Journal of Chemical Health Risks

www.jchr.org

JCHR (2024) 14(5), 2026-2038 | ISSN:2251-6727

Outcomes of Intertrochanteric Femur Fractures Treated with Proximal Femoral Nail and Proximal Femoral Nail Anti-Rotation Ii in Elderly Patients – A Randomized Controlled Trial

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Received Date: 20/08/2024 Revised: 14/09/2024 Acceptance Date: 30/09/2024

KEYWORDS

Intertrochanteric, Proximal Femoral Nail

ABSTRACT:

Background: Internal fixation is the most common surgical treatment for intertrochanteric fractures, and intra-medullary (nails) and extra-medullary (screws or plates) fixations are two commonly used implants or appliances. The established benefits of internal fixation treatments are immediate pain relief, mobilization, faster rehabilitation and maintenance of independent living in these patients. The PFNA by using a single helical blade was designed to achieve better stabilization of the intertrochanteric fractures rather than a screw system or double screw fixation like in PFN for fixation. The helical blade increases the bone-implant interface and result in compaction of cancellous bone, thereby providing excellent stability of fixation.

Methods: A Randomized Controlled Trial of 60 patients carried out in Department of Orthopaedics of Tertiary care teaching hospital during period of October 2018 till February 2020. Patients with unstable intertrochanteric fractures fulfilling inclusion and exclusion criteria, were randomized into 2 groups to undergo CRIF with either standard PFN (n=30)or PFNA-II (n=30). They were compared in terms of demography, per-operative variables and postoperative parameters including functional evaluation till 6 months and 1 yr postoperatively.

Results: Background demographic variables, fracture type and pre-injury ambulatory status were comparable between the groups. The average operative time, radiation exposure and blood loss in osteosynthesis with proximal femoral nail antirotation-II is significantly less in comparison with proximal femoral nail. Also local and systemic complications are negligible thereby reducing hospital stay.

Conclusions: Osteosynthesis with proximal femoral nail antirotation-II significantly reduces The average operative time, radiation exposure and blood loss as compare to proximal femoral nail. Also local and systemic complications are negligible thereby reducing hospital stay.

Introduction

Half of all hip fractures comprise of intertrochanteric femur fractures[1]. Intertrochanteric fractures occur most commonly in elderly patients and the outcome may be compromised if the patients are not mobilized early. Over 90% of hip fracture patients are older than 60 years old and they have pre- existing medical comorbidities like blood pressure and diabetes mellitus[2]. Factors like age and pre-existing comorbidities have an important influence in prognosis and treatment of this fractures[2].

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JCHR (2024) 14(5), 2026-2038 | ISSN:2251-6727

The best treatment for intertrochanteric fracture remains controversial. Many methods have been recommended. Stable fixation allows early mobilization and is the treatment of choice for intertrochanteric femur fractures[3]. The strength of the fracture fragment-implant assembly depends upon various factors including (a) bone quality, (b) fracture geometry, (c) reduction, (d) implant design and (e) implant placement. In cases of intertrochanteric factures, thepreferred type of fixation device is controversial. Intramedullary nails can be inserted with less exposure to fractures, less blood loss, although they may require more fluoroscopic exposure in comparison with extramedullary devices[4,5]. The goals of management of this fracture is to restore anatomical alignment, early mobilization, safely and efficiently while minimizing risk of medicalcomplications and technical failure[6].

Internal fixation is the most common surgical treatment for intertrochanteric fractures[7], and intra-medullary (nails) and extra-medullary (screws or plates) fixations are two commonly used implants or appliances[8]. The established benefits of internal fixation treatments are immediate pain relief, mobilization, faster rehabilitation and maintenance of independent living in these patients. These fragility hip fractures occur in a specific population with risk factors including increasing age, female sex, osteoporosis, a history of falls, and gait abnormalities. The Intertrochanteric region comprises of proximal femur extending from greater trochanter to the lesser trochanter distal to the neck of femur. The majority of the bone in the area is cancellous, extracapsular, and highly rich in blood supply(contrast with subcapital femoral neck) leading to a good healing environment. Several anatomic features influence treatment. The greater and lesser trochanters are the points of attachment of the primary hip abductors (gluteus medius and gluteus minimus) and primary hip flexor (iliopsoas), respectively[9].

The aim of treatment of any Intertrochanteric fracture is to restore early mobility and to minimize the risk of medical complications and restore the patient to the preoperative status. The dynamic hip screw (DHS) was considered as the standard device for comparison of outcomes, especially for the stable intertrochanteric fractures. The proximal femoral nail (PFN), introduced by the Association for Osteosynthesis/Association for the Study of Internal Fixation group in 1998, has gained widespread popularity for the treatment of trochanteric fractures since its introduction. The advantage of Proximal Femur Nailing fixation is that it provides a more biomechanically stable construct by decreasing the distance between hip joint and implant[10].

As Intertrochanteric fractures of the femur occur in elderly patients, some degree of osteoporosis is often seen in these patients and hence the wide variety of treatment available, poses difficulty in choosing a specific treatment. A sliding screw device was the implant of choice as it encourages impaction of the fracture. However, many authors have concluded that sliding compression screws may be associated with severe complications such as perforation of the femoral head, loss of reduction caused by excessive sliding of the lag screw, non-union and shortening of the affected limb . In unstable fractures this failure rate is 10-16% but the factors responsible for these complications are not well understood and remain controversial[11].

