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Comparative study of PFN vs PFNA 2 in intertrochanteric fractures: A randomised control trial

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Abstract

Introduction: As the life expectancy increases due to improved medical facilities, it leads to increased incidence of intertrochanteric fracture. The intertrochanteric fractures can be managed by conservative methods or by surgery. PFN comprise of an intramedullary nail with two screws of which one is the lag screw settling the fracture as it collapses and other is antirotation screw giving the rotational stability. PFN comprise of an intramedullary nail with two screws of which one is the lag screw settling the fracture as it collapses and other is antirotation screw giving the rotational stability.

Aim of our study is to analyze both the intramedullary devices as functional outcome and implant related complications.

Material and Method: A prospective, randomized, comparative study of 60 patients. This study was conducted in Patna Medical College and Hospital, Patna, Bihar, between June 2017- June 2019 for two Years.

Conclusion: From the study we concluded that the PFNA2 reduces the surgery time, blood loss, and image shots number as compared to PFN. As the union rate is more with PFNA2, the functional outcome is significantly better with PFNA2 than PFN. Implant related late complication is more with PFN which was markedly reduced with PFNA2.

Keywords: PFN vs PFNA 2, intertrochanteric fractures, Bihar

Introduction

As the life expectancy increases due to improved medical facilities, it leads to increased incidence of intertrochanteric fracture¹. The intertrochanteric fractures can be managed by conservative methods or by surgery. The basic principle of surgery is to use an implant that is minimally invasive, that has a less operative time and one which allows for early mobilization and weight bearing. The choice of surgical treatment (dynamic hip screw or proximal femoral nailing) is determined in part by whether the fracture is stable or unstable. The proposed advantages of intramedullary nailing include a short incision, less operative time, minimal blood loss and rapid rehabilitation, which is essential to minimise the risk of medical complications².

PFN comprise of an intramedullary nail with two screws of which one is the lag screw settling the fracture as it collapses and other is antirotation screw giving the rotational stability. PFN also has showed more number of post-operative complications, like implant failures, screw cut out in case of unstable intertrochanteric fractures³.

PFN comprise of an intramedullary nail with two screws of which one is the lag screw settling the fracture as it collapses and other is antirotation screw giving the rotational stability., when contrasted and other implant, there by essentially diminishing possibility of failure of implant in osteoporotic bone of old patients⁴.

In our study as "Comparative study of PFN vs PFNA 2 in intertrochanteric fractures: A randomised control trial", We have made an endeavor to analyze both the intramedullary devices as functional outcome and implant related complications.

Materials and Methods

Study Design: A prospective, randomized, comparative study of 60 patients.

Study site: This study was conducted in Patna Medical College and Hospital, Patna, Bihar

Study Period: June2017- June 2019

Study duration: Two Years

Follow Up:

Minimum-6months

Maximum-2years

Average- 16months

Inclusion Criteria

1. Patients who are skeletally mature (>18yrs),
2. Patients with intertrochantric fractures,
3. Medically fit patients,
4. Patients with closed fractures,

Exclusion Criteria

1. Patients with pathological fractures,
2. Patients who are medically unfit for surgery,
3. Patients with open injurie
4. Patients refusing to give written informed consent

All patient in this study was admitted from emergency room, with the complain of pain in affected hip and/or other affected body part after trauma, either due to fall or due to RTA. All the patients were evaluated completely and routine investigation was done. Diagnosis was made on the basis of clinical finding and radiological examination. X-ray pelvis with both hip antero-posterior view and lateral view of affected hip was sufficient for diagnosis.

Pre-Operative Evaluation

Patients with suspected trochanteric fracture satisfying inclusion and exclusion criteria were included in our study. All the patients were evaluated for associated medical problems and necessary treatment were given. Associated injuries were evaluated and treated simultaneously. Local ethical committee approval was taken and written informed consent from patients was obtained. All the patients were divided into two groups, group A for PFN and group B for PFNA2 by simple randomization. All the patients underwent Pre anaesthetic check up, once they are fit, they were operated as early as possible, with either PFN or PFNA2.

Evaluation for intraoperative blood loss, numbers of image intensifier shots, and surgery time (skin to skin) was done. A modified Garden's alignment index was used to assess the quality of reduction. On the AP view, the central axis of the medial group of trabeculae in the capital fragment and the line of the medial femoral cortex was used to determine an angle. On the axial view, the anterior or posterior angulation of the head was measured from the angle between a line drawn from the midpoint of the fracture surface of the distal fragment to the center of the femoral head and a line through the central axis of the neck of the femur. In order for the reduction to be acceptable, the anterior-posterior angle should be between 160 and 180 degrees and the axial angle should be less than 20 degrees.

