Randomized controlled trial comparing open versus closed interlocking nail for closed fracture shaft of femur in Adults

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Abstract

Background: Close reduction and intramedullary fixation of fracture shaft femur proposed by Kuntscher, is the most biological way of treating the fracture shaft femur. But an open version of this procedure, by which the fracture is stabilized by opening the fracture site and fixing it by retrograde method, became popular because of less complication and more predictable operating time. With the development and emergence of image intensifier and modification in the technique, the locked intramedullary gained popularity. Locked intramedullary nailing can be inserted in a static or dynamic fashion.

Aim and Objectives: To compare outcome of open versus closed interlocking nail for fracture shaft of femur in Adults in term of: union, Blood loss, infection rate, functional outcome, Complications if any.

Methods and Materials: It is Randomised Controlled Trial Study. Randomization was done using Excel random number generation technique into two groups, each of size 40. Group A: Diaphyseal fracture treated with closed methods. Group B: Diaphyseal fracture treated with open methods. Sample size: 40 in each group

Results: A total of 80 patients (49 male and 31 female) were included in the study. 15 patients were less than 25 years age group followed by 30 patients between 25-40 yrs, 25 patients between 41-60 age group and 10 patients more than 61 years. Road traffic accident is commonnest mode of injury followed by fall from height. The average blood loss is 119.5 ml in Closed nailing group and 139.5 ml in open nailing group. The procedure time is 71 mins in closed nailing group as compared to 97 mins in open nailing group.

Discussion: A total of 80 patients (49 male and 31 female) were included in the study. 15 patients were less than 25 years age group followed by 30 patients between 25-40 yrs, 25 patients between 41-60 age group and 10 patients more than 61 years. Road traffic accident is commonnest mode of injury followed by fall from height. The average blood loss is 119.5 ml in Closed nailing group and 139.5 ml in open nailing group. The procedure time is 71 mins in closed nailing group as compared to 97 mins in open nailing group.

Conclusion: Closed IML nailing group needs fracture table and image intensifier. Operating time and blood loss is more in Open nailing group. Cost of treatment and union is comparable in both groups. Infection is more in open group as compared to closed group.

Keywords: Open, close nailing, fracture shaft of femur

Introduction

Close reduction and intramedullary fixation of fracture shaft femur proposed by Kuntscher, is the most biological way of treating the fracture shaft femur. But an open version of this procedure, by which the fracture is stabilized by opening the fracture site and fixing it by retrograde method, became popular because of less complication and more predictable operating time. With the development and emergence of image intensifier and modification in the technique, the locked intramedullary gained popularity. Locked intramedullary nailing can be inserted in a static or dynamic fashion.

Method of open nailing can be considered at rural health centres as comparably good results could be obtained with less expertise required and avoiding the radiological hazards and giving surgical assistance at a very economical basis. This additional benefit could be added by doing locking of the nail at proximal and distal levels with the help of distal locking zig arm without
the help of image, without hampering the benefits of open nailing. Keeping the multiple factors in mind, e.g., overcrowded orthopedics wards with fracture femur, early disposal of the patient, less resources, and unequipped peripheral hospitals (no facility of image and fracture table) and to avoid the hazards of radiation and various other benefits of open nailing, it was decided to conduct a study of open interlock nailing and its comparison with closed methods in fracture femur.

**Review of Literature**

Ali MA, Hussain SA, Khan MS *et al*: Interlocking nailing is one of the best options for the management of femoral shaft fractures due to high velocity gunshot injuries. Webb LX, Grisitina AG, Fowler HL *et al*: Among 60 femur fractures not amenable to fixation by simple intramedullary nailing, 30 were treated with balanced skeletal traction followed by cast bracing or spica casting, and 30 were treated with closed interlocking nailing. The criteria for using an interlocking nail were fractures with less than 50% cortical contact or fractures with rotationally insecure purchase of the nail in either the proximal or distal fragment. In terms of fracture severity, patient age, injury severity, and clinical follow-up, the patient groups were similar. There were three open fractures in each group. The average hospital stay was 61 days for the traction group, and 19 days for the interlocking nail group (p < 0.001). Time to clinical and radiographic union averaged 34 weeks with traction and casting and 18 weeks with interlocking nail fixation (p < 0.001). Failure by the criteria of Johnson *et al* (2) occurred in 67% of the traction group and in 3% of the interlocking nail group (p < 0.001). Minor complications were more common in the traction group. On the basis of this study and the experience of others, interlocking nail fixation appears to be the method of choice for managing unstable femoral shaft fractures.