Patients who have intertrochanteric fractures are slightly older and have a higher rate of morbidity and mortality compared with patients who have fractures of the femoral neck. People of this age group usually have other systemic diseases such as diabetes, liver & cardiovascular diseases, hypertension, parkinsonism, dementia. The impact of these diseases causes rapid deterioration of the general condition of those patients especially in the bed ridden condition. The goals of the treatment for these patients are to restore the pre-fracture activity status of the patients, to allow early full weight bearing, and to try to avoid possible second operation to correct one of the complications of the first one[12].

Regardless of PFN proved to be best to extramedullary device for fixation of the unstable intertrochanteric fractures, screw cut-out, varus collapse, back out, Z-effect and rotational instability are significant postoperative complications, with up to 31% complication[13].

The PFNA by using a single helical blade was designed to achieve better stabilization of the intertrochanteric fractures rather than a screw system or double screw fixation like in PFN for fixation. The helical blade increases the bone-implant interface and result in compaction of cancellous bone, thereby providing excellent stability of fixation[14].

The helical blade provides additional anchoring to head neck area of the femur and can be inserted without reaming out, especially in osteoporotic bone. Helical blade has superior resistance to rotation and varus collapse by compaction of cancellous bone around and has been proven by biomechanical studies [15]. Clinical studies are much needed to confirm whether this device is superior over other devices and also has benefits in terms of functional outcomes and complication rates as has been claimed[16].

Materials and Methods

A Randomized Controlled Trial of 60 patients carried out in Department of Orthopaedics of Tertiary care teaching hospital during period of October 2018 till February 2020.

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All elderly patients getting admitted with intertrochanteric fractures fulfilling the inclusion criteria were treated with closed reduction and internal fixation with proximal femoral nail andproximal femora l nail antirotation-II after randomization of patient using computer based randomization software sealed envelop Ltd. 2017 ver. 1.13.3

- Patient operated with closed reduction and internal fixation with proximal femoral nail antirotation-II as a case
- Patient operated with closed reduction and internal fixation with proximal femoral nail as control Boyd and Griffith classification of intertrochanteric fracture femur was used to classify fracture.

Harris hip score was used to measure functional outcom es.
Follow up was takenon 1st, 3rd and 6th month after sur gery.

Inclusion criteria:

- All Inter-trochanteric femur fractures amenable to osteosynthesis by either PFN or PFNA-II
- Patient aged 55 years and above

Exclusion criteria:

- Associated fracture neck of femur
- Fracture shaft femur
- Patients with associated fractures in ipsilateral lower limb
- Compound fractures.

Study instruments:

- Proximal femoral nail: Intramedullary fixation device for intertrochanteric femur fractures.
- Proximal femoral nail anti-rotation II: New generation Intramedullary fixation device for intertrochanteric femur fractures.
- Fracture table: A specialized table assembly used for the fixation of intertrichanteric femur fractures.

METHODS

PREOPERATIVE EVALUATION

On admission to the institute detailed history of the patient was taken into consideration including mechanism of injury, associated injury, medical illness and pre injury status. A detailed systemic and general examination was carried out to evaluate complete status of the patient. Detailed examination of the fractured limb, status of skin and soft tissue was carried out. All routine hematological investigations were done. On day one after proper radiological investigation, skin traction was applied to injured limb.

The general condition was built up if necessary and complications of recumbency prevented as far as possible with good nursing care. Anaesthesia and physician fitness was taken. The intervalbetween admission and surgery varied, though the aim was to take up patient as soon as surgically fit.

Radiograph

- Standard antero-posterior view of pelvis with both hip joints and lateral view of the affected hip were taken in all cases to know accurately fracture geometry, canal diameter and type.
- Chest X-ray PA view was taken if indicated.
- Other x-rays of associated injury were taken.

Pre-op planning

- Determination of nail diameter: Nail diameter was determined by measuring diameter of the femur at the level of isthmus on an AP and lateral x-ray.
- Determination of neck shaft angle: Neck shaft angle was measured on the unaffected side on an AP x-ray using goniometer.

Preoperative preparation

- Injection Xylocaine 0.5 cc Intradermally and injection TT 0.5 cc Intramuscularly given the day prior to surgery.
- Intravenous antibiotic were given an hour befo re the surgery.
- The back, lateral aspect of the hip from the iliac crest to the distal thigh , groin was prepared.
- Written and informed consent taken.
- Blood units arranged. (if necessary)

OPERATIVE TECHNIQUES

A. Closed reduction and internal fixation with proximal femoral nail.

Anaesthesia

Patients were operated under spinal or epidural or general anaesthesias decided and thought appropriate by the anaesthetist.

Patient Positioning

A fracture table was used for all the cases. Following suitable anaesthesia patient was place supine on fracture table. Patient's injured leg was placed in neutral or adduction with 10-15 degree of internal rotation and uninjured leg placed in flexion and abduction as far as possible to accommodate the image intensifier. The

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JCHR (2024) 14(5), 2026-2038 | ISSN:2251-6727

image intensifier was positioned so that simultaneous anterior-posterior and lateral views can be taken.

Reduction of fracture

Closed reduction was carried out in all patients. All steps of reduction were carried out under image intensifier television control. The first step of reduction is in the antero-posterior plane and is accomplish through traction. Traction probably was the most important element in reducing fractures. Once it appears that appropriate angle has been obtained and that the tip of trochanter is at the centre of the femoral head then a lateral view was obtained.

