

Locked Plating Versus Cephalomedullary Nailing of Unstable Intertrochanteric Femur Fracture

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Abstract

Intertrochanteric fractures of femur are common in elderly. Intramedullary nailing is becoming more popular, particularly in unstable fractures. Although, intramedullary devices are technically difficult, they seem to have a biomechanical advantage over proximally fixed side plates. we aimed to analyze results of cephalomedullary nailing & locked plating for treatment of unstable intertrochanteric femur fractures. This randomized controlled clinical trial was conducted on twenty patients with unstable intertrochanteric fractures that were treated with cephalomedullary nail and locked plate, at orthopedic surgery department at Al-Zahraa University Hospital for girls, Faculty of Medicine, Al-Azhar University Egypt from December 2019 to December 2021. The patients were randomly divided into two groups: Group I: received cephalomedullary nail treatment, group II: received proximal femur anatomical locked plate treatment. 20% and 40% of patients in group I, II respectively had developed complications, 10% of patients had infection with mechanical failure in group I & 20% of patients had infection in group II. Also in group II, reoperation, mechanical failure, and nonunion were higher than that in group I. Cephalomedullary nail is superior to proximal femur anatomical locked plate in treatment of unstable intertrochantric fracture of femeur as regard post-operative complications, mechanical failure, malunion, nonunion and reoperation.

Keywords: Intertrochanteric femur fracture, Cephalomedullary nailing, Locked plate.

1. Introduction

Hip intertrochanteric fractures are common in elderly compared to intracapsular fractures. While the frequency of these fractures has been reduced in the Western world. The absolute rise in the elderly population has resulted in doubling the percentage of these fractures over the last 30 years [1]. Because of elderly's increased life expectancy and proportional loss of bone density, these fractures become more complicated with age, making surgery more difficult [2]. Intramedullary nailing has become more popular, particularly in unstable intertrochanteric fractures. Although, intramedullary devices are technically

difficult. they seem to have а biomechanical advantage over proximally fixed side plates such as closed reduction, soft tissue dissection less of and comparatively less blood loss. Fracture hematoma is preserved that aids in natural healing process. [3] When compared with using of large proximal lag screw, locking plates have the advantage of allowing multiple angularly stable fixation points into the proximal femur, while leaving a smaller 'footprint' by preserving more bone stock after implantation compared to the use of large proximal lag screws. Biomechanical studies have shown locking plates to achieve stronger and stiffer fixation than other angularly stable implants. [4]. Aim of the work was to evaluate the result of cephalomedullary nail & locked plat for management of unstable intertrochanteric femur fractures.

2. Patients and Methods

This is a randomized controlled clinical trial that established on 20 patients aged (18-80), with unstable intertrochanteric fractures. They have been treated by proximal femoral anatomical locked plate and cephalomedullary nail at orthopedic surgery department Al-Zahraa at University Hospital, Al-Zhar University for girls, Faculty of Medicine, Egypt during the period from from December 2019 to December 2021. The patients were divided into two equal groups; Group I: ten patients treated by cephalomedullary nail and group II: ten patients treated by locked plate. Informed obtained consent was from all patients about surgery, potential risks. complications and follow-up protocol.

2.1 Inclusion criteria

Patients with unstable intertrochanteric femur fractures and skeletally mature patients' group (18-80) years old.

2.2 Exclusion criteria

Open fractures, pathological fracture, injuries that raise risk of surgery and prevent adherence to subsequent rehabilitation protocols (i.e., severe head injuries, spinal cord injury).

2.3. Preoperative assessment

On admission, Careful history taking and clinical examination were done for all patients as follows: Personal data. including name, age, gender, profession, address, and phone number, special habits of medical importance, such as smoking. Associated co-morbidities: Diabetes hypertension (HTN), mellitus (DM), Cardiac diseases, hepatic problems, renal failure, bronchial asthma. Clinical examination: careful examination was done to detect any associated fractures, bed sores, ecchymosis, on the affected hip. Pre fracture level of activity and mobility according to Parker mobility score [Error! Reference source not found.1. Radiological assessment: Plain x-ray: in the form of pelvis Antero-posterior (AP), affected hip with femur AP& Lateral and ipsilateral knee. Laboratory investigations: Routine pre-operative investigations in the form of complete blood count, prothrombin count, PC, international normalized ratio (INR), aspartate aminotransferase (AST), Alanine Aminotransferase (ALT), Random blood sugar (RBS) and creatinine were performed. Other laboratory investigation may be done according to the associated co morbidities as HBA1c, serum albumin and creatinine clearance.

