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EFFECTIVENESS OF INJECTION TERIPARATIDE IN OSTEOPOROTIC INTERTROCHANTERIC FRACTURE TREATED WITH PROXIMAL FEMUR NAILING

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Keywords:

Teriparatide, Osteoporosis, Fracture union, Intertrochanteric fracture

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ABSTRACT: Introduction: Osteoporosis is relatively a serious medical condition causing geriatric trauma, which leads to an increase in morbidity and mortality. Early fracture union is important for early mobilization and for good functional outcome. Recombinant parathyroid hormone has shown to accelerate the fracture union and improve the functional outcome. Therefore, in this study we have decided to evaluate the effectiveness of recombinant parathyroid hormone. **Methods:** Our study includes 24 osteoporotic intertrochanteric fracture patients who underwent surgical management at our institute. Post operatively Inj. Teriparatide 20mcg subcutaneously was started for 3 months. Radiological and functional outcome were evaluated at 4,8,12 and 24 weeks. **Results:** The average time of fracture union was 8-12 weeks using RUSH score and the patients had better functional outcome using Harris hip score and VAS score. **Conclusion:** We have evaluated the effectiveness of recombinant parathyroid hormone given post operatively for 3 months for osteoporotic intertrochanteric fracture, which showed a significant shorter time for fracture union and a significant improvement in functional outcome.

INTRODUCTION: Osteoporotic intertrochanteric fracture is a relatively common and serious medical issue resulting in serious health problems and decrease health related quality of life. Faster time-to-union is important for early return to daily activities and reduction of complications. Hip fractures are a burden on the healthcare system. Complications after hip fractures contributes to high mortality and adverse outcomes [1]. The average mortality rate after fracture fixation has reduced grossly up to 13.3%.[2]

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The incidence rates per 100,000 for a primary diagnosis of intertrochanteric hip and all hip fractures were 171 and 402, respectively. By sex, the incidence rates per 100,000 for all hip fractures were 223 and 555 in males and females respectively [1]. In many hip fractures leads to significant functional loss, poor health-related quality of life and higher mortality rate. Thus fast union is important for early return of daily activities and reduction of complications [1].

Recombinant parathyroid hormone (Teriparatide) is the only anabolic medication that has proven efficacy in stimulating bone formation in addition to promoting growth factors production for fracture healing [3]. It contains only amino terminal of human PTH, 1-34 amino acid of human PTH. Physiological actions of Parathyroid hormone (PTH) include: Regulation of bone metabolism,

renal tubular reabsorption of calcium intestinal calcium absorption. The biological action of PTH & teriparatide are mediated through binding to specific high affinity cell surface receptors. Teriparatide & the 34 N- terminal amino acids of PTH bind to these receptors with the same affinity & have the same physiological actions on bone & kidney [4].

The skeletal effects of Teriparatide depend upon the pattern of systemic exposure. Once daily administration of Teriparatide, there is stimulation of new bone formation on trabecular and cortical surface by preferential stimulation of osteoblastic activity over osteoclastic activity, thus teriparatide can play an important role in the treatment of these fractures. In some human trials, it appears to lessen the risk of non-union and enhance fracture healing. To further evaluate the potential effect of teriparatide on fracture healing, a well-controlled trials has been designed to test the hypotheses that teriparatide treatment would improve radiographic fracture healing. The aim of this study is to evaluate the role of Inj. Teriparatide in early bone union for patients who are operated for osteoporotic intertrochanteric fracture.

