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COMPARATIVE STUDY EFFECTIVENESS OF OF PROXIMAL FEMORAL NAIL WITH HELICAL BLADE VERSUS LAG SCREW IN INTERTROCHANTERIC FRACTURE: A PROSPECTIVE FOLLOW-UP STUDY

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ABSTRACT

Introduction: Intertrochanteric fractures are defined as extracapsular fractures of the proximal femur that occur between the greater and lesser trochanter and are extremely common fractures occurring in elderly osteoporotic individuals. Although there are multiple studies comparing PFN with other intra-medullary devices like Gamma nail, PFNA, limited studies are available which compares treatment outcomes of proximal femoral nail with lag screw and proximal femoral nail with helical blade.

Objectives of the study: In view of the extremely limited literature available, we conducted this study to compare the effectiveness of PFN with lag screw and helical blade PFN in management of intertrochanteric fracture.

Methodology: We randomized the patients into two groups Group 1: helical blade group and Group 2: lag screw group.. As per new AO/ OTA classification and fracture pattern, cases from both the groups were classified further into stable and unstable and various radiological and functional parameters were assessed accordingly.

Operative protocol: All patients with trochanteric fractures which were operated by two surgeons of our unit were taken on radiolucent table with traction applied on injured limb. In all patient attempt of closed reduction was given on traction table and in fractures where closed reduction was not achieved then fractures were reduced with mini open or percutaneous methods. All cases were provisionally fixed with K wires out of the path of the nail and these k wires were maintained until the nail insertion.

Results: In the present study we found that the operative time, blood loss, follow-up complications were significantly less with better outcomes patients who has undergone helical blade procedure compared to the patients who has undergone lag screw procedure. The functional outcome calculated using the modified Harris Hip score & Parker and Palmer mobility score, at the end of 12 months, had no significant difference between the two groups.

Conclusion: The observations of the present study indicates that the operative and postoperative functional outcomes are significantly better in helical blade group compared to lag screw group.

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Key-words: intertrochanteric fracture, lag screw, helical blade, operative time, and blood loss

Introduction

Intertrochanteric fractures are defined as extracapsular fractures of the proximal femur that occur between the greater and lesser trochanter and are extremely common fractures occurring in elderly osteoporotic individuals [1]. Recumbence following a hip fracture is known to be associated with increased mortality in this group of patients. The female to male ratio is between 2:1 and 8:1 [2]. These fractures are usually a result of a ground-level fall in the elderly population and are classified as either stable or unstable. Determination of stability is important as it helps determine the type of fixation required for stability. Stable fractures have an intact posteromedial cortex and will resist compressive loads once reduced. Examples of unstable fractures include: comminution of the posteromedial cortex, fractures extending up to lateral wall, displaced lesser trochanter fracture, subtrochanteric extension and reverse obliquity pattern [3]. Intertrochanteric fractures are extra capsular and have a much more robust osseous blood supply, and therefore are much less likely to result in chronic complications such as AVN or nonunion. Thus, the primary concerns of inadequate treatment of trochanteric fractures are related to the risks of acute instability and possible nonunion/malunion with post injury deformity. Nonoperative treatment is rarely indicated and should only be considered for non-ambulatory patients and patients with a high risk of perioperative mortality [4]. Although there are multiple studies comparing PFN with other intra-medullary devices like Gamma nail, PFNA, limited studies are available which compares treatment outcomes of proximal femoral nail with lag screw and proximal femoral nail with helical blade. In view of the extremely limited literature available, we conducted this study to compare the effectiveness of PFN with lag screw and helical blade PFN in management of intertrochanteric fracture.

Aim and Objectives

The objective of the present study is to compare effectiveness (operative time, non-union, implant failure and blood loss) of proximal femoral nail with helical blade vs. proximal femoral nail with lag screw in intertrochanteric fractures.

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Material and Methods

Source of data: This comparative study was conducted in the department of orthopedics, at our tertiary care hospital for the duration of one year.

Type of study: Randomized comparative study.

Sample size: 50 in both the groups.

