILES™ Rotating Hinge Knee System (DePuy Synthes) and the NexGen® Rotating Hinge Knee (Zimmer Biomet). We gathered data on patient demographics, diagnoses at the time of revision, revision dates, and causes of RHK implant failure. Failures were categorized into several types, including infection, aseptic loosening, periprosthetic fracture, instability, recurrent dislocation, and malalignment.

Implant survival was determined from the date of surgery, with the endpoint defined as the time at which revision surgery was required. This included exchanging modular components or partial or full implant removal. The reasons for these deviations were collected and categorized in a manner similar to the causes of the initial failure.

Statistical Analysis

Continuous data were represented as either mean ± SD or median (interquartile range) based on the data distribution. Categorical data were expressed as numbers and percentages. The Kaplan–Meier method was used to estimate implant survival. Logistic regression was used to explore the factors related to RHK implant failure. Statistical significance was set at $p < 0.05$.

RESULTS

This study included 37 patients who received RHK implants, consisting of four men (10.8%) and 33 women (89.2%). The mean patient age was 75 years (65.5–78). The mean body mass index (BMI) was 24.8 kg/m^2 (23.1–27.6). The most prevalent underlying conditions were diabetes mellitus (70.3%), hypertension (64.9%), and dyslipidemia (27%). The mean follow-up period was 2.75 years, with the longest follow-up being 8.73 years. The patient characteristics are shown in Table 1.

The most common reasons for RHK revision were PJI and instability, each occurring in 11 knees (29.7%), followed by aseptic loosening in eight knees (21.6%). Figure 1 illustrates the causes of RHK revision.

Survival Rate

Kaplan–Meier analysis revealed that the mean survival time in our study was 2.08 years, with a 95% confidence interval (CI) of 0.60 to 3.56 years. According to the Kaplan–Meier analysis, the revision-free rate was 94.6%. The overall failure rate of RHK was 5.4% (two RHKs), with all failures attributed to infection. All the patients who underwent re-revision were women. The first case involved a 64-year-old woman with diabetes mellitus, hypertension, and dyslipidemia who

underwent revision RHK for PJI. Two years after the revision surgery, she developed pain, and the sinus tract of the affected knee was diagnosed with chronic PJI. She underwent debridement and prosthesis removal. The second case involved an 85-year-old woman with diabetes mellitus and dyslipidemia who underwent revision RHK for a periprosthetic fracture. Three months after the revision surgery, the patient developed pain and swelling of the knee, was diagnosed with acute PJI, and underwent debridement and modular part exchange. In our study, the 2-year survival rate of patients with RHK was 91.67% as shown in *Fig. 2*.

Table 1 Demographic data.

Characteristics[1]	**RHK patients (n=37)**
Age	75 years (65.5 – 78)
Height	151.3 cm (144.85 – 156.45)
Weight	56.8 kgs (51.85 – 62.55)
BMI[2]	24.8 kg/m^2 (23.05 – 27.55)
Gender	
Female	33 patients (89.2%)
Male	4 (10.8%)
Side	
Rt	21 (56.8%)
Lt	16 (43.2)
UD	
DM[3]	26 (70.3%)
HT[4]	24 (64.9%)
DLP	10 (27%)
None	9 (24.3%)
Cause of Failure	
Aseptic Loosening	8 (21.6%)
Instability	11 (29.7%)
Mal Alignment	1 (2.7%)
Periprosthetic Fracture	5 (13.5%)
PJI[5]	11 (29.7%)
Recurrent Dislocation	1 (2.7%)
Re-revision	2 (5.4%)
Cause of Failure	
Infection	2 (100%)
Implant	
Exchange Liner	1 (50%)
Remove implant	1 (50%)

[1]Characteristics: Mean (range) values are presented for age, height, weight, and BMI, [2]BMI: Body Mass Index, [3]DM: Diabetes Mellitus, [4]HT: Hypertension, [5]PJI: Prosthetic Joint Infection

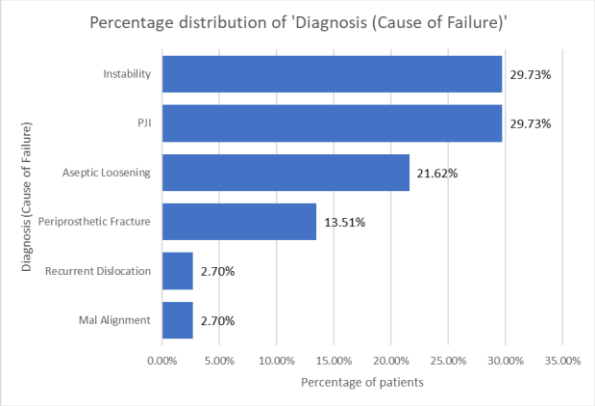

Fig. 1 Causes of failure. PJI, prosthetic joint infection.

(This figure illustrates the distribution of various causes of failure for RHK revisions in our study cohort. Each category is presented as a percentage of the total failures observed in the study. This detailed breakdown helps to identify the most common reasons for RHK failure, informing clinical practices and potential areas for improvement in surgical techniques and postoperative care.)

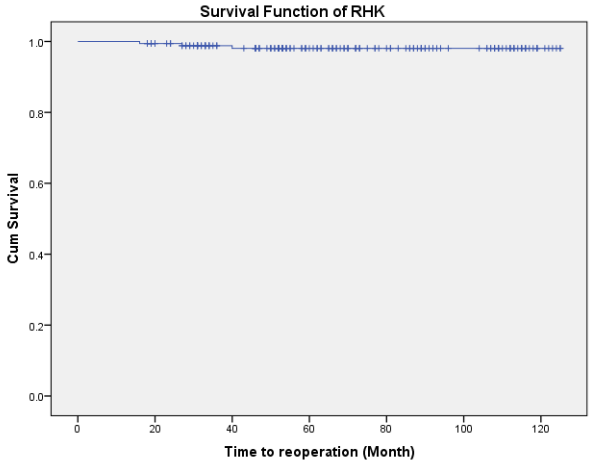

Fig. 2 Survival rate.

(This figure presents the Kaplan-Meier survival curve for RHK implants over a follow-up period. The survival rate is defined as the percentage of implants that have not required re-revision surgery over time. The curve illustrates the durability and performance of RHK implants in our study cohort, providing insights into their long-term efficacy.)

Factors Influencing RHK Implant Failure

We performed both univariate and multivariate analyses to identify factors associated with RHK implant failure. The results are summarized in Table 2. Univariate analysis showed that age had an odds ratio (OR) of 1.016 (95% CI, 0.867–1.191; p = 0.841), and BMI had an OR of 1.279 (95% CI, 0.906–1.805; p = 0.162). In the multivariate analysis, age showed an OR of 1.011 (95% CI, 0.865–1.183; p = 0.890), and BMI showed an OR of 0.276 (95% CI, 0.904–1.802; p = 0.165).

DISCUSSION

RHK arthroplasty uses a highly constrained prosthesis in complex knee arthroplasty. The average age of the patients at the time of revision in our study was 75 years (65.5–78), which is in line with Gilles et al.'s systematic review [9], which reported a mean age range of 60 to 79 years across various studies. Our study found that the most common causes of RHK were infection (29.73%), instability (29.73%), and aseptic loosening (21.62%). These findings align with Shalen et al.'s systematic review [10], which identified infection (43%), instability (24%–30%), and aseptic loosening (45%–60%) as the primary indications for revision with RHK.

In our study, neither age nor BMI were statistically significant predictors of RHK implant failure. Univariate analysis showed no significant association between age and BMI. Multivariate analysis confirmed these findings, with age (OR 1.011; 95% CI, 0.865–1.183; p = 0.890) and BMI (OR 0.276; 95% CI, 0.904–1.802; p = 0.165) remaining non-significant, indicating that other factors may influence implant survival apart from age and BMI.

To the best of our knowledge, this is one of the few Asian studies on revision knee arthroplasty using RHK implants. The study showed a 2-year survival rate of 91.67%, which was the highest among previous Asian studies, as demonstrated in Table 3 [11, 12], and was comparable to the findings of Cottino et al.'s report [3], which revealed survival rates of 84.5% after 5 years and 71.3% at 10 years. Similar to the report by Giurea et al. [5], the 2-year survival rate was 85.4%. Conversely, Farid et al. [4]

observed a decrease in survival rates, with 73% at 5 years and 51% at 10 years, potentially due to their higher infection rates, which were 43% compared to our rates of 29.73%. A point of concern in these comparisons was the follow-up period, which varied among the studies.

The main limitations of our study were its small sample size, retrospective cohort study design, incomplete data, and relatively short follow-up duration. Future studies should include larger patient cohorts with longer follow-up periods.

Table 2 Univariate and Multivariate Analysis of Factors Associated with RHK Implant Failure. CI, confidence interval.

Factors	Univariate			Multivariate		
	Odds ratio	95% CI	p-value	Odds ratio	95% CI	p-value
Age	1.016	0.867 – 1.191	0.841	1.011	0.865 – 1.183	0.890
Body mass index (kg/m^2)	1.279	0.906 – 1.805	0.162	0.276	0.904 – 1.802	0.165

Table 3 Survival rate of Revision RHK in Asian studies.

Author (year of publication)	No. of Knees	Duration of follow up (years)	Overall Revisions (Rate)	Revisions for Aseptic Loosening (Rate)	Revisions for Infection (Rate)	Complications (rate)	All-Cause Survivorship (Rate)
Rajgopal (2020)	117	10.3	10.2%	5.12%	5.12%	12.82%	10 years survival rate 90.65%
Hwang SC (2010)	13	2.4	38.5%	-	15.4%	38.5%	61.5%
Current study	37	2.8	5.4%	-	5.4%	5.4%	2-year survival rate 91.67%.

CONCLUSIONS

RHK implants are essential for managing complex revision knee arthroplasties. In our study, we observed a 91.67% 2-year survival rate and a 94.6% re-revision-free survival rate. Logistic regression analysis revealed that the patient characteristics were not significantly associated with the risk of RHK failure. The primary indications for RHK revision are PJI and instability. These results suggest that RHK implants effectively provide stability and control infections in cases of revision TKA.

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Seating of the Femoral Stem after Washing versus Un-washing the Femoral Canal in Cementless Short Stem Hip Arthroplasty

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Purpose: This study aimed to evaluate the effect of washing the femoral canal on the seating of the short femoral stem in cementless short-stem hip arthroplasty.
Methods: This single-center randomized controlled trial included 50 patients divided into unwashed and washed groups. All patients underwent cementless short-stem hip arthroplasty with the Metha® short-stem. The primary outcome measured was the discrepancy between the final rasp and implanted stem, with a mismatch of >2 mm considered clinically significant. Secondary outcomes included intraoperative factors associated with a significant mismatch. Univariate logistic regression analysis was used to identify factors related to a clinically significant mismatch between the final rasp and implant. The subsidence and revision were recorded at 4 years follow-up.
Results: The study found that 44% of the cases in the unwashed group had a clinically significant mismatch, compared with 8% in the washed group (P=0.001). The mean discrepancy was 2.4 mm in the unwashed group and 1.2 mm in the washed group (P<0.001). Univariate regression analysis indicated that not washing the canal was associated with a higher rate of significant mismatches (odds ratio [OR]=9.05, P=0.009). No cases of stem subsidence or revision were observed at 4 years follow-up in either group.
Conclusions: Washing the femoral canal with saline significantly reduced the discrepancy between the final rasp and the implant in cementless short-stem hip arthroplasty, potentially improving surgical outcomes and reducing leg length discrepancies.