All the patients underwent clinical and radiological judgment of fracture morphology and union rate, first post-operatively which is repeated at 6 weeks, 3months, and 6months. Functional assessment was done on every follow up. At 3wks, 6wks, and 3months assessment was and final assessment at 6 months was done by using Modified Harris Hip Score (MHHS).

Result

There were 25 males and 5 females in PFNA2 group whereas there were 23 males and 7 females in PFN group. P value was .52(Table-1). Mean age in PFNA 2 group was 66.23 yrs and 63.6yrs in PFN group.P value was (Table-2).Most of the patients in both the group was injured due to trivial fall. In PFN group patients with fall was 18 and with RTA was 12, and in PFNA2 group patients with fall was 25 and with RTA was 5 with P value .045. Right hip involved predominantly in both groups.In PFN group right hip involvement was 18 and left was 12, and in PFNA2 group right was 19 and left was 11. P value was. 79 (Table-3). Fracture pattern in both group was same. In both group A1 was 8, A2 was 13, and A3 was 9 with P value 1 (Table-4).

Mean time interval between injury and surgery was 8.4 days in PFN group and 7.5 days in PFNA2 group. This was also statistically not significant. Mean operative time was 49.53 min in PFNA2 group and was 52.07 min in PFN group. P value was. 12. Post operative hospital stay was 7.67 days in PFNA2 group and 8.77 days in PFN group. This was also not statistically significant.Mean image intensifier shots number was 34.67 in PFNA2 group and 38.33 in PFN group with P value was .00027. Mean blood loss was 73.33 ml in PFNA2 group and 82.67ml in PFN group with P value was .005. Post operative weight bearing was started after 7.15days in PFN group and 5.03 days in PFNA2 group. This was also statistically not significant. (Table-5). Modified Harris hip score was 78.53 (72-84) in PFNA2 group and 75.9 (70-84) in PFN group at 6 months follow up. P value was .0041. Late complications as 1)Residual thigh pain was 3 in PFN group and 2 in PFNA2 group. 2)Malunion was 2 in each group. 3)Z-effect was 2 in PFN group. 4)Screw cut out was 2 in PFN group and 1 in PFNA2 group. 5)Broken nail was 1 in each group. (Table-6).

Table 1: Sex distribution

Sex	Type		Total	P Value
	Pfn	Pfna2		
Male	23	25	48	.52
Female	7	5	12	
Total	30	30	60	

Table 2: Age distribution.

	PFN (N=30)	PFNA2 (N=30)	t score	P value
Mean age	63.6 Yrs	66.23 Yrs	-0.95	.17
SD	11.67	9.74		

Table 3: Side involvement

Side	Type		Total	P Value
	PFN	PFNA2		
Right	18	19	37	.79
Left	12	11	23	
Total	30	30	60	

Table 4: AO Classification

AO class	PFN	Pfna 2	Total	P Value
A1	8	8	16	1
A2	13	13	26	
A3	9	9	18	
Total	30	30	60	

Table 5: Operative details

	TYPE	MEAN	SD	t- SCORE	P VALUE
Injury to surgery time (days)	PFN(N=30)	8.4	3.2	1.12	.27
	PFNA2(N=30)	7.5	2.8		
Surgery time (min)	PFN(N=30)	52.07	9.6	1.17	.12
	PFNA2(N=30)	49.5	7.5		
Blood loss (ml)	PFN(N=30)	82.67	13.3	2.65	.005
	PFNA2(N=30)	73.33	12.2		
IIT Shots (no.)	PFN(N=30)	38.33	4.71	3.66	.00027
	PFNA2(N=30)	34.67	2.81		

Result Summary

	PFN	PFNA2
Average surgery time	52.07	49.53
Average blood loss	82.67	73.33
Average no. of IIT shots	38.33	34.67
Post op hosp. stay	8.77	7.67
MHHS at 6 months	75.9	78.53
Radiological union at 6months	93.3%	100%
Screw cut out	2	1
Zeffect	2	0
Broken implant	2	2
Revision surgery	5	2

Statistical Analysis

In our prospective randomized comparative study, Statistical analysis was done using SPSS software (IBM Version-20). Statistical difference between continuous variables were assessed using Student t-test. Categorical variables were compared using Chi square test. Statistical significance was set at P value of 0.05 or less.