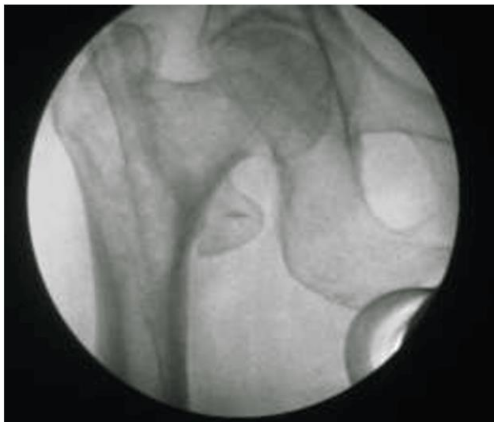

Figure 1: C-arm images after reduction of fracture in AP view

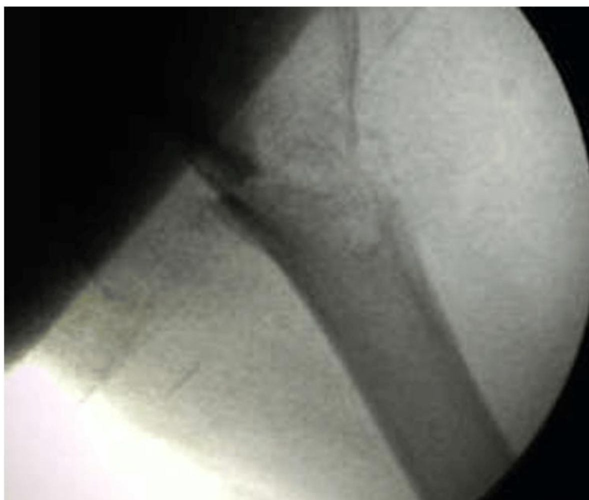

Figure 2: C-arm images after reduction of fracture in lateral view

If the fracture was not reducible in lateral view, without disturbing the AP view then the leg should be placed in approximately 15 degrees external rotation followed by gentle but firm internal rotation. Usually satisfactory reduction was obtained in both AP and lateral views. If reduction is not achieved by closed methods then open reduction has to be performed. The patient was given a scrub and then parts were painted and draped for the standard hip fracture fixation. Prophylactic antibiotic were given to all the patients.

Approach

The tip of greater trochanter was located by palpation or occasionally by using image intensifier in obese patients. A 5 cms longitudinal incision was taken proximal from tip of trochanter. Fascia lata was opened in line of incision and the gluteus medius was split in line with fibers and tip of trochanter was exposed.

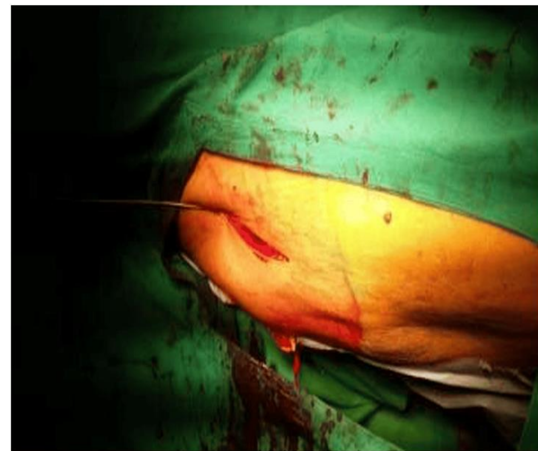

Figure 3: Skin incision and approach

Entry point:

Entry point was taken with the help of curved awl by placing it upon tip of greater trochanter (in AP view). On the lateral view, it was conformed that tip of awl lies in the center of medullary canal. Awl was driven into cancellous bone till medullary canal was opened. Awl removed and guide wire inserted in entry point made with awl using T handle under image intensifier.

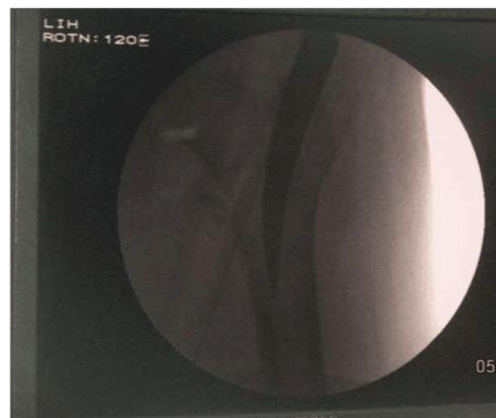

Figure 4: Entry point on tip of Greater Trochanter

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Reaming:
Proximal cannulated reamer was used to open the proximal portion of femur to 14 mm to accommodate the proximal portion of nail (14 mm). Reaming was carried out over the guide wire.
Also serial reaming was done to open a medullary canal by 8, 9, 10, 11 size reamer.

Insertion of PFN:
Nail selected as per preoperative planning was tightly connected to the insertion handle and all the guide holes were matched up to the screw holes in the nail. Then the nail placed over guide wire. The nail is then gently pushed through the trochanter region and across the fracture area under Image Intensifier using gentle twisting movements of handle. Nail is then pushed down until the profile of proximal locking holes is noted to appear to just pass the inferior aspect of the neck. Slight twisting hand movements help insertion. Guide wire is now removed. Proximal and distal screws were inserted

Guide Wire & Screw Insertion:
These are inserted with the help of aiming device tightly secured to the insertion handle and using the appropriate guide wire sleeves. A 1.8 mm threaded guide pin is inserted through the sleeves approximate to the lateral cortex to avoid misdirection of the guide wire. Position of the guide wire in the inferior aspect of the neck in AP view and center in lateral view for the 8 mm hip screw is ascertained with the help of image intensifier.
Similarly, another guide wire was inserted through the proximal hole for insertion of the 6mm derotation screw. Proper positioning of the nail will aid in proper anteversion of the guide wire as there is inbuilt anteversion in the hole of the nail.

