“A PLACEBO CONTROL TRIAL TO ASSESS THE ROLE OF CALCITONIN IN EARLY FRACTURE HEALING IN INTERTROCHANTERIC FRACTURE TREATED SURGICALLY AT TERTIARY CARE HOSPITAL,BELAGAVI’’

BY

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LIST OF ABBREVIATIONS

AP	-	Anterior
ASIS	-	Anterior Superior Iliac Spine
BMD	-	Bone Mineral Density
BMI	-	Body Mass Index
D_2	-	Calciferol
D_3	-	Cholecalciferol
Ca	-	Calcium
DAL	-	Disability Adjusted life Years
CGRP	-	Calcitonin Gene Related Peptide
ECF	-	Extra Cellular Fluid
H/O	-	History
IP No.	-	Inpatient Number
IU	-	International Unit
IT #	-	Intertrochanteric Fracture
Lat	-	Lateral
Lt	-	Left
PO_4	-	Phosphate
PSIS	-	Posterior Superior Iliac Spine

PTH	-	Parathyroid Hormone
ROM	-	Range of movement
Rt	-	Right
RUSH	-	Radiographic Union Score for Hip
Sl No.	-	Serial Number
TRP	-	Tubular Resorption
VAS	-	Visual Analogue Scale

ABSTRACT

TITLE: "A PLACEBO CONTROL TRIAL TO ASSESS THE ROLE OF CALCITONIN IN EARLY FRACTURE HEALING IN INTERTROCHANTERIC FRACTURE TREATED SURGICALLY AT TERTIARY CARE HOSPITAL"

INTRODUCTION:

Intertrochanteric fracture femur burden is 250,000 annually and indicates a increasing morbidity in old age population in America as well as Globally, they often as a result of trivial injury in the old age patient. These fracture account for the largest morbidity in the old age patient and are usually linked with osteoporosis, hip fracture occurring due to osteoporosis are increasing socioeconomic problem and cause reduced life quality.

Intertrochanteric fracture are among commonly operated fracture in the old age patient, they have high post-operative mortality rate leading to prolonged hospitalization and lead to poor recovery of functional independence after conventional fracture care.

Calcitonin is used to treat patients with hip fracture because it is a potent inhibitor of bone resorption. Calcitonin decreases pain intensity and promote early mobilization.

The present study has been conducted in our hospital which is a tertiary care centre to evaluate the efficacy of Salmon calcitonin in early fracture of intertrochanteric fracture treated surgically.

AIMS AND OBJECTIVES:

To evaluate the outcome of salmon calcitonin in early fracture healing of intertrochanteric fracture patients treated surgically.

MATERIALS AND METHODS:

A randomised clinical trial was carried out in KLE'S Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi from 1st January 2018 to 31st December 2018 and required data was collected from the 40 patients who underwent surgical fixation for intertrochanteric fracture followed by Salmon calcitonin therapy (Group A) or Placebo therapy (Group B) the outcome was assessed in terms of early fracture union X-RAY of femur full length anteroposterior(AP) and lateral views are taken on 1st week ,6th week and 10th week of post-operative period and compared between each group using Radiographic Union Scale for Hip (RUSH) score. Patients are also assessed for pain at the same time with VAS score.

RESULTSand Conclusion:

The obtained data was statistically analysed using SPSS software. To compare the rate of fracture healing between the interventional group (Calcitonin group) and the control group (Placebo group) on basis of RUSH score, MANN-WHITNEY TEST was used. The minimum Rush score in interventional group at 1st week is 14 whereas in control group is 12 and maximum score in interventional group is 16 and control group is 14.

The minimum Rush score in interventional group at 6th week is 23 whereas in control group is 18 and maximum score in interventional group is 26 and control group is 21.

The minimum Rush score in interventional group at 10^{th} week is 30 whereas in control group is 23 and maximum score in interventional group is 30 and control group is 28.

This test signifies that the rate of fracture healing assessed using RUSH score at 1^{st}, 6^{th} and 10^{th} in interventional group is significantly more when compared to control group as p value is <0.0001.

The intensity pain as calculated by VAS score was compared between the interventional group and the control group on 1^{st} week,6^{th} week & 10^{th} week using MANN-WHITNEY test which showed that the interventional group had a lesser intensity of pain as compared to the control group as showed by the p value which is less than 0.0001. So helping in early mobilization of the patients.

In, our study the rate of Fracture healing was faster in the patient treated with Salmon Calcitonin group as compared to Placebo (control) group and the pain intensity was significantly lower in patient treated with Salmon Calcitonin group as compared to placebo group.

Thus, we conclude that the rate of fracture healing as assessed using RUSH score was faster showing early fracture union, complete consolidation of fracture and early disappearance of fracture line and reduced intensity of pain in calcitonin treated group.

KEY WORDS:

Osteoporosis, Intertrochanteric Fracture, Calcitonin, Callus, RUSH (radiographic union score for hip), VAS(visual analogue scale) Score .

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INTRODUCTION

Intertrochanteric fractures femur burden is 250,000 annually and indicatesa increasing morbidityin old age population in the America. Most of Intertrochanteric fractures happen in patients over 6th decade of age, and fractures are common in females (3 of every 4 fractures). Intertrochanteric fractures often result of trivial injury in the old age patient[1].Intertrochanteric fracture is the fracture occurring outside joint capsule. The intertrochanteric area of femur is situated in between lesser trochanter and greater trochanters containing thick trabecular bone.[2]

These fractures account for the largest morbidity in the oldage population and are usually linked with osteoporosis. They are associated with trivialinjury in old people and road traffic accidents in young people (<40 years). Trivial falls from a 5feet height account for 80% of hip joint fractures in geriatric group[21] and is the common fractures in women above age of 65years[3].

Hip fractures resulting from osteoporosis are increasing socioeconomic problem and cause reduced life quality. Elderly, osteoporotic women are at danger of sustaining such fractures[4].Osteoporosis causeslower strength in bone, reduced bone quality and quantity and decreased bone quality, leading in enhanced risk for fracture and is common, particularly in women after menopause[31]. In females above 5decade of age, on an average lifetime risk of fragility fractures is 40–50 percent and is about two-third lesser in males[5].Intertrochanteric fractures occur in elderly and the young, but they are more prevalent in oldpopulation with osteoporosis due to trivial fall. In the younger population, thesefractures typically result from a RTA[2].On an average nine million fracture across the world in the year 2000 itself[6].Leading to loss of five point eight million DAL (disability adjusted life years).

These fractures along with other hip joint fractures causes increased morbidity& mortality[22].Currently, 280,000 fractures occur yearly, with almost half of them due to intertrochanteric fractures. By 2040, the pelvic fracture[26] is expected to rise to 500,000. The stability of intertrochanteric fracture is mainly on how many parts fracture one, two or three part fracture. Intertrochanteric fracture which are unstable may require surgery[2].

Intertrochanteric fracture is among commonly operated fracture form in the geriatric patients, they have the high post-operative mortality rate and lead to prolonged hospital stay and late mobilization due to the population they commonly affect and lead to poor recovery of functional independence after conventional fracture care[3].

Calcitonin is used to treat patients with hip fracture because it is a potent inhibitor of bone resorption. Age is the most important risk factor for osteoporosis. Calcium loss continues in geriatric age at rate of 1–3% per year and is increased by immobilization. It may be further increased after hip fracture. Calcitonin decreases pain intensity and promote early mobilization, apart from stabilizing 'callus' formation and promoting fracture healing[3].

Systemically administered calcitonin triggers calcification of Physes plate and an acceleration of skeletal growth and cartilage callus maturation[3]. Callus vascularization plays a significant role in its maturation as it contributes to the gradual replacement of cartilaginous callus by bone tissue. In patient having vertebral[41] fracture due to old agethe pain[42] reducing effect of calcitonin is of great significance[7].

Calcitonin partly inhibits osteoporosis below the implant and enhances the mechanical properties of experimental osteotomies. It has been found that, apart from the mechanical improvement in the osteotomy region,there is an increase in the mechanical parameters of the non-affected leg.It is significant to note the effect of calcitonin administration for the reduction of post-surgical bone loss, especially in patients with hip fractures[7]. Calcitonin responds to high serum ionic calcium levels by lessening the number and functions of osteoclasts[8].

Calcitonin Gene Related Peptide[47] (CGRP)-alpha signallinghad specific effects on periosteal mineralizing surface activation in response to mechanical loading leading to earlier mobilization. Use of calcitonin permits early mobilization, and increased quality of fracture healing[3].

OBJECTIVE

To evaluate the outcome of salmon calcitonin in early fracture healing of intertrochanteric fracture patients treated surgically.

REVIEW OF LITERATURE

ANATOMY AND PHYSIOLOGY OF THE HIP JOINT

The hip joint is as a 'ball-and-socket joint' of the head of the femur and the acetabulum.

CAPSULAR ATTACHMENT

The capsule is protective structure which covers the joint, in case of hip joint, the capsule covers the acetabulum along its margin it extends distally on the anterior aspect and merges near the line passing between both the trochanter and posteriorly it attached about half inch above the line joining the trochanter hence it covers the joint on the anterior aspect more when compared to posterior aspect.

ILIOFEMORAL LIGAMENT,

It is the thick ligament present on the anterior aspect of the hip joint it has two band which gives it a peculiar shape of alphabet Y. As it passes distally toward the trochanteric line, it divides into two separate bands. The lower most band passes obliquely downward and is tightened when the hip is fully extended. The y ligament is the chief stabilizer of the hip in erect standing posture. It is ¼ inch thick and is rarely disrupted by trauma as it is the strongest ligament of the hip joint. Its preservation prevents excessive displacement and provides fulcrum about which manipulative reduction of dislocation and fracture can be effected.

PUBOFEMORAL LIGAMENT,

The inferior aspect of the capsule is thickened to form pubofemoral ligament it runs from superior pubic rami and merges near the neck of femur.

ISCHIOFEMORAL LIGAMENT,

It’s a weak band within the posterior capsule weakest ligament among the three ligament attaches above to ischium of pelvic bone and below to neck of femur.

TRANSVERSE LIGAMENT OF ACETABULUM,

It is a strong band of fibers that bridges the acetabular notch and the rim of acetabulum is completed by it, acetabular notch margin is covered by it. The vessels and nerves enter the joint through the foramen beneath the ligament.

THE LIGAMENT OF TERES,

The ligament of head of femur, is flat and fan shaped. Its narrow end is inserted into a pit in the femoral head, its flattened end is bifurcated and attached to the transverse ligament. Head of femur is trans-versed by artery of ligament of teres. Before epiphyseal fusion, the artery of the ligament of teres contributes to the blood supply of the epiphysis.

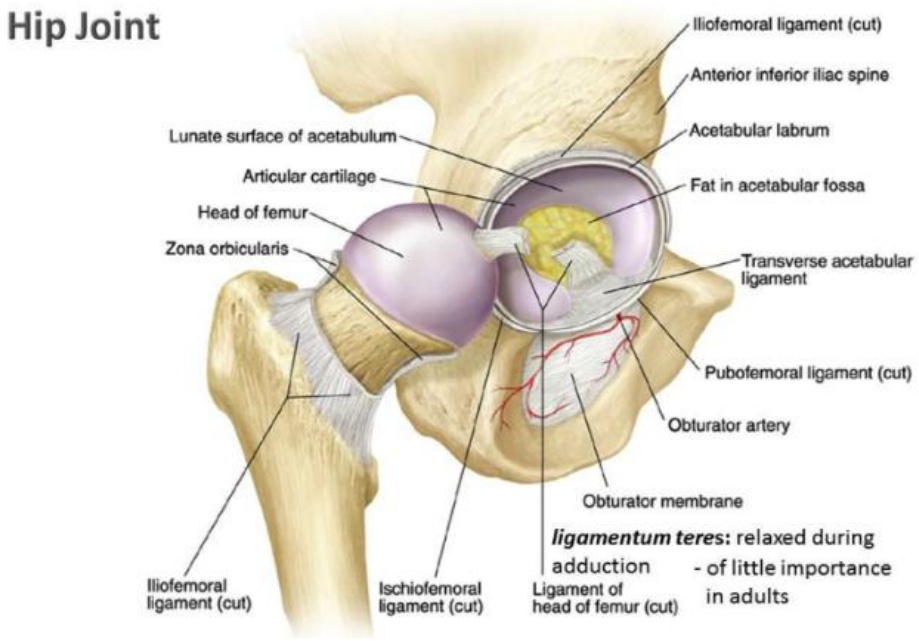

Fig 1: Hip joint

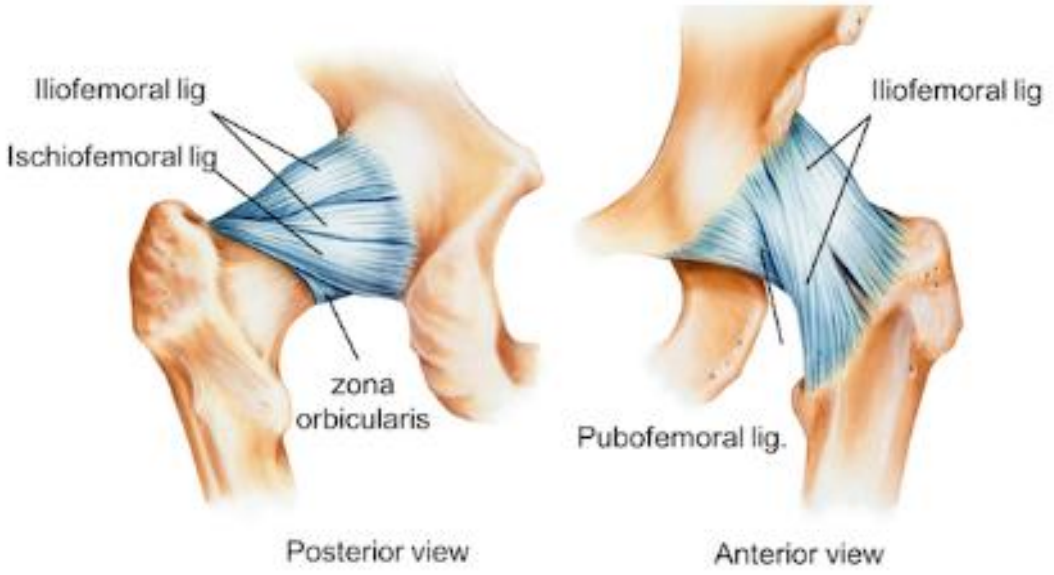

Fig 2: Ligaments around Hip Joint

SYNOVIAL MEMBRANE

The synovial membrane covers the inside part of the capsule and encloses the ligamentumteres and labrumglenoidale.

At the distal synovial reflection some of fibers of capsular are likewise reflected and run upward on the femoral neck, raising the synovium as ridges called retinacula. The retinacular folds are prominent over the posterior aspect of the neck where they enclose cervical arteries that constitute the main vascular supply to femoral head.

VASCULAR SUPPLY OF UPPER END OF FEMUR

The major supply of blood to the growing end of proximal femur is mainly contributed by two vessels one is medial circumflex vessel and other is lateral circumflex vessel. Ascending branches from the arterial ring penetrates the capsule along the intertrochanteric line and passes upward under the synovial reflections towards the junction of articular cartilage and the femoral neck, where an intra-articular sub-synovial ring has formed. From ascending arteries of the femoral neck arise branches that enter metaphysis, and epiphyseal arteries to upper end of femur. The acetabular branch of obturator artery usually give rise to artery of ligament of teres or it may arise from medial circumflex femoral artery.

VASCULAR ARRANGMENTS

The blood supply of the head of femur is derived from three source

1 MEDIAL ASCENDING CERVICAL ARTERY (inferiormetaphyseal of Trueta): this series of 6-15 straight vessels seems to arise from the metaphysis and penetrates the cartilage head directly. Each vessel ends at a definite distance from articular surface in a cauliflower-like arrangement of capillaries, which in turn drain into a vein that retraces the course of artery.

