

Original Article

Comparison of the Outcome between Conventional Open Technique and Minimally Invasive Technique Using Dynamic Hip Screw for Fixation of Inter-Trochanteric Fracture of Femur

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Abstract

Background: Inter-trochanteric fracture of femur causes significant morbidity and mortality in elderly. Dynamic Hip Screw (DHS) fixation is the most effective and safe method of treatment. Conventional open technique (CDHS) is the popular and familiar one; however, minimal incision technique (MIDHS) has many advantages like: smaller incision, lesser dissection/blood loss, less requirement of transfusion, less painful, faster recovery etc. **Objectives:** To Compare CDHS and MIDHS technique of DHS fixation for inter-trochanteric fracture femur in terms of functional outcome, safety and associated complications (if any).

Methods: Eligible patients presenting within study period were randomized into CDHS group (n= 33) and MIDHS group (n= 32). Success of randomization was tested by analyzing demographics, injury characteristics and pre-op. clinical data ($p > 0.05$). They were followed up at 2, 6, 12, 24 and 52 weeks post-op. for clinico-radiological and functional assessment. **Results:** The duration of surgery, lag screw positioning, post-operative hospital stay and surgical site infection were not significantly different between the groups. However, need for blood transfusion, length of incision and post-operative VAS score for pain were significantly lesser for MIDHS group than CDHS group ($p < 0.05$). Patients in MIDHS group started walking with aids significantly earlier in post-operative recovery period. The Harris Hip Score at final follow-up and grading of the results and surgical complications were not significantly different between the groups.

Conclusion: The minimal incision technique had various immediate / short term advantages over conventional technique; like: minimal scar, minimal soft tissue dissection / less blood loss requiring less transfusion, lesser pain in post-operative period and ability to ambulate early.

Keywords: Dynamic hip screw, Intertrochanteric fracture, Conventional technique, Mini-incision technique, Harris Hip Score.

Introduction

The morbidity and mortality of hip fractures is increasing due to increased life expectancy and its incidence will double for each decade beyond the age of 50 years.^{1,2} The lifetime risk of having hip fracture in industrialized countries is at present 6% for men and 18% for women.³ Intertrochanteric fracture of the femur is one of

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the most frequently occurring manifestations of this injury.^{4,5}

Despite many options,⁶⁻⁸ Dynamic Hip Screw (DHS) and plates with varying numbers of holes^{9,10,11} is the standard choice for achieving rigid fixation and early mobilization of people with intertrochanteric femoral fracture since it yields reproducibly reliable results.^{12,13} DHS fixation using conventional technique (CDHS) has potential drawbacks; like: larger skin incision and considerable soft-tissue dissection, more blood loss, more pain and delayed rehabilitation. Minimally invasive DHS fixation technique (MIDHS) offers the theoretical advantages of decreased blood loss, better cosmetic results, less pain and faster rehabilitation.

Rationale:

Recently several authors¹⁴⁻¹⁶ have reported better functional outcome with MIDHS, but apparently there have been no prospective randomized trials comparing these two techniques in this subcontinent, which forms the rationale of our study.

Materials and methods

Ethical Approval:

The research protocol was approved by Institutional Ethical Review Board (IERB) and Research Committee (RC) of the institute prior to the study. Written and informed consent was taken from all the eligible and mentally competent patients for voluntary participation. The study was conducted in accordance with the Helsinki declaration,¹⁷

Patient Selection – Inclusion/ Exclusion Criteria:

79 cases of Intertrochanteric fracture of the femur presenting to the Emergency and Out-

patient department of the institute between May 2014 and April 2015 were classified according to AO classification.¹⁸ Total of 65 patients aged 20 years and above with AO/OTA 31-A1, 31-A2 fractures presenting within first 2 weeks that could be reduced adequately by closed manipulation (anatomical to 10° of valgus on AP and posterior angulation < 5° on lateral view) and who were able to walk without any assistance before injury were included. However, patients with bilateral hip / multiple / compound fractures, nonunion or pathological fractures, previous ipsilateral hip fracture or surgery, congenitally deformed or abnormally bowed femur and patients not fit for anesthesia were excluded (n= 14).