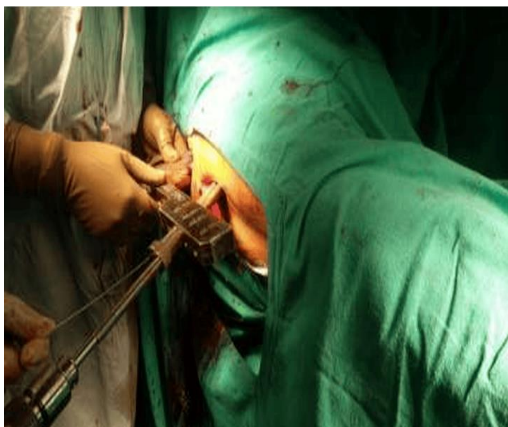

Figure 5: Guide wire with screw insertion in PFN

Care was taken that the threaded portion of guide wire is placed right upto the subchondral bone. Length of femoral neck screw is determined by placing the direct measuring device over the guide wire until it touches the bone. Measured length was set on reamer. Reaming done with the help of 8 mm reamer over the guide wire. Tapping was not required due to the self- tapping tip of femoral neck screw. Selected femoral neck screw was inserted over the guide wire. It was taken care that the tip of femoral neck screw reaches within 5 mm to 1 cm of articular surface of femoral head. Guide wire and protection sleeves are then removed.

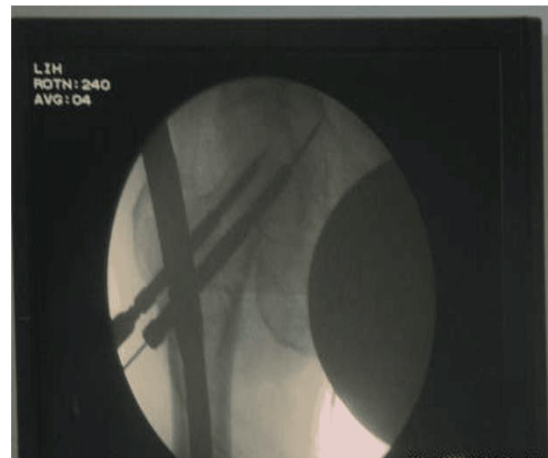

Figure 6: C-arm image showing proximal screw insertion in PFN

Distal locking:
Two holes are available one for static interlocking & the other for dynamic interlocking. Distal locking was done. Using appropriate guide, stab incision was made on lateral aspect of thigh and distal locking was done with
4.9 mm locking bolt after drilling both cortices using 4 mm drill bit and taking measure of screw length.

Figure 7: Distal locking

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Insertion of end cap:
End cap was not inserted.

Closure:
The instruments are removed, wash given with normal saline and wounds are closed in layers. At this time the position of screws were reviewed to make sure that there is no intra-articular penetration.
B. Closed reduction and internal fixation with proximal femoral nail antirotation-II
Anesthesia, positioning of patient and reduction method of fracture was same as of PFN in case of PFNA-II

Approach:
The tip of greater trochanter was located by palpation or occasionally by using image intensifier in obese patients. A 5 cms longitudinal incision was taken proximal from tip of trochanter. Fascia lata was opened in line of incision and the gluteus medius was split in line with fibers and tip of trochanter was exposed.

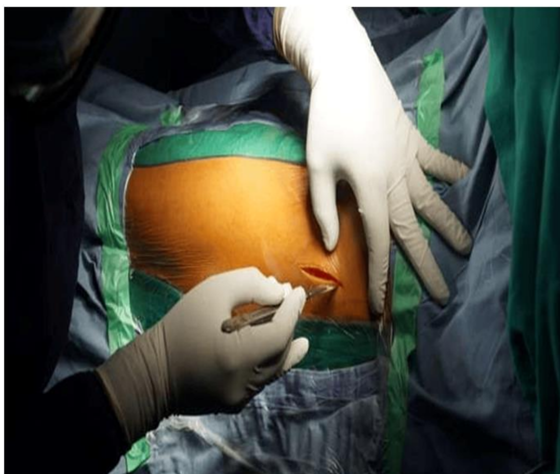

Figure 8: Incision site on lateral aspect of hip just above greater trochanter

Entry point:
Entry point was taken with the help of curved awl by placing it upon tip of greater trochanter (in AP view). On the lateral view, it was conformed that tip of awl lies in the center of medullary canal. Awl was driven into cancellous bone till medullary canal was opened. The awl was removed and guide a wire was inserted in entry point made with awl using T handle under image intensifier.

