Study protocol

Material and Methods

1. Patient

The Consolidated Standards of Reporting Trials (CONSORT) statement guidelines were followed in this single-center, prospective, parallel group, assessor-blinded, randomized controlled trial. All procedures were approved by the institutional review board of Police general hospital.

Patients who were diagnosed isolated closed fracture of distal end radius at Police General Hospital, Bangkok, Thailand between October 2021 and February 2023 were divided into the conventional group and the MIPO group at recruitment, using a computer-generated randomization program from www.randomizer.org. Patients were informed about the treatment options during a pre-interviewing session, and all eligible patients gave their written informed consent before the randomization and initialization of the allocated treatment. When patients arrived in the operating room, randomization took place using sealed envelopes containing assigned numbers. These envelopes were in the operating room and remained unopened until the patient's arrival. Neither the patient nor the attending physicians were informed about the randomization process. The orthopedic surgeon who assessed patient eligibility was not involved in randomization, thereby securing allocation concealment.

Inclusion criteria:

-We included those diagnosed with isolated closed fractures of the distal end radius requiring surgery,

-aged 18 years and older.

The Exclusion criteria were:

(1) Patients with bone fractures lasting more than 21 days

(2) open fractures

(3) articular multifragmentary comminuted fractures of the distal radius categorized as AO/OTA 2R3C3

(4) not suitable to undergo volar approach surgery

(5) individuals with combined carpal fractures or dislocation

(6) ulna fractures

(7) associated injuries

(8) a history of previous wrist surgery

(9) diabetes mellitus

(10) chronic wrist inflammation

(11) wrist bone deformities

(12) the use of anticoagulation drugs

(13) uncooperative behavior

(14) those refusing to participate in the research

2. Methods

According to the WALANT solution in our institute (Jaroenporn et al., 2022), the steps for preparing the solution are as follows (Figure 2A). Firstly, 40 ml of 1% Lidocaine with adrenaline (1:100,000) and 10 ml of 0.5% Marcaine are added to the solution. Marcaine, a long-acting local anesthetic, helps prolong the duration of pain relief. Additionally, 40 ml of Normal Saline Solution (NSS) is included; NSS acts as a diluent and ensures the appropriate volume of the anesthetic solution. Finally, 4 ml of 7.5% $NaHCO_3$ (sodium bicarbonate) is added to balance the acid-base pH. By following these steps, a total solution volume of 94 ml is prepared.

All patients underwent volar locking plate fixation under WALANT. First, the periosteum of the radius is infiltrated at three different points: proximal, middle, and distal (radial styloid), with each point receiving 10 ml of anesthesia. This ensures that the circumferential periosteum of the radius bone is adequately anesthetized. Next, a subcutaneous infiltration along the volar skin incision of 10 ml is injected (Figure 2B). After a 30-minute period of allowing the anesthesia to take effect

Operative Procedure for MIPO:

The patient, under WALANT, was in the supine position on the surgical table. A minimal 2 cm skin incision was made on the volar side of the wrist, proximal to the wrist crease 2 cm. The Trans flexor carpi radialis approach (Trans FCR) was performed, and the surgical plane was dissected using curved scissors to increase exposure. To mobilize and protect the flexor carpi radialis (FCR) and flexor pollicis longus (FPL) ulnarly, a self-retractor was employed. Care was taken to avoid damaging the radial artery on the radial side and the palmar cutaneous branch of the median nerve on the ulnar side. The distal aspect of the pronator quadratus muscle was elevated using a periosteal elevator. A partial transverse cut was made in the pronator quadratus muscle at the distal end to approach the fracture site. Closed reduction and temporary fixation with K-wires were used to assist in the reduction. The alignment was checked under fluoroscopy. The DePuy Synthes VA-LCP Two-Column Distal Radius Plates 2.4, volar, narrow, with 6 head holes and a width of 19.5 mm (Synthes USA Products, LLC), were utilized in the procedure. These plates were chosen for their minimal width, allowing easy insertion through a small incision. One cortical screw was inserted into an elongate hole, followed by the insertion of 4 distal locking screws. An additional proximal vertical mini incision of 1 cm was made for fixation with 2 proximal locking screws. No drain was inserted, and cast immobilization was not required.