MATERIALS AND METHODS: This is a prospective observational study, which was conducted at Mahatma Gandhi Medical College and Research Institute, Puducherry, between November 2020 until May 2022 after getting clearance from the Internal Ethical Committee MGMCRI/Res/01/2020/54/IHEC/281. Patients were selected from those who underwent surgical fixation for osteoporotic intertrochanteric fracture in Mahatma Gandhi Medical College and Research Institute. Skeletally mature patients with osteoporotic intertrochanteric fracture undergoing surgical management in our institute were included in the study. Patients with bone malignancy; polytrauma patients with multiple fractures were excluded from this study. All the enrolled patients had radiographic examinations including antero-posterior (AP) view of pelvis and AP and lateral views of the affected hip. Osteoporosis was graded using Singh's Index. Intertrochanteric fractures were classified according to AO classification and patients were taken up for closed reduction internal fixation with proximal femur nailing. Post operatively all the patients were started on Inj. Teriparatide 20mcg subcutaneously on day 2 and were given once daily for 3 months. On day 2 all the patients were mobilized with partial weight bear walking and static quadriceps strengthening exercises and ankle pump exercises were started. On postoperative day 2,5,7 wound inspection were done and on day 12 sutures were removed. Calling the patient over phone once weekly and assessed the compliance of the drug. Patients were reassessed on 4^{th} week, 8^{th} week, 12^{th} week and 24^{th} week. Radiological outcome was assessed using RUSH score and pain was assessed using VAS score whereas functional outcome was assessed using Harrison hip score (HHS).

RESULTS: A total number of 24 patients with osteoporotic intertrochanteric fractures, who attended the Outpatient department of Orthopaedics and Emergency Medical service, were selected on the basis of pre-defined inclusion criteria and recruited for the study after obtaining the informed consent. During the period of follow up one patient had died due to cardiac cause, and one patient developed implant failureand hence was excluded from statistical analysis.

In our study out of 22 patients, 62.50% (n=14) of the patients were males and 37.50% (n=8) of the patients were females. The average age of the study population was 67.2%. Most of the patients were farmers 27.2% (n=6), laborers 22.7% (n=5), homemakers 22.7% (n=5) and administrative professionals 27.2% (n=6). The commonest mode of injury was domestic fall 62.5% (n=14), 1 patient 4.2% had history of fall from height, 7 patients (33.3%) had history of road traffic accident. The commonest type of fracture pattern in our study as per AO classification was 31A2.2 37.5% (n=9). Right side was frequently injured in majority of the patients 66.7% (n=15), and 33.3% (n=7) had left side injury. 3 patients (12.5%) were diabetic, 3 (12.5%) patients were both diabetic and hypertensive, 2 patients (8.3%) were diabetic, hypertensive and had coronary vascular disease. 8 patients (33.3%) were exclusively only hypertensive, 1 patient (4.2%) had cardiac disease alone. 5 patients (29.2%) didn't have any co-morbidities. 10 patients (45.8%) were chronic smokers and 12 patients (54.2%) were non smokers in our study. 11 (50%) patients had Grade 2 Singh's Index, 10 patients (45.8%) had Grade 3

Singh's Index and 1 patient (4.1%) had Grade 4 Singh's Index in our study.

Analysis by Scoring System:

Radiological Union Score for Hip System: Friedman test was applied for Radiological union score for hip system to compare 4 weeks, 8 weeks, 12 weeks & 24 weeks. RUSH scoring at 4 weeks was 16.05 ± 2.058 which further increased to 21.77 ± 2.654 at 8 weeks and there was an increase to 26.36 ± 1.497 at 12 weeks and at 24 weeks it was highest with a mean value of 28.50 ± 1.566.

There was statistically significant difference seen ($p<0.00$), which indicates there is significant improvement in radiological outcome from 4 weeks to 24 weeks **Table 1.**

TABLE 1: RADIOLOGICAL ANALYSIS USING RUSH SCORE

	N	Mean	Std. Deviation	Chi square	p value
Rush Score 4 Weeks	22	16.05	2.058	65.129	0.001
Rush Score 8 Weeks	22	21.77	2.654		
Rush Score 12 Weeks	22	26.36	1.497		
Rush Score 24 Weeks	22	28.50	1.566		

Wilcoxon Signed Ranks Test:

TABLE 2: RADIOLOGICAL ANALYSIS COMPARING EACH WEEK

		Ranks				
		N	Mean Rank	Sum of Ranks	Z value	P value
Rush Score 8 Weeks - Rush Score 4 Weeks	Negative Ranks	0[a]	.00	.00	-4.208[a]	0.001
	Positive Ranks	23[b]	12.00	276.00		
	Ties	0[c]				
	Total	23				
Rush Score 12 Weeks - Rush Score 4 Weeks	Negative Ranks	0[d]	.00	.00	-4.118[a]	0.001
	Positive Ranks	22[e]	11.50	253.00		
	Ties	0[f]				
	Total	22				
Rush Score 24 Weeks - Rush Score 4 Weeks	Negative Ranks	0[g]	.00	.00	-4.115[a]	0.001
	Positive Ranks	22[h]	11.50	253.00		
	Ties	0[i]				
	Total	22				
Rush Score 12 Weeks - Rush Score 8 Weeks	Negative Ranks	0[j]	.00	.00	-4.025[a]	0.001
	Positive Ranks	21[k]	11.00	231.00		
	Ties	1[l]				
	Total	22				
Rush Score 24 Weeks - Rush Score 8 Weeks	Negative Ranks	0[m]	.00	.00	-4.119[a]	0.001
	Positive Ranks	22[n]	11.50	253.00		
	Ties	0[o]				
	Total	22				
Rush Score 24 Weeks - Rush Score 12 Weeks	Negative Ranks	0[p]	.00	.00	-3.949[a]	0.001
	Positive Ranks	20[q]	10.50	210.00		
	Ties	2[r]				
	Total	22				

Above **Table 2** depicts that there is significant improvement in the fracture union from 4 weeks to 24 weeks.

The p value at each interval is 0.001 which was maintained till the last follow up and was significant.

Harrison Hip Scoring: Using Npar test Harrison hip scores were calculated. HHS at 4 weeks was 69.95 ± 10.852, which further showed an increase to 80.95 ± 6.403 at 8 weeks followed by 88.73 ± 3.369 at 12 weeks and maximum increase of 93.45 ± 3.306 at 24th week **Table 3.**

TABLE 3: FUNCTIONAL ANALYSIS USING HHS

	N	Mean	Std. Deviation	Chi square	P value
HHS Score 4 Weeks	22	69.95	10.852	66.000	0.001

HHS Score 8 Weeks	22	80.95	6.403		
HHS Score 12 Weeks	22	88.73	3.369		
HHS Score 24 Weeks	22	93.45	3.306		

Wilcoxon Signed Ranks Test:

TABLE 4: FUNCTIONAL ANALYSIS COMPARING EACH WEEK

Ranks						
		N	Mean Rank	Sum of Ranks	Z Value	P value
HHS Score 8 Weeks - HHS Score 4 Weeks	Negative Ranks	0[a]	.00	.00	-4.203[a]	0.001
	Positive Ranks	23[b]	12.00	276.00		
	Ties	0[c]				
	Total	23				
HHS Score 12 Weeks - HHS Score 4 Weeks	Negative Ranks	0[d]	.00	.00	-4.113[a]	0.001
	Positive Ranks	22[e]	11.50	253.00		
	Ties	0[f]				
	Total	22				
HHS Score 24 Weeks - HHS Score 4 Weeks	Negative Ranks	0[g]	.00	.00	-4.113[a]	0.001
	Positive Ranks	22[h]	11.50	253.00		
	Ties	0[i]				
	Total	22				
HHS Score 12 Weeks - HHS Score 8 Weeks	Negative Ranks	0[j]	.00	.00	-4.114[a]	0.001
	Positive Ranks	22[k]	11.50	253.00		
	Ties	0[l]				
	Total	22				
HHS Score 24 Weeks - HHS Score 8 Weeks	Negative Ranks	0[m]	.00	.00	-4.125[a]	0.001
	Positive Ranks	22[n]	11.50	253.00		
	Ties	0[o]				
	Total	22				
HHS Score 24 Weeks - HHS Score 12 Weeks	Negative Ranks	0[p]	.00	.00	-4.115[a]	0 .001
	Positive Ranks	22[q]	11.50	253.00		
	Ties	0[r]				
	Total	22				

Above **Table 4** depicts that there is significant improvement in the functional outcome from 4 weeks to 12 weeks. The p value at 4 weeks is 0.001 which further shows an increase over 8 weeks & 12 weeks with the value of 0.001 & 0.001 respectively followed by significant improvement at 24thweek with p value of 0.001.