Keywords: Total hip arthroplasty, Short stem, Rasp, Wash, Seating, Metha

Cementless conventional stems have been reported to achieve reliable clinical and radiological outcomes in total hip arthroplasty (THA), including long-term survival rates[3]. However, successful outcomes require meticulous intraoperative surgical techniques to ensure proper fit and alignment, restore normal hip biomechanics, and promote osseointegration[10-12].

Short-stem THA was developed to address several challenges, including minimizing metaphyseal-diaphyseal mismatch, stress shielding, thigh pain, periprosthetic fracture, and loss of bone stock, as well as simplifying removal during revision surgery. The design focuses on true metaphyseal anchoring without diaphyseal engagement, thereby facilitating anatomical reconstruction. This

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approach avoids disruption of the greater trochanter and preserves bone in the femoral canal, thereby improving the potential for revision situations in which a standard implant can replace the need for a long revision stem[7,9,13,18].

Differences between the final rasp used for femoral preparation and the implanted femoral stem can affect leg length, implant fit, fill, and stability, potentially compromising the clinical outcomes of surgery[16]. The effectiveness of a rasp in preparing the proximal femur for a short metaphyseal uncemented femoral stem depends on the rasp design, tolerance between the rasp and implant, and surgical technique. Husseini et al.[8] demonstrated that washing the femoral metaphysis with saline to remove bone debris after rasping and before inserting the final implant significantly decreased the mismatch between the seating of the final rasp and the implant in this cementless short, metaphyseal-filling, tapered design stem. Our randomized controlled trial (RCT) extended this by examining the effects of canal washing, thus providing a higher level of evidence on this topic. An advantage of RCT is the minimization of bias and confounding factors, which enhances the validity of the findings.

The design of the rasp is crucial for determining the fit and stability of the implants. The Metha® short-stem used in this study features a trapezoidal shape, providing a geometry that helps distribute stresses evenly across the bone-implant interface, thus reducing the risk of stress shielding and promoting bone remodeling. The rasp has a double-tapered profile, narrowing in both the mediolateral and anterior-posterior dimensions, which facilitates secure metaphyseal fixation and provides a snug fit in the femoral canal, enhancing primary stability. Additionally, the rasp is collarless, which minimizes interference with the trochanteric region and allows for a more anatomical fit. This is particularly beneficial for preserving bone stock and reducing stress concentrations. The curved distal end of the rasp was designed to contact the proximal lateral cortex, enhance the lateral load transfer, and contribute to a three-point fixation system that ensures implant stability. The rasp surface was textured to mimic the surface characteristics of the implant, assisting in preparing the bone surface for optimal osseointegration by compacting the cancellous bone and creating a favorable environment for bone ingrowth. The rasp set includes a range of sizes that correspond precisely to the Metha® short-stem implants.

This study aimed to investigate the effect of washing the femoral canal on the seating of the short femoral stem in cementless short-stem hip arthroplasty. We hypothesized that washing the femoral canal could reduce the mismatch between the seating of the final rasp and the implant in cementless short-stem THA.

METHODS

Study Design

This study was designed as a single-center randomized controlled trial (RCT). This trial aimed to evaluate the impact of washing the femoral canal on the seating of the short femoral stem in cementless short-stem hip arthroplasty. This study was approved by the Institutional Review Board of our hospital (054/2019). Patient enrollment was conducted between July 2019 and January 2020.

Participants

Fifty patients were enrolled and randomly assigned to one of two groups: unwashed or washed. The inclusion criteria included patients aged ≥15 years with good bone quality, defined by the Dorr classification[6] as types A and B. Poor bone quality was defined as Dorr type C. Patients who had undergone post-traumatic or previous hip surgery and those who refused to participate in the study were excluded.

Sample Size Calculation

The sample size was calculated based on the expected difference in the primary outcome (clinically significant mismatch) between the two groups[8]. Using a significance level of 0.05 and a power of 80%, the estimated sample size required was 25 patients per group, assuming an effect size sufficient to detect clinically significant differences between the washed and unwashed groups.

Randomization and Allocation Concealment

Randomization was conducted using a computer-generated sequence to ensure the unbiased allocation of participants to each group. Allocation concealment was achieved using sealed opaque envelopes that were opened only after the participants were enrolled and provided consent. This process minimized selection bias and maintained the integrity of randomization.

Blinding

Owing to the nature of the intervention, blinding of the surgeons was not feasible. However, the outcome assessors were blinded to the group assignments to reduce detection bias in evaluating the outcomes.

Fig. 1 Metha® short-stem.

Intervention

All procedures in this study were performed by three surgeons using the modified Hardinge approach with a Metha short-stem (Metha Short Hip Stem, B.Braun Aesculap, Tuttlingen, Germany) and a cementless acetabular cup (Plasmafit Acetabular Cup System, B.Braun Aesculap, Tuttlingen, Germany). The Metha® short-stem is a cementless, collarless, and tapered prosthesis (Figure 1). Fixation relies on a closed ring of the femoral neck and lateral neck support to ensure primary implant stability. For osseointegration, the stem was coated with a combination of plasmapore, a rough microporous titanium coating, and a thin bioactive calcium phosphate surface finish. Calcium phosphate is osteoinductive, and the porous plasmapore structure provides an optimal foundation for potential bone ingrowth. The femoral preparation of Metha® short-stem relies on a broach only technique. The implants were oversized by 0.35 mm on each side relative to the broach.

In the washed group, after rasping the canal to the proper size, canal was irrigated with 100 ml of normal saline using an Asepto syringe before femoral implantation. In the unwashed group, the femoral canal was rasped to the appropriate size for the stem but was not irrigated prior to implantation of the femoral implant.

Outcome Measurement

The primary outcome was the discrepancy between the final rasp and implanted stem, with a clinically significant mismatch defined as >2 mm[8,14]. Intraoperatively, the distance in millimeters from the medial cortex of the neck cut to the upper border of the final rasp and from the medial cortex of the neck cut to the upper border of the medial porous coating of the implanted stem, was measured using a metallic ruler by an assessor (Figures 2 and 3). Discrepancies in seating between the final rasp and implant were compared. Secondary outcomes included intraoperative factors associated with significant mismatch, subsidence, and revision rates at four years follow-up.

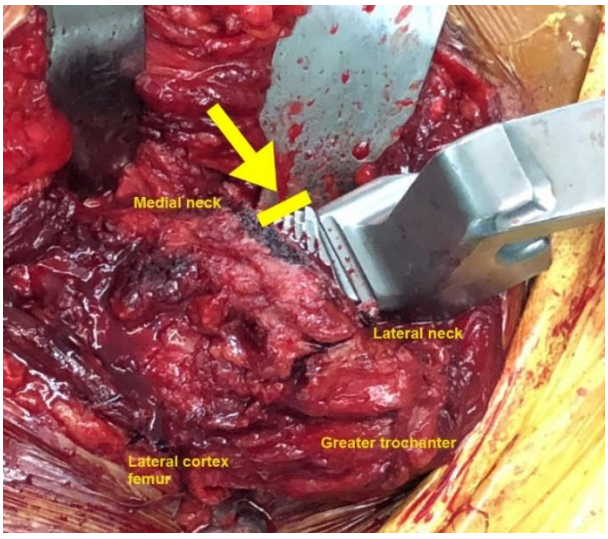

Fig. 2 The distance from the medial cortex of the neck cut to the upper border of the final rasp.

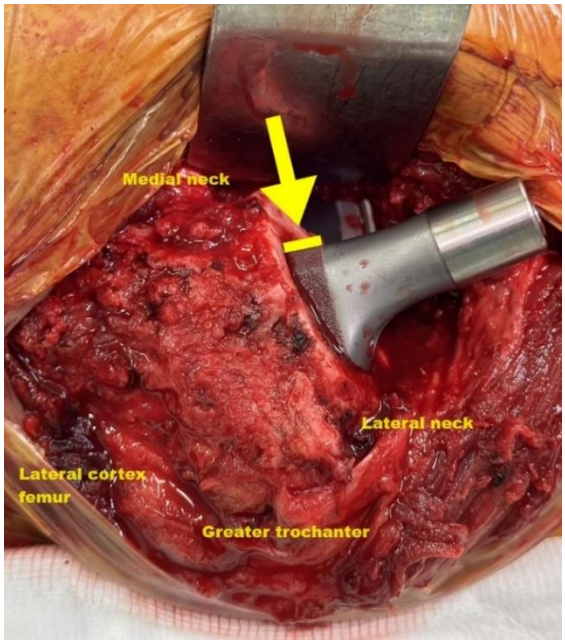

Fig. 3 The distance from the medial cortex of the neck cut to the upper border of the medial porous coating of the implanted stem.

Data Collection

Preoperative demographic data collected included patient sex, age, underlying disease, weight, height, body mass index (BMI), Dorr classification[6], surgical side, and diagnosis. The discrepancy between the distance from the medial cortex of the neck cut to the upper border of the final rasp and distance from the implanted stem was recorded.

Anteroposterior (AP) radiographs of both hips, with both legs in 15° internal rotation, and lateral cross-table radiographs were taken every 3 months during the first postoperative year, and then every 6 months thereafter. Stem subsidence >3 mm was defined as positive subsidence in comparison with radiographs taken after surgery[19]. The subsidence and revision were recorded at 4 years follow-up.

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics software (version 21.0). The Pearson chi-square test was used for categorical variables and the t-test was used for continuous variables to compare patient demographic data and discrepancies between the final rasp and implant. Univariate logistic regression analysis identified factors associated with a clinically significant mismatch between the final rasp and implant. Statistical significance was set at $P<0.05$.

Table 1 Demographic data of patients.

Parameters	Group 1 (Unwashed) (N=25)	Group 2 (Washed) (N=25)	P-value
Mean age (years) (range, SD)	49.5 (27-77, 13.7)	50.2 (27-67, 11)	0.85
Side (left/right)	10/15	10/15	1.0
Sex (male/female)	22/3	19/6	0.28
BMI (range, SD)	23.8 (15.6-34.2, 4.2)	23.6 (15.6-32.9, 3.9)	0.86
Mean follow-up (months) (range, SD)	56.3 (54-58, 1.2)	56.5 (54-58, 1.2)	0.56
Diagnosis (hips) (%)			0.41
ONFH	18 (72%)	15 (60%)	
OA	2 (8%)	3 (12%)	
FNF	3 (12%)	3 (12%)	
DDH	1 (4%)	3 (12%)	
Secondary OA	1 (4%)	1 (4%)	
Dorr classification			0.40
Type A	13 (52%)	10 (40%)	
Type B	12 (48%)	15 (60%)	

BMI, body mass index; ONFH, osteonecrosis of the femoral head; OA, osteoarthritis; FNF, femoral neck fracture; DDH, developmental dysplasia of the hip; SD, standard deviation

Ethical Considerations

The study was conducted in accordance with the principles of the Declaration of Helsinki. All participants provided informed consent, and the study protocol was approved by the IRB.