Post-operation:

Adhering to post-operative protocols, no drain was inserted, and cast immobilization was unnecessary. Immediate encouragement of active finger and wrist motion was provided after the operation. Both groups were administered pain medication for 7 days, including Tramadol (50 mg), 1 tablet three times daily; Naproxen (250 mg), 1 tablet twice daily; and Tolperisone (50 mg), 1 tablet three times daily. In cases where the patient's Visual Analog Scale (VAS) pain score exceeded 5, a 3 mg IV dose of morphine was administered as needed by the patient.

As part of their early post-operative rehabilitation, patients were instructed in the six-pack exercise and wrist range of motion (ROM) exercises.

3. Evaluation

The data collector, an orthopedic resident unaware of the surgical technique used, obtained information. Neither the collector nor the patients observed the surgical incision.

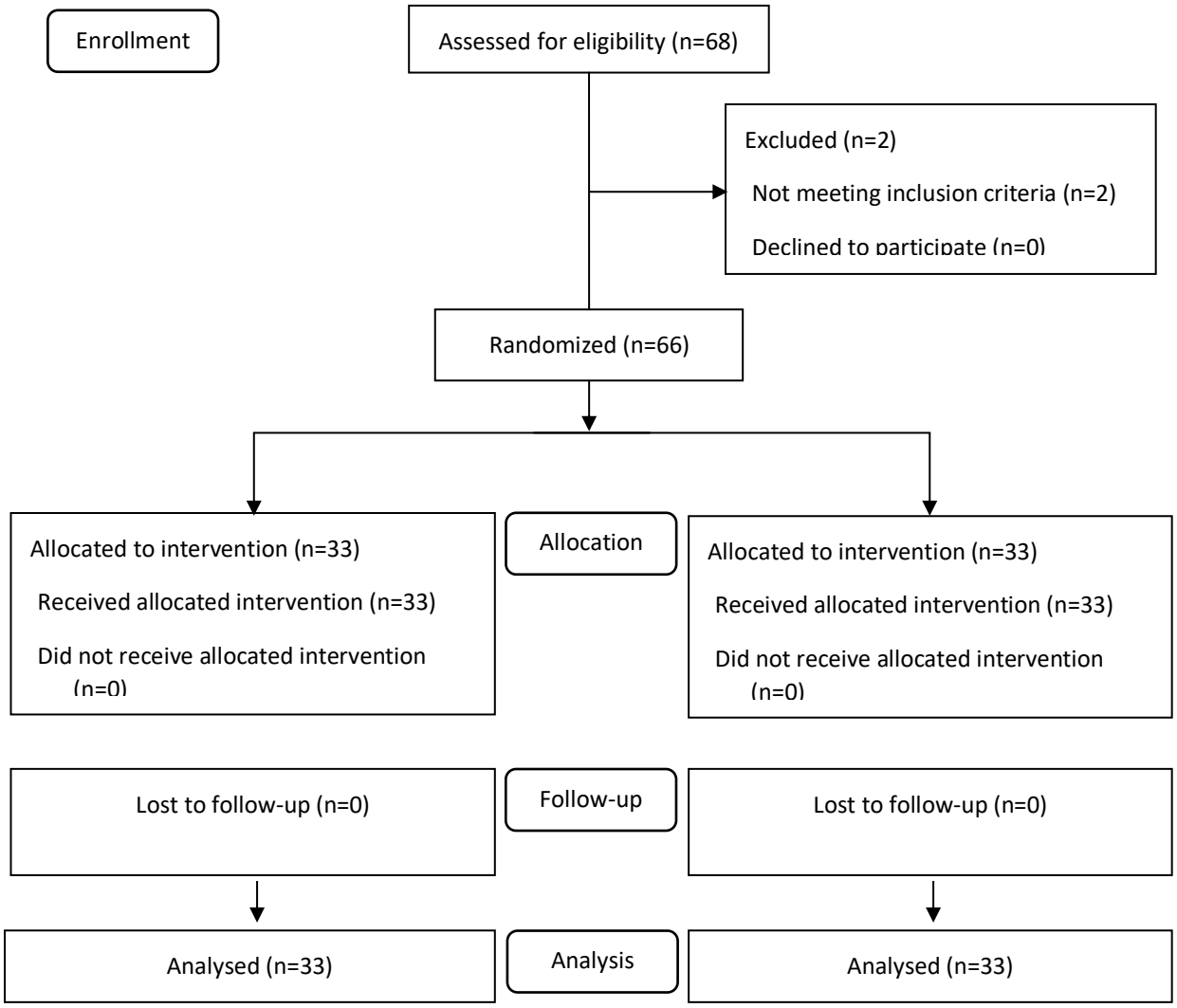
The primary outcome was measured using the pain visual analogue scale (VAS). Regarding the pain VAS, a score of 0 indicated no pain, and a score of 10 indicated the worst imaginable pain. The pain VAS score was recorded in the morning first 7 day then in the 2nd, 6th, 10th, 14th, and 24th weeks after surgery.