2.4 Radiological evaluation

X-ray was done immediately postoperatively, at six weeks, three months, six months and one year, by doing anteroposterior view of pelvis, anteroposterior view and lateral view of the operated hip. Anteroposterior radiographs were then evaluated for varus & valgus angulation, & lateral radiographs for apex anterior & posterior angulation. Lag screw position was considered good if it was in lower half of neck & in the center on AP & lateral views. Any changes in position of implant & extent of fracture union were mentioned in follow-up x-rays. If bridging callus was visible on three & four cortices in two views, fracture was regarded healed radiographically.

2.5 Clinical evaluation

After the union, the visits were scheduled for three months, six months, and twelve months. Walking, pain & hip function were evaluated at each visit. Hip function was evaluated by using; range of motion: The operated hip compared to the other hip, while the patient sleeping supine on the bed in most of cases and the degree of hip flexion, extension, abduction, adduction, external & internal rotation were recorded at 6 and 12 months postoperatively [**Error! Reference source not found.**]. Muscle power: was evaluated according to the muscle power grade (ASIA), compared to the other normal side.

The follow-up period was at least one year (from one year to two years) during the period from December 2019 to December 2021.

2.6 Postoperative care

Antibiotics were given two hours preoperative and analgesics were given as required. Low molecular weight heparin (clexane) after 12 hours was administrated. AP and lateral view X rays were done to assess fracture reduction, screw position and neck shaft angle. On the following day, cases in the study allowed studied quadriceps strengthening do quadriceps strengthening exercises. Stable intertrochanteric fracture patterns were made possible by partial weight carrying. On post-operative day fourteen, sutures were eliminated.

In the case of unstable intertrochanteric fractures, full weight-bearing was delayed until the studied cases were pain-free, &

bone union was confirmed by X-ray. Studies were seen six weeks, three months, & six months after surgery. Each follow-up visits included antero-posterior & lateral radiographs. Hip function & limb shortening were assessed at each follow-up. Radiographic evidence of callus with no tenderness was used to evaluate bone union. Time to union, limb shortening, varus collapse, & functional result were all evaluated using the Harris hip score (HHS). HHS is predicated on a total of one hundred points across several categories, including pain, function. functional activities, & range of motion. A score of 90-100 indicates excellent results, 80-90 indicates well, 70-79 indicates fair, 60-69 indicates poor, & less than sixty indicates failure.

2.7 Statistical Analysis

Statistical analysis was done by SPSS v27 (IBM©, Armonk, NY, USA). Shapiro-Wilks test and histograms were used to evaluate the normality of the distribution of data. Quantitative parametric data were presented as mean and standard deviation (SD) and were analyzed by unpaired student t-test. Quantitative non-parametric data were presented as the median and interquartile range (IQR) and were Whitney-test. analyzed by Mann Qualitative variables were presented as frequency and percentage (%) and analyzed using the Chi-square test or Fisher's exact test when appropriate. A two-tailed P value considered 0.05 was statistically < significant.

3. Results

This randomized controlled clinical trial that established on 20 patients divided into two equal groups.; Group I: ten patient treated by cephalomedullary nail and group II: ten patients treated by locked plate

3.1 Patient criteria

In group I, Patients' age ranged from 45 years to 65 years with mean ±

SD=56.40±6.33.1 years and median=56.0 years. Most of patients were females 6 (60%) and 4(40%) were males. Six patients fell from standing height, two patients fell from a height and two patients were car accident. Seven patients were type III by Evan classification and three were type IV. patients had Seven (70.0%)no comorbidities. One patient (10%) had hypertension, and two patients (20%) had diabetes mellitus. In group II, Patients' age ranged from 49 years to 65 years with mean + SD=56.40±6.33.1 years and median=55.0 years. Male and female were equal in this group; females 5 (50%) and 5 (50%) were males. Five patients fell from standing height, two patients fell from a height and three patients were in car accident. Six patients were type III by Evan classification and two were type IV and two type V. Eight patients (80.0%) had no comorbidities. One patient (10%) had hypertension, and one patient (10%) had diabetes mellitus Table (1). Regarding, time from fracture to surgery, there was an insignificant difference between the two groups. The mean surgery time was 93.70 in group I & 95.90 minutes in group II with an insignificant difference between both groups. Table (2).There was an insignificant difference between the two groups as regards blood Transfusion. Table (3).