RESULTS

Of the 50 patients included in the study, 41 (82%) were male and 9 (18%) were female. The mean age was 49.9 years (27-77, SD 12.3). 30 patients (60%) underwent surgery on the right side and 20 (40%) on the left side. The mean body mass index (BMI) was 23.7 (15.6-34.2, SD 4). Preoperative diagnoses included osteonecrosis of the femoral head (ONFH) in 33 (66%) patients, osteoarthritis in 5 (10%) patients, femoral neck fracture in 6 (12%) patients, developmental dysplasia of the hip (DDH) in 4 (8%) patients and post-traumatic osteoarthritis in 2 (4%) patients. The mean follow-up was 56.4 months (54-58, SD 1.2). According to the Dorr classification, the preoperative radiographic classification of the proximal femur was type A in 23 patients (46%) and type B in 27 patients (54%). There were no significant differences in the demographic data of the patients between the two groups (Table 1).

A clinically significant mismatch (>2mm) was found in 44% (11/25) of the cases in the unwashed group and in 8% (2/25) of the cases in the washed group. A significant difference in the incidence of clinically significant mismatches (>2mm) was found between the two groups (P=0.001). The mean discrepancy between the final rasp and the final implant was 2.4 mm (range 1-6, SD 1.2) in the unwashed group and 1.2 mm (range 0-3, SD 0.9) in the washed group. A significant difference was observed in the discrepancy between the two groups (P<0.001). There was no difference in femoral stem size between the two groups (Table 2). There were 3 cases (12%) with a mismatch of 4 mm or more in the unwashed group, and the maximum mismatch was 6 mm.

The univariate regression analysis showed that canal rasping without washing is associated with significantly higher rates of clinically significant mismatch (>2mm) compared to the washed group (Odds ratio [OR]=9.05, 95% confidence interval [CI]: 1.74-46.89, P=0.009). Additionally, the analysis showed that diagnosis, Dorr classification, and femoral stem size had no significant impact on the incidence of clinically significant mismatches (>2mm) (Table 3).

There were no cases of stem subsidence or revision at 4 years follow-up in either group. There were no significant differences in stem subsidence or revision between the two groups.

Table 2 Outcomes.

Parameters	Group 1 (Unwashed) (N=25)	Group 2 (Washed) (N=25)	P-value
Mismatch (hips) (%)			0.003
≤ 2 mm	14 (56%)	23 (92%)	
> 2 mm	11 (44%)	2 (8%)	
Height different (mm, SD)	2.4 (1-6, 1.2)	1.2 (0-3, 0.9)	<0.001
Stem size			0.82
Size 0	6 (24%)	6 (24%)	
Size 1	4 (16%)	6 (24%)	
Size 2	8 (32%)	6 (24%)	
Size 3	6 (24%)	6 (24%)	
Size 4	1 (4%)	1 (4%)	

SD, standard deviation; mm, millimeter

Table 3 Association factors with a clinically significant mismatch.

Variables	Univariate Analysis		
	OR	95% CI	P-value
Unwashed vs. Washed	9.05	1.74 – 46.89	0.009
Diagnosis			
ONFH	1	-	-
OA	0.67	0.07-6.79	0.73
FNF	0.53	0.06-5.21	0.59
DDH	0.89	0.08-9.69	0.92
Secondary OA	2.67	0.15-47.30	0.50
Dorr Classification Type A vs. B	0.99	0.28-3.52	0.99
Stem Size			
Size 0	1	-	-
Size 1	0.35	0.05-2.41	0.29
Size 2	0.38	0.07-2.13	0.27
Size 3	0.28	0.04-1.88	0.19
Size 4	1.40	0.07-28.12	0.83

OR, Odds Ratio; CI, Confidence Interval, ONFH, osteonecrosis of the femoral head.
OA, osteoarthritis; FNF, femoral neck fracture; DDH, developmental dysplasia of the hips.

DISCUSSION

Leg length discrepancy (LLD) in total hip arthroplasty (THA) is a common complication that can result in patient dissatisfaction, leading to symptoms such as limping; pain in the hip, knee, or lower back; and difficulties in balancing and walking. It occurs when there is a difference in leg length after hip replacement surgery. Achieving equal leg lengths is challenging owing to factors such as preoperative planning accuracy, intraoperative techniques, and patient anatomical variations. The issue of LLD highlights the complexity of THA and the need for meticulous planning and surgical techniques. Differences between the final rasp used for femoral preparation and the implanted femoral stem can affect the leg length, implant fit and fill, and stability, potentially compromising the clinical outcomes of surgery. Therefore, achieving an accurate match between the rasp and implant is crucial to ensure the best possible surgical results. This study aimed to investigate the effect of washing the femoral canal on the seating of the short femoral stem in cementless short-stem hip arthroplasty.

The Metha® short-stem THA was developed to minimize issues such as metaphyseal-diaphyseal mismatch, stress shielding, thigh pain, periprosthetic fracture, loss of bone stock, and difficulties encountered during removal for revision. This is achieved through the true metaphyseal anchoring of the short-stem, which avoids diaphyseal engagement. This design enables better anatomical reconstruction, eliminates disruption to the greater trochanter, and preserves bone within the femoral canal[2,17,20,21]. Suksathien et al.[21] found that the Harris Hip Score improved from 44.7 to 99.6 over 7 years in 83 patients with Metha® short-stem THA, with significant bone trabeculae development indicating good implant support. Tippimanchai et al.[22] reported 98% patient satisfaction and 96.4% felt that their expectations were met, linking these outcomes to improve quality of life.

Canal rasping is a crucial step in the placement of cementless femoral components. Several studies have explored different techniques for canal preparation and assessed their impact on the initial stability of the implant. Research involving cadaveric femora and animal models has demonstrated that canal preparation using a bone

compaction technique enhances initial rotational stability and reduces implant subsidence compared to a bone extraction technique, without compromising pullout strength[23-24]. Reduced initial stability may increase micromotion at the bone-implant interface, potentially leading to the formation of fibrous tissue instead of achieving bony osseointegration[1,4,5,15].

In this study, we demonstrated that washing the femoral canal with saline to remove tissue and bone debris after the final rasping and before implanting the final stem significantly reduced the discrepancy between the final rasp and the implant in the Metha® short-stem THA. Furthermore, we observed that not washing the canal was associated with significantly higher rates of clinically significant mismatch (>2mm) (OR=9.05, 95% CI: 1.74-46.89, P=0.009). Consistent with a previous study, Husseini et al.[8] demonstrated that washing the femoral metaphysis with saline to remove bone debris, after rasping and before inserting the final implant, significantly decreased the mismatch between the seating of the final rasp and the implant in this cementless short, metaphyseal filling, and tapered design stem. The implant used in their study was the Tri-Lock® Bone Preservation Stem (DePuy Orthopedics Inc., Warsaw, IN). This short-stem type was classified by Khanuja et al.[9] as type 4 (shortened tapered conventional stem). This stem type is similar to conventional proximally porous-coated tapered designs but with a shorter stem length. In our study, we used the Metha® short-stem, which Khanuja et al.[9] classified as type 2A (trapezoidal). The stem type is collarless, trapezoidal, and double-tapered. It features a curved distal end that contacts the proximal lateral cortex, enhances lateral load transfer and provides three-point fixation.

Washing the femoral canal before cement and stem implantation is a standard procedure in cemented total hip arthroplasty (THA). This technique is essential for ensuring optimal micro-interlocking at the cement-bone interface in cemented THA, which is crucial for the stability and longevity of the implant. In contrast to cemented THA, the effect of washing the femoral canal before the implantation of a cementless femoral stem is unclear. Cleaning the bone bed may reduce the risk of fat embolism during rasping and stem insertion, and decrease the incidence of heterotopic ossification. Conversely, arguments against cleaning include preserving the compressed bone within the femoral canal to avoid additional trauma to the cancellous bone and maintaining potential growth factors in the bone marrow. In this study, we found no stem subsidence or revision at 4 years follow-up, and there was no significant difference between the two groups. Consistent with a previous study, Zampelis et al.[25] conducted a study on 40 patients with primary osteoarthritis who underwent surgery using a cementless titanium grit-blasted stem. Patients were randomized to either the jet-lavage or no-lavage groups of the femoral canal before implant insertion. Stem migration patterns were monitored using radiostereometry (RSA) at 0, 3, 12, 24, and 72 months. They found no significant differences in the extent or pattern of migration as measured by RSA after six years, and no stems were revised or found to be loose. They concluded that washing the bone bed with jet-lavage prior to the insertion of cementless stems did not affect the stability of the cementless femoral components.

The limitations of this study include variations in surgical techniques among different surgeons, which may have introduced variability in the outcomes. This could be mitigated in future research by standardizing the surgical procedures or limiting the study to a single experienced surgeon. Additionally, the forces applied during rasping and insertion, which could influence implant seating, were not measured. Future research should include precise measurements of these forces to better understand their effect. The definition of a clinically significant mismatch of >2 mm may also be contentious, considering that head-length adjustments can potentially accommodate discrepancies of up to 3.5 mm. Future studies should explore different thresholds for clinical significance and employ more precise assessment methods. Furthermore, the single-center design and relatively small sample size of the study may limit the generalizability of the findings. Larger multicenter trials are recommended to enhance the

external validity of the results and provide more robust evidence on the effect of washing the femoral canal in hip arthroplasty procedures.

CONCLUSIONS

This study demonstrated that washing the femoral canal with saline before implanting the final stem in cementless short-stem hip arthroplasty significantly reduced the discrepancy between the final rasp and the implant. Washing of the canal significantly improves implant separation and enhances surgical outcomes. This mismatch reduction suggests that canal washing may be a beneficial step during surgical procedures.

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Effectiveness of the Capture the Fracture Program for Patients with Hip Fractures at Phrae Hospital: A 2-Year Follow-up After Surgery

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Purpose: To determine the effectiveness of the Capture the Fracture (CTF) program in preventing refractures, improving Barthel index scores for activities of daily living (ADL), and reducing mortality rates in patients with hip fractures.
Methods: This study enrolled patients with fragile hip fractures aged ≥50 years who underwent hip fracture surgery. The participants were classified into the intervention and control groups, each consisting of 46 patients. The intervention group underwent the CTF program with a multifactorial approach, whereas the control group received routine care. Participants were followed up 1 and 2 years postoperatively to assess outcomes, including the Timed Up and Go test, balance test, Barthel index scores for ADL, fall risk assessment, refracture, and mortality rate.
Results: In the intervention group, no recurrent fractures occurred within 1 year, compared to 6.5% in the control group (p=0.106). At the 2-year postoperative follow-up, 4.9% of the intervention group experienced recurrent fractures, whereas the control group had no fractures (p=0.508). The 2-year postoperative mortality rate was 18.0% and 37.0% in the intervention and control groups, respectively (p=0.042).
Conclusions: Multidisciplinary teams should implement the CTF program using a multifactorial approach to physical rehabilitation in patients with hip fractures. This program improved participants' quality of life and reduced the mortality rate 2 years postoperatively.

Keywords: the CTF program, hip fracture patients, recurrent fractures, mortality rate, Multidisciplinary teams

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Thailand's population is aging, and the number of patients with hip fractures is expected to increase from 180 cases per year to 450–750 cases per 100,000 older people by 2025[(1)]. The treatment-related economic burden to the government is estimated at 120,000 baht per case, with the cost of care post-discharge to the community reaching approximately 1.2 million baht per case[(2)]. The recurrence rate of hip fractures is 10%, with other fractures occurring at a rate of 12–20%. Hip

fractures pose a major challenge for patients and hospitals as 25% of patients die within 1 year, 40% experience reduced mobility, and over 80% require assistance with activities of daily living (ADL)[3]. Additionally, 10–20% of patients become bedridden within a year[4-7]. The International Osteoporosis Foundation (IOF) has reported a global gap in preventing recurrent fractures[8]. To address this, the IOF developed the Capture the Fracture® (CTF) program, which implements the Fracture Liaison Service (FLS) as an effective model to reduce the incidence of recurrent fractures[9]. The FLS consists of six components, including osteoporosis treatment, fall risk assessment, exercise program, nutrition education program, environmental modification, and community referral[10].