VAS Scoring: Using Npar test visual analogue scale were calculated. VAS at 4 weeks was 5.45 ± 0.739, which further showed decrease to 3.32 ± 1.129 at 8 weeks followed by 1.68 ± 0.894 at 12 weeks and decrease of 0.41 ± 0.590 at 24thweek **Table 5.**

TABLE 5: PAIN ASSESSMENT USING VAS SCORE

	N	Mean	Std. Deviation	Chi square	P value
VAS Score 4 Weeks	22	5.45	.739	64.833	0.001
VAS Score 8 Weeks	22	3.32	1.129		
VAS Score 12 Weeks	22	1.68	.894		
VAS Score 24 Weeks	22	.41	.590		

Wilcoxon Signed Ranks Test:

TABLE 6: PAIN ASSESSMENT COMPARING EACH WEEK

Ranks					Z value	P value
		N	Mean Rank	Sum of Ranks		
VAS Score 8 Weeks - VAS Score 4 Weeks	Negative Ranks	23[a]	12.00	276.00	-4.262[a]	0.001
	Positive Ranks	0[b]	.00	.00		
	Ties	0[c]				
	Total	23				
VAS Score 12 Weeks -	Negative Ranks	22[d]	11.50	253.00	-4.177[a]	0.001

VAS Score 4 Weeks	Positive Ranks	0[e]	.00	.00		
	Ties	0[f]				
	Total	22				
VAS Score 24 Weeks - VAS Score 4 Weeks	Negative Ranks	22[g]	11.50	253.00	-4.215[a]	0.001
	Positive Ranks	0[h]	.00	.00		
	Ties	0[i]				
	Total	22				
VAS Score 12 Weeks - VAS Score 8 Weeks	Negative Ranks	20[j]	10.50	210.00	-4.093[a]	0.001
	Positive Ranks	0[k]	.00	.00		
	Ties	2[l]				
	Total	22				
VAS Score 24 Weeks - VAS Score 8 Weeks	Negative Ranks	22[m]	11.50	253.00	-4.177[a]	0.001
	Positive Ranks	0[n]	.00	.00		
	Ties	0[o]				
	Total	22				
VAS Score 24 Weeks - VAS Score 12 Weeks	Negative Ranks	20[p]	10.50	210.00	-4.093[a]	0.001
	Positive Ranks	0[q]	.00	.00		
	Ties	2[r]				
	Total	22				

Above **Table 6** depicts that there is significant improvement in the visual analogue scale from 4 weeks to 12 weeks. The p value at 4 weeks is 0.001 which further shows an increase over 8 weeks & 12 weeks with the value of 0.001 & 0.001 respectively followed by significant improvement at 24 weeks with p value of 0.001. The case illustrations are described as **Fig. 1, Fig. 2** and **Fig. 3.**

Case Illustrations:

