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A PROSPECTIVE STUDY ON CLINICAL, FUNCTIONAL AND RADIOLOGICAL OUTCOMES IN UNCEMENTED VS CEMENTED BIPOLAR EMIARTHROPLASTY FOR VARIOUS TRAUMATIC ANDNON TRAUMATIC INDICATIONS IN ORTHOPAEDICS

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ABSTRACT

The main purpose of study is to analyze and compare the clinical and functional outcome of uncementedvs cemented bipolar hemiarthroplasty for various indications in orthopaedics mainly neck of femur fracture and intertrochanteric fractures. To establish if there are any intra-operative differences between uncemented and cemented hemiarthroplasty and to analyze and compare any differences in the advantages, complications, mortality and morbidity in both the procedures and to analyze the recovery period of each procedure.

Keywords
clinical outcome, arthroplasty, hip fracture, Enoxaparin, acetabulum

INTRODUCTION

The term ‘hip fractures’ is the most frequently used term for describing fractures of proximal end of the femur. Although the bony parts of the hip also include the acetabulum and the femoral head, the term is generally used for describing the fracture of the femoral neck, fracture of the trochanteric region or a fracture of the subtrochanteric area of the femur1 .Fractures described as lateral femoral neck fractures, transcervical fractures or extra-capsular femoral fractures are less common than intra- capsular neck fractures comprising approximately 7% to 8% of all femoral neck fractures2 . The incidences of hip fractures differ throughout the regions of the world. The number of annual hip fractures worldwide has been reported to be between 1.3 and 1.7 million3,4,5.

Standard radiograph in two planes will usually confirm the diagnosis. If the radiographs are inconclusive, other radiological modalities may in some cases reveal suspected fractures or other pathologies commonly seen that affect the femur such as avascular necrosis of the femoral head commonly presenting with chronic of history of pain around the hip joint which may or may not be preceded by a history of trauma. MRI has proved to a useful tool in these elusive cases6.

Almost all patients with femoral neck fractures, intertrochanteric fractures need to be surgically treated in accordance with its appropriate classification7,8. Rare exceptions may include extremely frail or patients with a high risk of impending death where the risk of surgery outweighs the prognosis without surgery. Non operative treatment will inevitably lead to a poor functional result and is associated with a high risk of further fracture displacement and pain9,10.

Internal fixation including screws and pins have been used for treating femoral neck fractures and more than 100 different types of internal fixation devices exist for treating various hip pathologies. These fractures are either treated with fixation without any attempt to reduce the fracture or with ‘Closed’ or “Open’ reduction prior to fixation. The results after internal fixation of undisplaced fractures are reasonably good11 with union rates as close as 90%and complication rates of around 10%to 15%. Internal fixation remains the evidence based treatment of choice for undisplaced fractures in patients of any age. Surprisingly, due to a presumed high mortality rate

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with arthroplasty internal fixation has been recommended for the very old and frail patients with displaced fractures, but evidence to support the same is very limited. With increasing skill and surge in patient's desire to mobilise as early as possible to get back to activities of daily living, there is a rise in hemiarthroplasties being the treatment of choice for the same.

Treatment with hemiarthroplasty involves the removal of the femoral head and most of the femoral neck including fracture and inserting a femoral stem with a femoral head of the same size as that of the patient. The acetabulum however is left intact. There Is substantial evidence that most patients with a displaced femoral neck fracture should be treated with a hip replacement. Over the last decade, there has been an increase in randomised controlled trials comparing Internal Fixation with arthroplasty, for the treatment of femoral neck fractures. Three meta analysis of Randomized controlled trials are available and the most consistent finding is a re-operation rate of 30% to 40% for Internal fixation and below 10% for arthroplasties9,11.

Choosing between the type of hemiarthroplasty whether uncemented or cemented has been debated over many years. Using a cemented prosthesis has been associated with increased intra-operative mortality as compared to using an uncemented prosthesis. However, cementation has been associated with better outcome especially in osteoporotic bones.