The FLS standards by the IOF focus on identifying target groups (men and women aged ≥50 years with osteoporotic fractures) to prevent recurrent fractures. This purpose employs instruments such as FRAX or the Garvan fracture risk assessment tool[10], bone density measure-ments, and fall risk assessment. Recommendations include promoting lifestyle and nutritional improvement, osteoporosis treatment, ensuring ongoing coordination of care between specialists and general practitioners, regular quality assessment, and preventing recurrent fractures[11]. In a 2011 study, patients enrolled in the FLS program had a refracture rate of 7.3% compared to 17% in the control group, indicating a significant 57% reduction in refractures[12]. Therefore, patients should be evaluated for osteoporosis and receive appropriate treatments such as calcium and vitamin D supplementation, strategies to increase bone density, and measures to reduce fall risk to decrease the incidence of hip and non-hip fractures. Measures to reduce the risk of falls, including home modifications and exercise programs, are recommended. Additionally, medications to treat osteoporosis, such as bisphosphonates, teriparatide, or denosumab are crucial. Multifactorial management in CTF clinics has been shown to significantly reduce refracture rate in patients with hip fractures[13,14].

Thailand became a completely aged society by 2023, with at least 20% of the population aged ≥60 years[15]. This demographic change affects the economic and social aspects, including the organization of welfare state systems, the quality of life for older adults, and the annual increase in healthcare expenditure. The high proportion of older people leads to age-related diseases such as osteoporosis and hip fractures, posing major challenges for the local healthcare system and social services.

In 2018, the CTF team established a CTF clinic to provide comprehensive care through a multidisciplinary team. This team provides assessment and treatment of osteoporosis by physicians, including calcium and vitamin D, fall risk assessment by nurses, education on environmental changes, and exercise programs for skills development. Physiotherapists perform follow-ups with Time Up and Go (TUG) and balance tests, whereas nutritionists assess and monitor nutritional status using body mass index (BMI) and albumin measurements, all within a multifactorial intervention framework.

Therefore, this study aimed to investigate the over 2 years postoperative effectiveness of the CTF program in reducing the incidence of recurrent fractures, improving functional capacity, and decreasing mortality in patients with hip fractures; the ultimate goal is to improve the care process for patients with hip fractures and expand the program to community hospitals.

METHODS

Study Design

Efficacy (Therapeutic) Research, non-randomized Controlled Trial.

Setting

Orthopedic Surgery and Orthopedic Clinic Outpatient Departments.

Study Population

Patients aged ≥50 years who underwent hip fracture surgery for fragility hip fractures.

Inclusion Criteria

1. Patients aged ≥50 years with hip fractures resulting from falls who were surgically

treated and discharged from the orthopedic department.

2. Patients with a BARTHEL Index score for ADL >16.

Exclusion Criteria

1. Patients with hip fractures who have an underlying disease that impairs ADL, including end-stage renal disease, congestive heart failure, a history of brain disease that impairs communication (such as Alzheimer's disease), previous cerebrovascular accidents (CVA) with weakness less than GRADE 4, pathologic fractures, or cancer with bone metastases.

2. Patients who experienced postoperative falls in the hospital and CVA readmission.

3. Patients with multiple fractures

Sample Size

The study used the TUG test to measure balance. A pilot study reported a mean TUG value of 30 ± 15.0 s in the control group and 19.8 ± 15.1 s in the intervention group. With a two-tailed test, a significance level of 5%, and a power of 90%, the calculated sample size was 46 patients per group.

Intervention Group

Patients received the CTF program with a multifactorial intervention approach.

Control Group

Patients received standard care, including

- X-ray follow-up for union fracture.
- Clinical follow-up (fracture union, walking ability, calcium, and vitamin D supplement).

Definition of Terms

Fragility fracture: Fractures resulting from low-energy trauma, such as a fall from standing height or less, indicated an underlying osteoporosis.

Variables

Independent variables: The CTF program incorporates a multifactorial intervention approach, including:

1. Physician: FRAX assessment, osteoporosis treatment, and albumin and TUG assessment.

2. Nurse: environmental change education and fall risk assessment.

3. Physiotherapists: exercise program.

4. Nutritionist: education on proper nutrition

Dependent Variables

TUG test, balance test (tandem standard), Barthel index, fall risk assessment tool (Thai falls risk assessment test [FRAT]), refracture, and mortality rate.

Data Collection Methods and Instruments

Patients attending the fracture prevention clinic who underwent the FLS program, including:

1. Osteoporosis assessment and treatment.

2. Fall risk assessment and environmental modification education by nurses.

3. Exercise program and TUG balance test follow-up by physiotherapists.

4. Nutrition education and follow-up with BMI and albumin assessment by nutritionists.

Patients were followed up at 1 and 2 years postoperatively at the Fracture Prevention Clinic, Orthopedic Clinic, and Department of Orthopedic Surgery every third Wednesday of the month.

Data Analysis

Data were analyzed using descriptive statistics, t-tests, and the exact probability test.

Institutional Review Board Statement

This study was approved by the Ethics Committee for Research Involving Human Subjects with approval number 23/2566.

RESULTS

The baseline characteristics of the intervention and control groups were not significantly different. In both groups, the majority of participants were women, accounting for 96.0% and 87.0% in the intervention and control groups, respectively (p=0.147). In the intervention group, 36.0% of the participants were aged >80 years, whereas 45.7% in the control group were aged 71–

80 years (p=0.146). BMI was <18.5 kg/m² in 40.0% and 43.5% of the intervention and control groups, respectively (p=0.964). (Table 1)

Clinical characteristics were similar in the intervention and control groups, with hip injuries predominantly in the intertrochanteric region (74.0% and 76.1%, respectively) (p=1.000). Most surgeries were performed with fixation devices, such as proximal femoral nail anti-rotation and G-nail, in 74.0% and 73.9% of the intervention and control groups, respectively (p=0.811).

In the intervention group, 40.0% had two comorbid medical conditions, and 70% were classified as the American Society of Anesthesiologists (ASA) class I or II, with 58.0% having Charlson comorbidity index (CCI) scores of 1 or 2. In the control group, 30.4% had a single geriatric disease, 60.9% were classified as ASA class I or II, and 58.7% had CCI scores of 1 or 2 (p=0.321, 0.394, and 0.138, respectively).

The lengths of stay ≤5 days were 76.0% and 50.0% in the intervention and control groups, respectively (p=0.011). In addition, 70.0% and 43.5% of the intervention and control groups, respectively, underwent surgery within 48 h and had length of stay ≤5 days (p=0.013).

FRAX (Hip fracture) scores ≥3% were observed in 74.0% and 82.6% of the intervention and control groups, respectively (p=0.335). In the intervention group, 62.0% had an albumin level <3.5 g/dL at baseline, while at the 1-year postoperative follow-up, 74.0% had an albumin level ≥3.5 g/dL. In the control group, 69.6% had an albumin level <3.5 g/dL at baseline, whereas at 1-year postoperative follow-up, 50.0% had an albumin level ≥3.5 g/dL. At 1-year follow-up, albumin levels were significantly different between the two groups (p=0.020).

Calcium and vitamin D supplementation was implemented in 88.0% and 67.4% of the intervention and control groups, respectively (p<0.001) (Table 2).

The 1-year postoperative fall scores differed significantly between the two groups (p=0.020). In the intervention group, 90% of patients had a fall score ≥4 pre-discharge, while 26% had a fall score ≥4 1 year postoperatively. Conversely, in the control group, 83.0% had a fall score ≥4 pre-discharge, and 50.0% had a fall score ≥4 1 year postoperatively.

Table 1 Baseline characteristics.

Baseline characteristics	Intervention group		Control group		p-value
	N	%	n	%	
Sex					
Male	2	4.0	6	13.0	0.147
Female	48	96.0	40	87.0	
Age (years)					
50–60	6	12.0	3	6.5	
61–70	10	20.0	4	8.7	
71–80	16	32.0	21	45.7	
> 80	18	36.0	18	39.1	
mean (SD)	74.6	(9.3)	77.2	(8.0)	0.146
Body mass index (kg/m²)					
< 18.5	20	40.0	20	43.5	
18.5–22.9	15	30.0	18	39.1	
≥ 23	15	30.0	8	17.4	
mean (SD)	20.0	(3.8)	19.9	(4.0)	0.964

SD, standard deviation

Table 2 Clinical characteristics.

Clinical characteristics	Intervention group		Control group		p-value
	N	%	n	%	
Diagnosis					
Femoral neck	13	26.0	11	23.9	1.000
Intertrochanteric	37	74	35	76.1	
Surgery					
Dynamic hip screw	0	0	1	2.1	0.811
PFNA, G-nail	37	74.0	34	73.9	
Austine Moor, Bipolar	13	26	11	23.9	
Comorbidity					
No	14	28.0	11	23.9	0.321
1	10	20.0	14	30.4	
2	20	40.0	11	23.9	
3	5	10.0	7	15.2	
>3	1	2.0	3	6.5	
ASA classification					
Ⅰ – Ⅱ	35	70.0	28	60.9	0.394
Ⅲ–Ⅳ	15	30.0	18	39.1	
Charlson Comorbidity Index score					
0	16	32.0	12	26.1	0.840
1–2	29	58.0	27	58.7	
3–4	4	8.0	6	13.0	
>4	1	2.0	1	2.2	
mean (SD)	1.1	(1.2)	1.5	(1.3)	0.138
Waiting time for surgery (hours)					
≤48	43	86.0	35	76.1	0.296
>48	7	14.0	11	23.9	
LOS (days)					
≤ 5	38	76.0	23	50.0	0.011
>5	12	24.0	23	50.0	
Surgery within 48 h and LOS ≤5 days					
Yes	35	70.0	20	43.5	0.013
No	15	30.0	26	56.5	
FRAX (Hip Fracture %)					
<3	13	26.0	8	17.4	0.335
≥3	37	74.0	38	82.6	
Preoperative albumin level (g/dL)					
<3.5	31	62.0	32	69.6	0.521
≥3.5	19	38.0	14	30.4	
Postoperative albumin level at 1-year follow-up (g/dL)					
<3.5	13	26.0	23	50.0	0.020
≥3.5	37	74.0	23	50.0	

Table 2 Clinical characteristics. (Cont.)

Clinical characteristics	Intervention group		Control group		p-value
	N	%	n	%	
Medication use					
No	0	0.0	11	23.9	<0.001
Ca, vit D	44	88.0	31	67.4	
Vit D, bisphosphonate	0	0.00	1	2.2	
Ca, vit D, bisphosphonate	6	12.0	3	6.5	

ASA, American Society of Anesthesiologists; LOS, length of stay; PFNA, proximal femoral nail anti-rotation

Quality of life before falls (measured by the Barthel Index) showed no significant difference between the groups (p=0.707), with both groups having scores of ≥19–20 (94.0% and 91.3%, respectively). At 1-year postoperative follow-up, 76.0% and 43.5% of the intervention and control groups, respectively, had Barthel Index scores ≥19–20 (p<0.001). At 2-year postoperative follow-up, 65.9% and 75.9% of the intervention and control groups, respectively, had Barthel Index scores ≥19–20 (p=0.275).