2 LATERAL ASCENDING CERVICAL(lateral epiphyseal of Trueta): A large group of vessels arise from a common stem at the trochanteric notch and advances horizontally towards the centre of head. The vessels send offshoots ascending vertically and again ending in cauliflower-like arrangement of capillaries named as sinusoids.

3 VESSELES OF LIGAMENTUM TERES: At birth, these vessels supply only a limited area about the fovea with vessels radiating outward like a laurel leaf.

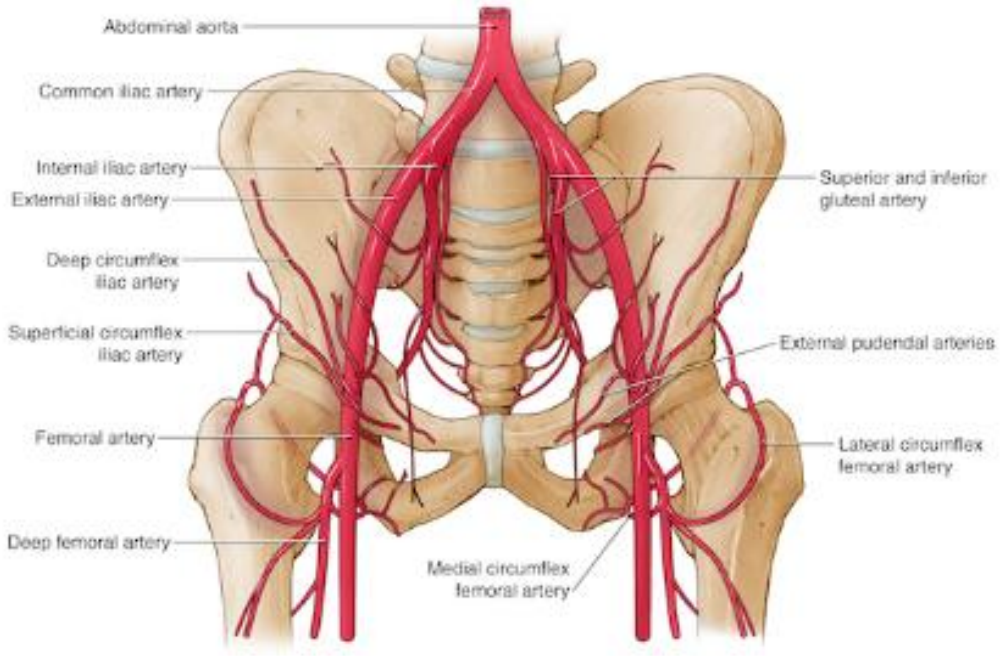

Fig 3: Vascular supply of Hip Joint.

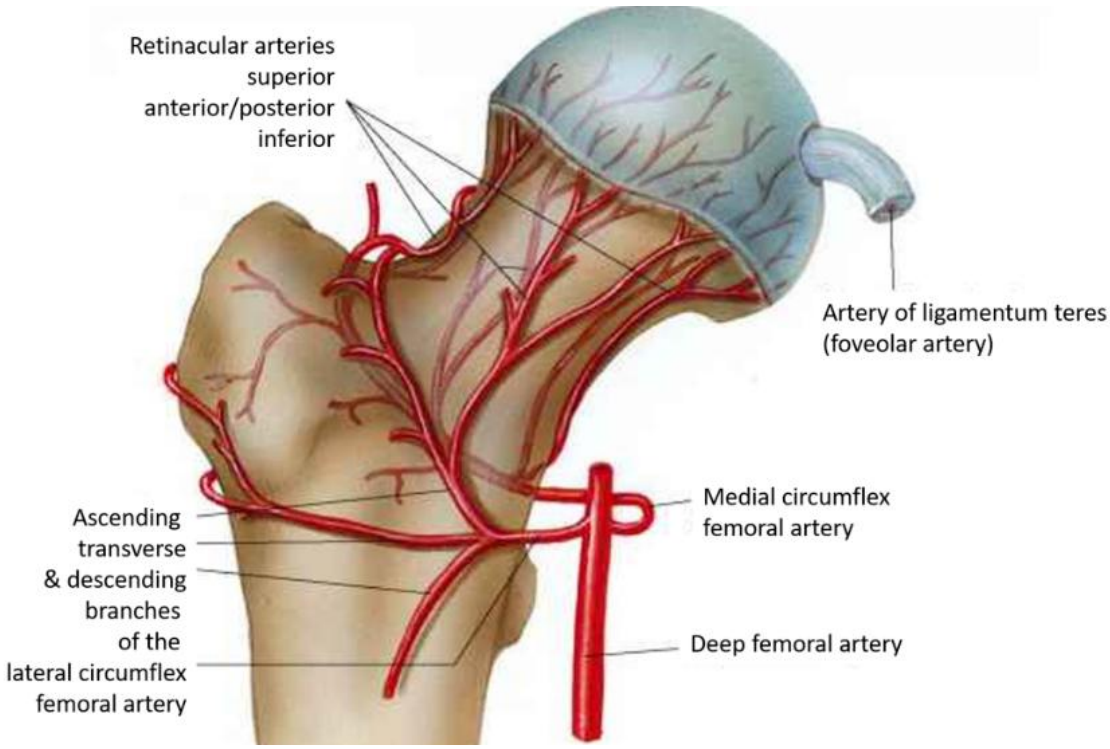

Fig 4: Vascular supply of Head Femur

Nerve supply of the hip joint[10]

FEMORAL NERVE- The femoral nerve mainly innervates the anterior aspect of the thigh, it enters the lower limb through the femoral canal, on its medial aspects lies femoral artery.Muscular branches include those to pectineus, sartorius. Cutaneous branches are the medial and intermediate femoral cutaneous and the saphenous.

SUPERIOR GLUTEAL NERVE- It is derived from the sacral plexus it exits the pelvis through the sciatic foramen, below it pyriformis is present, it supply medius, minimus and tensor facialata.

INFERIOR GLUTEAL NERVE – It is derived from Lumbosacral plexus it exits the pelvis via greater sciatic notch below the pyriformis muscles and supply maximus,

CUTANEOUS NERVES- Branches of the posterior rami of first three lumbar nerves cross the crest at the lateral border of Sacrospinalis.

The lateral cutaneous branches cross the crest anteriorly. At the lower border of Maximus, branches from posterior cutaneous nerve of thigh curve around edge of the muscle and run upwards[10].

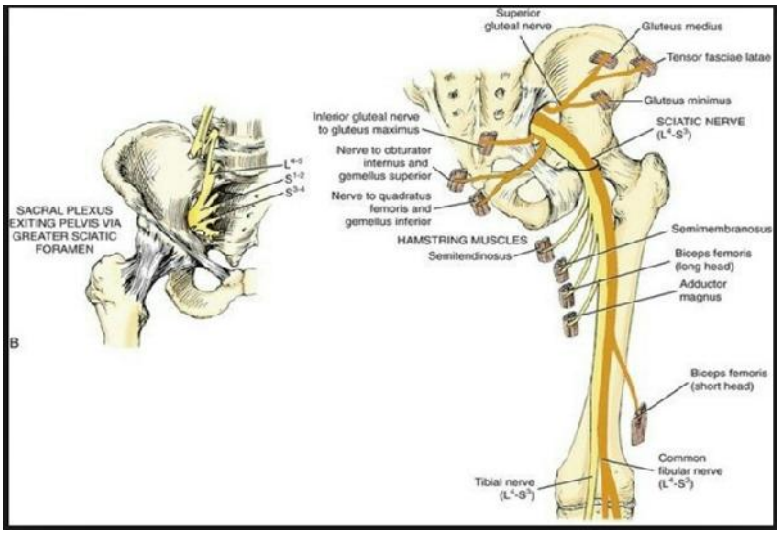

Fig 5: NervesOf The Hip Joint And Thigh

Muscular Anatomy

SARTORIUS- Itarises by a fibrous origin with inguinal ligament from ASIS. its inserted into anteromedial aspect of tibia below level of tubercleit flexes the knee, abducts and externally rotates hip. It is supplied by femoral nerve, the sartorius covers the roof of Hunters canal and is superficial to the lower half of the femoral vessels.

RECTUS FEMORIS- It is supplied by femoral nerve. It originates from straight head of ASIS and oblique head from the supra-acetabular rim, it extends the knee and flexes the hip joint.the three vasti muscles envelop the femur, they have no actions on the hip.

ADDUCTOR MUSCLES –The adductor mainly consists of adductor magnus, adductor brevis and adductor longus they originate mainly from the inferior pubic rami, the main action of these muscles are adduction, flexion and lateral rotation of the hip, Thelineaaspera and some part of supracondylar ridge gives attachment.

PSOAS MAJOR AND ILIACUS- Both of them originate intra-abdominally and enters the thigh behind the inguinal ligament. they are inserted on lesser trochanter. It is chief flexor of thigh.

GLUTEUS MAXIMUS – It arises from PSIS, a small portion of dorsum ilium, the Sacro tuberous ligament, the lower sacrum and coccyx. It passes laterally and distally toward the upper femur, where a portion of its deep fibres inserts into the gluteal tuberosity, the remaining ends in a band like aponeurosis of the tensor fascia lata, distal to the greater trochanterto form the iliotibial tract,the gluteus maximus is innervated by the inferior gluteal nerve. It extends the hip joint.

PYRIFORMIS- It emerges from the pelvis through greater sciatic foramen and passes laterally to attach to the tip of greater trochanter.

GLUTEUS MEDIUS – The main action of this muscle is abduction and it originates from gluteal surface of the ilium below the gluteus maximus and travel down and insert on to the greater trochanter of the femur.

GLUTEUS MINIMUS- The main action of this muscle is internal rotation of the hip joint, from the gluteal surface of the ilium arises minimus it passes down and the greater trochanter gives it attachment.

TENSOR FASCIA LATA – The main action of this muscle is flexion and abduction of the hip joint, it begins from the anterior superior iliac spine and travel down merges with iliotibial tract via greater trochanter.

QUADRATUS FEMORIS- It is an oblong muscle. It arises from lateral border of ischial tuberosity and extends laterally and gets inserted into quadrate tubercle. It is supplied by nerve to quadratus.

OBTURATOR-INTERNUS, SUPERIOR-GEMELLUS, INFERIOR-GEMELLUS- Obturatorinternus arises from innominate bone and exits through lesser sciatic foramen, the ischial spine of the pelvic bone give rise to the superior gemellus whereas the ischial tuberosity of the pelvis gives rise to inferior Gemellus and they both are inserted adjacent to obturatorinternus.

ILIOTIBIAL TRACT- The fascia lata forms a thickened band on the lateral aspect of the thigh. It arises from the iliac crest and runs laterally in the thigh the main action this is to extend, lateral rotation and abduction of the hip and the Gerdy's tubercle of the tibia gives attachment to iliotibial tract.

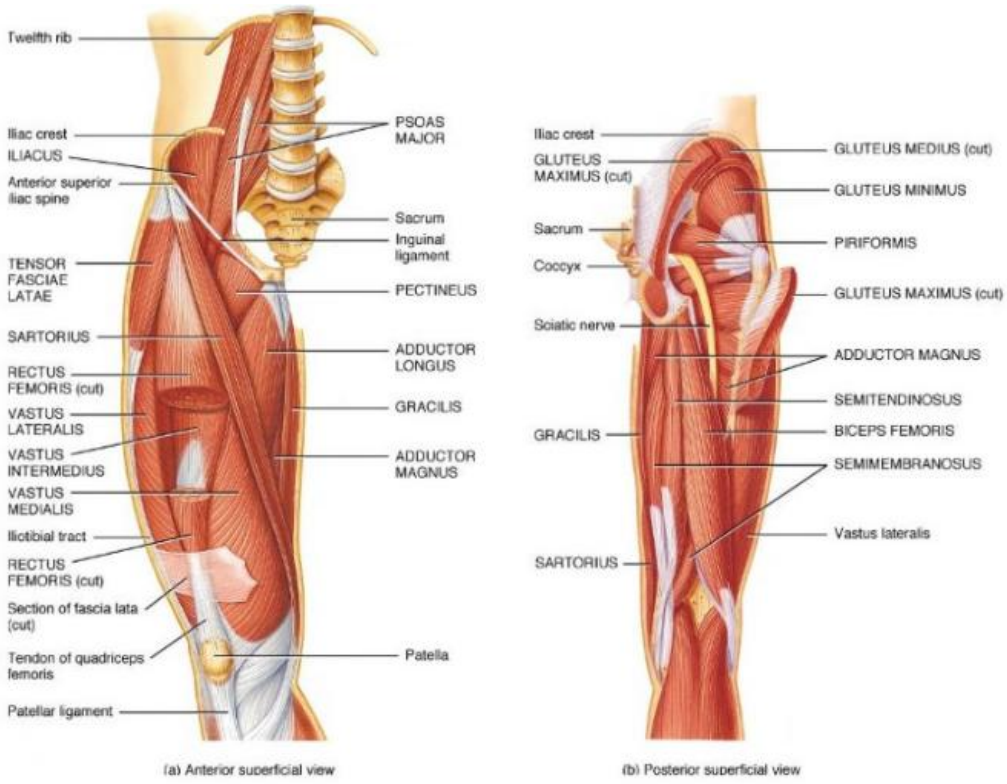

Fig 6: Muscular anatomy of Hip Joint & Thigh

Movements of hip joint: :[11]

Muscles producing movements:

MOVEMENTS	RANGE	PRIME MOVER	NERVE SUPPLY	ASSISTED BY
FLEXION	O^0-120^0 to 130^0	PSOAS MAJOR	L 2-3	RECTUS FEMORIS, SARTORIS, PECTINEUS, TENSOR FASCISA LATA, ADDUCTOR LONGUS, ADDUCTOR BREVIS, ADDUCTOR MAGNUS
EXTENSION	0^0-20^0	GLUTEUS MAXIMUS, SEMINTENDINOSUS, SEMIMEMBRANOUSUS, BICEPS FEMORIS,	INFERIOR GLUTEAL (L5, S1-2) SCIATIC NERVE (L4,5,S1,2,3)	
ABDUCTION	0^0To 45^0-55^0	GLUTEUS MEDIUS	SUPERIOR GLUTEAL NERVE (L4,5,S1)	GLUTEUS MINIMUS GLUTEUS MAXIMUS TENSOR FASCIA LATA
ADDUCTION	O^0 To 35^0-45^0	ADDUCTOR LONGUS ADDUCTOR MAGNUS ADDUCTOR BREVIS PECTINEUS GRACILIS	OBTURATOR NERVE (L3,4) FEMORAL NERVE (L2,3,4)	
EXTERNAL ROTATION	0^0 To 40^0-50^0	OBTURATOR EXTERNUS OBTURATOR INTERNUS QUADRATUS FEMORIS PYRIFORMIS GEMELLI SUPERIOR GEMELLI INFERIOR	S3,4 S1,2,3 L5, S1 S1, 2 S1, 2, 3 L5, S1	SARTORIUS LONG HEAD OF BICEPS FEMORIS
INTERNAL ROTATION	0^0 To 30^0 - 40^0	GLUTEUS MINIMUS TENSOR FASCIA LATA	SUPERIOR GLUTEAL NERVE (L4, 5, S1)	GLUTEUS MEDIUS SEMIMEMBRANOSUS SEMITENDINOSUS

BIOMECHANICS OF HIP JOINT

The body weight pressure forces passes to the head and neck of femur at angle of 165 to 175 degree the line of force usually passes along trabeculae which are developed strongly and lies in medial aspect of femoral neck,it extends above through the superior and medial aspect of the femoral head .These trabeculae are in line with similar pressure trabecula that start at acetabulum and run upward and medial to the sacroiliac joint. the reactionary forces run 90^0 degree to the cartilaginous physes plate.

when the weight of the body above the lower extremities' rests equally on two normal hip joints, the static force on each hip is one-half of, or less than one third, the total body weight.

For example when the left lower extremity is lifted as in the swing phase of walking, the weight of the left lower extremity is added to that of, and the center of the body gravity, normally in the median sagittal plane is displaced to the left.