were insignificant There differences between two groups as regards postoperative hospitalization and follow-up period Table (4). This table finds that no mortality detected in group I but its rate 20% in group II with no variations between both groups and as regard malunion & nonunion was detected in 0%, 10% in group 1 & 20%, 30% in group II respectively with insignificant differences between both groups and as regard reoperation there was 10% in group I & 40% in group II. Table (5). This table finds that as regards complications 80% of group I and 60% of group II were free from any complications and in group I one patient had an infection, no patients had DVT and one patient had infection with mechanical failure, in group II 2 patients had infection 2 patients had infection with and mechanical failure and one patient developed DVT. Table (6). Regarding HSS, in group I ,5(50%) had excellent HHS,3(30%) had good HHS, 1(10%) had fair HHS, and 1(10%) had poor HHS. Regarding HSS, in group II, 2 (20%) had excellent HHS, 4 (40%) had good HHS, 1(10%) had fair HHS, and 3(30%) had poor HHS. Table (7). As shown in Table (1) it shows that both groups were matched with regard to demographic data and smoking history

	Group I (n = 10)		Group II (n = 10)		р
	No.	%	No.	%	
Sex					
Male	4	40 %	5	50.0	^{FE} p=
Female	6	60 %	5	50.0	1.000
Smoker					
No	8	80 %	7	70.0	^{FE} p=
Yes	2	20 %	3	30.0	1.000
Age (years)					
Min. – Max.	45.0 - 65.0		49.0 - 65.0		
Mean \pm SD.	56.40	56.40 ± 6.33		40 ± 4.22	1.000
Median (IQR)	56.0 (54.0 - 60.0)		55.50 (55.0 - 59.0)		
BMI (kg/m ²)					
Min. – Max.	25.0-30.0		25.0 - 30.0		
Mean \pm SD.	26.80 ± 1.69		27.20 ± 1.55		0.588
Median (IOR)	26.0 (26.0 - 28.0)		27.0 (26.0 - 28.0)		

IQR: Inter quartile range, SD: Standard deviation , χ^2 : Chi square test, FE: Fisher Exact, p: p value for comparing between the studied groups

Table (2): Comparing between two groups according to time from fracture to surgery and mean surgery time.

	Cepholmedullary Nail Fixation Group (Group I) (n = 10)	Locked Plate Fixation Group (Group II) (n = 10)	Test of Sig.	Р
Time from fracture to surgery (days)				
Min. – Max.	1.0 - 3.0	1.0-2.0	U=	0.796
Mean ± SD.	1.55 ± 0.69	1.40 ± 0.46	46.0	
Median (IQR)	1.25 (1.0 – 2.0)	1.25 (1.0 – 2.0)		
Mean surgery time (minutes)				
Min. – Max.	80.0 - 105.0	90.0 - 105.0	t=	0.475
Mean ± SD.	93.70 ± 7.42	95.90 ± 5.97	0.730	
Median (IOR)	92.50 (89.0 - 100.0)	95.0 (90.0 - 102.0)		

IQR: Interquartile range, SD: Standard deviation, t: Student t-test, U: Mann-Whitney test, p: p-value for comparing between tested groups.

Table (3): Comparison between the two groups according to blood transfusion.

Blood transfusion	(Group I)	(Group II)	U	р
	(n = 10)	(n = 10)		
Intraoperative (units)				
Min. – Max.	0.0 - 1.0	0.0-1.0	48.500	0.912
Mean ± SD.	0.20 ± 0.35	0.25 ± 0.42		
Median (IQR)	0.0 (0.0 - 0.50)	0.0 (0.0 – 0.50)		
Postoperative (units)				
Min. – Max.	0.0 - 0.50	0.0 - 0.50	45.0	0.739
Mean ± SD.	0.05 ± 0.16	0.10 ± 0.21		
Median (IQR)	0.0 (0.0 - 0.0)	0.0 (0.0 – 0.0)		
IQR: Inter quartile range	SD: Standard deviation	U: Mann Whitne	ey test	

p: p value for comparing between tested groups.

Table (4): Comparison between both groups according to postop hospitalization & follow up

	(Group I)	(Group II)	Test of	р
	(n = 10)	(n = 10)	Sig.	
Postop. Hospitalization\days				
Min. – Max.	2.0 - 5.0	2.0 - 6.0	U=	0.436
Mean ± SD.	3.60 ± 0.97	3.30 ± 1.16	39.0	
Median (IQR)	3.50 (3.0 – 4.0)	3.0 (3.0 – 4.0)		
Follow up (months)				
Min. – Max.	6.0 - 13.0	6.0 - 13.0	t=	0.620
Mean ± SD.	9.0 ± 2.31	9.50 ± 2.12	0.504	
Median (IQR)	8.50 (7.0 - 11.0)	9.0 (9.0 – 11.0)		

IQR: Interquartile range, SD: Standard deviation, t: Student t-test, U: Mann-Whitney test, p: p-value for comparing the tested groups

Table (5): Comparing between both studied groups according to outcome

	Cepholmedullary Nail Fixation Group		Locked Plate Fixation Group		FEp
	(Group I) (n = 10)		(Group II) (n = 10)		
	No.	%	No.	%	
Mortality	0	00.0%	2	20.0%	1.000
Malunion	0	00.0%	2	20.0%	1.000
Nonunion	1	10.0%	3	30.0%	0.582
Reoperation	1	10.0%	4	40.0 %	0.303

 χ^2 : Chi-square **test**, FE: **Fisher Exact**, p: p-value for comparing between tested groups.