Patients attended outpatient department (OPD) follow-up appointments in the 2nd, 6th, 10th, 14th, and 24th weeks after surgery. The Quick Disabilities of the Arm, Shoulder, and Hand (Quick DASH) score indicated a functional outcome. The patient's satisfaction, along with the cosmetic score (rating the scar's appearance on a scale of 0 to 5, with 5 being excellent),. Hand grip strength was measured as a percentage of the strength in the other hand using a baseline hydraulic hand dynamometer with a JAMAR device (lbs force) from Sammons Preston, Inc., Bolingbrook, IL 60440-4989, in a 90 degree raised and extended arm position. The patient squeezed the dynamometer three times, and the highest score was recorded. Pinch strength was assessed by raising the patient's arm in front of them and bending it at a 90-degree angle, testing with a JAMAR Hydraulic Pinch Gauge. Three pinches on the device provided the highest score.

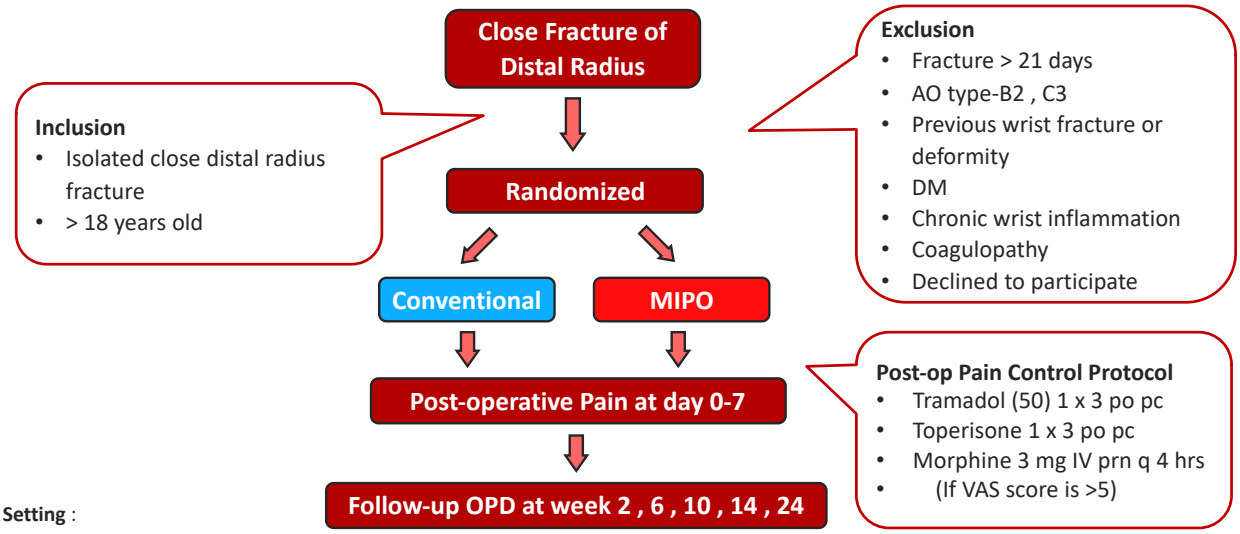
4 Statistical Analysis

IBM SPSS Statistics 27.0 was utilized for statistical analysis. Results were expressed as the mean ± standard deviation. Statistically significant differences were determined based on $P < 0.05$ and the 95% confidence interval (CI). The Fisher's exact test was used to evaluate baseline characteristics including sex, fracture side, cause, AO/OTA type. The paired t-test was used to evaluate the age, incision length, VAS pain score, Quick DASH, functional outcomes (grip, pinch strength, range of motion), operative time, Aesthetics, Satisfaction and radiographic parameters. All subjects were analyzed and none of the subjects were lost to follow-up.