MATERIALS AND METHODS

In this prospective study 50 patients were assessed who presented with both non-traumatic as well as traumatic indications of hip pathologies and were divided into 2 groups of 25 each with patients getting assigned randomly in each group. In one group the patients were operated with bipolar hemiarthroplasty using cementation to fix the implant, while the other group was fixed using an uncemented prosthesis. The study was conducted in the Orthopaedics department of SreeBalaji Medical college between 2017 and 2019. The ethical clearance for this study was obtained from the ethical clearance committee prior to commencement of the study.This study was carried out to analyse the immediate short term and long term advantages, morbidity and mortality rates along with complications , the recovery period to physical independence that we encountered in each type of fixation and to conclude based on these results as to which of the above type of fixation proved to be a better option in comparison with each other for treatment of hip pathologies requiring a hemiarthroplasty.

Source of Data: Data is collected from patients presenting to SreeBalaji medical college to the department of orthopaedics .

Method Of Collection Of Data

Data was collected after taking an informed consent from the patient in the following manner. Oral history taking with documentation was done. Thorough clinical examination was done involving both local examination as well as systemic examination.Radiological investigation involved taking X rays for all patients and other imaging modalities when warranted.Pre op investigations involving all routine blood tests were performed . Pre op complications were documented if present.Follow up period was noted upto 1 year for all patients. They were documented at regular intervals at 6 weeks , 6 months and 12 months.Follow up included the clinical assessment regarding pain , signs of sepsis and assessment with reference to symptom and Harris Hip score was done.Radiological follow up was done at 6 months and 12 months in correspondence with the symptoms as needed.

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Inclusion Criteria:Age: 45 - 65 years
1. Sex: Male and Female both included
2. Pre operative diagnosis: Both cold and traumatic causes of hip arthropathy.

Exclusion Criteria:
1. Patients not falling under the above age criteria are excluded.
2. Pathological fractures due to tumours are excluded.
3. Previously operated hip pathologies for either cold or traumatic conditions are excluded.

Minimum 12 months
Maximum 30 months

The patient was admitted to the hospital and all necessary information was gathered and recorded in the pre setproforma prepared for the study. They were observed diligently during their hospital stay until their discharge. After discharge they were instructed to come for regular follow ups to the outpatient department. Those who did not turn up on the said dates were reminded via telephonic intimation. All the data including the follow up data was recorded in the proforma.

Pre Operativework up:
Patients were admitted to the ward. History taking was done in detail with emphasis on the mode of injury as well as any existing medical or surgical co-morbidities that the patient had.In all patients pre-operatively Bucks traction was applied with appropriate weight, to the affected limb in an effort to relieve pain, restrict movement and prevent shortening. Oral or parenteral NSAID was given to the patients to relieve pain. Anteroposterior radiographs keeping the affected limb in 15 of internal rotation with traction in order to bring the neck parallel to the X ray film with both hips for comparison and visualisation was done and recorded.
Routine surgical pre-op investigations were done including blood grouping and typing, urine routine, Random blood sugar level, Serum urea and creatinine, pre-op serology with HbsAg and HIV spot test, chest X ray and ECG were done in all cases. Pre-existing medical and surgical comorbidities like diabetes, hypertension, COPD and asthma were evaluated and treated adequately before taking the patients to surgery. Certain exercise regimens were taught to the patient pre-operatively like deep breathing exercises, static quadriceps exercises, ankle pump exercises and were asked to be continued post operatively.
Patients as well as their by-standers were explained about the procedure in detail along with its associated risks and complications and a written consent was taken from all patients with their sign. The limb along with the lower back and perineal region was prepared pre-operatively. A single dose of IV antibiotic (after test dose) and tetanus immunisation was administered an hour before the surgery.

Position of the patient:
Patient is positioned in lateral position, lying on the unaffected site. Pre-wash is given with povidone iodine scrub followed by application spirit over the same. The extremity is then painted in povidone iodine solution and then draped from the affected lumbar region, covering the groin, till the toes in sterile drapes. The foot is draped separately to enable easy manipulation of the foot during surgery.