One year postoperatively, TUG was ≤30 s in 68% of the intervention group, compared to 41.3% in the control group (p<0.001). At 2-year postoperative follow-up, TUG was ≤30 s in 87.8% and 72.4% of the intervention and control groups, respectively (p=0.126).

One year postoperatively, the balance test time was ≥20 s in 62.0% of the intervention group, compared to 32.6% in the control group (p=0.002). At 2-year postoperative follow-up, the balance test time in both groups was ≥20 s in 63.4% and 24.1%, respectively (p=0.003) (Table 3).

No recurrent fractures occurred in the intervention group within the first year, while the control group had a 6.5% recurrent fracture rate (p=0.106). At 2-year postoperative follow-up, no recurrent fractures occurred in the control group, while the intervention group had a 4.9% recurrent fracture rate (p=0.508).

In the intervention group, an 18.0% mortality rate was reported 2 years postoperatively, compared to 37.0% in the control group (p=0.042) (Table 4).

Table 3 Outcomes at 1- and 2-year postoperative follow-up.

Outcomes	Intervention group		Control group		p-value
	N	%	N	%	
Pre-discharge fall score (points)					
≥4	45	90	38	82.6	0.375
<4	5	10	8	17.4	
1-year postoperative fall score (points)					
≥4	13	26.0	23	50.0	0.020
<4	37	74.0	23	50.0	
Pre-fall Barthel index (points)					
16–18	3	6.0	4	8.7	0.707
19–20	47	94.0	42	91.3	
Pre-discharge Barthel index (points)					
≤15	48	96.0	46	100.0	0.496
16–18	2	4.0	0	0.0	

Table 3 Outcomes at 1- and 2-year postoperative follow-up. (Cont.)

Outcomes	Intervention group		Control group		p-value
	N	%	N	%	
1-year postoperative Barthel index (points)					
≤15	0	0.0	7	15.2	<0.001
16–18	12	24.0	19	41.3	
19–20	38	76.0	20	43.5	
2-year postoperative Barthel index (points)					
<16	2	4.9	3	10.3	0.275
16–18	12	29.2	4	13.8	
19–20	27	65.9	22	75.9	
1-year postoperative TUG (seconds)					
≤30	34	68.0	19	41.3	0.013
>30	16	32.0	27	58.7	
2-year postoperative TUG (seconds)					
≤30	36	87.8	21	72.4	0.126
>30	5	12.2	8	27.6	
1-year postoperative balance test (seconds)					
≤10	11	22.0	26	52.5	0.002
11–19	8	16.0	5	10.9	
≥20	31	62.0	15	32.6	
2-year postoperative balance test (seconds)					
≤10	12	29.3	17	58.6	0.003
11–19	3	7.3	5	17.3	
≥20	26	63.4	7	24.1	

TUG, Time Up and Go

Table 4 Comparison of recurrent fracture and mortality rates at 2-year postoperative follow-up.

Recurrent Fracture and Mortality Rates	Intervention group		Control group		p-value
	n	%	n	%	
Recurrent fracture 1 year after surgery					
Yes	0	0.0	3	6.5	0.106
No	50	100.0	43	93.5	
Recurrent fracture 2 years after surgery					
Yes	2	4.9	0	0.0	0.508
No	39	95.1	29	100	
Mortality 2 years after surgery					
Yes	9	18.0	17	37.0	0.042
No	41	82	29	63.0	

DISCUSSION

The Recurrent Fracture Prevention Clinic at the Hospital implements the CTF program with a multidisciplinary team, including doctors who diagnose osteoporosis using techniques such as dual-energy X-ray absorptiometry scans to determine bone mineral density and vertebral fracture assessment. Treatment for osteoporosis was guided

by the Thai and international clinical practice guidelines, which categorize patients into high- and very-high-risk groups, with treatment plans tailored accordingly. According to previous studies, all patients received vitamin D supplementation to reduce the fall risk[16]. The recommendations emphasize vitamin D supplementation, medication use assessment, and comorbidities management to prevent falls, addressing health risk factors through a multifactorial approach[17-20]. Studies evaluating vertebral fractures have shown that fractures can manifest with or without symptoms, necessitating spine X-ray evaluation and treatment, as they are associated with frailty and lead to reduced quality of life and increased disability and mortality[21-23].

In this study, after 1 year of follow-up in the CTF program, no recurrent fractures or mortality was recorded among the participants. In contrast, the control group had a 6.5% incidence of refractures. During the 2-year postoperative follow-up, the intervention group had a 4.9% incidence of refractures, while the control group had no recurrent fractures due to discontinuation of the program after the first year. The control group did not attend follow-up appointments after 1 year, and patients with poor TUG scores did not follow up after 1 year. These results are consistent with those of the FLS study[24], which also demonstrated a lower mortality rate. Additionally, meta-analyses have shown that vitamin D supplementation with or without calcium does not reduce the incidence of falls in older adults[25]. Similarly, a meta-analysis found that vitamin D supplementation with or without calcium did not prevent hip fractures in older individuals residing in hospitals or care facilities[25]. Nurses provide education and assess risk factors for falls to prevent recurrent falls, promote proper self-care, and improve home safety to reduce risk factors. In this study, tailored and intensive training was provided in various ways that were suitable for both individuals and their primary caregivers. It was found that older people with hip fractures can improve home safety in practice.

After completing the CTF program for 1 year, the percentage of participants with a high risk of falling (fall score ≥4) decreased from 90% to 26%, with no fracture recurrence within 1 year. However, some individuals still required government support for home improvements. This finding is consistent with that of a previous study, which showed that assessing and improving home safety reduced the risk and incidence of falls by 19% and 12%, respectively[26]. Older individuals are recommended to undergo a home safety assessment and receive individualized guidance. However, previous studies have shown that individualized risk factor assessment and multifactorial intervention over a 1-year follow-up period did not significantly affect hip fracture rate, fall average, or mortality rate. These results are not consistent with those reported in this study.

Nutritionists provide education and guidance on behavioral modification and nutritional care for patients, family members, and caregivers. The impact of the CTF program on albumin levels, nutritional knowledge, and dietary recommenddations for patients and their families was monitored for 1 year. Monitoring blood albumin levels revealed that 31 cases in the intervention group had levels below 3.5 g/dL preoperatively. Upon re-examination, 18 older patients showed improved albumin levels exceeding 3.5 g/dL, indicating better nutritional status in the intervention group compared to the control group. Nutritional counseling for older patients with hip fractures participating in the program included recommendations such as adding one egg per meal, increasing consumption of high-fiber foods (e.g., fruits), and maintaining dietary logs to identify beneficial foods. For cases of malnutrition diagnosed by the physician, where serum albumin levels were <3.5 g/dL, pre-serum albumin levels were <157 mg/L, and lymphocyte counts were <2,000 /mm^3, a nutritional assessment and therapy are crucial to ensure patients receive adequate energy and nutrients. This approach can mitigate malnutrition-associated risk of complications and mortality, enhance immunity, and empower older adults to manage their nutritional status. Effective nutritional care promotes sufficient nutrient intake, facilitates patient recovery, and expedites the return to normalcy[27].

Physical therapists use exercise programs to assess physical abilities, mobility, posture, and muscle strength. This study found that within 1 year postoperation, 76.0% of the intervention group had a Barthel Index score of ≥19–20 compared to 42.6% in the control group[28]. This difference persisted at the 2-year postoperative follow-up, with 54.0% and 47.8% of the intervention and control groups having Barthel Index scores ≥19–20, respectively. These findings suggest that the continuous exercise stimulation after the CTF program improved postural control, flexibility, and muscle strength recovery. At the 1-year postoperative follow-up, 68% of the intervention group completed the TUG Test in ≤30 s, compared to 41.3% in the control group. At the 2-year postoperative follow-up, an increased proportion of both groups achieved this time, with 87.8% and 73.3% in the intervention and control groups, respectively. Regarding the balance test, 62.0% and 32.6% of the intervention and control groups achieved a test time ≥20 s at the 1-year follow-up, respectively; the proportion was 63.4% and 26.7%, respectively, at the 2-year follow-up. A mortality rate of 18.0% and 37.0% was reported in the intervention and control groups, respectively. Thus, older patients with hip fractures who received the CTF program to treat osteoporosis and improve nutrition could recover physically, regain near-normal function, and develop stronger leg muscles. The intervention group had a significantly lower mortality rate compared to the control group 2 years after hip fracture surgery. This is consistent with the results of the FLS programs, which have demonstrated a 35% reduction in mortality rates compared to those who did not participate in the program[29]. However, the lack of continuity in the postoperative care provided by the CTF program over 1–2 years could negatively affect the ability to perform ADL, muscle strength, and flexibility and increase the risk of recurrent fractures.

Patients with hip fractures who participated in the CTF program, a multifactorial intervention, for 1 year and were subsequently followed up for 2 years in the Osteoporosis Prevention Clinic showed promising results. Among the 50 patients enrolled in the CTF program, none experienced recurrent fractures, whereas 6.5% of the 46 patients in the control group did. Moreover, 76.0% of the intervention group demonstrated near-normal abilities to perform daily activities compared to 43.6% in the control group. At the 2-year postoperative follow-up, nine out of the 50 patients in the intervention group had died, compared to 17 out of 46 patients in the control group. The mortality rate in the control group was 37.0%, aligning with the previous study, which also reported a 35% reduction in mortality[29]. These results indicate the effectiveness of the CTF program in reducing the risk of recurrent fractures and mortality in patients with hip fractures.

The CTF program follows the principles outlined in the Type A FLS by Ganda et al., which emphasizes clear identification of target populartions, assessment, diagnosis of osteoporosis, and treatment provision, resulting in a 35% reduction in mortality[30]. This approach is consistent with the UK National Osteoporosis Society FLS clinical trial, which is based on the 5IQ principles and effectively covers the care of older patients with hip fractures.

The strength of the CTF program lies in its interdisciplinary approach, with a team continuously addressing individual risk factors. This includes nutritionists who tailor the diet and physicians who provide vitamin D and calcium supplementation.

However, the CTF program has some limitations, particularly regarding patient accessibility to the Fracture Prevention Clinic. Transportation challenges for patients and their families may lead to discontinuity in postoperative follow-up assessments and exercises. Therefore, expanding the establishment of Fracture Prevention Clinics in community hospitals with potential capabilities is recommended to improve accessibility.

Recommendations

1. Continuity of care: Encourage continued participation in the CTF program beyond the initial 1 year and facilitate referrals to geriatric clinics, family medicine centers, and community-based long-term care or Home Health Care services for ongoing care.

2. Comprehensive care: Further studies on the impact of social support and environmental modifications on recovery, including enhancing home safety and assisting with daily activities for patients after hip fracture surgery, are required.

3. Program expansion: Consider expanding fracture prevention clinics to community hospitals within the Ministry of Public Health with suitable resources to ensure broader access to care.

CONCLUSIONS

The CTF program is an effective multi-disciplinary model for optimizing care in patients with hip fractures to prevent recurrent falls and refractures. This approach involves assessing fall and fracture risk factors using the Thai FRAT self-assessment questionnaire and implementing interventions such as exercise, nutritional optimization, and vitamin D and calcium supplementation. Therefore, healthcare teams should consider adopting the CTF program, which has been shown to facilitate patients' return to normal activities and reduce postoperative mortality rates in patients with hip fractures when monitored over 2 years.