Complication	Cepholmedullary Nail Fixation Group (Group I) (n = 10)		Locked Plate Fixation Group (Group II) (n = 10)		мср
	No.	%	No.	%	
No	8	80.0%	6	60.0%	0.11
Infection	1	10.0%	2	20.0%	0.45
DVT	0	00.0%	1	10.0%	0.27
Infection, mechanical failure	1	10.0%	2	10.0%	0.45

Table (6): Comparison between the 2 tested categories according to complication

 $\chi^2\!\!:$ Chi square test, MC: Monte Carlo, p: p-value for comparing between tested groups.

HHS	Cepholmedullar ((ry Nail Fixation Group Group I) (n = 10)	Locked Plate Fixation Group (Group II) (n = 10)		
	No.	%	No.	%	
Excellent	5	50.0%	2	20.0%	
Good	3	30.0%	4	40.0%	
Fair	1	10.0%	1	10.0%	
Poor	1	10.0%	3	30.0%	

Table (7): Comparison between both groups according to functional outcome (HHS)

4. Discussion

Hip fractures are an important orthopedic burden worldwide, by 2050, and are estimated to reach an incidence of at least six million fractures. Extracapsular hip fractures, which occur distal to hip joint capsule & are sometimes regarded as intertrochanteric fractures are frequently caused by low energy trauma caused by osteoporosis. Even global life as expectancy goes up, the prevalence of these fractures is predicted to skyrocket, with developing countries bearing brunt of rise. [1]. Morbidity and mortality from these injuries is greater at baseline and they worsen if surgical treatment is postponed mobilization allowing early & Internal rehabilitation. fixation has emerged as the gold standard for the treatment of intertrochanteric fracture. [1]

We aimed to analyze outcomes of cephalomedullary nailing & locked plating for treatment of unstable intertrochanteric femur fractures.

20 studied cases of unstable intertrochanteric fracture the cases were randomly equally divided into two groups; Group I: ten patients were received cephalomedullary nail treatment, group II: ten patients were received locked plate treatment. Both groups were matched regarding demographic data, co morbidity, regard mechanism of injury and smoking history.

In agreement with our result Öztürk [7] both showed that there was no variation in terms of age, sex, time since surgery, DM & comorbidities. The studied cases in the cepholmedullary nail fixation group were four years older than those in locked plate fixation group (58.2vs. 62.1) In consistent with our result Streubel PN et al [17] found that there were no variations in sex ratio, BMI, diabetes, time from admission to surgery, or follow-up. Although not statistically significant, CMN studied cases were eleven years older on average (68 vs. 57 years), smoked less commonly (26% vs. 42 %), & had fractures caused by low energy trauma more frequently (41% vs. 60 %) [1].

In the present study as regards time from fracture to surgery was insignificantly different between both groups.

Longer In ztürk R et al et al [7] research, average time between injury & surgery was 1.7 days in locked plate fixation group (0-5 days) & 1.5 days (0-t3 days) in cepholmedullary nail fixation group.

In the present study mean surgery time was 93.70 in group I & 95.90 minutes in group II with insignificant differences between both groups

According to ztürk R et al, [7] average surgery time in in cepholmedullary nail fixation group was 101 minutes (70-145 minutes) & 103 minutes (80-180 minutes) in locked plate fixation group.

In the present study there were insignificant differences between both groups as regards blood transfusion.

Consistency with our findings, ztürk R et al [7] reported that intraoperative blood requirements transfusion in the cepholmedullary nail fixation group were 0.20 unit & 0.4 unit (zero-1) in locked plate Intraoperative fixation group. & postoperative blood transfusion needs were 0.20 unit (zero-one unit) & 0.9 unit (zero-2 unit) in cepholmedullary nail fixation group and locked plate fixation group, respectively, with unimportant variation.

In the present study hospital stay 3.60 vs 3.3 in group I, II respectively was there were insignificant difference between both groups regarding post-operative hospitalization and follow up period.

In ztürk R et al., 2018 [7] survey, length of hospital stay after surgery in locked plate

fixation group was 5.3 days (2-9 days) & 4.2 days (2-8 days) in the cepholmedullary nail fixation group.