Gavaskar AS, Kumar R: Open interlocking nailing and bone grafting coupled with aggressive rehabilitation can achieve acceptable results for patients with neglected femoral shaft fractures.

Ranji Lal Sahu, J Sikdar: concluded that this technique is advantageous because of early mobilization (early weight bearing), less complication with good results and is economical.

**Rationale of the study**

Fracture shaft femur is one of the most common fracture treated at tertiary level centre's requiring adequate radiological assistance. Providing distal locking zig arm support in the nail has made it possible to treat fracture shaft femur at primary level with acceptable locking, without the additional support of IITV with added benefits on surgeons part of less expertise, less surgery time, and good to excellent union rates and at the same time on patients part, avoidance of radiological exposure, being economical availability at the next door itself. With the development. There is still a dearth of prospective randomized trials in this area. There are few literatures available and virtually no such study done in Nepal. So, we want to examine whether there is a difference in clinical outcomes.

**Objectives**

a) To compare outcome of open versus closed interlocking nail for fracture shaft of femur in Adults in term of:

- Union
- Blood loss
- Infection rate
- Functional outcome
- Complications if any

**Methods and materials**

**Study Design**: Randomised Controlled Trial Study

Randomization was done using Excel random number generation technique into two groups, each of size 40

- Group A: Diaphyseal fracture treated with closed methods
- Group B: Diaphyseal fracture treated with open methods

- Sample Unit: closed fracture shaft of femur in adults
- Study sample/ Sample size: 40 in each group

Sample size was calculated based on the number of adults patients with closed fracture shaft of femur attending the emergency and Orthopaedic department of the institute and number of patients undergone such operation for last year.

- Sampling technique: Consecutive patients undergoing elective Orthopaedic surgery at Department of Orthopaedics at BPKIHS

**Exclusion Criteria**

- Open Fracture
- Pathological fracture
- Presence of infection

**Materials/ Instruments**

1. Written informed consent form,
2. Semi-structured proforma
3. Data Collection: The subjects will be enrolled after informed consent. The relevant information about demographic variables like age, sex, address, occupation; mode of injury, duration of injury, operative procedure, date of surgery and post-operative findings will be recorded in a semi-structured proforma. The proforma will be filled by the on duty residents of orthopaedics
4. Ethical consideration: A. Informed written consent from subjects, b. Strict confidentiality, c. Ethical clearance from the ethical view board of BPKIHS
5. Data analysis: The data will be entered in Microsoft EXCEL8 file. The data obtained was analyzed with Statgraphic software package version 5.0 (Statistical Graphics Corp. Inc., Rockville, MD).

Patients with diagnosis of fracture shaft of femur were admitted to Orthopaedic ward. Skin traction was applied and analgesics were administered. He/She underwent full investigations pertaining to pre-anaesthetic check up.

**Results**

A total of 80 patients (49 male and 31 female) were included in the study. 15 patients were less than 25 years age group followed by 30 patients between 25-40 yrs, 25 patients between 41-60 age group and 10 patients more than 61 years. Road traffic accident is commonest mode of injury followed by fall from height. The average blood loss is 119.5 ml in Closed nailing group and 139.5 ml in open nailing group. The procedure time is 71 mins in closed nailing group as compared to 97 mins in open nailing group.
Discussion
Operative reduction and internal fixation of a fracture of a long bone invariably affects the vascularisation of the fracture area. The advantages of a stable reduction must therefore be weighed against the knowledge that an impaired blood supply after exposure of the fracture may result in deficient nutrition of the osteogenic cells and subsequent delayed union. Experiments have shown (G# {246}thman 1961, Trueta and Cavadas 1955, 1964) that the inner two-thirds of the cortex is nourished by branches from the medullary arteries, whereas the outer third of the cortex obtains its blood supply from the periosteal vessels. Severance of the medullary vessels does not result in nutritional changes in the cortex, because reactive activation of the periosteal vessels compensates for the severed medullary system (G# {246}thman 1961).

In animals and in man fracture healing after intramedullary nailing is basically brought about by proliferation of the inner layer of the periosteum and subsequent formation of an ensheathing callus mass around the broken bone ends. The progress of healing thus largely resembles fracture repair during normal conditions.

Thus, theoretically, closed intramedullary nailing is preferable to open intramedullary nailing, because by a closed technique the periosteal blood supply is preserved, and revascularisation of the fracture area can occur within a reasonable time. Further, if intramedullary nails of appropriate size are used, stable fixation can be achieved, which makes early mobilisation of the fractured limb possible. It emerges from the present series that in femoral shaft fractures both the early and late results of treatment were better after intramedullary nailing than after conservative treatment. It is interesting that it was the difficult fractures in the older patients that benefited most from intramedullary nailing, whereas low-energy injuries in young people healed equally well regardless of the method of treatment.