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Early Hip Dislocation Rate in a Consecutive Series of 1093 Primary Total Hip Arthroplasties Using Imageless Navigation

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Purpose: Postoperative hip dislocation remains a major complication in total hip arthroplasty. Various studies have demonstrated that several factors influence dislocation. While computer-assisted navigation has been proposed to enhance component alignment, its impact on dislocation rates remains unclear. This study aimed to investigate the early dislocation incidence and associated risk factors in primary total hip arthroplasty (THA) using imageless navigation.
Methods: A retrospective review of patients undergoing imageless-navigated THA between February 2013 and December 2022 was conducted. Inclusion criteria comprised primary THA with a minimum 6-month follow-up. Statistical analysis included univariate regression to identify dislocation risk factors.
Results: A total of 1093 THAs were analyzed. Dislocation occurred in 16 cases (1.5%), six in elective procedures (0.76%), and 10 in femoral neck fracture (FNF) (3.28%). The univariate regression analysis revealed that FNF emerged as a significant risk factor (OR = 4.418, P = 0.004), while age, gender, femoral head size, and save zone cup placement of Lewinnek did not significantly affect dislocation rates.
Conclusions: Navigation use showed a reduced rate of early dislocation. FNF is a factor associated with postoperative hip dislocation in primary THA.

Keywords: Primary, Total hip arthroplasty, Dislocation, Imageless computer navigation

Dislocation after total hip arthroplasty (THA) is a major cause of revisions in the United States [1], presenting as one of the most challenging complications in orthopedic surgery. This issue holds significant implications for both patient outcomes and healthcare costs [2,3]. The incidence of dislocation is 1%–4% in primary THA [4,5] and mostly occurs within the first 3-6 months after surgery. Approximately 75% of dislocations occur within the first year, with recurrent dislocations affecting 16%–59% of patients [6-8].

The causes of THA dislocation are multifactorial [9-11], and one major factor is acetabular cup malalignment. According to Wera et al [12], the most common causes of unstable THA are acetabular cup malposition (33%) and abduction deficiency (36%).

Many previous studies demonstrated that navigation use is associated with reduced outliers of abduction and anteversion angles [13-20]. In our prior investigation, Suksathien et al. [21] demon-

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strated the precision of acetabular cup placement using imageless computer navigation, with 100% of cases being within Lewinnek's safe zone in both abduction and anteversion angles. However, few studies have addressed the clinical benefits derived from using computer navigation, especially in decreasing dislocation [22].

This study aimed to analyze the incidence and identify the risk factors of early THA dislocation using imageless navigation.

MATERIALS AND METHODS

This study retrospectively reviewed patients who underwent primary THA from February 2013 to December 2022. The inclusion criteria were patients who underwent THA using imageless computer navigation and had a minimum follow-up of 6 months. The exclusion criteria included dislocation due to a high-energy mechanism, revision cases, and the absence of radiographic data. It was approved by our Institutional Review Board (No. 045/2024). Of these, 659 were men (60.3%) and 434 were women (39.7%). The mean age of the patients was 53.5 years (range, 15-101 years). A total of 1,093 patients were enrolled: 598 cases (54.7%) were diagnosed with osteonecrosis of the femoral head (ONFH), 305 cases (27.9%) had a femoral neck fracture, 130 cases (11.9%) had primary osteoarthritis of the hip (1° OA), and 60 cases (5.5%) had developmental dysplasia of the hip (DDH) (Table 1).

Surgical Technique

Imageless navigation was utilized in all hips using THA cup-only software of the OrthoPilot (Aesculap AG) by three experienced surgeons (SY, SJ, and TT.) through a modified Hardinge approach. Two small pins were inserted into the ipsilateral iliac crest, one centimeter above the anterior superior iliac spine (ASIS), and connected with a two-pin transmitter fixation. A navigation passive transmitter was attached to the two-pin transmitter fixation and the bony landmarks which are both ASIS and pubic symphysis were registered by using a straight pointer. The OrthoPilot software uses registered data to generate a digitized anterior pelvic plane (APP), which is used as a reference plane for determining the abduction and anteversion angles of the acetabular cup.

The cementless acetabular cup (Plasmafit, B.Braun Aesculap, Tuttlingen, Germany) with a polyethylene liner (Vitelene, Vit E Stabilized Highly Crosslinked Polyethylene, B.Braun Aesculap, Tuttlingen, Germany) was used in all hips, with target angles for acetabular cup abduction and anteversion of 40° and 15°, respectively. The number of fixation screws used depended on the bone quality and implant stability. A metal head was used in all hips. The 28 mm diameter was used in 43 cases (3.9%), 32 mm in 470 cases (43%), and 36 mm in 580 cases (53.1%) (Table 1)

Regarding the femoral cementless stem, both short (Metha, B.Braun Aesculap, Tuttlingen, Germany) and conventional stems (Excia, B.Braun Aesculap, Tuttlingen, Germany) were utilized. The Metha stem, designed for metaphyseal fitting without diaphyseal anchorage, was chosen for young patients with good bone quality and who were diagnosed with DDH, ONFH, and OA. For elderly patients with good bone quality, the Excia stem was used. In cases of poor bone quality and advanced age, a cemented stem (cemented Excia) was preferred to prevent intraoperative periprosthetic fractures and subsidence.

Table 1 Demographic data.

Parameter	Values
No of Hip	1093
Mean age (yr) (range, SD)	53.5 (15-101, 15.3)
Gender (male/female)	659/434
Diagnosis, n (%)	
Elective case	788 (72.1%)
ONFH	598
OA	130
DDH	60
Femoral neck fracture (non-elective)	305 (27.9%)
Femoral head size, n (%)	
28 mm	43 (3.9%)
32 mm	470 (43%)
36 mm	580 (53.1%)
Mean cup abduction angle (degree) (range, SD)	41.6 (34-50, 2.5)
Mean cup anteversion (degree) (range, SD)	10.3 (6-16, 2.1)

Post-Operative Protocol

Patients were allowed to stand and progress to full weight-bearing using crutches or walkers on the second postoperative day. A standard protocol for anteroposterior (AP) digital radiographs of both hips with both legs at 15° internal rotation and lateral cross-table were conducted on the first postoperative day and at each follow-up period. Patients were routinely contacted every 3 months during the first postoperative year and then every 6 months thereafter.

Postoperative AP digital radiographs were calibrated using a known femoral head size to minimize magnification errors. The cup abduction angle was assessed by forming an angle with the acetabular cup in an AP view, referencing the inter-teardrop line. Anteversion was calculated using Liaw's method [23-24].

Statistical Analysis

A univariate regression analysis was conducted to determine the factors associated with early dislocation, including age (≥ 60 years), gender, diagnosis, abduction angle, anteversion angle, and femoral head size. Statistical analyses were performed using SPSS version 25.0 (SPSS Inc., Chicago, IL), with significance set at $p < 0.05$.

RESULTS

In the entire cohort, dislocation occurred in 16 cases (1.5%), with the mean time to dislocation of 3.2 weeks (range, 2-8) after the index surgery. Among the cases of dislocation, the mean age was 61.7 (range, 48-88) years, affecting 10 men and 6 women. This included 6 cases of elective procedures (0.76%) (2 cases of ONFH, 2 cases of OA, and 2 cases of DDH) and 10 cases of FNF (3.28%) (Table 2).

The univariate regression analysis revealed that factors such as age, gender, femoral head size, and cup alignment within Lewinnek's safe zone did not significantly influence early dislocation. However, the diagnosis of FNF emerged as a significant influencing factor [odds ratio (OR) = 4.418; 95% confidence interval (CI) = 1.592 – 12.264; p = 0.004] (Table 3).

The mean abduction angle of the acetabular cup was 40.8° (range, 34–50°), and the mean anteversion was 8.8° (range, 6–15°) (Table 2). Thirteen cases were successfully managed with close reduction under fluoroscopy, one underwent open reduction, and two underwent revision to enhance stability by increasing the head length. (Table 4)

Table 2 Details of patients with dislocation.

Parameter	Values
Number (n) (%)	16/1093 (1.5%)
Mean time from index surgery	3.2 weeks
Mean age (yr) (range, SD)	61.7 (48-88, 15.31)
Gender (men/women)	10/6
Diagnosis, n (%)	
Elective case (788/1093)	6 (0.76%)
ONFH	2
OA	2
DDH	2
Femoral neck fracture (non-elective) (305/1093)	10 (3.28%)
Femoral head size, n (%)	
28 mm	1 (6.25%)
32 mm	9 (56.25%)
36 mm	6 (37.5%)
Mean cup abduction angle (degree) (range, SD)	40.88 (34-50, 2.4)
Mean cup anteversion (degree) (range, SD)	8.87 (6-15, 2.17)

Table 3 Result of univariate regression analysis of 16 cases with dislocation.

Variables	OR	95%CI	*P*-value
Age (≥60)	1.427	0.527 – 3.861	0.484
Gender			
Male	1.099	0.397 – 3.046	0.856
Diagnosis			
Elective case (ONFH, DDH, OA)	Ref		
Femoral neck fracture	4.418	1.592 – 12.264	0.004
Femoral head diameter			
36 mm	Ref		
32 mm	2.274	0.268 – 19.327	0.452
28 mm	1.860	0.657 – 5.265	0.657

Table 4 Details of dislocation cases.

No	Age	Gender	Diagnosis	Femoral head size	Abduction angle	Anteversion Angle	Time to dislocation	Treatment
1	59	M	ONFH	32	38	8	2 weeks	Revision
2	50	F	NOF	28	35	9	2 weeks	Closed reduction
3	52	F	NOF	32	43	7	2 months	Closed reduction
4	74	F	NOF	32	46	12	1 week	Revision
5	53	F	NOF	32	39	9	1 month	Closed reduction
6	48	M	DDH	32	39	8	1 week	Closed reduction
7	73	M	OA	36	47	7	3 weeks	Closed reduction
8	56	M	NOF	36	41	8	3 weeks	Closed reduction
9	88	M	NOF	32	34	6	1 month	Closed reduction
10	52	M	DDH	32	50	12	1 month	Closed reduction
11	50	F	NOF	36	37	7	1 week	Closed reduction
12	58	M	ON	36	44	15	2 months	Closed reduction
13	73	M	OA	36	42	7	3 weeks	Closed reduction
14	63	M	NOF	32	39	10	1 week	Closed reduction
15	64	F	NOF	32	42	7	3 weeks	Closed reduction
16	74	M	NOF	36	38	10	1 month	Open reduction

DISCUSSION

Our retrospective study found that image-less computer navigation THA may decrease the dislocation rate compared to manual techniques, with (FNFs emerging as significant influencing factors. We observed dislocation in 16 of 1,093 cases (1.5%), all of which occurred spontaneously and non-traumatically. When comparing the dislocation rate in this study with manual techniques reported in previous studies, it is evident that the dislocation rate in our study was lower (Table 5).

Consistent with Bohl et al. [25], they demonstrated that using computer-assisted navigation was associated with a dislocation reduction (hazard ratio [HR] = 0.69; 95% CI = 0.58 to 0.82; $p < 0.001$), with a reported dislocation rate of 1.00% from 14,540 cases, compared to 1.7% from non-navigated 803,732 cases. A study by Agarwal et al. [22] supports this finding; they indicated that using navigation can lower the rate of revision for dislocation (HR = 0.46; 95% CI = 0.29 – 0.74; $p = 0.002$).

In our study, six dislocations occurred in elective procedures and exhibited a dislocation rate of 0.76%, which is notably lower than the rates reported by Gausden et al. [26], where all cases were elective with a dislocation rate of 1.4% with the manual technique.