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Approach

For all our patients the posterolateral / Southern Moore approach to hip was used. This approach is essentially the same as the Lateral/Kocher Langenbeck approach, but exposure is limited to the hip joint, respecting but not displaying the sciatic nerve. The femoral attachment of short external rotators and hip capsule should be repaired post operatively to reduce the risk of postoperative dislocation. The approach involves the skin incision posterior to the lateral side of the greater trochanter and carry it distally about 6cm along the femoral axis. Proximally the incision runs slightly curved towards the PSIS to a point approximately 6cm proximal to the greater trochanter. Straight sharp dissection of the fascia lata and the gluteal muscle across the greater trochanter. Incise the fascia lata in line with the skin incision. Retraction of the gluteal muscle flap posteriorly shows short external rotators inserting on femur (at least partially obscured by fat). The sciatic nerve can be palpated posteriorly in the depths of the wound. Its exposure is not necessary for uncomplicated hip arthroplasty, but awareness of its location is a necessity. Blunt dissection of the tendinous insertions of the external rotators is then done. Before dividing the tendons, heavy non absorbable stay sutures were placed for retraction and subsequent repair. After reflecting the external rotators, the capsule is exposed which is then reflected as a broad based flap. The fracture site is then visualised and the femoral head and neck are then extracted using a corkscrew. The size of the head is then measured using a femoral head gauge.

The size was confirmed after using a trial prosthesis to check its suction fit within the acetabulum. The femoral shaft is prepared by meticulous rasping using a broach of adequate size after serial reaming, adequate lateralisation is done and prepared for insertion of prosthesis following check with trial. In patients where the femoral neck appeared to be long, it was nibbled keeping the entire length to be maintained at 2 to 2.5cm of calcar above the lesser trochanter. The prosthesis insertion was then done into the femur maintaining an anteversion of about 10 to 15 degree of anteversion and then impacted into the femur. Reduction manoeuvre applying traction and rotation was then done gently to place the prosthesis into the acetabulum and movements and limb length measurement was then checked intraoperatively and corrected accordingly.

For our study involving cemented prosthesis only first generation cementing technique was done using hand mixing of the cement in a bowl with spatula. A piece of cancellous bone extracted from the femoral head was pushed deep inside as a cement restrictor. After kneading of the cement by the surgeon it was then placed into the medullary canal using finger packing and thumb pressure.The amount of blood loss was estimated by using the swab weighing method and calculating the amount of blood present in the suction container.For closure the capsule was sutured followed by suturing of the short external rotators. A suction drain was left in situ and then wound was closed in layers . The drain was removed on wound inspection and dressing done 48 hours after the surgery.

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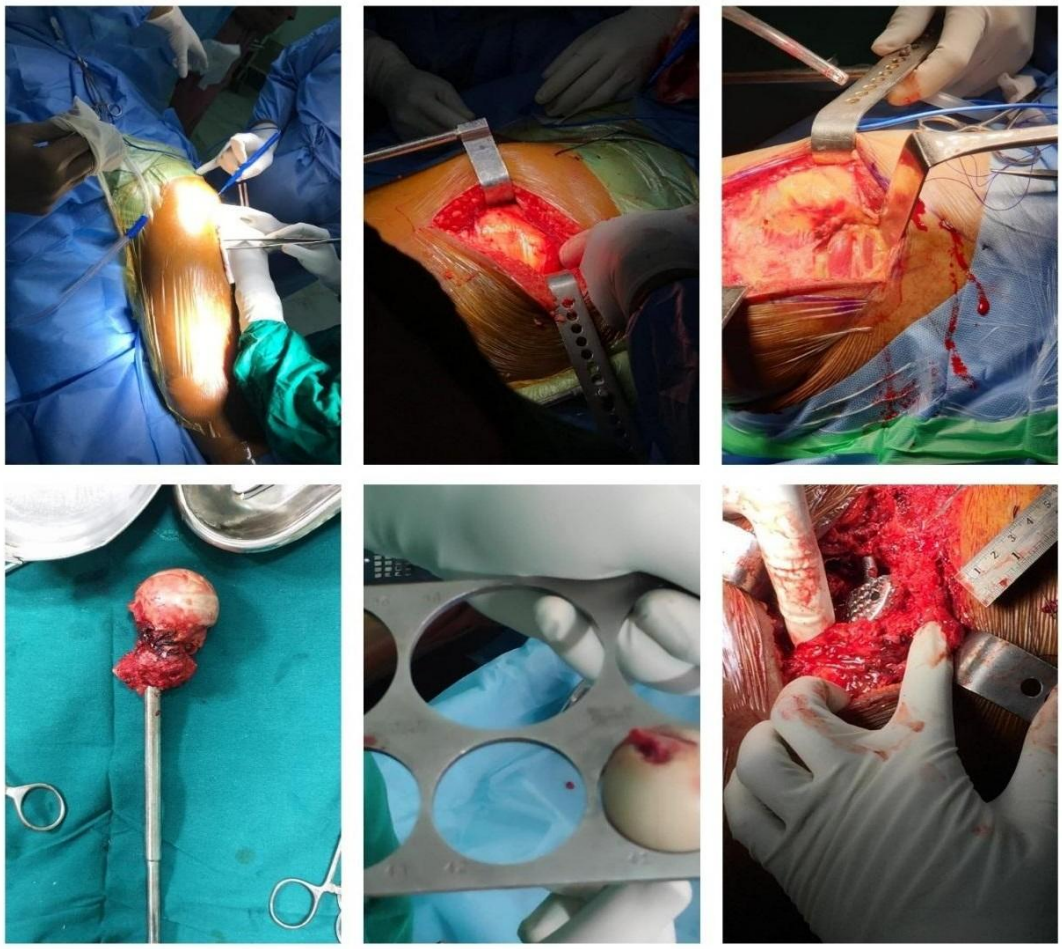