The abductor muscles exert a counterbalancing force to maintain equilibrium. The pressure exerted on the head of the right femur is the sum of these two forces. Each force is related to the relative length of levers, if the abductor lever is one third that of the lever arm from the head to the center of gravity, the downward pull of the abductor must be three times the force of the gravity to maintain balance. Therefore, the total pressure on the head is four times the superimposed weight. The longer the abductor lever, the less the ratio between the levers, the less the abduction force required to maintain the balance and the less the pressure force on the femoral head

CLINICAL APPLICATIONS

When a hip is in valgus, the short abductor lever arm requires tremendous abduction pull on the hip, and the resultant pressure on the head may be seven or eight times the supported weight.To reduce the pressure and the pain, the patient lifts the trunk towards the hip and displaces the center of gravity in that direction. Consequently, less pull on the abductors is required and force on the femoral head is reduced.This is the characteristic waddle and limp of coxa valgus, a means of relieving stress on the hip. The secondary strain on the lumbar spine caused by this lateral lurching produces backache,increased pressure on femoral head increases degeneration. The use of a walking aid in the opposite limb by working through a long lever arm can reduce static force on the hip in multiples of pressure force exerted downward on the cane. Thus, 20 LB of push on the stick can reduce static force on the opposite hip by 8-10 times that amount. When the femoral neck has been converted by osteotomy to a valgus position, the tremendous increase of load on the head makes it mandatory to relieve pressure by support, at least until the head is strong enough.so usually in replacement surgeries it is advisable to restore or maintain the length of the neck. Maintenance of an adequate abductor lever will lessen pressure and enable the prosthesis to withstand stresses for a longer period of time[12].

EPIDEMIOLOGY:

Intertrochanteric fractures femur burden is 250,000 annually and indicates increasing morbidityin old age population in the America. Most of Intertrochanteric fractures happen in patients over 6^{th} decade of age, and fractures are common in females[43] (3 of every 4 fractures). Intertrochanteric fractures often result of trivial injury in the old patient[1].Intertrochanteric fracture are fracture occurring outside joint

capsule. The intertrochanteric area of femur is situated in between lesser trochanter and greater trochanters containing thick trabecular bone[2].

These fractures account for the largest morbidity in the old population and are usually linked with osteoporosis[32]. They are associated with trivialinjury in old people and road traffic accidents in young people (<40 years). Trivial falls from a 5feet height account for 80% of hip joint fractures in geriatric group and is the common fractures in women above age of 65years[3].

These fractures along with other hip joint fractures causes increased morbidity& mortality. Currently, 280,000 fractures occur yearly, with almost half of them due to intertrochanteric fractures. By 2040, the pelvic fracture is expected to rise to 500,000. The stability of intertrochanteric fracture is mainly on how many part fracture one, two or three part fracture. Intertrochanteric fracture which are unstable may require surgery[13].

ETIOLOGY

Hip fractures resulting from osteoporosis are increasing socioeconomic problem and cause reduced life quality. Elderly, osteoporotic women are at danger of sustaining such fractures[4].Osteoporosis causeslower strength in bone[44], reduced bone quality and quantity and decreased bone quality, leading in enhanced risk for fracture and is common, particularly in women after menopause[33]. In females above 5decade of age, on an average lifetime risk of fragility fractures is 40–50 percent and is about two-thirds lesser in males[5].Intertrochanteric fractures occur in elderly and the young, but they are more prevalent in oldpopulation with osteoporosis due to trivial fall. In the younger population, thesefractures typically result from a RTA[2].On an average nine million fracture across the world in the year 2000 itself[6].Leading to loss of five point eight million DAL (disability adjusted life years).

CLASSIFICATION

BOYD AND GRIFFIN CLASSIFICATION

Type 1 – nondisplaced intertrochanteric fracture

Type 2 – communited intertrochanteric fracture

Type 3 – communited intertrochanteric fracture with subtrochanteric extension

Type 4 – reverse obliquity fractures

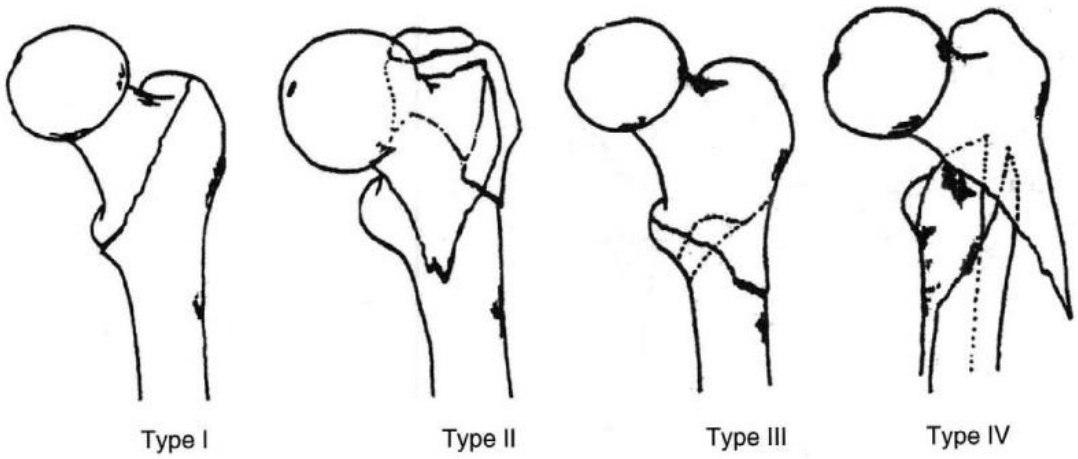

Fig 7: Boyd & griffin Classification

EVANS CLASSIFICATION

Type 1 – Facture line extends upward and downward from lesser trochanter they are further subdivided as

Type 1a – Un-displaced two fragment fracture

Type 2b – Displaced two fragment fracture

Type 1c – Fracture has three fragments without posterior lateral wall support,

Type 1d – Fracture has three fragments without medial wall support,

Type 1e – Four fragment fracture without postero-lateral and medial support

Type 2 – Subtrochanteric fracture

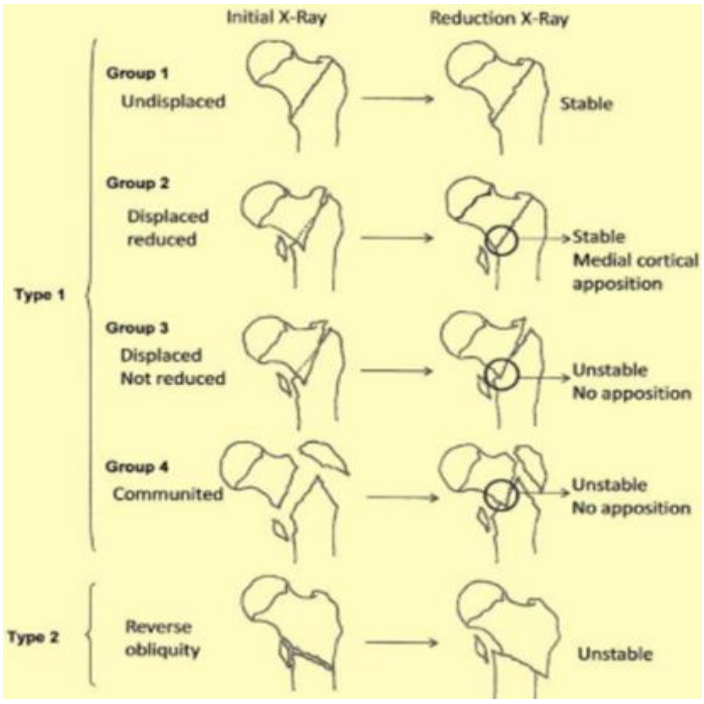

Fig 8: Evan Classification

Clinical Assessment

PREOPERATIVE EVALUATION

It is worthwhile spending 12 to 24 hours in assessing thepatient clinico-radiologically before operation. Clinicalassessment should be done for nutritional status,associated injuries, blood loss and associated medicalproblems. As the trochanteric area is vascular, blood lossmay be considerable. Most of our patients in India areundernourished and anaemic because of ignorance,poverty and food faddism. Many patients suffer fromcardiac disease, senile dementia and neurologicaldisorders at this age. Make the patient stable beforemaking the fracture stable.

Medical assessment for fitness for surgery is importantDiabetes, hypertension, cardiac problems,neuro-deficitetc must be assessed and treated.

CLINICAL FINDINGS

When the patient comes to casualty sustaining injury around the trochanteric region look for associated injuries.

Typically, patient with intertrochanteric fracture will be unable to bear weight on the fractured limb there might be swelling in the trochanter region tenderness will be present crepitus can be felt the attitude of the limb be externally rotated shortening will be present range of movements will be restricted and painful.

Treatment

The aim of treatment is to achieve fracture healing as early possible so that the patient is mobilized as soon as possible to prevent the complication associated with bedridden and to bring the patient back to his/her normal life.

Indication for Non-operative Treatment

A patient who has multiple systemic illness and the risk of surgery possess threat to his life in such patient surgical intervention is avoided and conservative line of management is preferred.

The conservative treatment by skeletal tibial tractionmay be tried for 8-12 weeks or with a de-rotation cast. Intensive medical andnursing care is required to prevent pressure sores,pneumonia, urinary tract infection, thromboembolismand pin tract infection.

OPERATIVE INTERVENTION

The main of treatment of intertrochanteric fracture patients is to treat the patient surgically and bring him back to normal routine activities.

The main aim of surgical fixation is rigid fixation and it mainly depends on the type of fracture pattern, mineral density of bone, fracture reduction, implant design and its placement, among these the operating surgeon has control over reduction of the fracture, implant choice and its placement.

When the patient comes to casualty other associated injuries should be ruled out such as head injury, blunt trauma abdomen and pelvic fractures. Some studies have suggested that if the patient with intertrochanteric fracture are treated with 24-48 hrs there is significant reduction in the mortality of the patients.

There multiple option for surgical intervention

1- PLATE CONSTRUCT
2- CEPHALOMEDULLARY NAILING
3- EXTERNAL FXIATION
4- ARTROPLASTY

FRACTURE HEALING

PHASES OF FRACTURE HEALING

There are three main phases of fracture healing,

1. Reactive phase: Inflammatory phase

2. Reparative phase: Soft callus formation

Lamellar bone deposition

3. Remodelling phase: Remodelling

Reactive

Following fracture there is break in continuity of bone, when bone is broken into fragments the periosteum is torn and it bleeds and forms a clot in and around fracture site. The blood vessels get sealed by haemostatic mechanism. Furthermore, the periosteum and marrow bordering on the fracture also becomes necrotic, the distance from the fracture line over which avascular necrosis develops varies depending upon on the site and type of bone involved.

REPAIRATIVE PHASE

A new tissue, callus develops around and between the fragments forming a bridge by which fragments are initially united. The callus that forms around the outer aspect of fractured bone is called external callus[60] and the callus which forms between the fractured bones ends called internal callus. Within first 2 days following fracture at short distance from fracture the osteogenic cell proliferate and elevate the fibrous

layer of periosteum away from bone, also osteogenic cells of marrow proliferate but to lesser extent compared to periosteal osteogenic cells.

The proliferative cells form a collar around the fractured bone within few days & capillaries also proliferate.

The osteogenic cells within a highly vascular area around the fractured fragments form into osteoblastic cells to form a bone trabecula. The newly formed bone trabecula can be compared to embryonic one as it immature and poorly organized they firmly attaches to both live and dead bone.

The osteogenic cells lying in the areas of the collar remote from the bone have proliferated so rapidly that they are far removed from slow growing capillaries, lacking adequate blood supply they transform into chondrocytes and chondroblast and consequently cartilage develop in outer region of collar.

The amount of cartilage which mainly depends on rapidity with which collar forms since formation capillaries lags behind the rate of cell proliferation & motion at fracture site.

The collar when completely develops exhibits 3 layers, in the deep inner layer the bone trabecula are firmly adherent to bone, in the intermediate layer, the cartilage firmly merges with the outer parts of newly formed bone trabecula with proliferating cells of periosteum deep layer which constitute third and outer layer.

Collar from two bone fragments become thicker advance towards each other and fuse with trabecular cartilage and proliferating cells forming bridge thus initial bridge is formed thus initial union is achieved.

The cartilage in the callus has temporary existence a later replaced by bone mainly by process of endochondral ossification those cartilage cells nearest to newly formed bone mature, matrix calcifies chondrocytes die and vascular tissue with osteoblast lay

down bone to replace disintegrating calcifies cartilage. Original v shaped cartilage become progressively smaller and is eventually completely replaced by bone, finally within the resulting cancellous bone small remnants calcified cartilage might be seen in bony trabecula[16].

The internal callus, or medullary callus, is the chief source of union between the fractured bone fragments, vascular sprouts accompanied by osteoclasts invade from the adjacent fragment end, burrowing enlarging tunnels that extends from one fragment to other. Ultimately, concentric lamellar line these tunnels to form osteons that bridge the fracture site and restore continuity. Once the internal callus has invaded the fracture interval, the osteogenic process within the medulla is resorbed and replaced by hematopoietic marrow or fatty tissue.

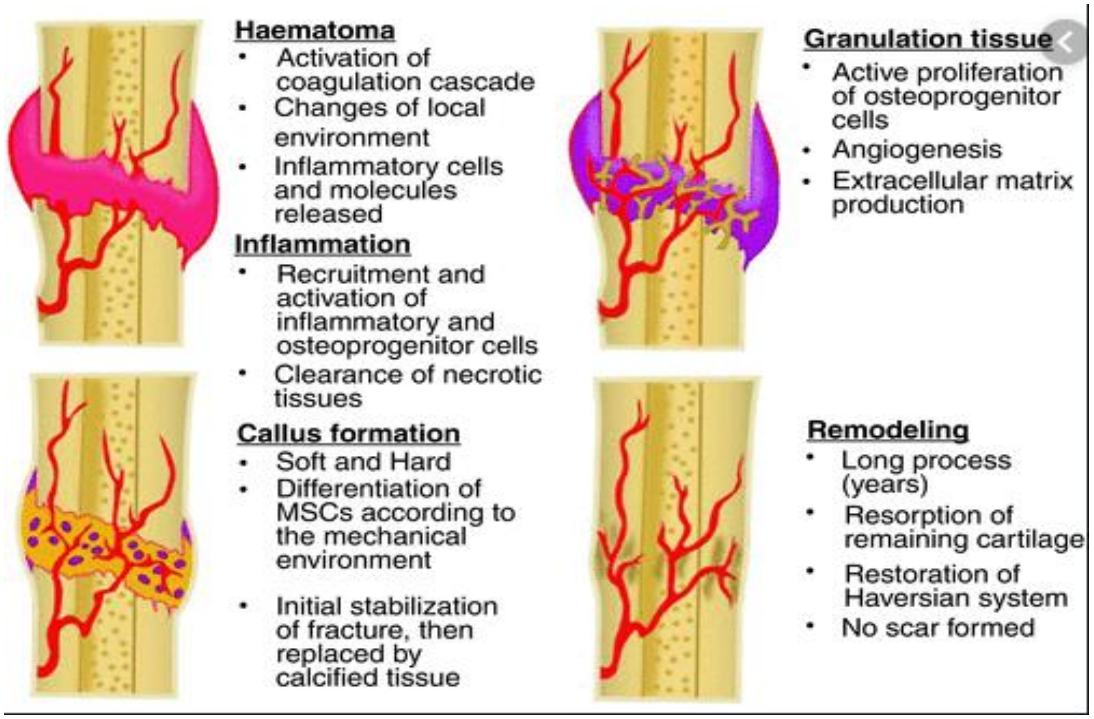

Fig 9: Fracture Healing

REMODELLING PHASE

The newly formed trabeculae of bone are firmly adherent to the original bone. More-over the fragments are bridged with cancellous network. The internal callus bridging the fragment has meanwhile developed trabeculae from both endosteum that lines the marrow cavity and osteogenic cells of the marrow itself. In addition, a portion of the internal callus[58] originates from the external surface of bone fragments which have grown down into the fracture gap adding to the cancellous bone joining the bone ends. With the passing of time, the cancellous bone is remodeled[57] and converted into compact bone.