Random Allocation:

All the patients eligible for the study were randomized into either conventional dynamic hip screw (CDHS) group or minimal invasive dynamic hip screw (MIDHS) group according to computerized random number generation technique. The conventional group was treated by standard open technique which required a longer incision with relatively more soft tissue and muscle dissection while the minimal invasive group by minimal incision technique that required relatively smaller incision with less muscle and soft tissue dissection.

Patient Work-up:

After detailed history and examination including pre-hospital treatment received, conventional plain radiographs that included X-ray Pelvis with both hips – AP view, lateral view of hip with thigh of the injured side were done to assess the fracture geometry, fracture classification, bone quality, other associated injuries (e.g. fracture of acetabulum/ pelvis, fracture head/ neck of femur, associated fracture

of lesser trochanter etc.). Relevant biochemical and hematological investigations were done for pre-anesthetic assessment of the patient before undergoing surgery. Standard preoperative evaluation was followed with complete assessment by physician and anesthetist. Routine institutional protocol was followed for preoperative preparation and surgery.

Intervention: Technique of Minimally Invasive Dynamic Hip Screw Fixation (MIDHS):

A commercially available FDA approved stainless steel (grade 316 L) dynamic hip screw (DHS) device manufactured locally (Greens Surgical Pvt. Limited, India / Shakti Orthopaedics Pvt. Limited, India) was used. The standard 135° dynamic hip screw (DHS) device with adequate plate length and lag screw, depending on fracture configuration and indication, was used to internally fix the fracture after reduction by closed manipulation under image intensifier over a fracture table.

All the cases in MIDHS group were performed by the same surgeon (RM). Cases in CDHS were performed either by a surgeon with the same number of years of experience as the surgeon who performed MIDHS, or by a surgeon supervised by another with the same number of years of experience as RM.

All patients were operated in supine position using the same standard lateral approach. Intravenous cefuroxime for 48 hours followed by oral antibiotics for another 7 days in appropriate dose was used as prophylactic antibiotics for all cases. Drain was used for none of the cases and no medical prophylaxis for venous thromboembolism was given.

Surgical Steps¹⁹:

Adequate reduction of the fracture was achieved first by closed reduction under image intensifier and confirmed on AP and lateral views.



Fig: 1



Fig: 2

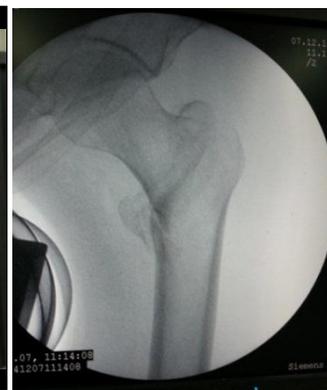


Fig: 3

Fig 1: X-ray showing intertrochanteric fracture of Left femur

Fig 2: Lateral view of closed reduction of fracture under image intensifier

Fig 3: Anterior-Posterior view of closed reduction of fracture under image intensifier

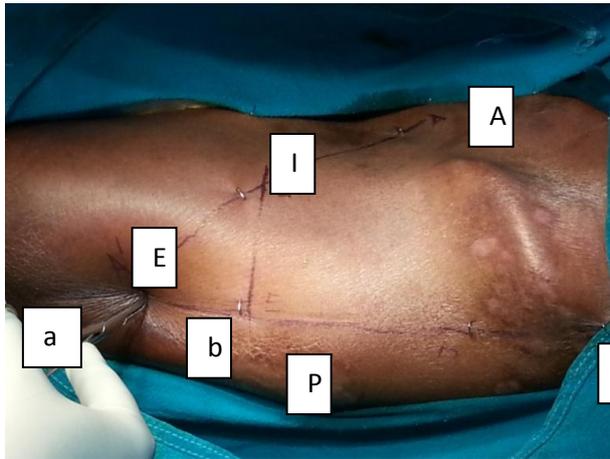


Fig: 4



Fig: 5

Fig 4: Determination of guide wire entry point on skin

Fig 5: DHS Lag Screw Insertion after proper reaming

First line Aa' is drawn along the center of femoral neck and head in anterior-posterior view under image guidance. I is the point where this line meets with the lateral cortex of the femur. Bb is the line drawn along the center of the neck in lateral view drawn under image guidance. P is the point where perpendicular from I meets the line BB'. Mark the guide wire entry point E (shown by tip of artery forceps) which is at a distance equal to that of IP distally along Bb.