In the current study, we discovered a higher proportion of reoperation, mechanical failure, & nonunion in studied case group treated with locked plate fixation compared to group treated with cephalomedullary nail, which was consistent with Streubel PN et al.

In agreement with our research, Haidukewych GJ et al. and Whitelaw GP et al. showed that Intertrochanteric femur fractures (AO/OTA type 31A3), When sliding hip screws are used, fracture lines that expanded through lateral femoral cortex distal to vastus ridge of greater trochanter have unique mechanical & anatomic features that have been shown to lead in disappointing results.

In harmony with our present study, Sadowski C et al. and Streubel PN et al. had approved that cephalomedullary nails have become the best way of treatment of these fractures4.

In the present study no mortality rate detected in group I & one patient (10%) in group II with insignificant differences between two groups.

This present study showed that in cephalomedullary nails group, one studied case (10%) had infected nonunion that required reoperation (removal of hardware, irrigation, & debridement) & then healed in varus. Three studied cases (30%) in locked plate fixation group needed reintervention.

Also, according to findings of this research, two studied cases with varus collapse & screw cutout required hardware removal. two studied cases with loosening hardware of deep infection as result needed irrigation, debridement, & hardware removal. Three studied cases required bone grafting & revision fixation due to nonunion. One mechanical failure (10%) occurred in cephalomedullary nails group & three (30%) in locked plate fixation group.

In consistent with our result Öztürk R et al [7] found that in first year, there was no variation in mortality (P> 0.05). As result, three cases (25%) in the cephalomedullary nails group & six cases (25%) in locked plate fixation group developed major complications.

In first & second generation cephalomedullary nails group, Fusion rate was 87-100 %, the nonunion rate was 3-13%, malunion rate was 3-6%, and implant failure rate was 0-4% in the first and second generation. [9.10]

Negatives of IMNs were greater incidence of need for intraoperative fluoroscopic imaging, difficulties in method implementation, need for experienced surgeons, difficulty in implant removal when needed, & difficulty in implantation, especially in fractures extending trochanter major & fossa piriformis. [1]

There is very few research comparing cephalomedullary nails group & locked plate fixation group. In this research, higher-than-expected failure rates of locking plates raised concerns. Recently, Collinge et al. [12] conducted research in which all 111 proximal femur fractures were managed with proximal femur anatomic plates, & 41%, 4% cure failure was discovered. Fixation loss, malunion, nonunion, surgical malalignment, deep & combination infection. of these were causes.

Mirbolook et al. [13] compared the locked plate fixation group & cephalomedullary nails group in another research with 114 studied cases. Infection occurred in 27% of all studied cases, side device failure in twelve percent, malunion in 11%, nonunion in 8%, & combinations of these in varying rates. In this research, Mirbolook et al. hypothesized that plate & IMN selection may not be factor in complications that developed. Kanthimathi et al. [14] hypothesized that surgeon's skill & use of appropriate technique could reduce complications.

In the present research as regard complications 80% of groups I and 60% in

group II were free from any complications and in group I one patient had infection, one patient had infection with mechanical failure, in group II two patients had infection and one patient had infection with mechanical failure which indicate higher proportion of complication in patients treated by plate than those treated with cephalomedullary nails group.

Öztürk R et al [7] found that in one studied case in PFLP team, mechanic failure occurred. & another studied cases developed pseudo arthrosis. There was no infection in anv of cephalomedullary nails group studied cases. In the locked plate fixation group, however, infection was observed in three cases studied (12.4%). (Two with deep & one with superficial infection).

Irrigation + debridement was used to treat superficial infection, & irrigation + debridement + implant removal was used to treat deep infection. Studied case who underwent implant removal recovered with 1 cm shortness. DVT occurred in two studied cases (16.6%) of the cephalomedullary nails group & one studied case (4.1% of the locked plate fixation group.). [1]

High complication rate after surgical fixation of an unstable proximal femur fracture in elderly studied cases prompted use of primary hip prosthesis. Internal fixation was suggested for young & active elderly people because of luxation risk, high level of mortality, & complication risks in case of revision. (81, 82)

5.Conclusion:

Cephalomedullary nail is superior to locked plate treatment as regards post-operative complications, mechanical failure, malunion, nonunion and reoperation. Further larger studies are needed to validate our findings.

6.Consent for Publication:

I confirm that all authors accept the manuscript for submission

7. Availability of data and material:

Available

8. Competing interests:

None 9. Funding:

No funds

10. Conflicts of Interest:

The authors declare no conflicts of interest regarding the publication of this paper.

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