Figure No 8 : Intra-operative pictures from left to right

1. Positions and draping of the patient
2. Visualisation via posterior approach of the trochanteric bursa.
3. The short external rotators
4. Extracted head
5. Measurement of head size.
6. Post reaming – checking of measurement after fixation of trial .

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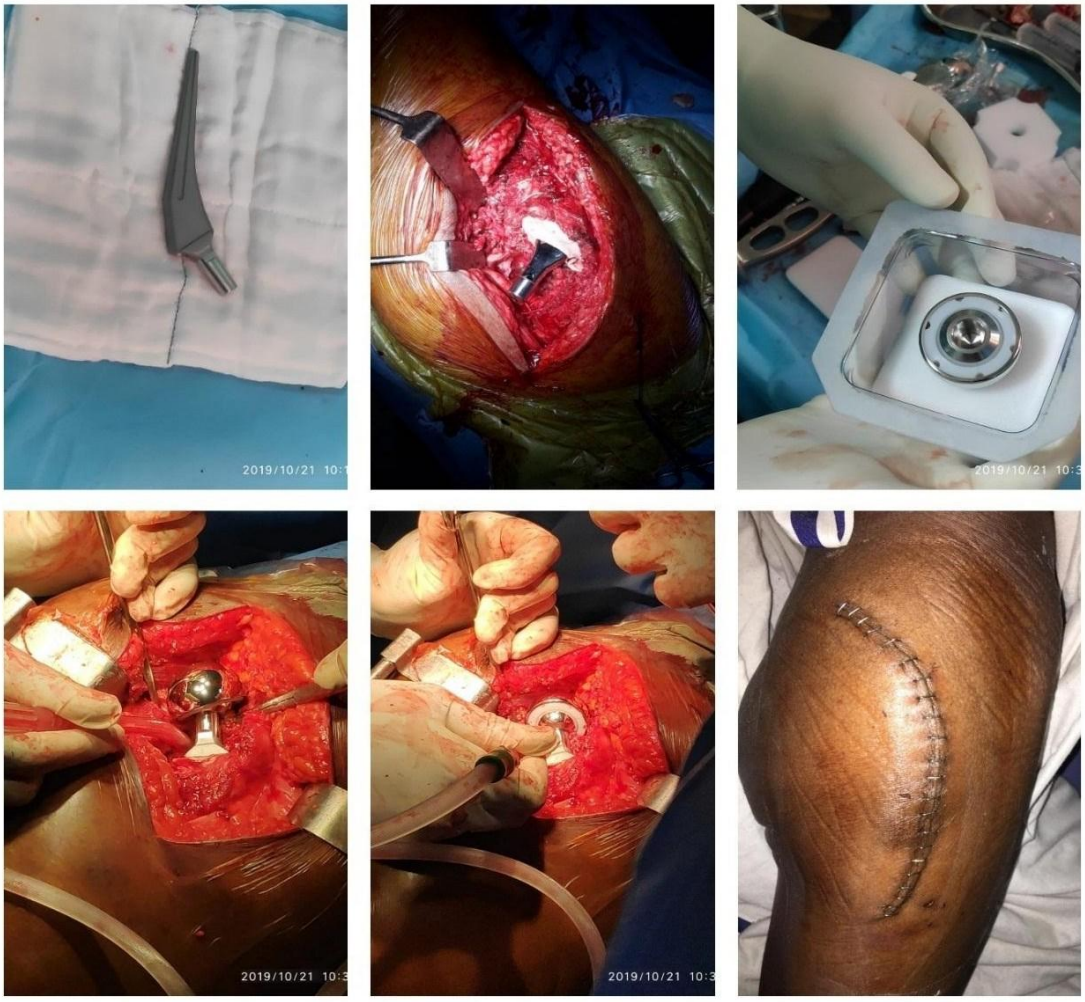