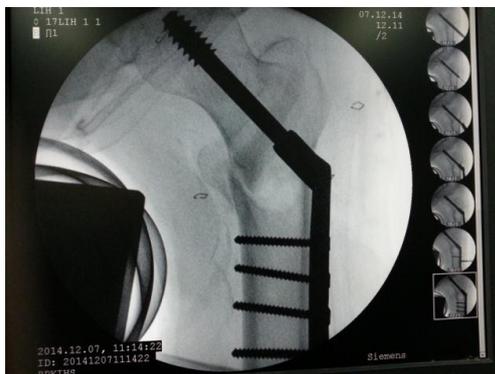


Fig: 6



Fig: 7

Fig 6- 7: Antero-Posterior and Lateral view on Image intensifier after fixation with DHS



Fig 8: The incision size measures about 2 inches (5 cms.) before final closure

Data Recording and Patient Follow-up:

Necessary data regarding patient's demographic profile, length of incision, operative time, blood loss, implant details including intra-operative complications etc. were noted. Post-operative x-rays were assessed for adequate fracture reduction, satisfactory lag screw positioning and tip-apex distance (TAD).²⁰ Post-operative pain, drop in hemoglobin level were noted for both the groups. Same post-operative rehabilitation protocol was followed by trained orthopedic physiotherapist under supervision.

Each were then followed up in immediate post-operative period, then at 2, 6, 12, 24 and 52 weeks post-operative period to assess fracture healing, ambulatory status, functional outcome of the patient using Harris Hip Score²¹ (at 1 year follow-up), range of motion, any fracture/implant related complications (if any) etc. and compared between the groups. The final outcome was also graded²² as poor (< 70), fair (70 – 79), good (80 – 89) and excellent (90 – 100) depending upon Harris Hip Score (total of 100) at 1 year.

CONSORT 2010 Flow Diagram:

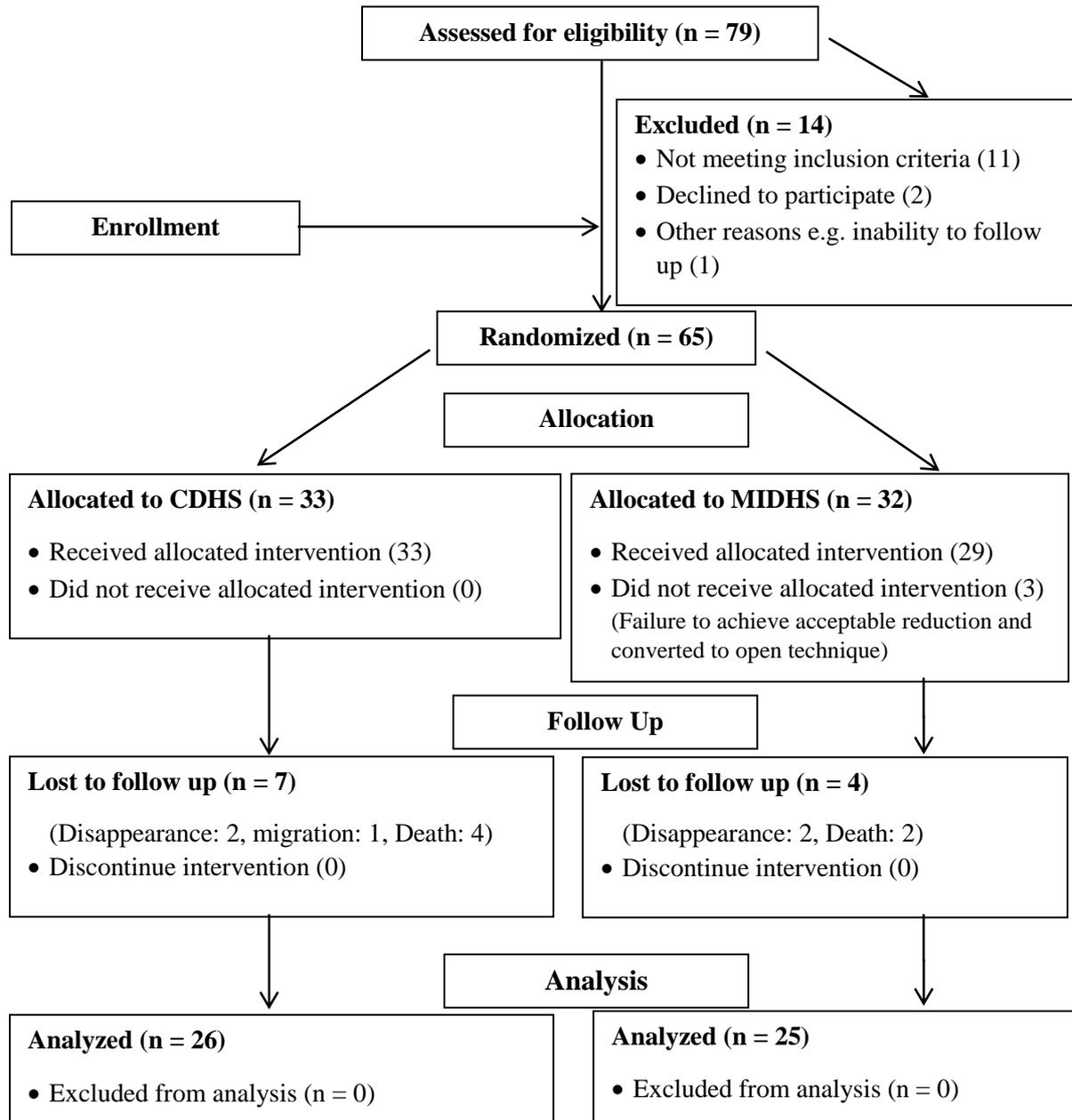


Fig 9: Flow of participants through the trial

Out of 79 adult patients with intertrochanteric fracture of femur presenting to us in the study period, 65 eligible were randomized into CDHS (n= 33) and MIDHS (n= 32) group. Three patients from MIDHS group were converted to

conventional open incision group because of failure to achieve acceptable closed reduction prior to surgery. Patients lost to follow-up were 7 and 4 in CDHS group and MIDHS group respectively for various reasons. The patients

available for final analysis, thus, comprised of 26 for CDHS group and 25 for MIDHS group (Fig 9).

We analyzed the patients who completed a minimum of one-year follow-up after surgery since most of the parameters under study as well as those related to functional outcome could have been assessed adequately by one year. We believed that it could better reflect the effects of treatment when taken in an optimal manner and provides an estimate of the true efficacy of an intervention. Patients with inadequate data and those who deviated from protocol were excluded during final analysis.

Results

All participants included in outcome analysis remained in their primary randomization group regardless of secondary procedures, according to the intention-to-treat principle, and Consolidation Standards of Reporting Trials (CONSORT) guidelines were followed. Magnitude and significance of the difference was tested assuming $p < 0.05$ (two-sided) as significant.

Statistical Analysis

Statistical analysis was performed using Statistics Software (version 17.0; SPSS, Chicago, Illinois). Mean and standard deviation of the numerical variables were calculated for both the groups and success of randomization was tested by comparing descriptive variables like age, gender, mode of injury, AO / OTA classification (Table – 1).

Similarly, Mean Injury to Surgery interval, Mean Pre-operative Hemoglobin level and American Society of Anesthesiologist (ASA) classification for both the groups were calculated for testing the randomization (Table – 2).

Testing Randomization

The demographic profile of the patients and injury characteristics as well as pre-operative clinical parameters were homogenously distributed among both the groups ($p > 0.05$). Hence, there was no bias and the randomization was successful.

