

COMPARATIVE ASSESSMENT OF PRIMARY AND SECONDARY OUTCOME WITH PFNA AND HEMIARTHROPLASTY FOR SENILE INTERTROCHANTERIC FRACTURES MANAGEMENT: A PROSPECTIVE RANDOMIZED CLINICAL STUDY.

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Abstract

Aim: assessment of primary and secondary outcome among patients treated with PFNA and hemiarthroplasty.

Materials and Methods: 20 patients each were included in PFNA group and hemiarthroplasty Patient followed. Patients were evaluated with multiple variables, complications and Harris hip score. The statistical test applied for the independent sample analysis was student t-test using SPSS version 20.

Results: PFNA groups had significantly less blood loss, less surgery time, less hospital stay as compared to hemiarthroplasty group. There were no significant differences between the two groups regarding to the Harris Hip Score.

Conclusion: From the present investigation it seems that intertrochanteric fractures treated with PFNA may achieve better functional results than treated with hemiarthroplasty. It can definitely be a better option than replacement in elderly intertrochanteric fracture.

Keywords: Harris hip score, Hemiarthroplasty, PFNA, Intertrochanteric fracture

Introduction

With increase in life expectancy, the incidence of these fractures is also increasing.ⁱ This may be due to Intertrochanteric Fractures typically occurred in the elderly population. Unstable intertrochanteric fractures are a major cause of concern due to an increase in morbidity and mortality associated with such fractures.ⁱⁱ

Historically, treatment of intertrochanteric fractures involved intramedullary hip screw and arthroplasty.ⁱⁱⁱ Hemiarthroplasty for intertrochanteric fractures has been described as early as 1973. It is now being considered as a primary treatment for comminuted unstable type of IT fracture in elderly on the grounds that it allows early mobilization and full weight bearing. Recently popular modality is fourth generation of intramedullary nails like the Proximal Femoral Nails.^{iv}

Biomechanical studies have shown that for intertrochanteric fractures, intramedullary fixation methods are more appropriate as they carry more load due to the short lever arm, and they can control excessive shear.^{v,vi} Additional clinical studies have proven the effectiveness of PFNA.^{vii}

In addition to intramedullary fixation devices to treat intertrochanteric fractures, the alternative treatment of hemiarthroplasty is not yet accepted as a primary treatment.^{viii} However, varus displacement and excessive collapse of the fracture area is a common problem with

sliding femoral nails, especially in elderly women, who often suffer from osteoporosis and poor bone quality.⁶

For this reason, primary arthroplasty was proposed by some authors.^{ix,x} A lot of clinical studies have not found proof that hemiarthroplasty is more effective than and superior to intramedullary (apart from PFNA) or extramedullary fixation.^{9-xi} In addition, there are virtually no studies in the literature showing that PFN is superior and effective compared to hemiarthroplasty.

So far, however, there was no prospective randomized study comparing PFNA with hemiarthroplasty for senile intertrochanteric fractures in the literature. Which method is better for treating these fractures in elderly patients remains controversial due to the insufficient clinical evidences. The purpose of this study was to compare the results of PFNA with hemiarthroplasty for senile intertrochanteric fractures.

Materials and methods

A Prospective randomized clinical study was conducted for the period of feb 2017 to march 2018 among patients with confirmed unstable intertrochanteric fractures who were admitted to the emergency Department of Orthopedics, **Katihar Medical College and Hospital, katihar,Bihar,India.**

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

Inclusion criteria

- Patient who signed the “informed consent” form
- Patients \geq 60 years of age
- Unstable intertrochanteric fractures
- Medically fit for surgery.

Exclusion criteria

- Patient who were Bedridden before fracture
- Pathological fractures and Polytrauma
- Medically unfit for surgery

Sample selection

The sample size was calculated using a prior type of power analysis by G* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum sample size of each group was calculated, following these input conditions: power of 0.80 and $P \leq 0.05$ and sample size arrived were 40 patients i.e 20 per group.