Calcium and vitamin D involvement in bone remodeling and homeostasis

Calcium is indispensable to life. The total calcium content in the body is about 1killogram. Only about 1g is found in plasma and extracellular matrix, whereas most of calcium is in the skeleton as phosphates, carbonates and hydroxides.

There is greater need of calcium during rapid period of growth phase, pregnancy, lactation and later stages of life. calcium supplementation with usual diet in postmenopausal women and older men has lower rate of loss of bone mineral density. It reduces the fracture risk.

The cation calcium is the physiologically active portion that is necessary for blood coagulation, for neuromuscular excitability, in muscular contraction, as a constituent of mucoproteins and mucopolysaccharides and is essential ionic for many enzymes.

The normal daily requirement for a normal adult weighing 70kg is 0.65g:1.0 g is required for growing children and pregnant women.

Most people on a balanced diet ingest between 0.6 and 1.0g/day. About 200-250mg is absorbed in the average adult who ingest 1g/day, and reminder is lost in feces.

Absorption takes place from the upper small intestine, the absorption from small intestine depends on various factor such as Vitamin D, PTH, and Calcitonin. Other factors may modify absorption. An acidic pH will favour absorption by increasing the solubility of calcium salts. Calcium may be complexed, chelated or precipitated by a variety of substance in the diet, rendering it unavailable for absorption. Bile salts increase absorption by emulsifying fat. Thus, decreasing loss of fat-soluble Vitamin D thus diminishing the formation insoluble calcium fatty acid soap which render calcium non absorbable.

Normal level of serum calcium level is maintained at 8.8-10.8mg/dl with somewhat higher values in children. It occurs in non-diffusible form, which is mainly bound to proteins, and a diffusible form, most of which is ionized.

About 40% of serum calcium is bound to proteins, (4/5 albumin, 1/5 globulin), 47% ionized and 13% is complexed to PO_4, HCO_3, and citrates.

Excretion of calcium mainly occurs through the kidney. A small portion is exerted by colon. The usual level of calcium excretion is 400mg/day in adults and generally 4-6mg/kg/body weight in children.

Both ionized and nonionized calcium filters through the glomerulus and then resorbed in both proximal and distal tubules. The resorptive rate for calcium depends on the level of vitamin D and PTH, normally 95% of filtered calcium is absorbed back.

FATE OF Ca AND PO_4

Approximately 150mg of Ca is accumulated per day during active skeletal growth and maturation. with an average of 700mg calcium entering and leaving per day in an adult bone. Ninety nine percent of the body's calcium and 80-90% of phosphorous are stored in the bones.

Calcium absorption is very ineffective in normal human life only 10-30% is absorbed and rest is excreted.

The Calcium and Phosphorous metabolism and homeostasis is mainly controlled by PTH, Vitamin D and Calcitonin all of which act to maintain the concentration of physiologically active ionized calcium and phosphates to a normal physiological value.

PTH affects diuresis of phosphates by decreasing its resorption and mobilizes calcium and phosphates from the bone. This hormone also acts on intestine absorption of calcium and plays a major role in maintaining the calcium level in ECF and bone matrix.

Calcitonin is a hypocalcemic principle that counteract the effect of PTH by inhibiting the resorption of calcium from bones and resorption of calcium from renal tubules.

Normally, calcium and phosphorous ions in serum exists in ratio of 2.5:1. The minerals are continually being excreted and replaced from the bone reservoir and dietary intake. Calcium phosphate in bone undergo dissociation under influence of PTH. These ions are in constant equilibrium and subjected to law of dissociation.

Increase in phosphate ion results in decrease of calcium ions with consequent deposition of calcium phosphate in bone. Reversely fall of phosphate ions produce a rise of calcium ions by withdrawal from bone, and the excess of calcium is excreted in the urine. An increase of both calcium and phosphates, particularly in the presence of vitamin D, causes deposition of calcium phosphate in cartilage[51] or bone matrix.

VITAMIN D

Vitamin D is one of the most important regulators of bone metabolism[28]. It also regulates calcium, the principle component of bone, by controlling its entry into the intestine and exist through kidney and storage in the bone.

Vitamin D is also involved in the stimulation of the PTH secretion, which is responsible for increased bone turnover. It deficiency causes decreased gut absorption

of calcium and phosphate, which leads to suboptimal bone mineralization and osteomalacia. In elderly people poor renal function also increases PTH production, which further accelerates bone loss. Vitamin D concentration is of clinical significance as it is a part of various pathway necessary for bone health.

The two principle vitamin Ds are calciferol(D2) and cholecalciferol(D3). Both D_2 and D_3 are fat soluble sterols.

7-dehydrocholesterol, synthesized endogenously from cholesterol are stored in skin. By the action of UV light on the skin the ergosterol is converted to D_2 and 7-dehydrocholesterol is converted to D_3. Then D_2 and D_3 undergo metabolic conversion in the liver to form 25-hydroxyvitamin D, which is more active form. which later converted to more active form 1,25-dihydroxyvitaminD under the influence of PTH which acts on intestine and help in calcium absorption, mobilizing calcium from bone and resorbing calcium from renal tubules.

Vitamin D aids absorption of calcium from intestine and is necessary for deposition of mineral in bones. On the other hand an excess of Vitamin D stimulates PTH resulting in resorption of calcium from bone, elevation of serum calcium and increased urinary excretion of calcium phosphates casts and stones.

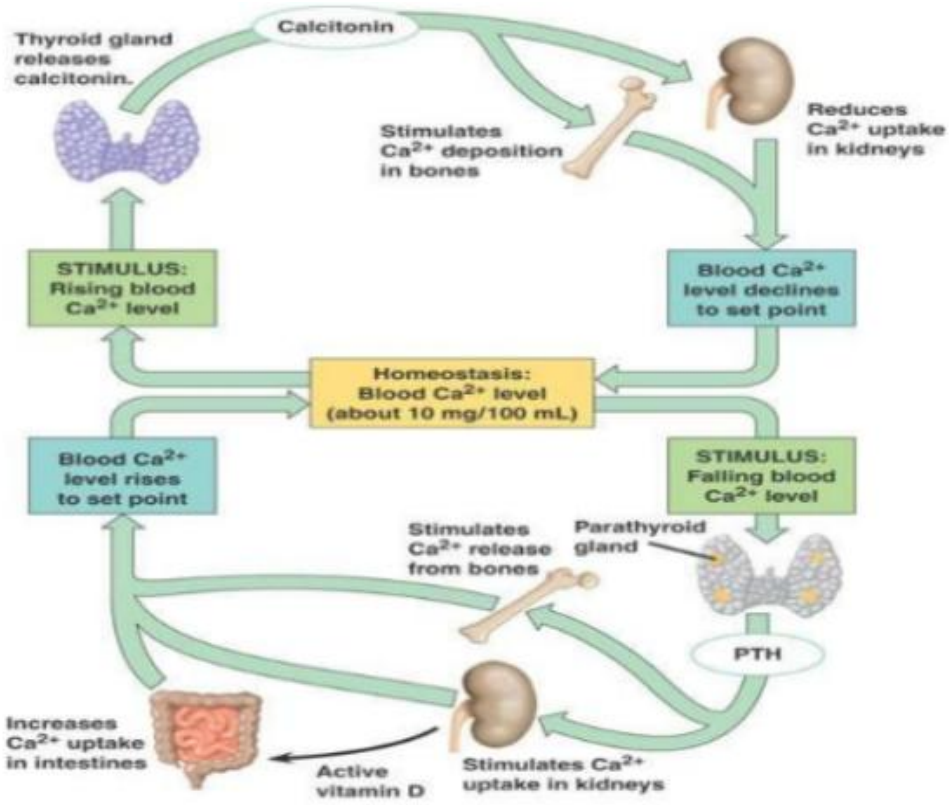

Fig 10: Calcium Homeostasis

PTH

PTH contains an 84 amino acid peptide, which is secreted by parathyroid gland[37]. An active form PTH is packaged into dense secretory granules for their regulated secretion is under the control of serum calcium, which inversely affects the parathyroid secretion. PTH has following function

1- Maintains blood calcium levels by resorption of bone, promoting tubular resorption of calcium and acting with vitamin D to promote intestinal absorption of calcium.

2- Lowers serum phosphorus levels by inhibiting tubular resorption (TRP) from the glomerular filtrate.

3- Encourages glomerular filtration of calcium and phosphate ions.

4- Stimulates osteoclasis.

5- Directly affects dissolutions of bone.

6- Increases solubility of calcium and phosphate.

7- Inhibits the mineralizing effect of vitamin D.

The Hormone maintains calcium homeostasis as follows

1- Promotes transfer of mineral from bone to ECF through its action on lining cells.

2- Promotes resorption of calcium in the kidney by the tubules from glomerular filtrate, thus elevating the serum calcium level.

3- Inhibits TRP, thus lowering the serum phosphate level, which in turn encourage elevation of serum calcium.

4- Acts with vitamin D to promote intestinal absorption of calcium.

5- Interferes with excretion of hydrogen ion and resorption of amino acids,calcium homeostasis require both PTH and Calcitonin, each acting in opposite way on bone resorption.

CALCITONIN

Calcitonin is a 32 amino-acid peptide hormone whose principle effect is to inhibit osteoclastic[45] mediated bone resorption[34]. Increase in serum calcium level causes calcitonin secretion and lower level of serum calcium inhibits calcitonin secretion[49]. Calcitonin increases calcium and phosphorous excretion, decrease the calcium and phosphorous level in blood and finally inhibits the resorption of bone[35].

Calcitonin is secreted from the C cells[36], which are situated in thyroid in the perifollicular areas but are also known to exists elsewhere, such as in the parathyroid and thymus, although they are difficult to demonstrate[50].

The main effect of Calcitonin is to inhibit resorption of bone and to decrease the tubular resorption of calcium.

The stimulus to produce and release the hormone is higher level of calcium in the blood. Its hypo calcemic effect counteracts the hypercalcemic effect of PTH. When Calcitonin activity is high, hypocalcemia may ensue and may induce a compensatory hyperthyroid response.

The hormones property of inhibiting bone resorption appears to have therapeutic effect value in condition of excessive of bone resorption.

Pagonis TA, et al., conducted a study to compare the role of calcitonin vs bisphosphonates in treatment of spinal fracture[55] in osteoporotic patients treated conservatively. This study was prospective double blind study, they evaluated data which was taken from medical documents of two similarly comparable groups of osteoporotic patient .Group 1 patient were given calcitonin in combination with calcium and the other group 2 was given bisphosphonates both these group were initially diagnosed as fracture in osteoporotic patient and were treated non surgically with brace and medication for osteoporosis ,these patients were examined radiographically,X-RAYS was taken at the time of diagnosis and followed by 3,6,9 & 12months and later CT spine was performed at 6 months & 12 months to assess the union of the bone , The patients were assessed using quality of life questionnaire of the European foundation for osteoporosis. The study signified that use of calcitonin causes early fracture union early stopping of analgesic drugs early mobilization without the brace. Calcitonin is helpful in fracture consolidation in patient in spinal fracture due to osteoporosis and indirectly improves the quality of life[6].

Karachalios T, et al. conducted a study to assess the role calcitonin in averting bone loss after a fracture around hip joint and decrease the relativity of fracture in the same patient. The study was conducted on fifty women in between the age group of 70-80 who had fracture around hip joint. These fifty women were divided randomly in two group, group 1were given salmon calcitonin intranasally 200IU[27] for 90days and the other group 2 was given placebo .The level of alkaline phosphatase and osteocalcin was assessed on 15^{th} day post trauma and 90^{th} day post trauma which showed significant increase in its level , the level of urinary excretion of c-telopeptide was assessed on 15^{th},45^{th}& 90^{th} days post trauma which showed less in group 1 that calcitonin group which signifies bone turnover rate and in group 1 there was documentation of reduced level of urinary hydroxyproline on 15^{th}.45^{th}&90^{th} post trauma day. The mineral density of bone[56] was assessed in both groups, group 1 had significant increase in mineral density of bone in all recorded areas expect in one region that is greater trochanter done after 90days & 365days post-surgical intervention. The patients were observed for 4 years clinical to see for new fracture, 5 patient in group 2 had fresh fracture around the hip joint among 5 four patient had fresh fracture on opposite side of the old fracture. The result of this study showed that calcitonin has significant role in reducing acute bone loss in patient who have sustained fracture around the hip joint and also reduces the chance or probability of new fracture in same or opposite hip in geriatric patient[4].

Lyritis GP, et al., conducted the role of calcitonin on healing of fracture and in averting disuse osteoporosis post fracture. This study had two component invitro and in vivo, The in vivo study was conducted using 80male rats of 5 day old they were divided in two groups in one group 0.2IU salmon calcitonin was given

subcutaneously on daily basis the other group was given a placebo .Histologically the Physes plate & proximal tibial metaphysis was examined on 7,14,21& 28 days.

They concentrated mainly on Physes plate thickness, reproducing zone cell number, gain in rat weight and length of tibial bone compared to baseline. Animals receiving calcitonin had rapid skeletal growth as there was increase in number of cells in reproducing zone of Physes plate and thickness of Physes plate even the length of tibia was also increased. In vitro part of study consisted of culturing the chondrocytes in medium rich with calcitonin derived from thyroid it was observed that cell proliferation was doubled andhad significant rise in production of glycosaminoglycan.

The calcitonin[48] administered systemically interacts with musculoskeletal tissue & cartilage to significant level causing faster skeletal growth & calcification of Physes plate. Calcitonin also accelerates the maturation of cartilage cells[7].

Huusko TM, et al., conducted a study to assess the role of intranasal calcitonin in management of hip fracture in geriatric patient and was assessed depending upon pain, loss of bone, recovery and no of days hospital stay they also compared fusion of hip fracture who underwent fusion surgery using a screw or nail. The study was randomized double blinded in which260 patients between the age of 65 years and above having hip fracture were randomly allotted to intranasal calcitonin and placebo the intranasal calcitonin 200IU was given daily for 90 days .After 90days post procedure of fracture fixation median pain score was calculated according to visual analog scale and in the placebo group pain was significantly reduced in calcitonin treated group and mean change in mineral density of calcaneal bone[23,24] was calculated from baseline to 90days which didn't show any improvement as compared to placebo group and it also showed no difference in duration of stay in hospital or

difference in mortality. X-RAY was taken after 90days post procedure to assess the fusion of hip fracture treated with screw or nail it showed that fusion was seen in 84percent of group treated with calcitonin and 63 percent in placebo group. From this study we can concludethat intranasal calcitonin may be helpful for patients with hip joint fractures but to confirm clinical significance more studies has to be conducted having more patient & longer follow up period & increased dose of calcitonin[19].

Bulbul M, et al., conducted a study to assess the role of calcitonin in fracture repair based on histology bio mechanical properties they studied on 80wistar rats which they divided into four groups prior to study they artificially induced fracture of right tibia at the level of mid diaphysis and was stabilized with k-wire (intramedullary). Two groups A&B acted as control which received placebo injection and other two groups was administered with 5international units per kg bodyweight per day intramuscularly for 42days in C group and 70days in group D the outcome was assessed by taking X-RAY, biomechanical test and histological examination. This study showed no any difference in A group and C group after 42 days or in group C and group D after 70 days on radiological examination but when histologically assessed the group treated with salmon calcitonin showed early fracture healing with increased strength of callus even the biomechanical properties were high.

The study clearly shows benefits of salmon calcitonin in early fracture healing and improving bio-mechanical properties of callus so when clinically implicated the patient can be mobilized early & allows early bearing of weight after use of calcitonin in patient with rigid fixation[8].

Li X, et al., conducted a study to assess the role of salmon calcitonin in the rats which underwent ovariectomy to see the fracture healing in porotic bone and study conducted in hospital of GuanghouMedical College China they conducted the study from the month of march 2002 to December 2004 they used a sample of 120 rats in their trial in 120, 90 rats they did ovariectomy and the remaining they did sham procedure.All the sample wistar rats their left tibia bone was fractured then ovariectomized rats were subdivided into group of 30 the sham procedure rat served as control group. The fractured rats which were divided in three group one group was administered with subcutaneous calcitonin other with normal saline the last group with estrogen.Healing of the fracture was assessed by taking X-RAY,BMD assessment and lastly with histological studying. The result of the study showed that the rats treated with calcitonin had higher values of BMD union and early callus formation.