Demography and Injury Characteristics			
Variables	CDHS (n=26)	MIDHS (n=25)	p-value
Age in years (Mean ± SD):	67.9 ± 9.12	66.3 ± 9.54	> 0.05
Gender (M : F) :	19:07	17:08	> 0.05
Mode of Injury:			
Slip on Ground / Floor	14	15	> 0.05
RTA	7	6	
Fall from Height	5	4	
AO / OTA Classification:			
31 - A1.1	12	13	> 0.05
31 - A1.2	9	9	
31 - A2.1	0	2	
31 - A2.2	5	1	

Table 1: Demography and Injury Characteristics

RTA: Road Traffic Accident			
AO: Arbeitsgemeinschaft fur Osteosynthesefragen			
OTA: Orthopaedic Trauma Association			

Slip on ground or floor was the most common mode of injury and males sustained more injury than females according to this study, mean age around 65 years. Simple pertrochanteric two-part fracture (31 - A1.1) was the most common fracture pattern we included in our study while those with postero-medial fragment with

multiple intermediate fragments (31 – A2.2) was the least included (Table 1) since more complex fractures cannot be reduced adequately under image control prior to surgery and DHS might not be a suitable device to fix such unstable fractures.

Pre-operative Clinical Parameters			
Variables	CDHS (n=26)	MIDHS (n=25)	p-value
I - S Interval in days(Mean ± SD):	9.16 ± 1.88	9.98 ± 1.93	> 0.05
Pre-op. Hb in gm/dl (Mean ± SD):	10.12 ± 2.24	11.33 ± 3.08	> 0.05
ASA Classification:			
I	5	6	> 0.05
II	14	12	
III	7	6	
IV	0	1	

Table 2: Pre-operative Clinical Parameters

I - S Interval: Injury to Surgery Interval

ASA: American Society of Anesthesiologist

The mean injury to surgery (I – S) interval might have been large basically of long waiting list for Operation Theatre as well as delayed presentation to the hospital in few cases. The pre-operative Hemoglobin level was assessed the day prior to surgery. ASA grading was done by the anesthesiologist on the day of surgery (Table 2). The above pre-operative clinical parameters were symmetrically distributed among the two groups (p> 0.05).

Outcome Variables:

The relevant surgical data and clinical outcome were obtained from both the CDHS and MIDHS groups as per pro forma. The data were analyzed to determine if there was any statistically significant difference among the two groups under study.

Surgical Data and Clinical Results			
Variables	CDHS (n=26)	MIDHS (n=25)	p-value
Duration of Surgery (min.)	47.2 ± 9.3	44.7 ± 8.7	>0.05
Hemoglobin decrease (gm./dl.):	2.3 ± 1.2	2.1 ± 1.3	<0.05
Length of Incision (cms.):	19.3 ± 3.7	5.9 ± 1.1	<0.05
Tip-Apex Distance, TAD (mm.):	23.2 ± 4.9	18.6 ± 4.4	>0.05
Post-Op. VAS Score (1-10):	6.8 ± 2.1	2.7 ± 1.6	<0.05
Need for Blood Transfusion (ml.):	147.8 ± 183.2	27.5 ± 104.4	<0.05
Hospital Stay (days):	2.3 ± 0.7	2.2 ± 0.6	>0.05
Surgical Site Infection (n):	1	1	>0.05

Table 3: Surgical data and Clinical Results

VAS: Visual Analogue Scale

The duration of surgery included the time from incision till the closure of the surgical wound. For maintaining uniformity, the pre-operative and post-operative (usually after 6 hours) Hemoglobin level was assessed from the same routine lab of the institute. The Tip-Apex Distance was measured manually on the post-operative x-rays adjusting for magnification. Post-operative VAS score for pain was assessed after 24 hours of surgery since this is the period when the patients were no more receiving potent parenteral analgesics. Blood was transfused when the Hemoglobin was reduced below 9 gm/dl. The hospital stay excludes the pre-operative stay (while waiting) period before

surgery. Surgical site infection includes local stitch abscess as well as local and/or systemic features of infection. One case in each group developed surgical site infection which healed with routine antibiotics and wound care without leaving any long term sequel (Table 3).