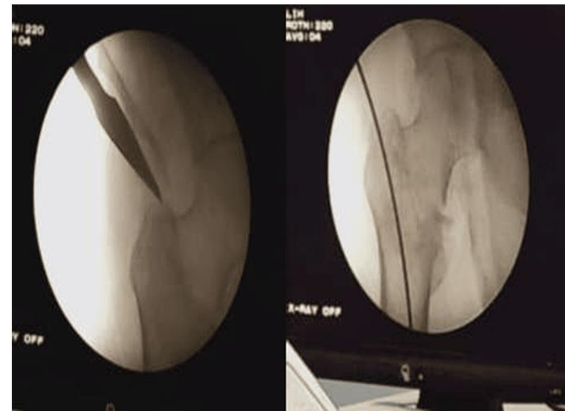

Figure 9: Entry point at the tip of Greater Trochanter

Reaming:
Proximal cannulated reamer was used to open the proximal portion of femur to about 14 mm to accommodate the proximal portion of nail (14 mm). Reaming was carried out over the guide wire.
Also serial reaming was done to open a medullary canal by 8, 9, 10, 11 size reamer.

Insertion of PFNA-II:
Nail selected as per preoperative planning was tightly connected to the insertion handle and all the guides are matched up to the holes. Then the nail placed over guide wire. The nail is then gently pushed through the trochanter region and across the fracture area under image intensifier using gentle twisting movements of handle. Nail is then pushed down until the profile of proximal locking hole is noted to appear to just pass the inferior aspect of the neck. Slight twisting hand movements help insertion. Guide wire was then removed. Proximal and distal screws were inserted through the insertion handle.

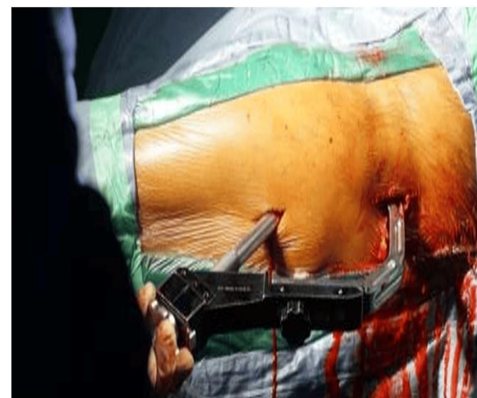

Figure 10: PFNA-II insertion along with inserting jig

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Guide Wire & Screw Insertion:
These are inserted with the help of aiming device tightly secured to the insertion handle and using the appropriate guide wire sleeves. A 1.8 mm threaded guide pin is inserted through the sleeves approximate to the lateral cortex to avoid misdirection of the guide wire. Position of the guide wire in the inferior aspect of the neck in AP view and center in lateral view for the single helical blade hip screw.

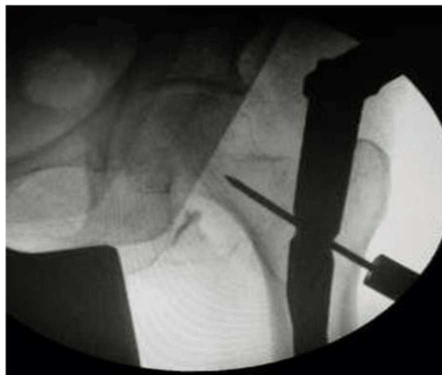

Figure 11: Guide wire position for helical screw insertion

Care was taken that the threaded portion of the guide wire was placed right upto the subchondral bone. Length of femoral neck screw is determined by placing the direct measuring device over the guide wire until it touches the bone. Measured length was then set on the reamer. Reaming done with the help of reamer over the guide wire. Tapping was not required due to the self-tapping nature of the tip of the femoral neck screw. Selected femoral neck screw was then inserted over the guide wire and hammered till 5mm of hip joint line. Anti-rotation with screw driver done and reduction achieved. It was taken care that the tip of femoral neck screw reaches within 5 mm to 1 cm of articular surface of femoral head in both AP and lateral view. Guide wire and protection sleeves removed.

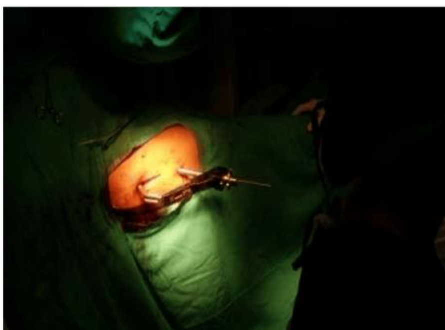

Figure 12: Guide wire insertion with sleeve and jig for screw insertion

Distal locking:
One single hole is available one for static & dynamic interlocking on the device. Distal locking was done in most of the cases with single locking bolt (static in most cases). Using appropriate
guide stab incision was made on lateral aspect of thigh and distal locking was done with 4.9 mm locking bolt after drilling both cortices using 4 mm drill bit and taking measure of screw length.

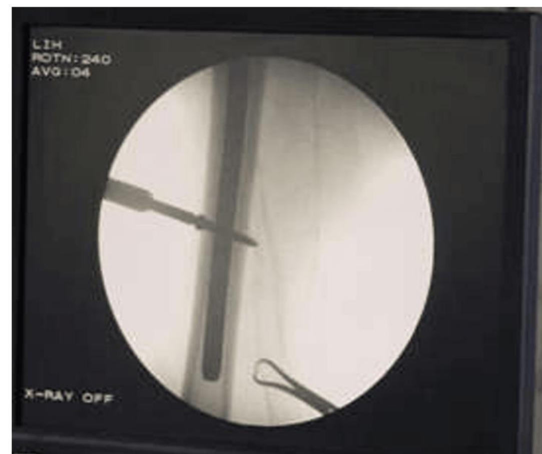

Figure 13: Distal screw locking

Insertion of end cap:
End cap was inserted in some cases.