Figure No 9 : Intra-operative pictures with post-operative day 2 wound (from left to right)

1. Prosthesis – Stem component
2. Fixation with cementing
3. Prosthesis – Head with polyethylene component
4. Reduction of head
5. Reduction of head
6. Post operative day 2 dressing after drain removal.

Post-Operative Protocol

In case of spinal anaesthesia, foot end elevation was maintained while a Nil Per Oral status of 4 hours was maintained for spinal and 6 hours for general anaesthesia cases. Epidural lines maintaining analgesia was given for a few patients which was removed on the second post

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operative day. Temperature, pulse, blood pressure and respiratory rate was monitored every fourthly hourly for the first 24 hours.

DVT prophylaxis was given in the form of ankle pump exercises which the patients were trained at bedside by a team of physiotherapists. They were also started on Enoxaparin given subcutaneously 0.4cc subcutaneously for the first three days followed by low dose aspirin for the next three weeks. Ward assistants were trained adequately and administered back care for all patients post operatively. Three doses of Intravenous antibiotics (Cefperazone+Sulbactam 1.5g IV) were given to the patients followed by oral antibiotic (Cefixime 200mg) for the next 5 days. Calcium supplementation was given for three months post operatively and Tereparatide injections for 6 months were given to patients who presented with an osteoporotic index of 4 or more.Surgical site drain removal was done within 48 hours post operatively. Sterile dressings for the wound was done on Day 2 postoperatively followed by day 5 , day 9 and then suture removal was done between 12 and 14 days.

Patients were motivated to perform weight bearing mobilisation once pain tolerance developed at an average of second post operative day. They were asked to mobilise using walker support bearing weight and static dynamic quadriceps strengthening exercises were encouraged. They were asked to keep the limbs in abduction by placing a pillow in between and were asked to use an elevated toilet seat. They were advised against squatting or sitting cross legged. They were encouraged to walk independent of a walker at the end of four weeks.

RESULTS

Table no.1 Distribution of study subjects according to age.

Age group (in years)	Total N(%)
45-50	07(14.00)
51-55	12(24.00)
56-60	16(32.00)
61-65	15(30.00)
Total	50(100)
Mean±SD	57.16±5.23
Range	45-65

Graph.1Bardiagramshowingdistributionofstudysubjectsaccording to age.

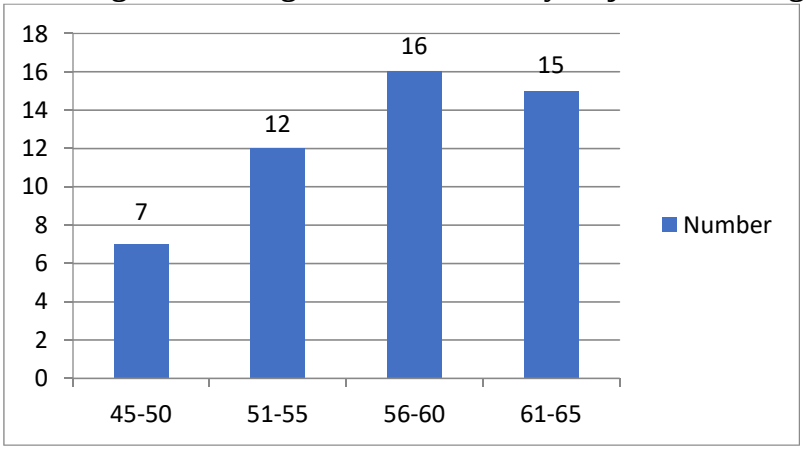

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Table no.1 & graph no.1 shows distribution of study subjects according to age. Majority 16(32%) of subjects were in age group of 56- 60 years followed by 15(30%) in age group of 61-65 years. 12(24%) subjects were in age group of 51-55 years.

Table no.2 Distribution of study subjects according to gender.