Conclusion of this study shows superiority of salmon calcitonin as it increases BMD helps in early fracture healing with stronger callus in fractured porotic bone.

METHODOLOGY

Sample size:According to universal sample size

All the patients who full fill the criteria and who are advised to undergo surgical intervention for intertrochanteric fractureat THE KLE'S DR. PRABHAKAR KORE HOSPITAL AND MRC,BELAGAVI.

In the last three years number of patients operatefor intertrochanteric fracture on an average was40 each year.Hence 40 patients would be studied as a part of the study.

2. **Study Design:** Hospital-based Placebo control trial.

3. **Duration of study:** 1 year

4. **Period of study**: January 2018- December 2018

5. **Methodology proper**:All the patients with intertrochanteric fractures, will be enrolled inthe study after taking written and informed consent

INCLUSION CRITERIA:

1)Patients from age 30-90 years with intertrochanteric fracture

2)Patients giving consent to enroll in the study

EXCLUSION CRITERIA:

1) Patients with Chronic Illness
   - Chronic liver diseases
   - Chronic kidney diseases
   - Metabolic bone diseases
   - Septic arthritis of hip
   - Osteomyelitis

- Marfans disease
- Ehlers danols syndrome

2)Patients not wiling for surgery

3)Patients allergic to calcitonin

After enrolling the subjects in the study, they will be subjected to block randomizationtechnique using the Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE). At the time of randomization, envelopes will be allocated in sequence to assign with identification numbers using standardized procedures.

After the surgical treatment of intertrochanteric fractureeach subject will receive salmon calcitonin which will be administered through intramuscular injection 100 IU OD till POD-7. After POD-7 the patients are administered with intranasal[52] calcitonin for 3 months or a placebo (normal Saline) for the same duration as of calcitonin according to the envelop that will be assigned to them.

X-RAY of femur full length anteroposterior(AP) and lateral views are taken on 1st week ,6th week and 10th week of post-operative period and compared between each group using Radiographic Union Scale for Hip (RUSH) score. Patients are also assessed for pain at the same time with VAS score.

6. Statistical analysis:

Outcome measures will be analyzed using SPSS program.

Data will be computed and analyzed by various statistical methods.

1) The subject enrolled in this study will be administered intramuscular salmon calcitonin injection 100 IU OD till POD-7

After POD-7 the patients are administered with intranasal calcitonin for 3 months

2) X-RAY of femur full length anteroposterior(AP) and lateral views are taken on 1st week ,6th week and 10th week of post-operative period and compared between each group usingRadiographic Union Scale for Hip (RUSH) score. Patients are also assessed for pain at the same time with VAS score.

RESULTS

The patient in our study were randomly divided into 2 groups using Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) each group 20 patients once group is control and the other group is interventional group.

AGE-WISE DISTRIBUTION

INTERVENTION GROUP

AGE	NUMBER	PERCENTAGE
30 – 45	3	15
45 – 60	0	0
60 – 75	7	35
75 – 90	10	50
TOTAL	20	100

Table 1: Age Distribution Intervention Group

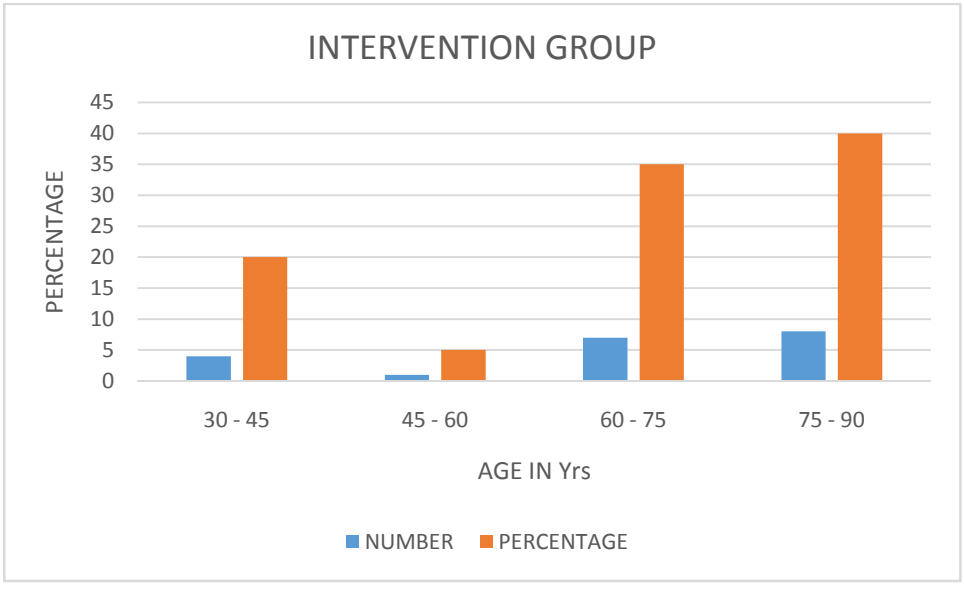

Chart 1: Age Distribution Bar Diagram Intervention Group

In intervention group among 20 Patients there were 3 patients in age group of 30-45years, 0 patient between 45-60years of age group, 7 patients between age group of 60-75years and 10 patients between the age group of 75-90 years.

CONTROL GROUP

AGE	NUMBER	PERCENTAGE
30 – 45	4	20
45 – 60	1	5
60 – 75	7	35
75 – 90	8	40
TOTAL	20	100

Table 2: Age Distribution Control Group

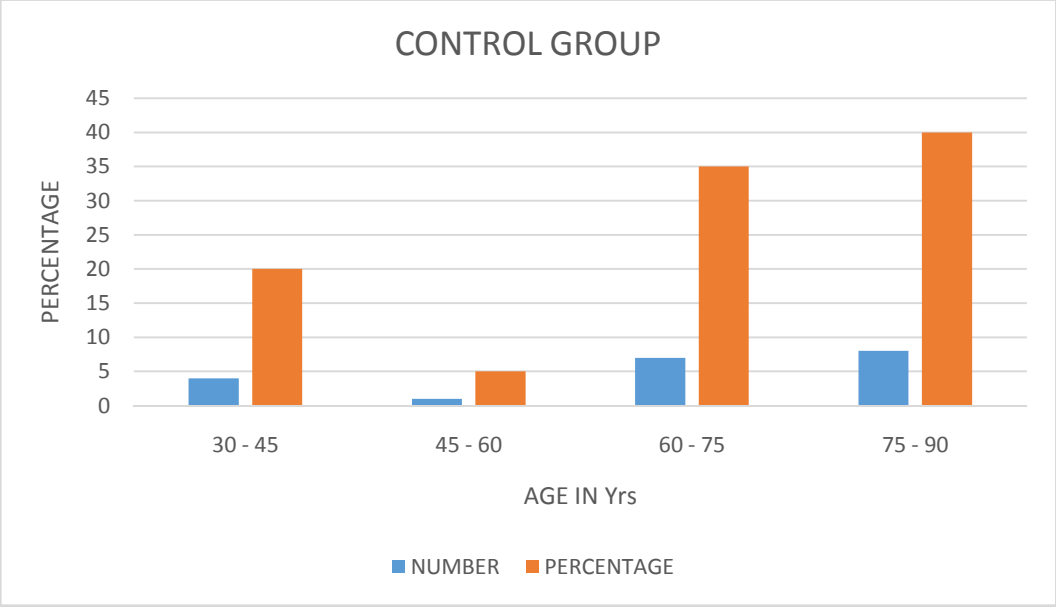

Chart 2: Age Distribution Bar Diagram Control Group

In control group among 20 patients there were 4 patients among the age group between 30-45years of age group, 1 patient in the age group between 45-60years, 7 patients among the age group between 60-75years of age and 8 patients among the age group of 75-90 years of age group.

	Intevention group				Control group					
	Mean	**S.d.**	**Minimum**	**Maximum**	**Mean**	**S.d.**	**Minimum**	**Maximum**	**P value**	**Inference**
AGE	70.75	15.64	30	85	65.70	18.26	30	87	0.3535	NS

Table 3: Age Comparison Between Intervention And Control Group

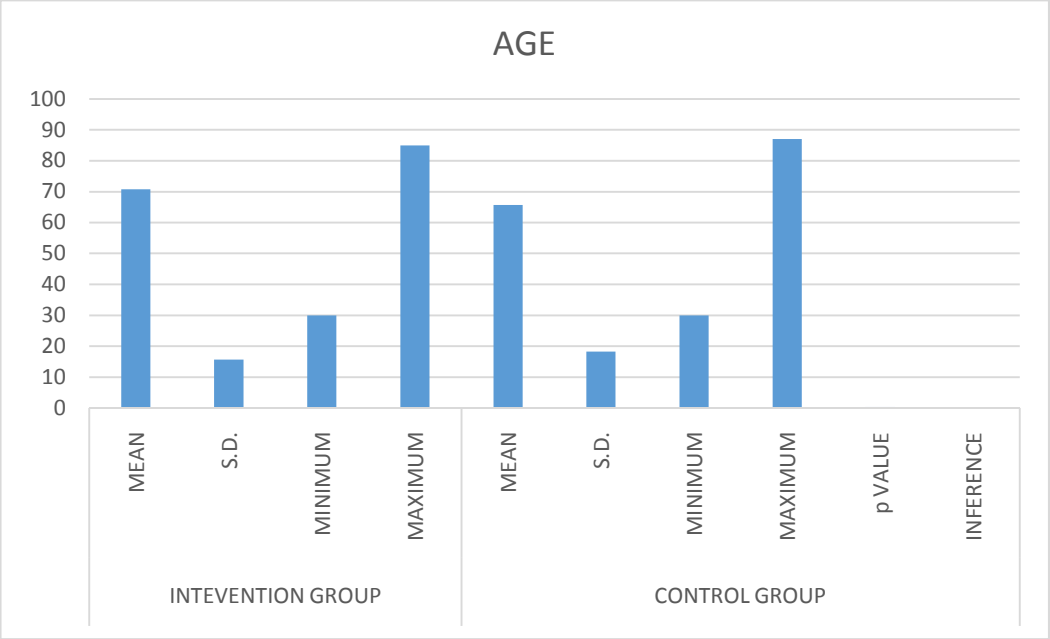

Chart 3: Age Comparison Bar Diagram

The mean age group in interventional group is 70.75 and that of control group is 65.70 and minimum age in interventional group is 30 and which is same as that of control group and maximum age in interventional group is 85 and that in control group is 87 using the CHI-SQUARE TEST the p value is 0.3535. The difference was not statically significant.

GENDER DISTRIBUTION

	INTEVENTION GROUP	CONTROL GROUP	TOTAL
FEMALE	10	11	21
MALE	10	9	19
TOTAL	20	20	40

Table 4: Gender Distribution

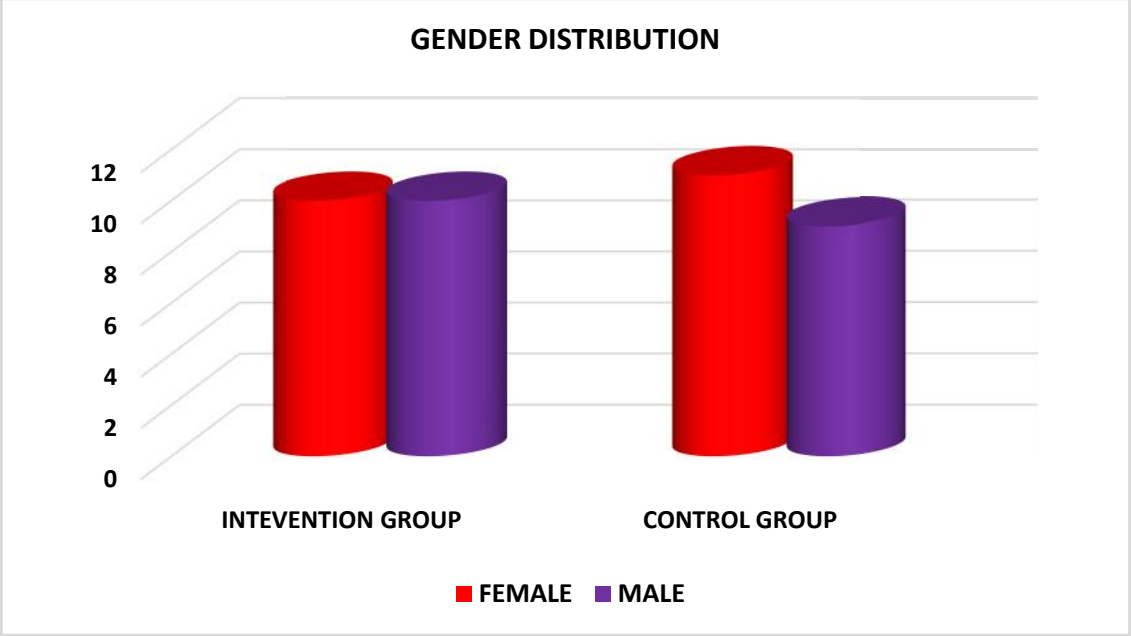

Chart 4: Gender Distribution Comparison

The gender distribution among the two group shows that in interventional group there were 10 females and 10 males whereas in the control there were 11 females and 9 males.

SIDE DISTRIBUTION

	INTEVENTION GROUP	CONTROL GROUP	TOTAL
LEFT	4	9	21
RIGHT	16	11	19
TOTAL	20	20	40

Table 5: Side Distribution

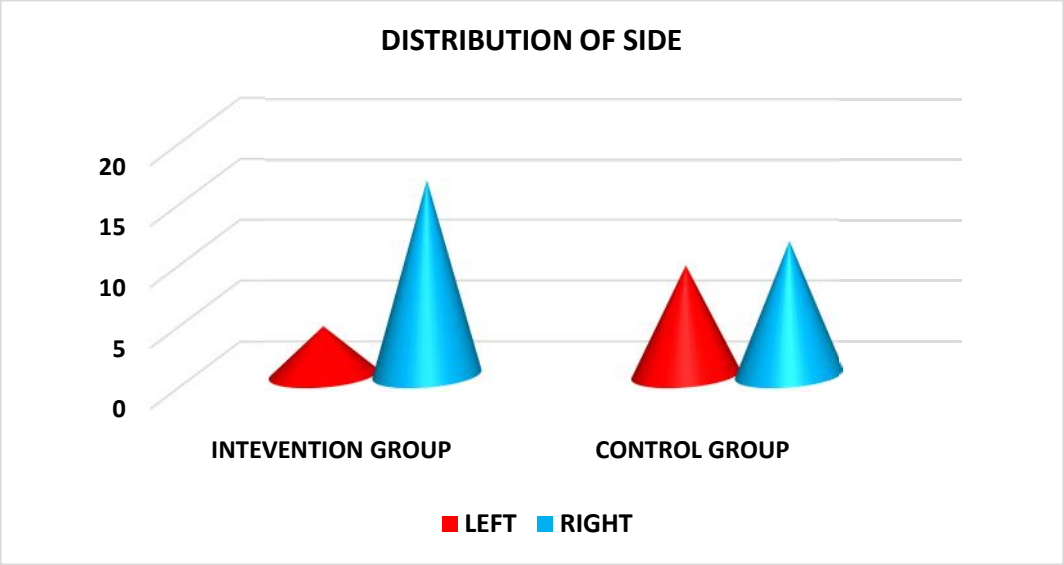

Chart 5: Side Distribution Chart

In our study the side distribution whether right sided or left sided fracture, among 20 patients in interventional group 4 had left sided fracture and 16 had right sided fracture whereas in the control group among 20 patients 9 patients had left sided fracture and 11 Patients had right sided fracture.the side variability was compared using CHI-SQUARE test the p value is 0.0914 which shows that there no association between the group and the side factor which is not significant statistically.