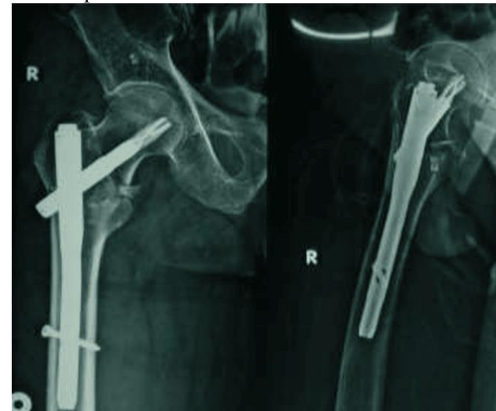

Figure 14: End cap with distal locking

Closure:
The instrument are removed, wash given with normal sa line and wounds were closed in layers. At this time the position of screws were reviewed to make sure that there is no intraarticular penetration.

Postoperative protocol:
Postoperative protocol was same for both the groups i.e. for Proximal femoral nail and Proximal femoral nail antirotation-II.

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Check x-ray taken after the surgery. I.V. antibiotics were given 12 hourly for 72 hours. Active and passive knee and hip exercises are started on the 1st POD.
1st check dressing was done on 2nd POD. 2nd dressing was done on 7th POD. Suture removal was done on 10th/11th POD. Crutch walking taught in the hospital. Patients were kept nonweight bearing till 1st follow up. Patient was advised to do active hip and knee exercises.

Follow up:
All patients were advised regular follow up at least once in four weeks till there was some evidence of union. Weight bearing was started as per union of fracture assessed on the basis of radiological evaluation of fracture union.

Results
Hip scoring done as per
Harris hip score53 on 1st, 3rd and 6th week.
Data was collected by using a structure proforma. Data thus was entered in MS excel sheet and analysed by using SPSS 24.0 version IBM USA.
Qualitative data was expressed in terms of percentages and proportions Quantitative data was expressed in terms of Mean and Standard deviation Association between two qualitative variables was seen by using Chi square/ Fischer's exact test Comparison of mean and SD between two groups will be done by using unpaired t test to assess whether the mean difference between groups is significant or not.
Descriptive statistics of each variable was presented in terms of Mean, standard deviation, standard error of mean.
A p value of <0.05 was considered as statistically significant whereas a p value <0.001 was considered as highly significant.

Table 1: Distribution according to age group

		PFNA 2		PFN	
		Frequency	**Percent**	**Frequency**	**Percent**
Age group in years	55-65	17	56.7	16	53.3
	66-75	8	26.7	6	20.0
	76-85	4	13.3	7	23.3
	86-95	1	3.3	1	3.3
	Total	30	100.0	30	100.0

Total of 60 subjects were taken for the study and 30 were in group A i.e. PFNA2 and 30 in group B i.e. PFN In group A out of 30 subjects majority of subjects belongs to age group of 55 to 65 that were 17(56.7%) and followed by 8(26.7%) subjects in age group of 66 to 75 and least number of subjectswere fro m age group of 86-95 i.e. 1(3.3%).

In group B out of 30 subjects majority of subjects belongs to age group of 55 to 65 that were 16(53.3%) and followed by 6(20.0%) subjects in age group of 66 to 75 and least number of subjectswere fro m age group of 86-95 i.e. 1(3.3%).

Table 2: Distribution according to mode of injury

		PFNA 2		PFN	
		Frequency	**Percent**	**Frequency**	**Percent**
MODE OF INJURY	DOMESTICFALL	16	53.3	20	66.7
	RTA	14	46.7	10	33.3
	Total	30	100.0	30	100.0

Chi square test-1.11, p-0.29(>0.05), Not significant
According to the mode of injury group A had a total 16(53.3%) subjects having injury due to domestic fall and number of subjects having injury due to RTA were 14(46.7%).

In group B mode of injury was domestic fall in 20(66.7%) subjects and injury due to RTA was seen in 10(33.3%) subjects.

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Table 3: Comparison of mean surgery duration between PFNA2 and PFN group

Group		N	Mean	Std. Deviation	t	p	Inference
DURATION OF SURGERY (MINS)	PFNA2	30	56.67	8.24	-12.43	0.0001 (<0.01)	Highly significant
	PFN	30	82.67	7.96			

Mean duration of surgery for PFNA2 was 56.67+/-8.24 minutes and that for PFN group was 82.67+/-7.96 minutes with a p value <0.01 which is highly significant.

Table 4: Comparison of mean full wt bearing between PFNA2 and PFN group

Group		N	Mean	Std. Deviation	t	p	Inference
FULL WT. BEARING (WEEKS)	PFNA2	30	4.79	0.86	2.24	0.024 (<0.05)	Significant
	PFN	30	4.00	1.70			

Full weight bearing as observed in group A was having a mean 4.79+/-0.86 weeks and mean full weight bearing in group B was 4.00+/-1.70 with a p <0.05 which is significant.

Table 5: Comparison of mean time of union between PFNA2 and PFN group

Group		N	Mean	Std. Deviation	t	p	Inference
TIME OF UNION	PFNA2	30	3.97	0.72	0.47	0.63 (>0.05)	Not Significant
	PFN	30	3.83	1.37			

In group A mean time for union was 3.97+/-0.72 months and mean time for union in group B was 3.83+/- 1.37 months.