Gender	TotalN(%)
Male	28(56.00)
Female	22(44.00)

Pie diagram no. 1 showing distribution of study subjects according togender

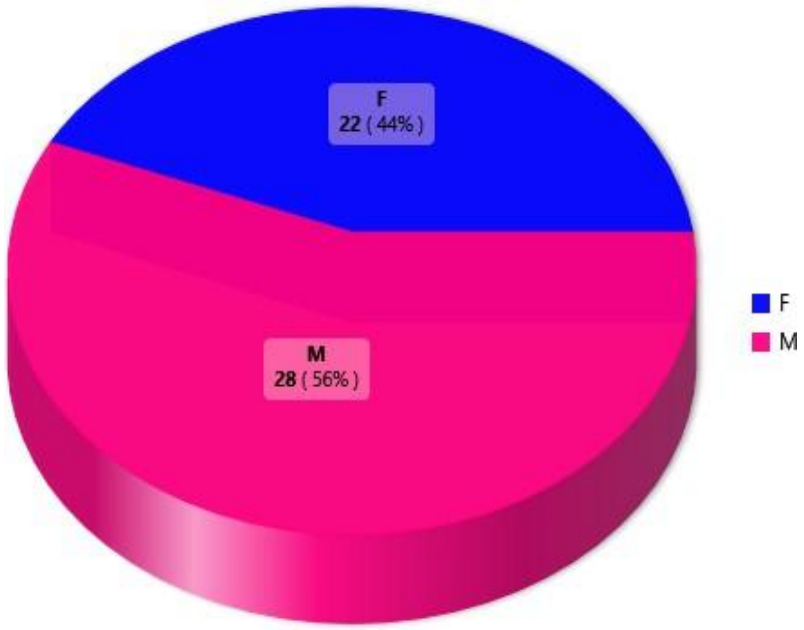

Table no.2 & Pie diagram no. 1 shows distribution of study subjects according to gender. Majority 28(56%) of subjects were males and 22(44%) were females.

Table no.3 Distribution of study subjects according to type of fractureand gender.

Type of fracture	Malen(%)	Femalen(%)	TotalN(%)
Neck of femur	15(42.86)	20(57.14)	35(70.00)
Intertrochanteric	11(84.62)	02(15.38)	13(26.00)
Stress fracture	01(2.00)	00(00)	01(2.00)
AVN	01(2.00)	00(00)	01(2.00)
Total	**28(56.00)**	**22(44.00)**	**50(100)**

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Graph no.2 Bar diagram showing distribution of study subjectsaccording to type of fracture.