RUSH SCORE

Table 6: INTRA GROUP COMPARISON USING WILCOXEN TEST

INTEVENTION GROUP

RUSH SCORE

	MEDIAN	MINIMUM	MAXIMUM	p VALUE	INFERENCE
1 WEEK	15	14	16	--	--
6 WEEK	25	23	26	< 0.0001	HS
10 WEEK	30	29	30	< 0.0001	HS

The variables RUSH Scores and VAS scores are discrete in nature, with

Median Score as an appropriate average for such variables.

For discrete variables nonparametric tests are applied which are also based on median. Within the interventional group, the same patient RUSH score was compared with using 1week RUSH score as baseline and it seemed that there was significant improvement in the rush score over period of 6 weeks and 10 weeks the p value <0.0001showed statistical significance showing that there was fracture healing.

Table 7:INTRA GROUP COMPARISON USING WILCOXEN TESTCONTROL GROUPRUSH SCORE

	MEDIAN	MINIMUM	MAXIMUM	p VALUE	INFERENCE
1 WEEK	12	12	14	--	--
6 WEEK	19	18	21	< 0.0001	HS
10 WEEK	25	23	28	< 0.0001	HS

Even in the control group the same patient RUSH score calculated on the first week was compared as a baseline with the RUSH score calculated on 6^{th} week and 10^{th} week using WILCOXEN test and the p value <0.0001 shows that the value or statically significant denoting that there was improvement in RUSH score indicating fracture healing even in control group.

Table 8: INTER GROUP COMPARISON IS DONE USING MANN WHITNEY TEST

MEDIAN FOR RUSH SCORE								
	INTEVENTION GROUP	**MINIMUM**	**MAXIMUM**	**CONTROL GROUP**	**MINIMUM**	**MAXIMUM**	**p VALUE**	**INFERENCE**
1 WEEK	15	14	16	12	12	14	< 0.0001	HS
6 WEEK	25	23	26	19	18	21	< 0.0001	HS
10 WEEK	30	29	30	25	23	28	< 0.0001	HS

To compare the rate of fracture healing between the interventional group and the control group on basis of RUSH score, MANN-WHITNEY TEST was used. The minimum Rush score in interventional group at 1st week is 14 whereas in control group is 12 and maximum score in interventional group is 16 and control group is 14.

The minimum Rush score in interventional group at 6th week is 23 whereas in control group is 18 and maximum score in interventional group is 26 and control group is 21.

The minimum Rush score in interventional group at 10th week is 30 whereas in control group is 23 and maximum score in interventional group is 30 and control group is 28.

This test signifies that the rate of fracture healing assessed using RUSH score at 1st, 6th and 10th in interventional group is significantly more when compared to control group as p value is <0.0001.

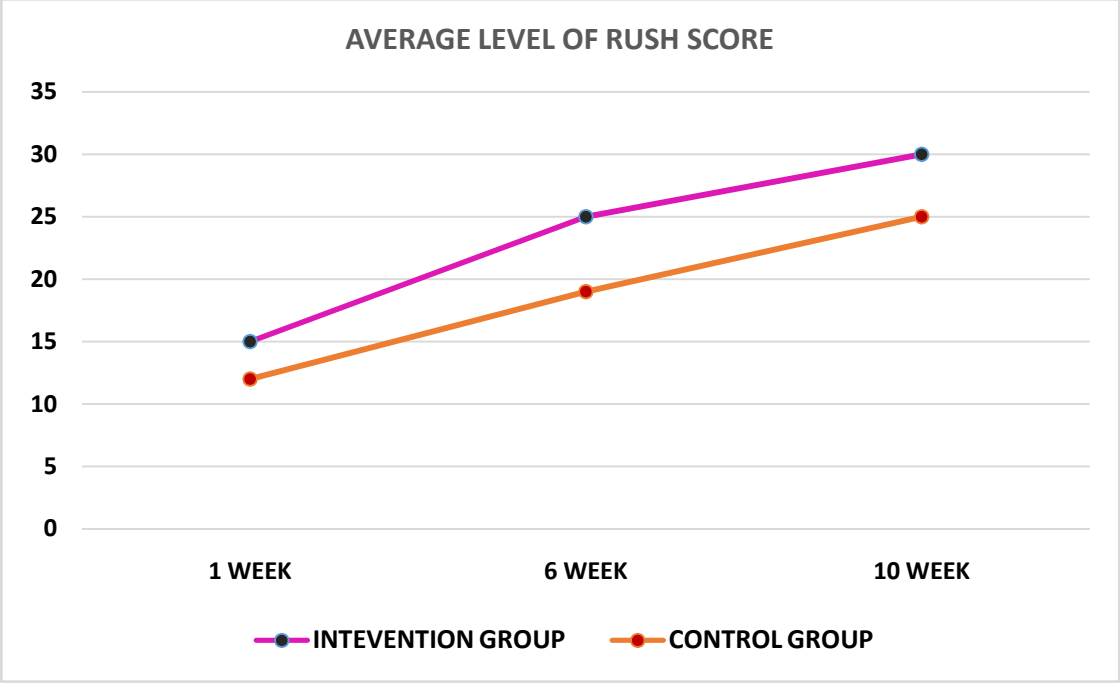

Chart 6: Rush Score Comparison chart

PAIN

Table 9: INTRA GROUP COMPARISON USING WILCOXEN TEST

INTEVENTION GROUPVAS SCORE

	MEDIAN	MINIMUM	MAXIMUM	p VALUE	INFERENCE
1 WEEK	4	2	4	--	--
6 WEEK	1	1	3	< 0.0001	HS
10 WEEK	0	0	1	< 0.0001	HS

The variables RUSH Scores and VAS scores are discrete in nature.

Median is an appropriate average for such variables.

For discrete variables nonparametric tests are applied which are also based on median score.

When the intensity of the pain at 1^{st} week was compared it with that 6^{th} week and 10^{th} week using WILCOXEN TEST the intensity of the pain has significantly reduced suggested by p value <0.0001.

Table 10:

VAS SCORE CONTROLGROUP

	MEDIAN	MINIMUM	MAXIMUM	p VALUE	INFERENCE
1 WEEK	5.5	4	7	--	--
6 WEEK	4	3	5	< 0.0001	HS
10 WEEK	1	0	1	< 0.0001	HS

In the control group,when the intensity of the pain at 1st week was compared it with that 6th week and 10th week using WILCOXEN TEST the intensity of the pain has significantly reduced suggested by p value <0.0001 but the patient were not completely pain free.

Table 11: INTER GROUP COMPARISON IS DONE USING MANN-WHITNEY TEST

	Median For Vas Score							
	Intevention Group	**Minimum**	**Maximum**	**Control Group**	**Minimum**	**Maximum**	**P Value**	**Inference**
1 week	4	2	4	5.5	4	7	< 0.0001	Hs
6 week	1	1	3	4	3	5	< 0.0001	Hs
10 week	0	0	1	1	0	1	< 0.0001	Hs

The intensity pain as calculated by VAS score was compared between the interventional group and the control group on 1st week,6th week & 10th week using MANN-WHITNEY test which showed that the interventional group had a lesser intensity of pain as compared to the control group as showed by the p value which is less than 0.0001. So helping in early mobilization of the patients.

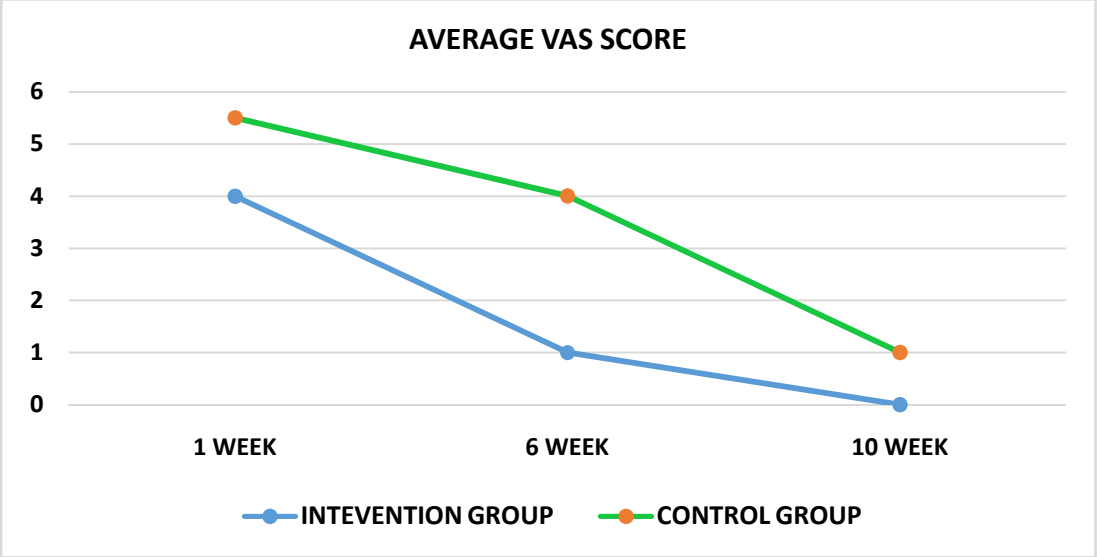

Chart 7: Vas Score Comparison Chart

DISCUSSION

Intertrochanteric fracture is one of most commonly treated fracture by a Orthopaedic Surgeon, the incidence of Intertrochanteric fracture is high usually in elderly people mainly after the age group of 60 years and more commonly in female because of postmenopausal osteoporosis[46].

Henceforth the intertrochanteric fracture causes significant burden on the patient as well as the society.

There is high morbidity and mortality post intertrochanteric fracture as the patient becomes immobile and bedridden as a result get more prone for chest infection, deep vein thrombosis, bed sores, improper nutritional intake leading to increased morbidity and mortality.

The intertrochanteric fracture has to be surgically fixed as soon as possible if there is no contraindication for surgery.

Once the surgery done the patient should be mobilized as soon as possible to prevent the complications.

The calcitonin[53] helps to prevent the resorption of the bone especially helpful in osteoporotic patient and as intertrochanteric fracture are more common in elderly osteoporotic fracture.

We did a study to assess the role of calcitonin in early fracture healing of intertrochanteric fracture treated surgically and also the analgesic effect of calcitonin.

In present study 40patients were included and were randomly distributed in 2 groups 20 each.

One group treated with salmon calcitonin intramuscular salmon calcitonin injection 100 IUOD till POD-7. After POD-7 the patients are administered with intranasal calcitonin for 3 months.

And other control group placebo was given and the pain assessment using VAS scale and fracture healing assessment was done using RUSH score.

FRACTURE HEALING

In the present study within the interventional group, the same patient rush score was compared with using 1week RUSH score as baseline and it seemed that there was significant improvement in the RUSH score over period of 6 weeks and 10 weeks the p value <0.0001showed statistical significance showing that there was fracture healing.

Even in the control group the same patient RUSH score calculated on the first week was compared as a baseline with the RUSH score calculated on 6^{th} week and 10^{th} week using WILCOXEN test and the p value <0.0001 shows that the value or statically significant denoting that there was improvement in RUSH score indicating fracture healing even in control group.

To compare the rate of fracture healing between the interventional group and the control group on basis of RUSH score, MANN-WHITNEY TEST was used. The minimum Rush score in interventional group at 1^{st} week is 14 whereas in control group is 12 and maximum score in interventional group is 16 and control group is 14.

The minimum Rush score in interventional group at 6th week is 23 whereas in control group is 18 and maximum score in interventional group is 26 and control group is 21.

The minimum Rush score in interventional group at 10th week is 29 whereas in control group is 23 and maximum score in interventional group is 30 and control group is 28.

This test signifies that the rate of fracture healing assessed using RUSH score at 1st, 6th and 10th in interventional group is significantly more when compared to control group as p value is <0.0001.

In a study conducted by Huusko TM, et al., to assess the role of intranasal calcitonin in management of hip fracture in geriatric patient and was assessed depending upon pain, loss of bone, recovery and no of days hospital stay they also compared fusion of hip fracture who underwent fusion surgery using a screw or nail. The study was randomized double blinded in which260 patients between the age of 65 years and above having hip fracture were randomly allotted to intranasal calcitonin and placebo the intranasal calcitonin 200IU was given daily for 90 days .After 90days post procedure of fracture fixation median pain was calculated according to visual analogue scale and in the placebo group pain was significantly reduced in calcitonin treated group and mean change in mineral density of calcaneal bone[25] was calculated from baseline to 90days which didn't show any improvement as compared to placebo group and it also showed no difference in duration of stay in hospital or difference in mortality. X-RAY was taken after 90days post procedure to assess the fusion of hip fracture treated with screw or nail it showed that fusion was seen in 84percent of group treated with calcitonin and 63 percent in placebo group. From this study we can

conclude that intranasal calcitonin may be helpful for patients with hip joint fractures but to confirm clinical significance more studies need to be conducted having more patient & longer follow up period & increased dose of calcitonin[19].

Even in our study the rate of fracture in calcitonin group was significantly more as compared to control group.

In another study conducted by Karachalios T, et al. conducted a study to assess the role calcitonin in averting bone loss after a fracture around hip joint and decrease the relativity of fracture in the same patient. The study was conducted on fifty women in between the age group of 70-80 who had fracture around hip joint. These fifty women were divided randomly in two group, group 1were given salmon calcitonin intranasally 200IU for 90days and the other group 2 was given placebo .The level of alkaline phosphatase and osteocalcin was assessed on 15^{th} day post trauma and 90^{th} day post trauma which showed significant increase in its level, the level of urinary excretion of c-telopeptide was assessed on 15^{th},45^{th}& 90^{th} days post trauma which showed less in group 1 that calcitonin group which signifies bone turnover rate and in group 1 there was documentation of reduced level of urinary hydroxyproline on 15^{th}, 45^{th}&90^{th} post trauma day. The mineral density of bone was assessed in both groups, group 1 had significant increase in mineral density of bone in all recorded areas expect in one region that is greater trochanter done after 90days & 365days post-surgical intervention. The patients were observed for 4 years clinical to see for new fracture, 5 patient in group 2 had fresh fracture around the hip joint among 5 four patient had fresh fracture on opposite side of the old fracture. The result of this study showed that calcitonin has significant role in reducing acute bone loss in

patient who have sustained fracture around the hip joint and also reduces the chance or probability of new fracture in same or opposite hip in geriatric patient[4].

In third study conducted by Li X, et al., to assess the role of salmon calcitonin in the rats which underwent ovariectomy to see the fracture healing in porotic bone and study conducted in hospital of Guanghou Medical College China they conducted the study from the month of march 2002 to December 2004 they used a sample of 120 rats in their trial in 120, 90 rats they did ovariectomy and the remaining they did sham procedure.All the sample wistar rat their left tibia bone was fractured then ovariectomized rats were subdivided into group of 30 the sham procedure rat served as control group .The fractured rats which were divided in three groups, one group was administered with subcutaneous calcitonin, other with normal saline and the last group with estrogen .Healing of the fracture was assessed by taking X-RAY ,BMD assessment and lastly with histological studying . The result of the study showed that the rats treated with calcitonin had higher values of BMD early fracture union and early callus formation.

Conclusion of this study shows superiority of salmon calcitonin as it increases BMD helps in early fracture healing with stronger callus in fractured porotic bone.

In 4th study conducted by Pagonis TA, et al., conducted a study to compare the role of calcitonin vs bisphosphonates in treatment of spinal fracture in osteoporotic patients treated conservatively. This study was prospective double blind study, they evaluated data which was taken from medical documents of two similarly comparable groups of osteoporotic patient .Group 1 patient were given calcitonin in combination with calcium and the other group 2 was given bisphosphonates both these group were initially diagnosed as fracture in osteoporotic patient and were treated non surgically

with brace and medication for osteoporosis,these patients were examined radiographically,X-RAYS was taken at the time of diagnosis and followed by 3,6,9 & 12months and later CT spine was performed at 6 months & 12 months to assess the union of the bone, The patients were assessed using quality of life questionnaire of the European foundation for osteoporosis . The study signified that use of calcitonin causes early fracture union early stopping of analgesic drugs early mobilization without the brace. Calcitonin is helpful in fracture consolidation in patient in spinal fracture due to osteoporosis and indirectly improves the quality of life[6].