Inclusion criteria:

We included the patients with fracture intertrochanteric femur (AO/OTA classification) of both the genders in the aged >30 years after obtaining informed written consent for both the treatments i.e. proximal femoral nail with helical blade and lag screw.

Helical blade group: Patients with intertrochanteric fracture operated using proximal femoral nail with helical blade.

Lag screw group: Patients with intertrochanteric fracture operated using proximal femoral nail with lag screw.

Randomization: To avoid selection bias computer generated random numbers were obtained and sealed in an envelope. The slip was then taken out by office clerk not involved in the study and whether to put helical blade or lag screw was then decided according to the coded slip. The patients and the operating surgeon were blinded in the present study till the insertion of column screw. Patients were followed up at 3 and one year after discharge.

Exclusion criteria:

1. Patients with previous ipsilateral hip or femur surgery.
2. Patients with pathological fractures.
3. Fractures extension into subtrochanteric region.

As per new AO/ OTA classification and fracture pattern, cases from both the groups were classified further into stable and unstable and various radiological and functional parameters were assessed accordingly.

Operative protocol: All patients with trochanteric fractures which were operated by two surgeons of our unit were taken on radiolucent table with traction applied on injured limb. In all patient attempt of closed reduction was given on traction table and in fractures where closed reduction was not achieved then fractures were reduced with mini open or percutaneous methods. All cases were provisionally fixed with K wires out of the path of the nail and these k wires were maintained until the nail insertion.

After Palpating the greater trochanter, around 5 cm incision was given proximal to the tip of greater trochanter. Entry was made just medial to the tip of the greater trochanter and was

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confirmed on image intensifier in both AP and roll over lateral view, in lateral view the entry point was in line with the axis of the intramedullary canal of shaft and femoral neck. Then guide wire was inserted, femur canal was opened with solid cannulated reamer of appropriate size. Medullary canal was not reamed during the surgery. In our study, after estimating the nail size and diameter preoperatively using image meter pro and confirming it on image intensifier

intraoperative, guide wire for both cervical screws was inserted in dead center of femoral head and neck on roll over lateral view and slightly inferior or in center on AP view on image intensifier.

Proximal locking with helical blade: Select the appropriate length helical blade as measured. Align the back end of the helical blade with the impactor. Thread the connecting screw into the helical blade and finger-tighten the assembly. Hold the handle of the inserter and advance the

blade as far as possible by hand. Use light hammer blows on the back of the connecting screw to seat the helical blade. Insert to the stop. The blade is fully inserted when the helical blade impactor comes to a stop at the back of the blade guide sleeve.

Proximal locking with lag screw: After selecting appropriate length lag screw, pass the screw insertion assembly over the guide wire, through the blade guide sleeve and through the nail. Advance the screw by turning the inserter clock- wise until the mark on the inserter meets the flange surface of the blade guide sleeve. Both the type of column screws were locked in static mode using a set screw. The result of this surgical procedure was analyzed on the basis of various radiological and functional parameters. Follow up was done at third month and one year. At each visit clinical, various radiological parameters and along with this function outcome was assessed using Harris hip score [5].

Statistical analysis: The data from the present study was systematically collected, compiled and statistically analyzed to draw relevant conclusions using SPSS Statistics-26 version. The observations were tabulated in the form of mean Standard Deviation (SD) and Number with percentage. In parametric data, unpaired student t test was used. Quantitative variables were correlated using chi square test. The data was analyzed and level of significance was determined as its ‘p’ value with $p<0.05$ as significant and $p<0.001$ as highly significant.

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RESULTS

Table 1: Shows the demographic profile of the patients included in the study (no=50)

	Number	Percentage
Gender distribution		
Males	26	52%
Females	24	48%
Age group		
30-50	12	24%
51-65	24	48%
>65	14	28%
Stability		
Stable	28	56%
Unstable	22	44%

Table 2: Shows the comparison of operative parameters between two groups (no=50)