Numerous studies have demonstrated varying dislocation rates of THA in FNF when using manual techniques, ranging from 1.9%–30% (Table 6). A large sample of more than 60,000 FNF studies by Pangaud et al. [27] showed a dislocation rate of 5.69%. In our study where imageless navigation was utilized for THA in FNF, we observed 10 cases of dislocation of 305 cases (3.28%), which was lower than the dislocation rate in manual techniques (Table 6).

Table 5 Dislocation rate in manual THA.

Study or Subgroup	Dislocated cases	Total cases	Dislocation rate
Bargar 1998 [32]	4	62	6.5 %
Honl 2003 [33]	3	30	3.8 %
Kamara 2017 [34]	1	198	0.5 %
Nakamura 2009 [35]	2	78	2.6 %
Nakamura 2010 [36]	1	71	1.4 %
Siebel 2005 [37]	1	35	2.9 %
Total	12	524	
Average			2.3 %
Our study	16	1093	1.5 %

Table 6 Dislocation rate of THA in FNF [38].

Study or Subgroup	Dislocated cases	Total cases	Dislocation rate
Baker 2006	3	40	7.5 %
Cadossi 2013	2	42	4.8 %
Dorr 1986	7	39	17.9 %
Keating 2006	3	69	4.3 %
Macaulay 2008	1	17	5.9 %
Mouzopoulos 2008	2	16	12.5 %
Narayan 2006	3	10	30 %
Ravikumar 2000	18	89	20.2 %
Schleicher 2003	1	54	1.9 %
Van de Bekerom 2010	8	115	6.9 %
Chammout 2016	4	69	5.8 %
Zhoukai 2024	7	51	13.7 %
Bhandari 2019	34	718	4.7 %
Total	93	1329	
Average			6.9 %
Our Study	10	305	3.3 %

Understanding the significant factors linked to predicting dislocation rates after THA is crucial for pre-operative planning and post-operative protocols. In this study, we identified FNF as the primary significant risk factor among patients. Our regression analyses highlighted the statistical importance of this correlation (OR = 4.4; 95% CI = 1.592–12.264; p = 0.004).

After analyzing the data, we found no significant difference in dislocation rates between the elderly and younger groups. This may be because, while soft tissue tension is typically worse in older patients compared to younger patients, the activity of the patient also decreases, potentially contributing to the lack of difference in dislocation rates. One reason for this may be that in our study group, the mean age is 53.5 years and 61.7 years in the overall and dislocated groups, respectively, which is not excessively high. Perhaps if we use another age group cutoff, the results may differ significantly.

Despite the differences in muscle mass, laxity, and activity between men and women, patient gender is not a risk factor for dislocation according to many studies [39-42], ranging from single institution to registry studies. Additionally, the rate of revision did not differ. Our study also shows no difference between men and women in the rate of dislocation.

The alteration in femoral head diameter significantly affects the head-neck ratio and jump distance, resulting in a diminished dislocation rate. Kelley et al. [28] highlighted that the use of a 22 mm diameter head escalated the dislocation rate in comparison to a 28 mm head (35% vs. 0%; p = 0.012). Similarly, Singh et al. [29] observed a substantially reduced dislocation rate with a 36 mm diameter head relative to a 28 mm head in primary THA (0.6% vs. 6.4%; p = 0.0107). However, our study suggests that femoral head size does not emerge as a significant factor; there exists no substantial difference in the dislocation rate among 28 mm, 32 mm, and 36 mm heads. Our findings are in line with those of Hedlundh et al. [30], who reported no significant disparity in the dislocation rate between the 22 mm and 32 mm femoral head.

One of the renowned studies guiding the alignment of acetabular cup placement is Lewinnek's safe zone [20], which prescribes 40 +/- 10° for the abduction angle and 15 +/- 10° for anteversion. They reported a dislocation rate of 1.5% within the safe zone, while alignment outside this range resulted in a dislocation rate of 6.1%. In this study, we also employed imageless computer navigation in all cases, resulting in none outside Lewinnek's safe zone. However, despite 16 dislocation cases meeting the safe zone criteria for abduction and anteversion angles, they still experienced dislocation. This observation resonates with Abdel et al.[31], who examined 206 dislocated cases of 9784 primary THAs and found that 58% of dislocated cases (120/206) maintained alignment within the Lewinnek safe zone. Therefore, while Lewinnek's recommended values for acetabular cup abduction and anteversion may offer guidance, they do not ensure stability, given the multifactorial nature of dislocation.

Limitations of the research include its retrospective design, which introduced inherent biases and limitations. Additionally, the study's single center may restrict the generalizability of the results. Variations in patient demographics, surgical practices, and institutional protocols at this single-center might not accurately represent the diversity seen in other hospitals or regions, raising concerns about the external validity of the study. Despite analyzing 1093 cases, the relatively small sample size may compromise the statistical power needed to detect significant associations between variables, particularly when identifying less common risk factors or conducting effective subgroup analyses.

CONCLUSIONS

Imageless computer-assisted THA shows a low hip dislocation rate. FNF has emerged as a significant influencing factor.

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Effectiveness of Cannabis Oil as an Adjuvant Therapy in Patients with Severe Knee Osteoarthritis: A Randomized, Double-Blind Study

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Purpose: The removal of cannabis from Thailand's narcotic drug list presents both opportunities and challenges for medical use. The effectiveness of cannabis oil in treating severe knee osteoarthritis in patients awaiting total knee arthroplasty was evaluated in this study.
Methods: Thirty-two patients with severe knee osteoarthritis, unresponsive to conservative treatment, were enrolled and divided into two equal groups. The control and experimental groups received syrup and cannabis oil, respectively, at night for 30 days. Pain and quality of life (QOL) were assessed using the Numeric Rating Scale (NRS), and the Knee Injury and Osteoarthritis Outcome Score (KOOS), respectively. Liver and kidney functions were also assessed.
Results: The experimental group showed a significant reduction in NRS scores compared to the control group ($p = 0.00015$). Significant improvements were observed in KOOS subscales for pain, activities of daily living (ADL), and QOL ($p = 0.01$). However, the symptoms subscale improvement was not significant ($p = 0.14$). When comparing the KOOS subscales, no significant differences were observed between the groups ($p > 0.05$). Liver and kidney function remained stable in both groups. Despite these improvements, the changes did not reach a minimal clinically important difference (MCID), indicating limited clinical perceptibility to the patients.
Conclusions: Cannabis oil was associated with significant improvements in pain, ADL, and QOL in severe knee osteoarthritis. Although improvements did not meet MCID thresholds, observed benefits suggest potential for pain management. Larger controlled studies are recommended to confirm its clinical efficacy in pain management.

Keywords: cannabis, THC, CBD, knee osteoarthritis, KOOS, MCID

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Severe osteoarthritis (OA) significantly affects the activities of daily living of patients, rendering them unable to work, placing a burden on their families, and affecting their physical and mental well-being. Knee replacement surgery is an effective treatment that often enables patients to resume near-normal postoperative activities of living. According to data from the NHSO [(1)], >60,000 individuals require knee replacement surgery, but

only 20,000 undergo surgery annually. The waiting time for surgery in government hospitals is as long as 1-2 years. These patients suffer owing to extended waiting periods; therefore, exploring alternative therapies that alleviate pain and enhance function during this waiting period is imperative.

Cannabis is a promising alternative to be used as an adjunctive treatment for patients with OA waiting for surgery. It exhibits diverse therapeutic effects, including analgesic, anti-inflammatory, antioxidant, and anxiolytic properties[2,3]. These patients often experience pain, knee inflammation, stress, and anxiety[4]. Given its properties, cannabis can potentially manage these symptoms effectively. Lykins W.[5] explored the use of cannabis in the treatment of patients with knee OA and revealed that cannabidiol (CBD) can be used as an alternative treatment for knee OA that may provide symptomatic relief with minimal risk. In addition, Echeverria-Villalobos M.[6] revealed that cannabis did not affect knee replacement surgery when used at low doses and was discontinued before surgery.

Despite concerns regarding the long-term use of cannabis, particularly its potential adverse effects on the nervous and cardiovascular systems, as well as the risk of addiction, evidence suggests that these risks are mitigated by numerous factors, such as low dosage and frequency, older age at initiation, and the medical purpose[7,8]. In addition, a study by Lopez-Quintero,[9] revealed that the rate of drug dependence on cannabis is lower than that of cigarettes and alcohol. The cumulative probability of transitioning to dependence was estimated as 67.5%, 22.7%, 20.9%, and 8.9% for nicotine, alcohol, cocaine, and cannabis users, respectively. Therefore, if cannabis is used appropriately for medical purposes, the risk of addiction is low. Cannabis has emerged as a potential alternative treatment for patients with OA who are awaiting surgery, offering pain relief, and potentially improving quality of life (QOL) with a relatively low risk of addiction when used appropriately. The primary objective of this study was to evaluate the effectiveness of cannabis in relieving pain in patients with severe OA. Secondary objectives included assessing its impact on the QOL and monitoring any potential complications related to its use.

METHODS

This randomized controlled trial compared the efficacy of cannabis oil versus placebo syrup in relieving pain, improving QOL, and monitoring complications in patients with severe knee OA. It was conducted between March and May 2022 in the northern region of Sukhothai, Thailand. Patients with severe knee OA, as classified using the Kellgren and Lawrence grading system, who had previously undergone conservative treatment with unsatisfactory results and were scheduled for total knee arthroplasty were enrolled in this study. The inclusion criteria included the presence of Kellgren and Lawrence type 4 OA, indicating severe knee OA with large osteophytes, marked narrowing of the joint space, severe sclerosis, and definite deformity of the bone ends. Patients were excluded if they were allergic to cannabis oil, required warfarin, had cirrhosis, grade 4 or higher chronic kidney disease, a history of heart disease or stroke, or schizophrenia or depression.

A total of 32 patients were enrolled in the study, with 16 randomized to each of the experimental (cannabis oil) and control groups (placebo syrup). Systematic random sampling was employed, with patients drawing one of eight lottery tickets numbered 1-8. Patients who drew odd and even numbers were assigned to the experimental and control groups, respectively. To maintain a double-blind protocol, only the pharmacist responsible for preparing the study medications was aware of the group assignments. The study medications were prepared in identical bottles to ensure blinding of both patients and healthcare providers. Physicians prescribed the study medications according to a predetermined schedule without knowing whether the patient was receiving cannabis oil or placebo syrup.

Patients in the experimental group were administered 1:1 Tetrahydrocannabinol (THC): CBD cannabis oil sublingually at bedtime. Cannabis oil was manufactured and provided by Chaophraya Abhaibhubejhr Hospital and contained 2.7% THC and 2.5% CBD, corresponding to

approximately 4.59 mg of THC and 4.25 mg of CBD per drop. The dosing regimen was based on recommendations from the study by Bhaskar et al.[10], which suggested initiating treatment with 2.5-5 mg of THC daily. Patients in the control group received one drop of placebo syrup made from coconut oil adjusted for color and flavor to mimic cannabis oil. All patients, regardless of group assignment, received the following concomitant medications to manage their knee OA symptoms: gabapentin (300 mg) one capsule at bedtime, a muscle relaxant (orphenadrine 35 mg with paracetamol 450 mg) one tablet three times daily, meloxicam (7.5 mg) once daily after breakfast, and omeprazole (40 mg) one capsule before breakfast.