From all the above studies we can infer that the calcitonin has a significant role in fracture healing especially in old age[40] patients having osteoporosis due to its bone resorption inhibiting property, even in the current study the patient treated with calcitonin had a faster rate of fracture healing as compared to placebo group.

PAIN

In present study in interventional group when the intensity of the pain at 1st week was compared it with that 6th week and 10th week using WILCOXEN TEST the intensity of the pain has significantly reduced suggested by p value <0.0001.

Even in the control group the intensity of the pain at 1st week was compared it with that 6th week and 10th week using WILCOXEN TEST the intensity of the pain has significantly reduced suggested by p value <0.0001 but the patient were not completely pain free.

The intensity pain as calculated by VAS score was compared between the interventional group and the control group on 1st week,6th week & 10th week using

MANN-WHITNEY test which showed that the interventional group had a lesser intensity of pain as compared to the control group as showed by the p value which is less than 0.0001.So helping in early mobilization of the patients.

In a study conducted by Lyritis GP, et all. clin j pain to evaluate the role of calcitonin suppositories in reducing pain there study had 40 patients, 8 were men and 32 were postmenopausal women who had a vertebral fracture[29] as complication of osteoporosis which were non traumatic[59] they divide the patients randomly in to 2 group one group was given with calcitonin[54] suppository and other group was given placebo daily once for 28days. All the patient were permitted to take Paracetamol 500mg tab maximum up to 6tabs. The pain was assessed from day 1 today 28 using vas scale by applying direct pressure on the fractured vertebra the pain was also assessed at different locomotor of function during walking standing sitting and taking bed rest, The result showed that the patient treated with calcitonin suppositories had statistically significant reduction of the pain all p values <0.001 assessed by VAS and pain-meter device.

Salmon calcitonin suppositories 200IU used daily significantly reduces Pain in the patient with non-traumatic vertebral[39] fracture as result of osteoporosis[38].

In the current study also there was significant reduction in the intensity of pain in calcitonin group as compared by VAS scale compared to placebo group.

Salmon Calcitonin given 100IU intramuscularly OD daily for 7days followed intranasal[30] calcitonin for 30 days significantly reduce the pain in patients having intertrochanteric fracture.

CONCLUSION

In, our study the rate of Fracture healing was faster in the patient treated with Salmon Calcitonin group as compared to Placebo (control) group and the pain intensity was significantly lower in patient treated with Salmon Calcitonin group as compared to placebo group.

Thus we conclude that the rate of fracture healing as assessed using RUSH score was faster showing early fracture union, complete consolidation of fracture and early disappearance of fracture line and reduced intensity of pain in calcitonin treated group, Hence, therapy of combined intramuscular and intranasal salmon calcitonin given post operatively is useful for early healing and repair of intertrochanteric fractures and offers immediate and lasting pain relief.

However, further studies with large population will be needed in the future before Salmon Calcitonin can be added to the wide spectrum of treatment available in the management of Intertrochanteric fractures.

SUMMARY

The present study was aimed to compare the role of Salmon Calcitonin in early fracture of Intertrochanteric fracture treated surgically.

In the present study patient with Intertrochanteric fracture were admitted to the department of orthopaedics at the KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, in between 1st January 2018 and 31st December 2018, over a period of one year. 40 cases were subjected to block randomizationtechnique using the Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) distributed into two groups of 20 each.

Group A (Salmon Calcitonin) and Group B (Placebo).

In our study it was found that the rate of fracture healing, complete consolidation of fracture and early disappearance of fracture line as assessed using RUSH score was significantly more in Salmon Calcitonin treated group. The MANN-WHITNEY test signifies that the rate of fracture healing assessed using RUSH score at 1st, 6th and 10th week in interventional group is significantly more when compared to control group as p value is <0.0001.

The intensity of pain as assessed using VAS score showed that was significantly less in Salmon Calcitonin treated group as compared Placebo group. The MANN-WHITNEY test signifies that the intensity of pain assessed using VAS score on 1st, 6th and 10th week in interventional group was significantly less when compared to control group p value <0.001.

Overall, therapy of combined intramuscular and intranasal salmon calcitonin given post operatively is useful for early healing and repair of intertrochanteric fractures and offers immediate and lasting pain relief helping in early mobilization of patient and reduction of hospitalization. In order to support this hypothesis, larger trials at multiple centres are required.

LIMITATION OF STUDY

1- In our study we compared fracture healing using RUSH score which has observer bias.

2- Our study is a single centric study with a sample size of 40. Thus, we suggest multicentric, large sample size studies are needed to prove the similar hypothesis.

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INFORMED CONSENT

***Title of Research Study*: A PLACEBO CONTROL TRIAL TO ASSESS THE ROLE OF CALCITONIN IN EARLY FRACTURE HEALING IN INTERTROCHANTERIC FRACTURE TREATED SURGICALLY IN TERTIARY CARE HOSPITAL, BELAGAVI**

Principal Investigator: -

DR._____

Post graduate student,

Department of Orthopaedics,

J.N. Medical College, Belagavi

Co-investigator:

DR. _____

Prof & HEAD,

Department of Orthopaedics,

J.N. Medical College, Belagavi

INTRODUCTION AND PURPOSE:

You are requested to participate in a study that is an attempt to find out the effectiveness of calcitonin in early fracture healing

Intertrochanteric fractures account for the highest morbidity in the elderly populations and are generally associated with osteoporosis. They are associated with low energy trauma and high energy trauma in young populations low energy fall from standing height account for 90% of hip fracture in above 50 years of age

In an effort to avoid the above-mentioned problems, this study has been undertaken TO REDUCE THE NUMBER DAYS OF HOSPITAL STAY AND EARLY PAIN RELIEF

This study will be conducted by Dr._____ Post Graduate in Department of Orthopaedics, under the direct supervision and guidance of Dr. ProfessorandHOD, Department of Orthopaedics,J. N. Medical College, Belagavi.

BENEFITS: - This study leads to assess the effectiveness of calcitonin in early fracture healing of intertrochanteric fracture

RISK INVOLVED: -The side effects of this study are

1 NASAL IRRITATION

2 NASAL CONGESTION

3 NASAL BLEED

COMPENSATION: -Taking part in the study will not affect the cost of treatment i.e. it will be similar to the cost of standard procedure. In the event that you become injured as a result of taking part in this study, treatment will be offered to you or you will be given information about where to receive medical care. But you/your insurance company will be responsible for the costs. However, no reimbursement, compensation or free medical care will be given.

CONFIDENTIALITY: - Every effort will be made to protect the confidentiality of the information you provide. This means that the researchers will not let anyone, not a part of the study, see the information you provide. Only Dr. _____ and Dr. _____ will have access to the information collected. Results of this study may be published but your name will not be revealed.

VOLUNTARY PARTICIPATION / WITHDRAWAL: - Taking part in this study is voluntary; you may choose not to enrol in this study. Your decision will not change the present or future health care services offered to you at KLES Dr. Prabhakar Hospital, BELAGAVI. The alternative that you have is to undergo the traditional procedure that is carried out in KLES Hospital.

If you have any queries about the study, you may contact Dr_____ Dr. _____.If you need any further information regarding your rights as a study participant, you may also contact Dr. RoopaBellad$_{(MD)}$Chairman of Institutional Ethics Committee, JNMC, and Belagavi-10

CONSENT TO PARTICIPATE IN THE STUDY

I Mr./Ms._____

have been explained about the research study, the need of the study, theintervention, their risks, benefits and alternatives available in my own vernacular language.

I voluntarily agree to participate in this study by signing up this form below. I understand that I may withdraw at any time from this study. I have been given adequate time to clarify my doubts about the study and my rights as a study participant.

My signature / thumb impression below indicates that I have read or information in the consent been read to me including the risks and benefits and have cleared my doubts.

Name of participant: Signature/LTI:

Name of legally authorized Signature/LTI:

Representative (if applicable):

Relationship with participant:

Name of witness: Signature:

Name of investigator: Signature:

Date:

Place:

ANNEXURE II.ETHICAL CLEARANCE.

K.L.E.UNIVERSITY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
(Accredited 'A' Grade by NAAC)

Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ 77

Date: 22/11/2017

To,

PG student in Orthopaedics,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled "**A PLACEBO CONTROL TRIAL TO ASSESS THE ROLE OF CALCITONIN IN EARLY FRACTURE HEALING IN INTERTROCHANTRIC FRACTURE TREATED SURGICALLY IN TERTIARY CARE HOSPITAL,BELAGAVI**", is ethical and justifiable.

The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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PROFORMA

The proposed proforma / questionnaire to be used for data collection for the study titled **A PLACEBO CONTROL TRIAL TO ASSESS THE ROLE OF CALCITONIN IN EARLY FRACTURE HEALING IN INTERTROCHANTRIC FRACTURE TREATED SURGICALLY AT TERTIARY CARE HOSPITAL, BELAGAVI**

is as follows: -

1. PATIENT IDENFICIATION DATA

Group: Ward:

Name: IP No.:

Age: Sex: D.O.A:

Address:

Education:

Religion: Marital Status:

Occupation: Socio-Economic Status:

CHIEF COMPLAINTS:

HISTORY OF PRESENTING COMPLAINTS:

Past History:

ANY H/O OF

- Chronic liver diseases
- Chronic kidney diseases

- Metabolic bone diseases
- Septic arthritis of hip
- Osteomyelitis
- Marfans disease
- Ehlers danols syndrome

Personal History:

Family History:

GENERAL PHYSICAL EXAMINATION:

Built and Nourishment:

Weight:

Pallor / Icterus / Cyanosis / Clubbing / Edema / Lymphadenopathy

Vital Signs:

PR: /min; BP: mmHg RR: /min; Temp:

SYSTEMIC EXAMINATION

CNS:

CVS:

R S:

PA:

LOCAL EXAMINATION

HIP EXAMINATIONS

INSPECTION

PALPATION

SPECIAL TESTS

MEASUREMENTS

RANGE OF MOVEMENTES

CLINICAL IMPRESSION:

INVESTIGATIONS:

Blood routine :Hb : Total leucocyte count : Platelet Count:

Random blood sugar:

Blood urea:

Sr. creatinine:

LFT:

PT/INR:

URINE ROUTINE AND MICROSCOPY:

HIV-I:

HIV-II:

HBsAg:

X- RAY:

MANAGEMENT:

DATE OF SURGERY:

TYPE OF SURGERY:

RADIOGRAPHIC UNION SCALE FOR HIP (RUSH)

REVIEWER NAME-

SUBJECT ID-

DATE OF RADIOGRAPHY

SECTION 1 – GENERAL IMPRESSION

USING YOUR OVERALL GENERAL IMPRESSION HAS THE FRACTURE HEALED

HEALED NOT HEALED

SECTION 2 –

- CORTICAL INDEX – BRIDGING

CORTEX	NO CORTICAL BRIDGING SCORE =1	SOME CORTICAL BRIDGING SCORE =2	COMPLETE CORTICAL BRIDGING SCORE =3	TOTAL SCORE (4 TO 12)
ANTERIOR CORTEX				
POSTERIORCORTEX				
MEDIAL CORTEX				
LATERAL CORTEX				
OVERALL SCORE				

- CORTICAL INDEX – DISAPPERANCE OF THE FRACTURE LINE

CORETX	FRACTURE LINE FULLY VISIBLE SCORE = 1	SOME EVIDENCE OF FRACTURE LINE SCORE = 2	NO EVIDENCE OF FRACTURE LINE SCORE = 3	TOTAL SCORE (4 TO 12)
ANTERIORCORTEX				
POSTERIORCORTEX				
MEDIAL CORTEX				
LATERAL CORTEX				
OVERALL SCORE				

	NO CONSOLIDATION SCORE=1	SOME CONSOLIDATION SCORE=2	COMPLETE CONSOLIDATION SCORE=3	TOTAL SCORE 1 TO 3
AMOUNT OF CONSOLIDATION				

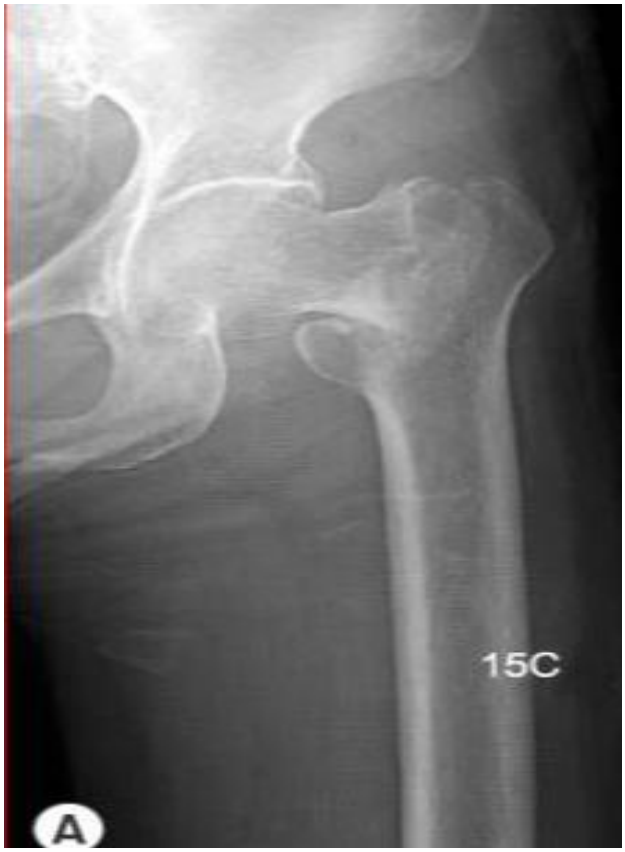
	FRACTURE LINE FULLY VISIBLE SCORE=1	SOME EVIDENCE OF FACTURE LINE SCORE=2	NO EVIDENCE OF FRACTURE LINE =3	TOTAL SCORE 1 TO 3
FRACTURE LINE				

VAS PAIN SCALE

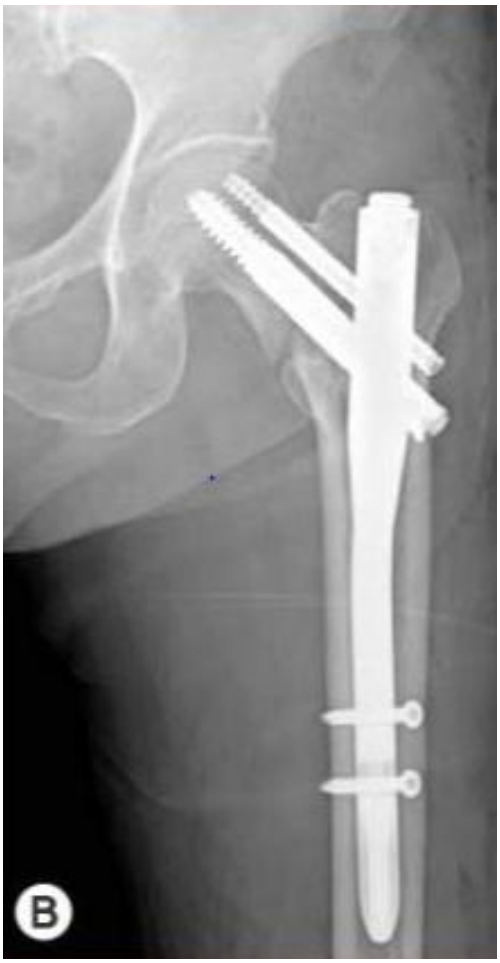
Worst Possible Pain										No Pain
10	9	8	7	6	5	4	3	2	1	0