Surgical methods

All operations were completed by two experienced orthopedic surgeons. Patients were given either general or spinal anaesthesia. All patients were administered prophylactic antibiotics 30 to 60 minutes before operation.

PFNA- Group A

The patients treated with PFNA were placed in the supine position on fracture traction table. The injured lower limb was put in straight and mild abduction with foot fixed in the boot on the traction device. After performed continuous mechanical traction, the limb was put at $10\sim 15^\circ$ adduction and rotation neutral position, then the state of reduction was checked by C-arm fluoroscopy, and was maintained by the traction device and nailing was done and interlocked by Screws.

Hemiarthroplasty- Group B

Hemiarthroplasty was performed by using posterolateral approach with patients positioned in the lateral position. The femoral head and neck was taken out after capsulotomy. The femoral medullary canal was reamed to the appropriate size. A cemented stem and a bipolar head were used. The greater and lesser trochanter were reset and stabilized by using the tension band wiring technique. The external rotators were sutured to their anatomical locations.

Post-operative

Patients were routinely given antibiotic prophylaxis for 48 h postoperatively. Low molecular heparin was given for two weeks as a mean of thromboprophylaxis. Patients were encouraged to do active and passive functional exercise from postoperative day 1.

Patients with stable fractures treated with PFNA started partial weight bearing with a walker from 1 week after surgery; whereas those with unstable fractures started

partial weight bearing 2-3 weeks postoperatively. Patients underwent hemiarthroplasty were encouraged to ambulate with support of a walker from postoperative day 2.

Follow-up and outcome

Patients were followed up at 1, 3, 6, 12 months for clinical and radiological evaluation after operation. Anteroposterior and lateral radiographs were performed to detect the fracture healing and implant-related complications. The Harris Hip Score^{xii} was used for functional evaluation. The secondary outcome measures were transfusion rate, surgical time, postoperative hemoglobin and duration of hospital stay.

Statistical Analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2010) and then exported to data editor page of SPSS version 20 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics included computation of percentages and means. The statistical test applied for the independent sample analysis was student t-test. The confidence interval and p-value were set at 95% and ≤ 0.05 respectively.

Results

Table 1: distribution of age and gender among study subjects

Gender	Group		Total
	A	B	
Female	11	13	24
	55.0%	65.0%	60.0%
Male	9	7	16
	45.0%	35.0%	40.0%
Total	20	20	40
	100.0%	100.0%	100.0%
Mean Age in Years (Mean \pm SD)			74.67 \pm 1.67

Table 1: depicts the mean age of the study population was 74.67 years. Majority of them were male 21 (80.7%) and rest 5 (19.3%) were female.

Table 2: distribution of Laterality of the Fracture among study subjects

Laterality	Group		Total
	A	B	
Right	7	9	16
	35.0%	45.0%	40.0%
Left	13	11	24
	65.0%	55.0%	60.0%
Total	20	20	40
	100.0%	100.0%	100.0%

Table 2: revealed that (40.0%) of the patients had right side hip joint followed by left side hip (60.0%).

Table 3: distribution of co-morbidities among study subjects

Co-morbidities	Group		Total
	A	B	
Diabetes	7 35.0%	5 25.0%	12 30.0%
Hypertension	5 25.0%	4 20.0%	9 22.5%
Cardio vascular	3 15.0%	3 15.0%	6 15.0%
Neurologic	2 10.0%	3 15.0%	5 12.5%
Respiratory	2 10.0%	3 15.0%	5 12.5%
Renal	1 5.0%	2 10.0%	3 7.5%
Total	20 100.0%	20 100.0%	40 100.0%

Table 3: depicts that diabetes (30.0%) was most associated co-morbidity observed in both the groups followed by hypertension (22.5%), cardio vascular (15.0%), neurologic (12.5%), respiratory (12.5%) and renal (7.5%).