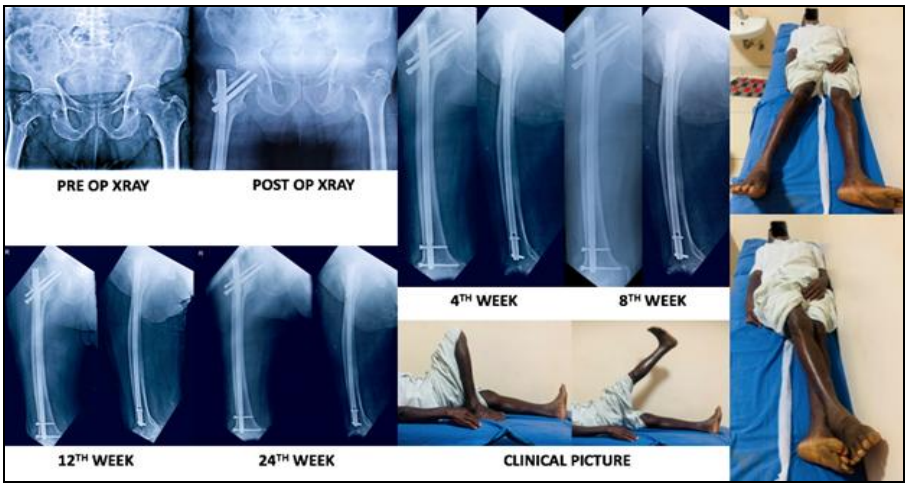

FIG. 1: TEMPORAL PROGRESSION

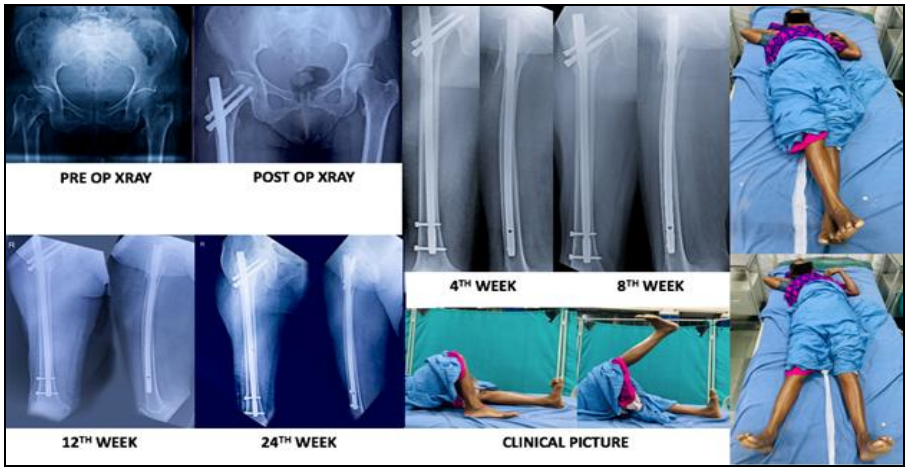

FIG. 2: MILESTONE IMPROVEMENT

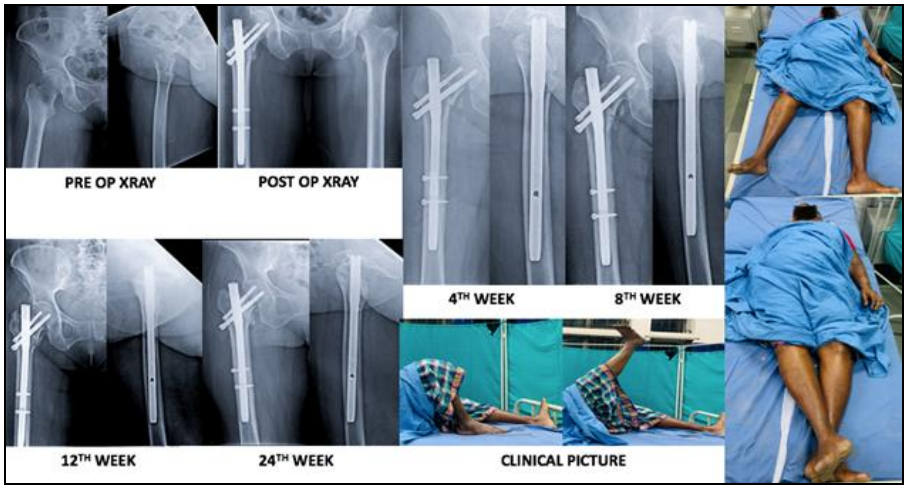

FIG. 3: COMPREHENSIVE EVOLUTION

DISCUSSION: Hip fractures in older population are frequently associated with delayed fracture healing due to low bone quality which causes long term pain & further immobilization leading to development of complications like bedsores, risk of deep vein thrombosis, urinary tract infection, pneumonia [5, 6]. The main aim in the treatment of hip fractures with osteoporosis is mobilization of patient, pain management and prevention of complications.[5] In many studies teriparatide has found to be effective in improving the bone mineral density and due to its osteoanabolic effect it accelerates the fracture union [6].