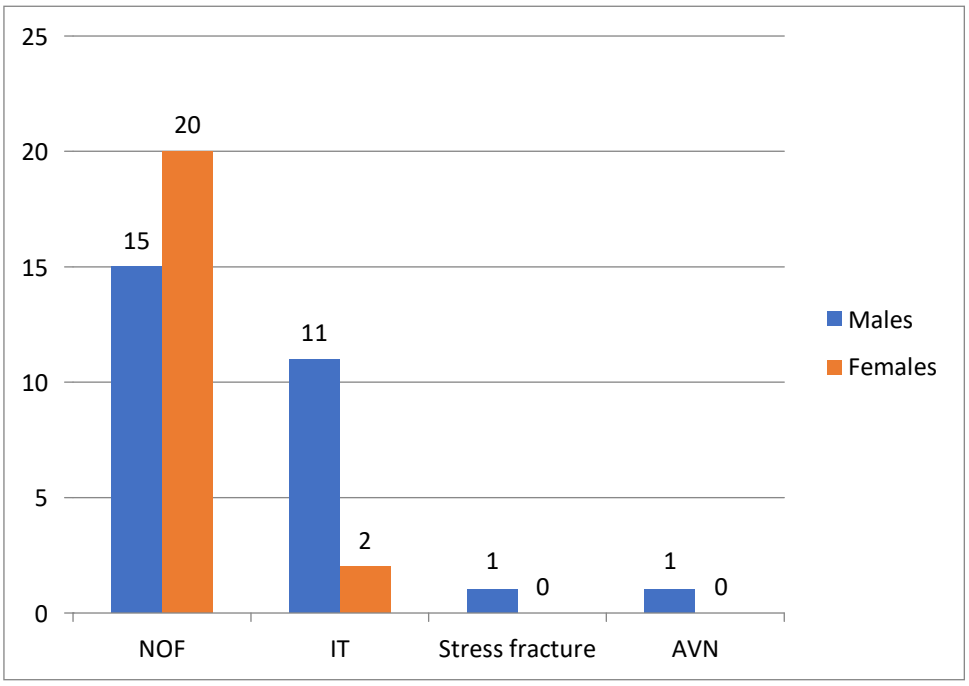

Table no.3 & graph no.2 shows distribution of study subjects according to type of fracture and gender. Out of total subjects, majority 35(70%) had fracture neck of femur. Neck of femur fracture was seen more 20(57.14%) in females as compared to males 15(42.86%). Intertrochanteric fracture was seen more 11(84.62%) in males as compared to females 02(15.38%).

DISCUSSION

The most common treatment for a displaced femoral neck fracture in the elderly is hemiarthroplasty. The hemiarthroplasty is either cemented into the femoral canal or uncemented with press-fit technique48. Femoral neck fracture is more common in females and the mean age of onset is 81 years. That with disability and mortality imposes high health care costs on the health system. The risk of femoral neck fracture is about 40-50% in females and 13-22% in males.The most common fixation method of the femoral stem has been cementing with bone cement. However, this method has some disadvantages. The duration of surgery is longer than in uncemented technique. Also, blood loss is greater and there is a risk of sudden death at the time of cementing. There is a long-standing debate on the superiority of the two methods48.The present study was conducted with an aim to compare uncementedvs cemented in bipolar hemiarthroplasty for various traumatic and non-traumatic indications.
The results were compared with other similar studies as follows:

1. AGE INCIDENCE:

The present study included 50 cases, 25 each in uncemented and uncemented group. The mean age of cases was 57.16±5.23 years ranging from 45-65 years. Majority 16(32%) of subjects were

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in age group of 56- 60 years. Mean age in cemented group was 57.4±5.85 years and in uncemented group it was 56.92±4.62 years.

2. GENDER DISTRIBUTION:

In present study, majority (56%) were males. There were 45.45% females in cemented group and 54.55% in uncemented group. Similar study conducted by Bell et al73included more females (65.21%) as compared to present study. Figved et al76 also included more females in both cemented and uncemented group(74% and 78% respectively).Kapoor et al(2) had more female cases in both cemented and uncemented group as compared to present study(65% and 63%) respectively. Mohabeyet al79 included 55% females and 45% males in their study. Hence there was female preponderance in similar studies when compared with present study.

3. MODE OF INJURY:

In our study, the mode of injury was slipping or fall in maximum cases (78%), RTA in (20 %) and repeated high energy activity representing stress fracture at the least (2%) cases. Similar results were found by Kapooret al77 and Mohabey et al79 showing slip or fall as commonest mode of injury .i.e. 90% and 97.5% respectively.

4. PROSTHESIS SIZE:

The present study showed that females require smaller prosthesis size (≤43 mm) as compared to males (≥45mm). Similar results were seen by NaiyaS et a86 who used 39 mm and 41mm number prosthesis commonly for females and 47 mm and 49 mm in males. Another study by Raoet al87 also used 41mm & 43mm for female and 45mm & 47mm for male cases in bipolar hemiarthroplasty.

5. TIME TAKEN FOR WEIGHT BEARING:

The present study showed that time taken for weight bearing was < 4 days in 80 % of cases. Only 20% cases had weight bearing after 4 days. Mobility was seen faster in cemented group as compared to uncementedgroup.Parker MD et al9 in their study found 5.7 days in cemented and 5.7 days in uncemented group as time taken by cases for weight bearing.

CONCLUSION

Bipolar hemiarthroplasty provides early freedom from pain and immobilisation and rapid return to unassisted activity with an acceptable complication rate for various traumatic and non-traumatic pathologies of the hip.It provides the advantage of mobilising a patient early , predictable pain which can be managed with analgesics given for a short period and return to activities of daily living at a faster pace.Intra-operative blood loss was lesser for uncemented bipolar hemiarthroplasty.Surgical time was less for uncemented bipolar hemiarthroplasty.Males required a larger size of prosthesis head as compared to females.Patients who underwent cemented hemiarthroplasty were able to weight bear faster as compared to patients who underwent uncementedhemiarthroplasty. Comparison between the functional outcome of cemented and uncemented did not reveal any statistical difference or prove for one to be advantageous over the other.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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