It is obvious that the first reports of the results of intramedullary nailing of the femur should not be compared with recent reports. In the beginning unsuitable nails and faulty equipment caused numerous technical difficulties and led to failures amounting, in some series, to 14 per cent of the nailed cases (Dencker 1964) [3]. Modern flexible drills and a complete assortment of nails are imperative for successful intramedullary nailing. Few methods of osteosynthesis are so liable to technical failure from faulty equipment. Correspondingly, an appropriate set of instruments and a high quality image intensifier make closed intramedullary nailing of the femur an expedient surgical procedure. Metal fatigue and nail breakage should no longer complicate the late course of fracture healing, as is evident from the present series where, in 80 nailed fractures, none of nail bent.

Although the differences between results after open and closed nailing are not very great, we prefer closed nailing. It is less traumatic and hence better tolerated by the patient, and in most instances it is an easier surgical procedure than open reduction and nailing. If reduction proves difficult, however, owing to shortening or interposed tissue, forcible attempts at reduction should be avoided. In such cases time is saved and tissue damage reduced if the fracture is exposed and nailed by the open method.

In the whole series there was no non-union at twelve months after the fracture.

Similar results have been reported by B# {246}hler (1965). But several authors have reported a high incidence of delayed union, the figures varying from 43 per cent to 25 per cent (Palmer 1951, Charnley and Guindy 1961, O'Brien 1963, Dencker 1965, Wickstrom and Corban 1967). In our series there was no evidence to suggest that nailing delays union. Neither did nailing in any way promote union of the broken bone ends, as judged from the radiographs. In our opinion, the good results of intramedullary nailing of the femoral shaft are because of the good vascular conditions throughout the deep-seated bone, which favour abundant ingrowth of capillaries into the fracture area in a wide variety of pathological conditions created either by the fracture or by surgical intervention. Intramedullary nailing of a superficial bone, such as the tibia, has not given such good results (Sl#{228}tis and Rokkanen 1967a).

The infection eventually subsided without any recurrences during the four-year follow-up period. In another five cases wound infection was recorded. Thus the incidence of deep infection was 06 per cent and the overall rate of infection 38 per cent. These figures are lower than those reported recently by other authors, according to whom the rate of deep infection after intramedullary nailing ranges from 1 to 1 1 per cent (B#{246}hler 1951, O'Brien 1963, Dencker 1965, Wickstrom et al. 1967).

Opinions diverge regarding the proper time for intramedullary nailing. Charnley and Guindy (1961) reported that in their experience delayed fixation of the fracture lowered the incidence of delayed union from 25 per cent to 7 per cent. Similarly, Smith (1964) reported an incidence of delayed union of only 08 per cent when the operation was postponed to the second week after the accident or later. Analysis of the present series, however, does not reveal any clear difference between early and delayed fixation of the fracture. Which types of femoral shaft fractures should then be treated by intramedullary nailing?

Most surgeons agree that the transverse and short oblique fractures are well suited for intramedullary nailing (B#{246}hler and B#{246}hler 1949; B#{246}hler 1951; K#{252}ntscher 1965; Muller, Allgower and Willenegger 1965; Wickstrom et al. 1967). We agree with this, but in our opinion the closed technique of nailing allows a broadening of the indications for intramedullary osteosynthesis of femoral shaft fractures. In our experience, slight comminution of the fracture is no contraindication to closed intramedullary nailing, provided that nails of an appropriate size are used. In fractures with severe comminution conservative treatment is usually resorted to, supplemented, if necessary, by bone grafting. However, in these cases too, recent experiences with closed intramedullary nailing have been encouraging. We have been forced to adopt rather broad indications by the fact that in our series over 70 per cent are traffic accident victims, with multiple injuries in two patients out of three. In these the plan of treatment as a whole may call for internal fixation of the femoral fracture: this is the case in severe brain injuries, multiple injuries to both lower extremities and in patients with simultaneous traumatic paraplegia, in which nursing problems are greatly reduced by internal fixation of the femoral fracture and avoidance of traction-suspension devices.

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Conclusion
Closed IMIL nailing group needs fracture table and image intensifier. Operating time and blood loss is more in Open nailing group Cost of treatment and union is comparable in both groups infection is more in open group as compared to closed group.

Recommendation
Lager sample size and longer follow up is needed to verify these results.

References