The duration of surgery, ideal lag screw position as inferred by TAD, post-operative hospital stay and surgical site infection were not different among the groups. However, the decrease in Hemoglobin level, need for blood transfusion, length of incision required and post-operative VAS score for pain were lesser for MIDHS group than CDHS group which is significant statistically ($p < 0.05$).

DHS Lag Screw Position in Femoral Head				
	Anterior	Central	Posterior	Total (n)
Conventional DHS group:				
Superior	0	4	1	5
Middle	3	11	2	16
Inferior	3	0	2	5
Total (n):	6	15	5	26
Minimal Incision DHS group:				
Superior	1	3	1	5
Middle	3	13	2	18
Inferior	0	1	1	2
Total (n):	4	17	4	25

Table 4: DHS Lag Screw Position in Femoral Head

We assessed the DHS lag screw positioning among the CDHS and MIDHS group as tabulated above. The ideal position is the central in femoral neck and head in both Antero-Posterior (AP) view and Lateral view. Inferior in AP view and Posterior in Lateral view is also

accepted but Superior in AP view and Anterior in Lateral view has high risk of DHS cut out and implant failure specially in osteoporotic bones. Most of our cases have ideal or at least acceptable lag screw position in head and neck (Table 4).

Functional Assessment			
Variables	CDHS	MIDHS	p-value
Ambulation			
With Aids (days):	2.9 ± 0.7	2.2 ± 0.7	<0.05
Without Aids (weeks):	15.3 ± 2.2	14.1 ± 1.7	>0.05
Harris Hip Score (0-100):	81.4 ± 9.2	88.6 ± 4.1	>0.05
Excellent (n):	5	4	>0.05
Good (n):	7	8	
Fair (n):	11	10	
Poor (n):	3	3	

Table 5: Functional Assessment

The ambulatory capacity of the patient with walking aids is considered as the early functional outcome of the surgery and without walking aids as late outcome. We had seen earlier ambulation using walking aids in MIDHS group than CDHS group which is statistically significant; however, there was no

significant difference in time taken by the patients for walking without aids. Similarly, the functional outcomes of CDHS and MIDHS group as measured by total Harris Hip Score as well as the number of cases with excellent, good, fair and poor outcome were similar in both the groups (Table 5).

Complication(s) / Adverse Outcome		
Variables	CDHS	MIDHS
Post-op Infection:	1	1
Skin Irritation / Bursitis:	2	4
Lag Screw Cut-out:	1	1
Non union:	0	0
Hip / Knee Stiffness:	0	0

Table 6: Complication(s) / Adverse Outcome

We had 4 cases of skin irritation / bursitis at the entry point in MIDHS group, while lag screw cut out in 1 case in each group. We had no case of nonunion and no hip / knee stiffness in either of the group (Table 6).

Discussion

Various devices can result in stable fixation and achieve union in intertrochanteric fracture of femur.^{6,23,24} DHS can achieve inter-fragmentary compression and controlled collapse resulting in

high union rate.^{9,25} However, the outcome depends on many additional factors; including: age of patient, time from injury to surgery and presence of concurrent medical conditions.

In our study, 84.6% (22/26) patients in CDHS group and 76.0% (19/25) patients in MIDHS group healed well without any complication. Most of our cases in both the CDHS and MIDHS group had adequate reduction with mean surgery time, about 50 minutes. Hence;

we conclude that both the CDHS and MIDHS were safe, simple and effective treatment methods. Many studies^{14,15,16,26} on MIDHS fixation had shown good results for intertrochanteric fracture but well-designed prospective randomized trials were lacking and some of the studies¹⁶ used a three-hole side plate and hence, their results could not be directly compared with our study where we used the four-hole side plate.