Table 4: comparison of primary (functional) outcome between the groups

Harris Score	Group		Total
	A	B	
Excellent	5 25.0%	3 15.0%	8 20.0%
Good	9 45.0%	7 35.0%	16 40.0%
Fair	4 20.0%	6 30.0%	10 25.0%
Poor	2 10.0%	4 20.0%	6 15.0%
Total	20 100.0%	20 100.0%	40 100.0%
Mean Score (Mean±SD)	79.24±2.18	78.11±1.17	78.67±1.67
p-value	0.487 (NS)		

Test applied: student t-test. NS-(Statistically Non significant)

Table 4: No statistically difference was observed between the two groups regarding to the Harris Hip Score at 1 year follow-up (79.24±2.18 for the PFNA group and 78.11 ±1.17 for the hemiarthroplasty group. (p=0.487)

Table 5: comparison of secondary outcome between the groups

Variables	Group A		Group B		p-value
	Mean	Std. Deviation	Mean	Std. Deviation	
Operative time (Minutes)	71.60	4.58	88.08	5.21	0.001 (Sig.)
Units transfused	1.21	0.45	3.81	1.12	0.026 (Sig.)
Decrease of Hb	1.18	0.23	3.08	0.97	0.011 (Sig.)
Hospital stay (Days)	4.89	1.63	8.36	2.01	0.001 (Sig.)

Test applied: student t-test.

Table 5: revealed that there were significant differences between the two groups with regard to operative time, units of blood transfused, postoperative decrease in Hb and hospital stay

Discussion

Intertrochanteric Fractures of the femur are relatively common injuries among the elderly individuals. In the last few decades, treatment of intertrochanteric fractures has evolved significantly.

Our study included 40 patients randomized for these two modalities of treatment (Proximal Femoral Nail Anti-Rotation and Cemented Hemiarthroplasty) and was followed-up for 12 months.

Some studies reported that hip arthroplasty in treating these fractures had more advantages than internal fixations.^{xiii,xiv} However, the findings of the present study did not support hemiarthroplasty as a preferred choice when compared with PFNA.

Present investigation revealed that there were significant differences between the two groups with regard to operative time, units of blood transfused, postoperative decrease in Hb and hospital stay. This was found in agreement with the study conducted by Luo X et al.^{xv} 2017 revealed significant differences in comparison of intraoperative blood loss, transfusion rate, medical complications and hospital stay. Patients treated with HAB had a trend of higher postoperative 1-year mortality than those who underwent PFNA (21.2% vs. 11.3%, P = 0.134). The study revealed one potential reason for such trend, noting a relative greater surgical trauma associated with HAB on aging patients.

Theoretically, patients treated with hemiarthroplasty can obtain better functional recovery than those treated with PFNA in the first few months after surgery. Nevertheless, the functional results were significantly affected by other factors, such as age, gender, health status, social dependency before fracture, and post-operative complications.^{xvi}

In the present study, at 1 year follow-up, there was no statistically difference between the two groups regarding to the Harris Hip Score (79.24±2.18 for the PFNA group and 78.11±1.17 for the hemiarthroplasty group, P=0.487). Tang et al.⁸ reported that at 3 years follow-up, there was no significant difference in Harris Hip Score between PFNA and hemiarthroplasty group (83.0±12.2 for the PFNA group and 80.2.1±10.9 for the hemiarthroplasty group, P=0.09), but significant difference was found in the rate of the excellent-to-fine functional results (PFNA 90.2% and hemiarthroplasty 79.6%).

Conclusion

Arthroplasty and PFN are commonly used for their advantages in allowing for early mobilization. From the present investigation it seems that intertrochanteric fractures treated with PFNA may achieve better functional results than treated with hemiarthroplasty followed by significant lower post operative complications. However more long term follow-up studies with bigger sample size are needed to confirm it.

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