Table 7: Comparison of mean HHS at 1 month after surgery between PFNA2 and PFN group

Group		N	Mean	Std. Deviation	t	p	Inference
HHS ON 1 MNTHREVIEW	PFNA2	30	64.55	2.98	1.754	0.085 (>0.05)	Not significant
	PFN	30	57.80	20.52			

Mean HHS review on 1 month was 64.55 +/-2.98 and mean HHH for group B was 57.80+/-20.52 which is not significant.

Table 8: Comparison of mean HHS at 3 month after surgery between PFNA2 and PFN group

Group		N	Mean	Std. Deviation	t	p	Inference
3 MTH REVIEW HHS	PFNA2	30	68.59	2.38	2.037	0.046 (<0.05)	Significant
	PFN	30	59.50	23.90			

Mean for 3 month review HHS score for group A was 68.59 +/- 2.38 and for group B it was 59.50+/-23.90 with a p value 0.046 i.e. <0.05 is significant.

Table 9: Comparison of mean HHS at 6 month after surgery between PFNA2 and PFN group

Group		N	Mean	Std. Deviation	t	p	Inference
6 MNTHREVIEW HHS	PFNA2	30	72.21	2.61	2.51	0.015 (<0.05)	Significant
	PFN	30	59.47	27.16			

Mean for 6 month review HHS score for group A was 72.21 +/- 2.61 and for group B it was 59.47 +/-27.16 with a p value 0.015 i.e. <0.05 is significant.

Table 10: Comparison of radiation exposure between PFNA2 and PFN group

Group		N	Mean	Std. Deviation	t	p	Inference
RADIATION EXP(SHOOTS)	PFNA2	30	31.50	4.76	-7.933	0.0001 (<0.01)	Highly significant
	PFN	30	41.17	4.68			

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Mean radiation exposure for group A was 31.50+/-4.76 shoots while in group B it was 41.17+/-4.68 shoots. p value <0.01 and is highly significant.

Table 11: Comparison of complication

		PFNA 2		PFN	
		Frequency	**Percent**	**Frequency**	**Percent**
Complications	Minor backout	1	3.3	0	0.0
	Implant cutout	1	3.3	2	6.7
	Surgical site infection	1	3.3	2	6.7
	Nil	27	90.0	26	86.7
	Total	30	100.0	30	100.0

Chi square test-0.16, p-0.68(>0.05), Not significant

Discussion

Half of all hip fractures comprise of intertrochanteric femur fractures[1]. Intertrochanteric fractures occur most commonly in elderly patients and the outcome may be compromised if the patients are not mobilized early. Over 90% of hip fracture patients are older than 60 years old and they have pre-existing medical comorbidities like blood pressure and diabetes mellitus[2]. Factors like age and pre-existing comorbidities have an important influence in prognosis and treatment of this fractures[2].

Internal fixation is the most common surgical treatment for intertrochanteric fractures[7], and intra-medullary (nails) and extra-medullary (screws or plates) fixations are two commonly used implants or appliances[8].

The established benefits of internal fixation treatments a re immediate pain relief, mobilization, faster rehabilitation and maintenance of independent living in these patients.

Regardless of PFN been proven to be best intramedullary device for fixation of the unstable intertrochanteric fractures, screw cut-out, varus collapse, back out, Z-effect and rotational instability are significant postoperative complications, with up to 31% complication[13].

The PFNA-II by using a single helical blade was designed to achieve better stabilization of the intertrochanteric fractures rather than a screw system or double screw fixation like in PFN for fixation. The helical blade increases the bone-implant interface and result in compaction of cancellous bone, thereby providing excellent stability of fixation[14].

The helical blade provides additional anchoring to head neck area of the femur and can be inserted without reaming, especially in osteoporotic bone. Helical blade has superior resistance to rotation and varus collapse by compaction of cancellous bone and has been proven by biomechanical studies[15].

This study was conducted on 60 adult patients with unstable trochanteric fractures who were managed operatively using either PFN or PFNA-II following closed reduction at a tertiary care centre. The patients in both the groups were comparable in terms of demography and the fracture type.

Comparison of age and sex

Our study had 60 patients in a age group of 55 to 95 years of age with mean age. Percentage of female in group PFNA-II was 46.7% to male was 53.3% and in group PFN there were 50% of male and 50% of female and there was no significant variation in relation to age and sex of patient studied.

Li J1, Cheng L1, Jing J2 *et al.* (2015) compare Asia proximal femoral nail antirotation (PFNA-II) was specifically designed for Asian patients, which could be more effective than the regular proximal femoral nail antirotation (PFNA) and found that due to its special design for the Asian population, PFNA-II offers a better match with the Chinese people's proximal femur anatomic structure. The operative time is shorter and hence less exposure to x-rays[17].

Kashid, Manoj & Gogia, Tushar & Prabhakara *et al.* (2016) study done at their centre on comparison of two devices PFN and PFNA-II for fixation of intertrochanteric fracture they concluded that there is less amount of xray exposure to PFNA-II[18].

Kashid, Manoj & Gogia, Tushar & Prabhakara *et al.* (2016) study done at their centre on comparison of two devices PFN and PFNA-II for fixation of intertrochanteric fracture they concluded that there is significantly less operative time, less amount of blood loss[18].

The mean duration of surgery was significantly lower in PFNA-II group as compared to PFN group. This was mainly because of the use of a single helical blade in PFNA-II as compared to two screws in PFN. The PFNA-II involves gentle tapping of the helical blade over a guide pin thereby avoiding the steps involved for insertion of lag screw and de-rotation screw as required in a PFN. The positioning of the guide wire for insertion of helical blade is also easier as compared to two guide wires for PFN.