Outcome variables like duration of surgery, Tip-Apex distance (TAD), lag screw position on femoral head/neck, hospital stay, surgical site infection, Harris Hip Score (at 1 year), time taken to be able to walk without aids and surgical complications were not different between CDHS and MIDHS group. However, drop in hemoglobin level, length of incision needed, VAS score for pain (at 2nd post-operative day), need for blood transfusion and time for ambulation with aids were significantly different between CDHS and MIDHS group. Blood loss and the need for transfusion was significantly more in CDHS group in our study, which was similar to previous randomized trial,¹⁴ and it had financial implications as well (less requirement of transfusion).

We have used only one incision about 5 cms for insertion of lag screw, for sliding the barrel plate sub-muscularly and for inserting the proximal two screws. Further, we made two stab incisions, each for the insertion of third and fourth screw respectively. The MIDHS group patients in our study were more comfortable with less pain, smaller scar and earlier to be ambulatory with walking aids as the soft tissue dissection was lesser in MIDHS group. However, as the limb physiotherapy continued during follow up, we found the walking capacity

without aids among the groups were not significantly different ($p > 0.05$).

We had used DHS barrel plate with minimum four-hole considering osteoporosis and unstable fracture pattern which comprised a large proportion of hip fractures and were the major risk factors for implant failure. Bio-mechanical studies had shown no advantage of four screws over three²⁷ and no difference in stability between two-hole and four-hole side plates;²⁵ a study²⁸ showed three bone screws to be optimal for uniform distribution of tensile force without screw loosening. Still few authors had reported the use of two-hole side plate produced satisfactory healing^{9,14,26} but, there was no control group for direct comparison with the results of a technique involving a four-hole plate and the sample size was too small to justify extrapolation of the results. However, two-hole DHS had never been used in our institute.

Another implant for minimally invasive treatment of pertrochanteric fracture is percutaneous compression plate (PCCP)²⁹ with advantages similar to MIDHS technique but needed to increase hospital inventory while MIDHS technique used the familiar and existing instruments with no added inventory.^{9,14,20,26,29} Retrospective case series (n= 118) on PCCP plate¹⁵ showed good results but no comparison was made with any control group and details of surgical technique were not provided.

Previous randomized trial¹⁴ compared MIDHS technique with CDHS technique but their surgeon randomization was not standard and the length of side plate used was not standard either - both two-hole and four-hole plates were used. They did not comment on radiological results also.

Angiographic study had shown that the average distance from the vastus lateralis ridge (DHS entry point) to the first significant branch was 9.3 cm which lied in a safe vascular zone¹⁴ provided the length of incision was 5 cm or less. We conclude that the lower amount of blood loss was due to less soft tissue dissection and an incision within the safe vascular zone.

Conclusion

The conventional open technique (CDHS) and minimal incision technique (MIDHS) both were safe and effective technique of Dynamic Hip Screw (DHS) fixation for Intertrochanteric fracture of femur. However, the minimal incision technique had various immediate / short term advantages over the other; like: minimal scar, minimal soft tissue dissection / less blood loss requiring less transfusion, lesser pain in post-operative period and ability to ambulate early.

Limitation

Relatively small sample size and lack of long term follow-up were our limitation but we are confident that we are unlikely to have had produced adverse effects in our patients undergoing MIDHS. One of the important confounding factors in our study was that all the cases in MIDHS was operated by single surgeon (RM), whereas several surgeons operated for CDHS group patients, which may reduce the external validity of the trial.

Several other factors upon which the outcome of the fracture fixation depends were not considered in our study, few important ones are pre-injury ambulatory status of the patient, presence/severity of osteoporosis, Body Mass Index (BMI), other co-morbid factors etc. Fracture type-whether open or closed as well as dominant/non-dominant side injury may also

play important role in outcome of treatment. Determining the entry point in the skin for guide wire in MIDHS group was problematic, especially, in obese patients. Lastly, we have also not compared the amount of radiation exposure needed in MIDHS group and CDHS group.

Recommendation

We recommend MIDHS technique only when adequate closed reduction can first be achieved which is not the case for all inter-trochanteric fractures. Also, in basic-cervical fracture pattern which require a de-rotation screw, MIDHS is not the preferred technique. Nevertheless, the surgeon should choose the technique guided by his own experience, confidence, available facilities and his learning curve not merely by the theoretical advantages of MIDHS.

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