The primary outcome measure was pain relief, assessed using a Numeric Rating Scale (NRS), whereas the secondary outcome was assessed using the Knee Injury and Osteoarthritis Outcome Score (KOOS). Additionally, complications or side effects associated with the use of cannabis oil were monitored. KOOS assessments were conducted by a trained research nurse who was blinded to the treatment allocation. NRS scores and KOOS outcomes were evaluated at baseline and one month after treatment. To monitor potential side effects, blood tests for kidney and liver function were performed at the beginning and end of the study.

Research Tools

KOOS[11,12] is a widely validated and extensively used questionnaire, developed in 1990. It is designed to assess patient perceptions of knee health across five distinct subscales: 1. Pain (KOOS Pain) 2. Other Symptoms (KOOS Symptoms) 3. Activities of Daily Living (ADL; KOOS ADL) 4. Function in Sport and Recreation (KOOS Sport) 5. Knee-related QOL (KOOS QOL). Each subscales is scored separately, enabling a detailed assessment of the specific aspects of knee function and the impact of OA on the life of patients. In this study, the KOOS Sport was excluded, as the study population may have been unsuitable for sports activities or unable to participate in such activities due to the severity of their condition. KOOS assessments were conducted at two time points: baseline (before the initiation of the intervention) and one month after treatment. The results from each subscale were analyzed separately, with comparisons made between the pre- and post-treatment scores to evaluate the effectiveness of the intervention.

General Characteristics Questionnaire: In addition to the KOOS, a general characteristics questionnaire was administered to obtain demographic and baseline health data from each participant, including sex, weight, height, body mass index (BMI), occupation, underlying diseases, and the frequency of painkiller use. Furthermore, kidney function and liver enzyme levels were monitored at baseline and end of the study to assess any potential renal adverse effects of the intervention on renal and hepatic function.

Data Analysis

Trained research nurses systematically collected all data to ensure blinding throughout the study period. Statistical analysis was performed using STATA, with significance set at $p < 0.05$. Paired t-tests were used for within-group comparisons of pain and KOOS and independent t-tests were used for between-group comparisons. The incidence of complications was compared between groups using independent t-tests. The sample size was calculated based on the formula from Bernard (2000) in "Fundamentals of Biostatistics" (7th ed.)[13]. This involved calculating the change in the KOOS values between the control group that received the placebo and the group that received cannabis oil. The resulting sample size was 16 participants per group. The study was approved by the Human Research Ethics Committee of the hospital (IRB number: 07/2565), and all patients provided written informed consent before participation. The patients were informed of their right to withdraw from the study at any time without any impact on their future medical care.

RESULTS

The general characteristics of the control and experimental groups were similar (Table 1). Participants were predominantly aged >60 years, with a higher proportion of females than males in

both groups. The average BMI for both groups fell within the range of class I obesity, and most participants required regular use of painkillers.

Following treatment, the NRS scores improved in both groups; however, only the experimental group demonstrated a statistically significant improvement (Table 2). When comparing outcomes between the groups, the experimental group exhibited a significantly greater reduction in NRS scores than the control group (Table 3), indicating the potential efficacy of cannabis oil in reducing pain.

Improvements in the KOOS were observed in both groups after treatment (Table 2). The KOOS values exhibited statistically significant improvements in the experimental group in the Pain, ADL, and QOL subscales, whereas the symptoms subscale did not show significant improvement. However, the control group did not exhibit statistically significant changes in any of the KOOS subscale scores. When comparing KOOS improvement between the groups, no statistically significant differences were observed (Table 3).

Blood tests for kidney (glomerular filtration rate) and liver functions (aspartate aminotransferase, alanine transaminase) were conducted at baseline and 30 days after treatment. No significant changes were observed in kidney or liver function in either group, indicating that cannabis oil use did not adversely affect these parameters (Table 2).

Table 1 General characteristics of the participants.

Characteristic	Control group (Receiving placebo)	Experimental group (Receiving cannabis)
Age (yr.)	62.62 ± 5.99 (55-77)	63.5 ± 5.25 (55-73)
Gender		
Male	1	3
Female	15	13
Weight (kg.)	69.19 ± 7.56 (55-83)	62.28 ± 11.33 (48-80.5)
Height (cm.)	156.25 ± 5.32 (148-165)	156.50 ± 6.64 (150-171)
Body mass index	28.30 ± 2.41 (24.14-31.63)	25.29 ± 3.59 (19.22-28.84)
Occupation		
None	7	7
Agriculturist	7	7
Laborer	1	2
Grocer	1	0
UD		
no UD	0	4
DM alone	0	1
HT alone	3	2
DLP alone	1	1
DM + HT	2	0
DM + DLP	0	0
HT + DLP	8	6
DM + HT + DLP	1	2
Frequency of painkiller used		
Every day	11	9
Every other day	6	5
Once a week	0	2

Underlying disease, UD; Diabetes mellitus, DM; Hypertension, HT; Dyslipidemia, DLP

Table 2 Variables before and after treatment.

Parameter	Control Group		Experimental Group		P-value
	Before Rx	After Rx	Before Rx	After Rx	
Pain (NRS)	8.06 ± 1.24	7.94 ± 1.29	8.35 ± 1.15	7.06 ± 1.48	0.43/0.00015
KOOS pain	34.02 ± 14.33	40.45 ± 17.36	31.94 ± 9.89	39.58 ± 11.89	0.1/0.01
KOOS Symptoms	37.28 ± 17.29	40.17 ± 18.65	34.40 ± 11.10	38.84 ± 7.59	0.51/0.14
KOOS ADL	33.99 ± 16.28	41.54 ± 22.00	31.88 ± 11.96	42.46 ± 14.67	0.16/0.14
KOOS QOL	19.92 ± 11.68	25.78 ± 12.26	17.57 ± 12.12	29.69 ± 12.39	0.1/0.01
GFR (L/min)	72.47 ± 17.10	69.16 ± 13.42	74.40 ± 24.03	76.51 ± 21.72	0.38/0.43
AST (U/L)	23.18 ± 4.29	25.91 ± 8.01	26.75 ± 8.48	29.36 ± 10.86	0.24/0.48
ALT (U/L)	25.56 ± 6.85	24.36 ± 12.01	35.88 ± 24.03	26.00 ± 14.22	0.32/0.28

Numeric Rating Scale, NRS; KOOS, Knee Injury and Osteoarthritis Outcome Score; Activities of daily living, ADL; Quality of life, QOL; GFR, Glomerular filtration rate; Aspartate aminotransferase, AST; Alanine aminotransferase, ALT

Table 3 Comparison of outcomes between control and experimental groups.

	Mean score improvement		p-value
	Control group	Experimental group	
Pain score (NRS)	0.125 + 0.15	1.31 + 0.34	0.003
KOOS Pain	5.38 + 3.72	7.63 + 2.91	0.64
KOOS Symptoms	2.90 + 4.29	4.44 + 2.88	0.77
KOOS ADL	7.56 + 5.08	10.58 + 3.48	0.63
KOOS QOL	5.85 + 3.44	12.11 + 2.99	0.18

Numeric Rating Scale, NRS; KOOS, Knee Injury and Osteoarthritis Outcome Score; Activities of daily living, ADL; Quality of life, QOL

DISCUSSION

Cannabis oil demonstrated notable efficacy in reducing pain, as reflected in improved NRS and KOOS Pain scores, which is consistent with other research. Lykins W.[5] and Lovecchio et al.[14] revealed that CBD and cannabis use significantly reduced pain in patients with OA and spine-related conditions. Similarly, Yassin et al.[15] demonstrated that the addition of medical cannabis to analgesics improved pain management in patients with fibromyalgia and low back pain. However, these studies utilized higher doses of cannabis, which were associated with more pronounced effects and increased side effects[7,8,16]. In contrast, our study employed a conservative initial dose of cannabis oil to balance the therapeutic efficacy and minimize adverse effects.

The anti-inflammatory properties of CBD likely contributed to the improvements observed in the KOOS Pain and ADL scores. Previous studies by Atalay et al.[17] and Boehnke et al.[18] revealed similar anti-inflammatory effects, emphasizing the role of CBD in reducing inflammation in OA and fibromyalgia. These anti-inflammatory effects may have played a crucial role in the improvement in pain and functional outcomes observed in our study.

Anxiety exacerbates physical symptoms in patients with OA.[19] Sharpe L.[20] revealed that CBD can reduce anxiety and improve the QOL. This may explain the improvements in KOOS QOL observed in our study.

Our findings are consistent with those of Francis et al.[21], who demonstrated that medical cannabis significantly improved pain, interference, and QOL in patients with OA. Frane et al.[22] also revealed that CBD use was associated with a reduction in pain and arthritis symptoms.

Vannabouathong et al.[23] suggested that cannabis may be a cost-effective strategy for managing chronic knee pain, which supports our findings.

The NRS and KOOS assessments are based on distinct principles. The NRS primarily evaluates pain intensity, whereas the KOOS Pain assesses the frequency of pain and the specific movements that exacerbate it. This distinction implies that while the frequency of pain and movement-induced pain may not exhibit significant improvement, cannabis can still effectively reduce the overall pain intensity. The KOOS ADL focuses on the ability of the patient to perform daily activities, whereas the KOOS QOL reflects the perception of the patient of the challenges posed by knee OA in daily life. In the cannabis group, although the differences compared to the placebo group were not statistically significant, the patients demonstrated significant improvements when comparing pre- and post-treatment measures. This improvement is likely attributable to the anxiolytic effects of cannabis, which may have contributed to the enhanced KOOS ADL and QOL outcomes. The KOOS Symptoms, which evaluates joint stiffness, is less likely to be improved by pharmacological interventions in patients with severe OA. Consequently, the experimental and control groups showed no significant improvements in KOOS Symptoms.

The Minimal Clinically Important Difference (MCID) is essential to determine whether statistically significant results correspond to clinically meaningful improvements. Suzuki H.[24] and Eleswarapu AS.[25] suggested that a change of 2 on the Numerical Rating Scale is necessary for clinically relevant pain relief. In our study, the change of NRS was 0.125 and 1.31 in the control and experimental groups, respectively, both of which fell below this threshold. This suggests that although a statistically significant reduction in pain was observed with the use of cannabis oil, the improvements may not have been clinically perceptible to patients. Similarly, the MCID values for the KOOS subscales[26] (pain, symptoms, ADL, and QOL) were not met in either group, indicating that, while the KOOSs improved significantly in the cannabis group, these changes were likely below the threshold for meaningful patient-perceived improvements.

In our study, cannabis oil significantly improved pain intensity, measured using the NRS, and QOL, assessed using the KOOS, in patients with knee OA. However, these improvements did not reach the MCID, suggesting that although the changes were statistically significant, they may not have been perceptible or meaningful to patients. Although cannabis oil has potential as a component of OA management, its use should be considered with caution. Future research with optimized dosages, larger sample sizes, and longer follow-up periods is needed to evaluate its true clinical relevance. Factors such as inflammation, psychological effects, and individual patient variability warrant further exploration to optimize the therapeutic use of cannabis for the management of knee OA symptoms.

CONCLUSIONS

Our study revealed that cannabis oil significantly reduced pain intensity and improved the QOL in patients with knee OA, as reflected by improvements in the NRS and KOOS scores. However, these changes did not reach the MCID, indicating that although the results were statistically significant, they may not have been perceived as meaningful by the patients. This suggests that, while cannabis oil shows potential as adjunctive therapy, further research with optimized dosages and larger sample sizes is needed to determine its clinical relevance in the management of OA.

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