	Helical Blade (no = 26)	Lag Screw (no=24)
Stable	14	13
Unstable	12	11
Surgery time (min)	37±2.34	39±7.8*
Blood loss (mL)	83.4±16.34	98.8±18.34*
Post-op electrolyte imbalances (hyponatremia)	2/26	6/22*
Complications		
Screw cut-out	0/26	2/22*
Z effect	0/26	1/22*
Lateral protrusion of implant	0/26	3/22*
Screw tip positioning	2/26	4/22*
Follow-up parameters		
Non-union implant failure	0/26	3/22*
Limb shortening >1 cm	0/26	2/26*
Varus malalignment	1/26	3/22*
Persistent pain	2/26	7/22*
Support walking	20/26	20/22*
Harris hip score	82.2±1.34	83.6±4.34
Full weight bearing at 6 months	17/26	16/22*

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P<0.05 significant represented by *.

DISCUSSION

With the increase in elderly population, the incidence of intertrochanteric fractures has increased year by year. Patients suffering from intertrochanteric fractures have a high incidence of morbidity and mortality. An early surgical procedure is now considered as preferred option for the treatment of intertrochanteric fractures providing an opportunity for early and full weight bearing mobilization. Surgical delay is associated with a significant increase in the risk of death and pressure sores [6]. Surgical implants employed to fix intertrochanteric fractures are dichotomized into being either intramedullary (cephalo-medullary nails) or extra-medullary (sliding hip screws). There is an increasing trend towards the use of intramedullary devices for the fixation of intertrochanteric fractures due to superior biomechanics and minimally invasive surgery particularly in unstable fracture patterns which enables immediate rehabilitation of the patient after surgery [7]. These devices allow controlled collapse at the fracture site.

Currently two different types of collum implants are available for proximal fixation, a traditional lag screw and a helical blade. Several randomized controlled trials and studies comparing helical blade with the lag screw in intramedullary fixations have demonstrated greatly different outcomes compared with published data and theoretical concepts. The optimal choice between the helical blade and lag screw is still controversial. We conducted this randomized comparative study of 50 patients with intertrochanteric fracture, majority of patients belonging to age group of more than 65 years, which were randomized in two groups i.e. helical blade group (n =26) and lag screw group (n =22). All the patients were followed up for a time period of 12 months. The aim of our randomized study was to assess if there were any differences in operative and follow-up complications parameters and functional outcomes of patients with intertrochanteric fracture fixed with proximal femoral nail with helical blade and a proximal femoral nail with lag screw. To avoid further bias in study, both the helical blade and lag screw were statically locked proximally to prevent undue collapse at fracture site.

In the present study we found that the operative time, blood loss, follow-up complications were significantly less with better outcomes patients who has undergone helical blade procedure compared to the patients who has undergone lag screw procedure. The functional outcome calculated using the modified Harris Hip score & Parker and Palmer mobility score, at the end of 12 months, had no significant difference between the two groups.

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A comparative study done by Talia chapman et al. [8] in 2018 on 126 patients treated with Trochanteric Fixation Nail (TFN; Synthes) with either a helical blade (71 [56.3%]) or screw (55 [43.7%]) concluded in their study that 7 failures of fixation (5.6%) occurred, all of which used a helical blade. 5 failures resulted from medial migration of the helical blade through the femoral head, while 2 resulted from typical supero-lateral cutout and varus collapse. There was no difference in average Tip Apex Distance (TAD) between the cases using blade versus screw fixation or between failures and the remainder of the cohort. This study showed a higher failure rate with use of the blade and supports the use of screw fixation in such fractures.

A Systematic Review and Meta-Analysis conducted by Kim et al. [9] in 2021 compared fixation failure between helical blade-type and lag screw-type CMNs with cut-out and cut-through rates as primary outcomes and degree of sliding length, time to union, and non-union rate as secondary outcomes. They concluded in their study that fixation failure (OR = 1.88, 95% CI: 1.09-3.23, P = 0.02), especially cut through (OR = 5.33; 95% CI, 2.09-13.56; P < 0.01), was more common with helical blades than with lag screws, although the cut-out rate was not significantly different between both the comparison groups (OR = 0.87, 95% CI: 0.38-1.96, P = 0.73).

CONCLUSION

The observations of the present study indicates that the operative and postoperative functional outcomes are significantly better in helical blade group compared to lag screw group.

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