ANNEXURE -IV PHOTOGRAPHS

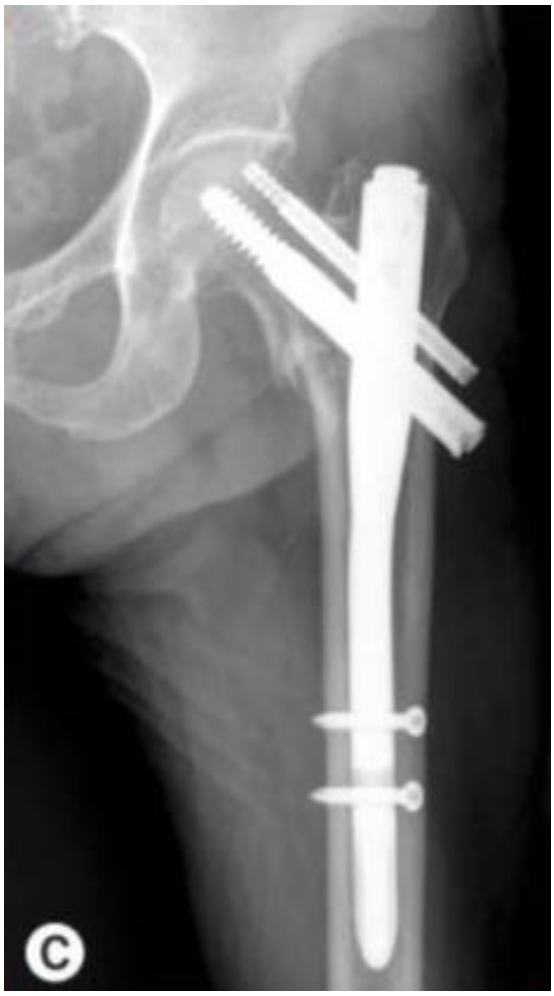
CASE 1 – CASE 6 OF MASTER CHART OF INTEVENTIONAL GROUP



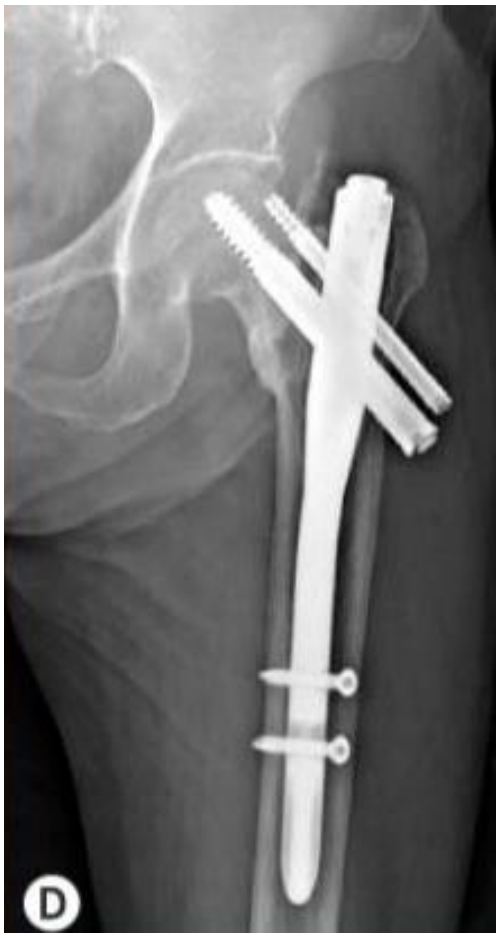
PRE-OP X-RAY OF LEFT HIP



X-RAY AT 1ST WEEK
RUSH SCORE -15
VAS SCORE-4

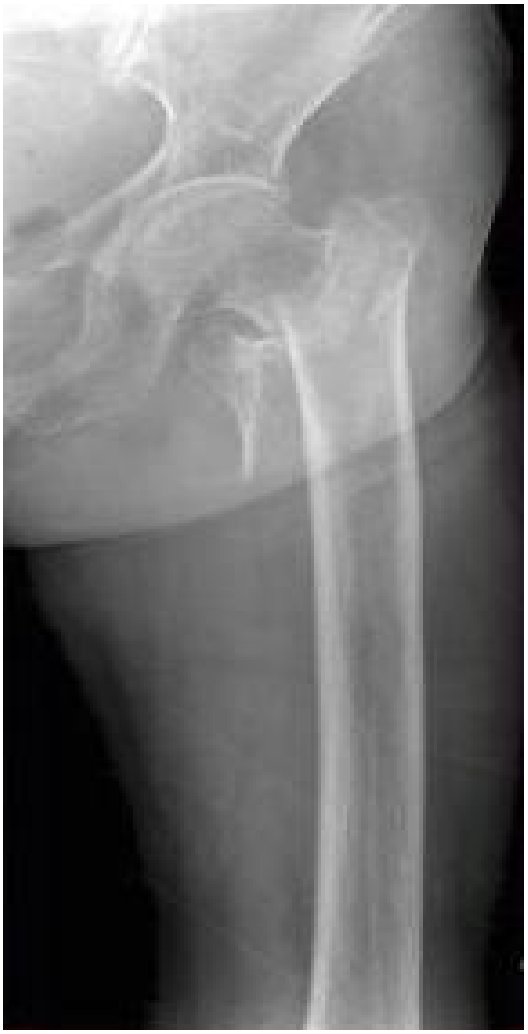


X-RAY AT 6TH WEEK
RUSH SCORE-24
VAS SCORE-3

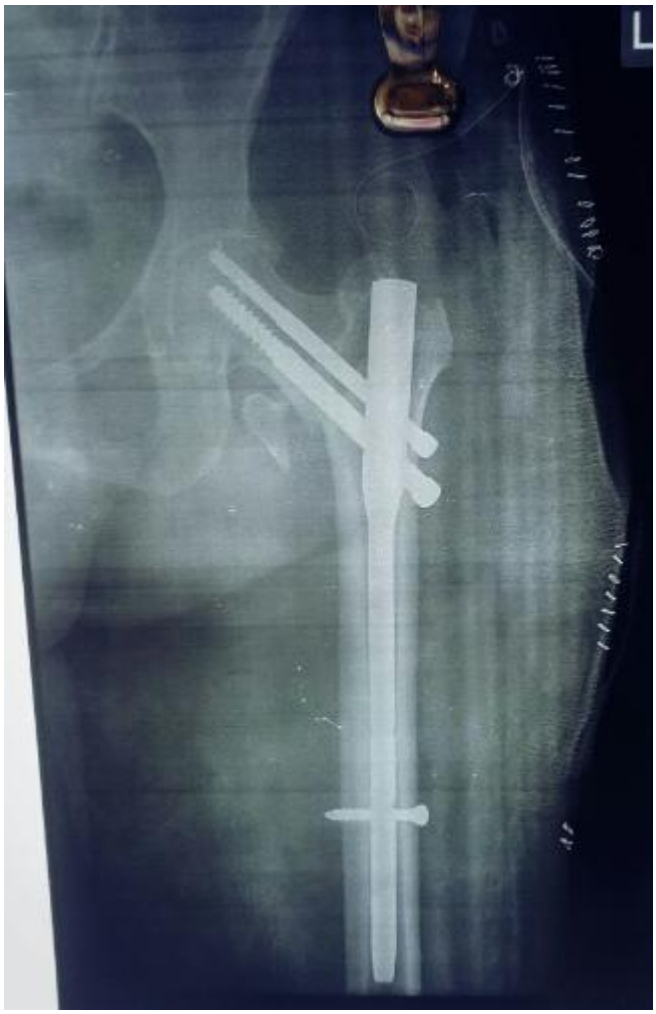


X-RAY AT 10TH WEEK
RUSH SCORE-30
VAS SCORE – O

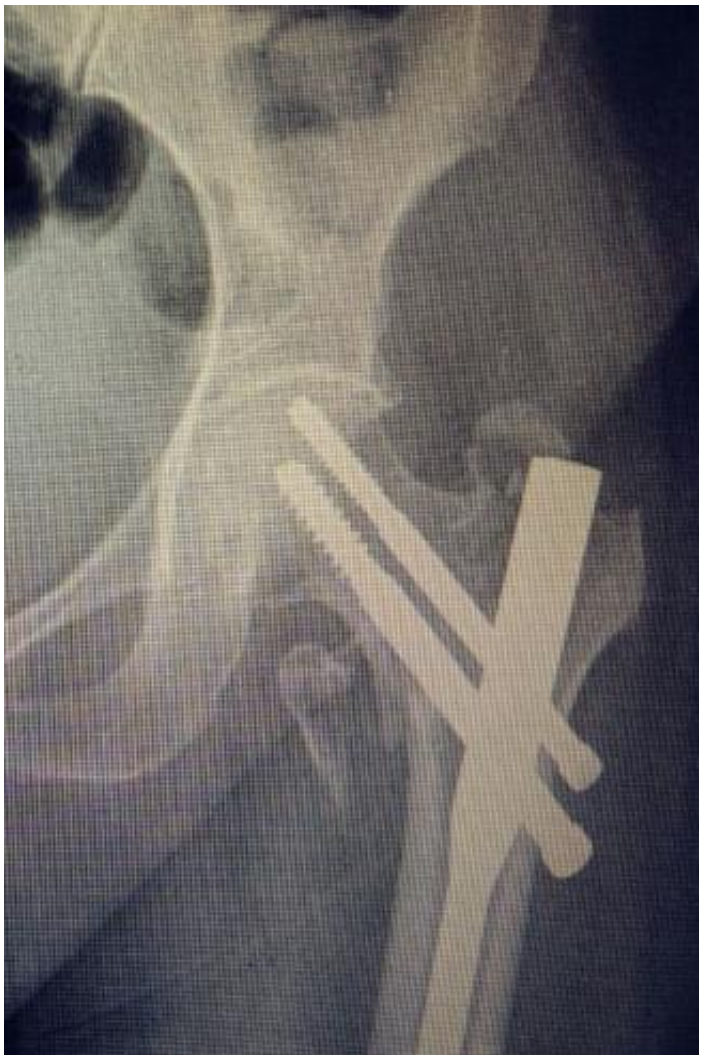
CASE 2- CASE 4 OF CONTROL GROUP



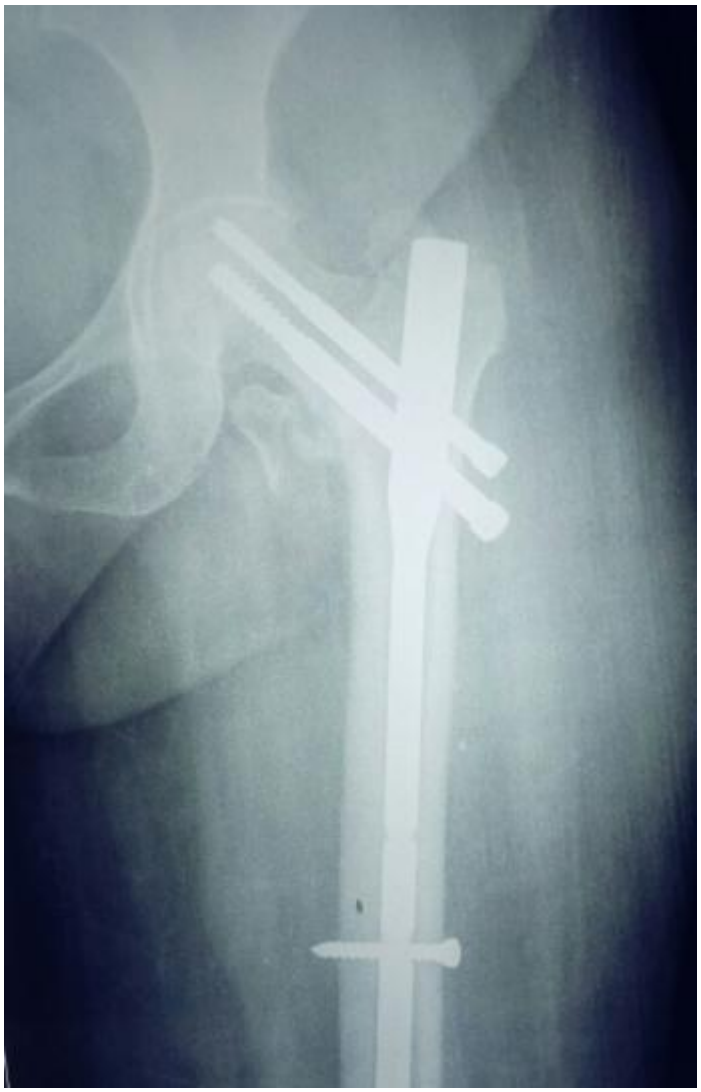
PRE-OP X-RAY OF LEFT HIP



X-RAY AT 1ST WEEK
RUSH SCORE-12
VAS SCORE-5



X-RAY AT 6TH WEEK
RUSH SCORE-19
VAS SCORE-4



X-RAY AT 10TH WEEK
RUSH SCORE-24
VAS SCORE-1

	INTEVENTION GROUP											CONTROL GROUP									
	IP NO	AGE	SEX	SIDE	RUSH SCORE			VAS SCORE				IP NO	AGE	SEX	SIDE	RUSH SCORE			VAS SCORE		
					1 WEEK	6 WEEK	10 WEEK	1 WEEK	6 WEEK	10 WEEK						1 WEEK	6 WEEK	10 WEEK	1 WEEK	6 WEEK	10 WEEK
1	854444	80 Yrs	Male	Left	14	24	30	2	1	0		849646	60Yrs	MALE	LEFT	12	19	23	5	3	1
2	856546	85 Yrs	Male	Right	15	25	29	4	2	1		857836	71Yrs	MALE	RIGHT	13	20	24	6	4	1
3	858753	65Yrs	MALE	Right	16	25	30	3	1	0		866899	70Yrs	MALE	RIGHT	12	19	24	5	4	1
4	860091	82Yrs	FEMALE	Right	14	23	29	4	2	0		861903	79Yrs	FEMAE	LEFT	12	19	24	5	4	1
5	861911	65Yrs	FEMALE	Right	16	25	30	4	2	1		866313	66Yrs	FEMAE	RIGHT	12	19	25	6	4	0
6	862151	70Yrs	FEMALE	Left	15	24	30	4	3	0		862556	70Yrs	FEMAE	LEFT	12	20	26	5	4	1
7	870177	80Yrrs	FEMALE	Right	14	23	30	4	3	0		881095	87Yrs	FEMAE	LEFT	12	20	25	5	4	1
8	869352	82Yrs	Male	Right	15	24	30	4	3	0		870869	40Yrs	FEMAE	LEFT	13	21	27	4	3	0
9	872897	82Yrs	Male	Right	15	24	29	4	3	0		872158	80Yrs	MALE	LEFT	12	20	26	6	4	1
10	885628	42Yrs	Male	Right	15	25	30	4	2	0		896187	82Yrs	MALE	RIGHT	12	19	26	5	4	1
11	887946	68Yrs	FEMALE	Right	14	25	30	4	2	0		897797	86Yrs	FEMAE	LEFT	12	19	26	6	4	1
12	892461	30Yrs	Male	Right	15	26	30	3	1	0		898094	63Yrs	MALE	RIGHT	12	19	26	6	4	1
13	899316	78Yrs	FEMALE	Left	14	25	30	4	1	0		899524	72Yrs	FEMAE	RIGHT	12	18	25	6	4	1
14	904442	80Yrrs	FEMALE	Right	14	25	30	4	1	0		906744	46Yrs	FEMAE	LEFT	13	19	26	5	3	0
15	902801	80Yrs	Male	Right	14	25	30	4	1	0		909085	30YRS	MALE	RIGHT	14	20	28	5	3	0
16	909502	74Yrs	FEMALE	Right	15	25	30	4	1	0		916727	79Yrs	FEMAE	RIGHT	13	18	24	6	4	1
17	912992	41Yrs	Male	Right	15	26	30	4	1	0		914039	31YRS	MALE	LEFT	14	18	24	7	5	1
18	918275	85Yrs	FEMALE	Left	14	25	29	4	1	0		906623	80Yrs	FEMAE	RIGHT	12	18	24	6	5	1
19	889214	74Yrs	FEMALE	Right	15	26	30	4	1	0		863178	80Yrs	FEMAE	RIGHT	13	19	24	6	4	1
20	898243	72Yrs	Male	Right	15	26	30	4	1	0		891904	42YRS	MALE	RIGHT	14	20	26	5	4	0