CONSORT diagram



Method

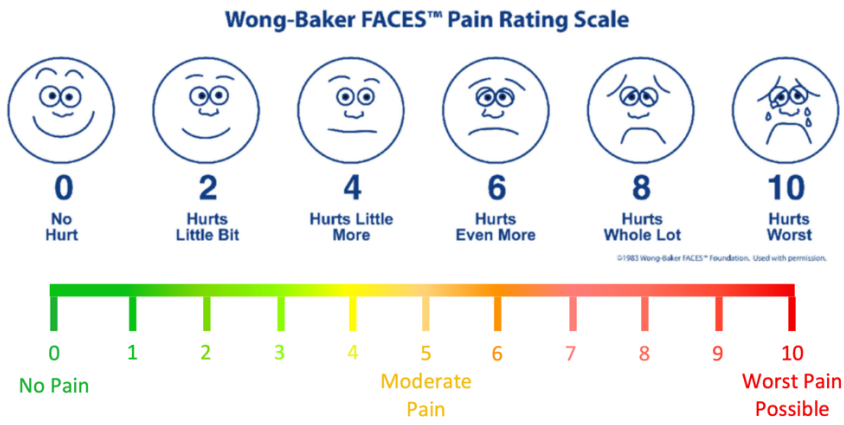


Setting :
- Police General Hospital, Thailand
- October 2021 - February 2023

Data collection process

1) Pain Visual Analog Score

Pain Rating Scale – Wong-Baker FACES™ & Visual Analogue Scale (VAS)



Source:
Pain assessment in children undergoing venipuncture: The Wong-Baker faces scale versus skin conductance fluctuations - Scientific Figure on ResearchGate. Available from: https://www.researchgate.net/figure/Wong-Baker-Faces-TM-Pain-Rating-Scale-Reproduced-with-Permission-of-the-Wong-Baker-Faces_fig1_236604762 [accessed 12 Feb, 2020]

Postoperative day	date	Pain VAS
0		
1		
2		
3		
4		
5		
6		
7		

2) QuickDASH form

*Quick*DASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

*Quick*DASH DISABILITY/SYMPTOM SCORE = $\left(\left[\frac{\text{sum of n responses}}{n}\right] - 1\right) \times 25$, where n is equal to the number of completed responses.

A *Quick*DASH score may <u>not</u> be calculated if there is greater than 1 missing item.

3) Table data collection

	MIPO	Conventional	p-value
Mean age, (SD); range			
Sex			
female			
male			
fracture side			
Dominant Hand			
Non-dominant Hand			
Cause			
fall			
road traffic accident			
sports			
AO/OTA 23			
A2			
A3			
B3			
C1			
C2			

	wk 2	wk 6	wk 10	wk 14	wk 24
(lbs)	F/U 1	F/U 2	F/U 3	F/U 4	F/U 5
Grip strength Fx					
Grip strength normal					
Pinch strength Fx					
Pinch strength normal					
ROM Fx					
Flexion					
Extension					
Supination					
Pronation					
Radial deviation					
Ulnar deviation					
Pain (0-10)					
QuickDASH					
Wound size (mm)					
Cosmetic score					
Satisfy score					

	MIPO	Conventional	P-value
Pain score			
Q-DASH score			
Grip strength			
Subjective cosmetic			
Satisfaction			

Volar tile	MIPO	Conventional	P-value
Initial			
Immediate post operation			
Final			

Radial inclination	MIPO	Conventional	P-value
Initial			
Immediate post operation			
Final			

Ulnar variance	MIPO	Conventional	P-value
Initial			
Immediate post operation			
Final			

patient	Pain (0-10)													mo	Q-DASH (0-100)						
(no #)	Pre	D1	D2	D3	D4	D5	D6	D7	wk2	wk6	wk10	wk14	wk24	(mg)	Pre	wk2	wk6	wk10	wk14	wk24	

patient	X-ray									Cos	Sat	Hand grip				
	RI			UV			VT									
(no #)	Pre	Post	F/U	Pre	Post	F/U	Pre	Post	F/U			wk2	wk6	wk10	wk14	wk24