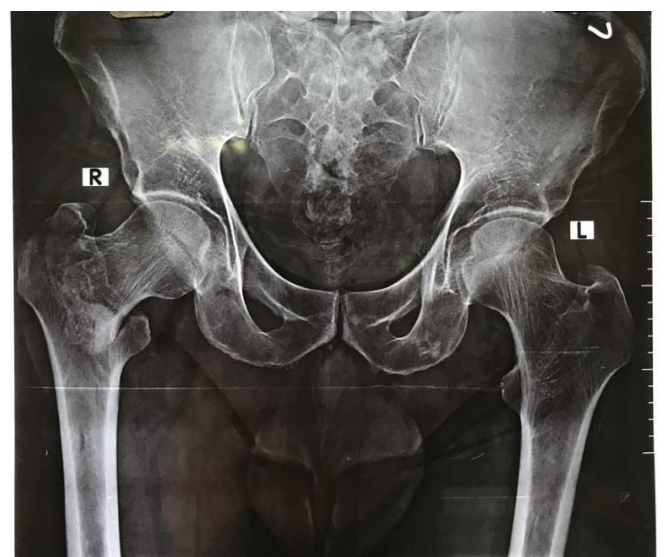
**Fig 1:** intertrochanteric fracture**Fig 2:** post-operative IT fracture using PFN**Fig 3:** intertrochanteric fracture



Fig 4: Post-Operative IT fracture using PFNA2

Discussion

Treatment of intertrochanteric fractures superadded with osteoporosis is a challenge in the community of orthopaedic surgeons. Screw pull out in a dual screw design due to osteoporosis in old age is the most common cause of implant failure [5]. Clinical studies have also shown that osteoporosis is associated with inferior outcomes in intertrochanteric fractures [6]. Various nail designs and augmentation techniques introduced in market to enhance the fixation in both stable and unstable intertrochanteric fracture. Selecting an ideal implant for these patients with osteoporosis is a challenge for showing functional outcomes. In view of this helical blade device introduced in PFNA2 for osteoporotic bones [7]. While introducing the helical blade inside the proximal femur the cancellous bone is retained thus the bone stalk is preserved. This is the main reason behind prevention of complications such as varus collapse and rotational stress [8]. This cancellous bone stalk within the proximal femur offers significant resistance to the implant and increases the purchase in the bone and also augments bone healing and better union rate [9].

In our study Mean age of subjects in PFN was 63.6 ± 11.67 years and in PFNA 2 was 66.23 ± 9.74 years. Kunderna *et al.* [10] in their study had 70% of the patients over 60 years of age with average age of 68 years ranging from 21 years to 94 years. This is comparable to my study. In our study PFN group 43.3% had A2 fracture and 30% had A3 fracture. In PFNA 2, 43.3% had A2 fracture and 30% had A3 fracture. Ming hui Li *et al.* [11] in their study of 163 patients with intertrochanteric fractures, according to AO, 53 (32.52%) fractures were classified as 31A1, 83 (50.92%) as 31A2, and 27 (16.56%) as 31A3. Mean duration of surgery in PFN was 552.07 ± 9.62 and in PFNA 2 was 49.53 ± 7.54 min Mohan N.S *et al* had similar finding in their study with 50 minutes the average duration of surgery for PFNA and 80 min for PFN. Average blood loss in PFN group was 82.67 ± 13.3 ml and in PFNA2 group was 73.33 ± 12.2 ml. Levent karapinar *et al* in their study average blood loss was 127 ml. Number of IIT shots in PFN group was 38.33 ± 4.71 and in PFNA2 group 34.67 ± 2.81 Comparable with Harshwardhna *et al.* [12]. Radiological union at 6 months in PFN group was 93.3% with average union time 16 weeks and in PFNA2 group was 100% with average union time was 14 weeks. In PFN 10% had residual thigh pain, 6.66% had Z effect, 6.66% had screw cut

out, 6.66% had malunion and 3.33% had broken implant as complications and in PFNA 2, 6.66% had residual thigh pain, 3.33% had screw cut out 6.66% had malunion and 3.33% had broken implant. This is comparable to study done by Kashid MR *et al.* [13]. In PFN 50% had excellent, 20% had Very good, 10% had good and 20% had poor outcome, in PFNA 2, 60% had had excellent, 20% had Very good, 5% had good and 15% had poor outcome in the patients with 1 year follow up. GN Kiran Kumar *et al.* [14] and Yu.W.Zhang *et al* [15]. In their study, Harris hip score was excellent in 15(35.7%), good in 18(42.8%), fair in 6(14.2%), poor in 3(7.1%). This is comparable to our study.

Conclusion

From the study we can conclude that the PFNA2 reduces the surgery time, blood loss, and image shots number as compared to PFN. As the union rate is more with PFNA2, the functional outcome is significantly better with PFNA2 than PFN. Implant related late complication was more with PFN which was markedly reduced with PFNA2.

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