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Soucanye de Landevoisin, A. Bertani *et al.* (2011) Retrospective study in 102 patients treated with PFNA-II they concluded that with PFNA-II device, surgical procedure is simple and less time consuming[19].

Exposure to X-rays, as determined by the number of intraoperative fluoroscopic images taken showed significantly lower scores for PFNA-II as compared to PFN. The reasons for this are the same as that for increased duration of surgery in case of PFN.

E. Soucanye de Landevoisin, A. Bertani *et al.* (2011) Retrospective study in 102 patients treated with PFNA-II they concluded that with PFNA-II, surgical procedure is simple and less time consuming . The helical blade used in the PFNA-II provides additional benefits in osteoporotic patients with intertrochanteric femoral fractures, by preventing rotation and by ensuring compaction of cancellous bone. The rate of complications associated with the several implant may diminish, provided the surgical procedure should be properly followed and fracture reduction is adequate[19].

Dr. Shashikant S Gadhe, Dr. Pramod Bhor *et al.* (2019) A comparative study of randomized control study on 50 patient treated with PFN and PFNA-II in unstable intertrochanteric fracture femur they concluded that , PFNA-II gives better outcome in terms of intraoperative complications, blood requirements[20].

G.N. Kiran Kumar, Gaurav Sharma, Kavin Khatri *et al.* (2015) In their study article on treatment of Unstable Intertrochanteric Fractures with Proximal Femoral Nail Antirotation IIconcluded that for fixation of unstable intertrochanteric fractures PFNA II is a best option with decreased operative time[21].

There was a significant difference between weight bearing in PFNA-II and PFN and the results of our studies were similar to following studies. The mean time of weight bearing in group PFNA-II was 4.79 weeks and that in group PFN was 4.00 weeks. With a p value <0.05 which is significant.

W. M. Gade gone & Y. S. Salphale *et al.* (2006), reported a study on Proximal femoral nail - an analysis of 110 cases of proximal femoral fractures with an average follow up of 2 year. Postoperative radiographs showed a near-anatomical fracture reduction in 90% of his patients.. The fracture consolidated in 4 months. Patients were allowed early weight bearing[22].

WL Loo, *et al.* (2011) in review of Proximal Nail Antirotation (PFNA) and PFNA-2 in their local experience they concluded that PFNA-II is a good device for the fixation of intertrochanteric fracture if fracture reduction done properly. Patient operated with PFNA-II regain their work within 6 months of surgery[23].

MingHui Li *et al.* (2014) in there study on 163 patients treated with PFNA-II in unstable intertrochanteric fractures their observation was that PFNA-II have advantage of simpler operative
technique with less complication and clinical efficacy in unstable fractures[24].

The mean blood loss was significantly lower in PFNA-II group as compared to PFN group. The decrease in blood loss in PFNA-II group is attributed to decreased duration of surgery and smaller surgical incision for the placement of PFNA-II Blade as compared to longer surgical time and longer incision for insertion of lag Screw and de-rotation screw in PFN Group. However the amount of blood loss was not severe enough to necessitate a blood transfusion in any case.

MingHui Li *et al.* (2014) in there study on 163 patients treated with PFNA-II in unstable intertrochanteric fractures their observation was that PFNA-II have advantage of simpler operativetechnique with le ss complication and clinical efficacy in unstable fractures[24].

Hospital stay was comparatively of short duration in our study in group PFNA-II as compared PFN group.

MingHui Li *et al.* (2014) in there study on 163 patients treated with PFNA-II in unstable intertrochanteric fractures their observation was that PFNA-II have advantage of simpler operativetechnique with le ss complication and clinical efficacy in unstable fractures[24]. Hence there was shorter duration of hospital stay with PFNA.

Mahendra Kumar Reddy Mundla*, Mohammad Rafi Shaik, Someswara Reddy Buchupalli, Chandranna B. *et al.* (2017) in there study on comparison between PFN and DHS inunstable intertr ochanteric fracture in elderly they found PFN as a better surgical implantation over DHS as there is less blood loss[25].

Comparison of time for union

Our study did not demonstrate any significant difference in time for union by use of either PFNA-II or PFN. The mean time for union in PFNA-II was 3.97 months and that in PFN was 3.83 months.

Comparison of Harris hip score

In our study demonstrates significant difference between mean HHS at 6 month after surgery between PFNA-II and PFN group. Average HHS at the end of study in PFNA2 group was 72.21 with SD of 2.61 and in PFN group was 59.47 with SD of 27.16.

Conclusion

From our study we can safely conclude that osteosynthesis with proximal femoral nail antirotation-II in intertrochanteric femur fracture in the elderly patients leads to better functional outcomes as

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JCHR (2024) 14(5), 2026-2038 | ISSN:2251-6727

compared with osteosynthesis with proximal femoral nail. We can safely consider it as a viable option in the treatment of intertrochanteric fractures in the elderly. So this surgery can give predictable outcomes in trained hands. The average operative time, radiation exposure and blood loss in osteosynthesis with proximal femoral nail antirotation-II is significantly less in comparison with proximal femoral nail. Also local and systemic complications are negligible thereby reducing hospital stay. Harris hip score at the end of 6 months is significantly good in patients treated with proximal femoral nail antirotation-II. Where as time to union and weight bearing time was not significant in both groups.

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