In our study we have analyzed the effectiveness of teriparatide on fracture healing in osteoporotic intertrochanteric fracture union and it has been found that teriparatide has significantly accelerated the fracture healing. This acceleration in healing time is required for the elderly patients especially patients with pelvic fractures as there is prolonged immobilization.

Various studies on animals as well as clinical data has recommended that the clinical advantage of using teriparatide are acceleration of fracture union and enhanced bone formation [7]. Lately acceleration of fracture union in association with teriparatide was reported in study of postmenopausal women with distal radial fractures [9]. Bashutski *et al* has reported in his study of clinical trial 40 patients with periodontitis when compared with patients taking placebo, patients who received 20mcg/d teriparatide for 6 weeks had better resolution of alveolar bone defects [10]. Our study included total 24 patients who were started on Inj. Teriparatide 20mcg s/c on postoperative day 2, out of which one patient had implant failure and had to undergo revision surgery whereas one more patient had died due to cardiac cause.

Out of 22 patients in our study of which 14(62.5%) were male patients and 8 (37.5%) were female patients. In other studies like Singhal *et al* the average gender distribution consist of 72.5% of females and the study done by Aspenberg *et al* had 76.7% female patients and 23.3% male patients [11, 12]. Lou *et al* reported 96.9% of females and 3.1% males in his study.[13] In Huang et al there were 67.7% female patients and 32.2% were male patients.[6] In a study done Prabhakaran *et al* in the year 2014- 2015 showed that majority 71.7% were male [2].

In our study the average age was 67.2 years when compared to other studies like 70.3 years in Lou *et al* study [13]. In Singhal *et al* study the average age was found to be 74 years [12]. Whereas in Huang *et al* study the average age is of 82 years [6]. Kim *et al* had an average age of 80.2 years in his study group.[14] In a study by Prabhakaran *et al* in the year 2014- 2015 showed that majority of the patients were more than 60 years of age (63.4%) [2].

In our study the most common mode of injury was simple fall (62.5%) where as in Huang *et al* study has observed both RTA and simple fall as the commonest mode of injury [6] and in the study done by Prabhakaran *et al* showed 76.7% patients had simple fall compared to RTA (23.3%) [2]. 66.7% had right side injury in our study. Aspenberg *et al* showed 51.5% patients had right side injury [11].

In the study done by Prabhakaran *et a*l majority had left side injury 55% [2]. In our study we have used AO classification to classify intertrochanteric fractures and it was found that most common type was 31A2.2 (37.5%), Aspenberg *et al* reported 50% of the population having 31A1 (50%) type of fracture [11], whereas Kim et al has reported 87.5 % of fracture type 31A2 [14]. In Huang *et al* study the maximum no of patients 64% had fracture type of 31A1 [6]. In our study majority of patients were taken up for surgery within a week where as in Aspenberg *et al* patients were operated within 2 days [11].

In our study we have analysed that administration of Inj. Teriparatide post operatively for 3 months has significantly reduced the time of fracture healing by 8- 12 weeks when compared to Borkar *et al* study where the patient who did not take Inj. Teriparatide had a fracture union time of 14-16 weeks [15]. In a study by Mishra S *et al,* 31 patients achieved union by 24 weeks, and no union was seen at 6 weeks in group A (control) and group B (study group with teriparatide), the union rate was only 13.33% (two patients) in group A by 12 weeks, which was lower than that in the study group B, where the union rate was 56.25% (nine patients) [16].

Peichl *et al* has reported the fracture union of 100% by 8 weeks in patients treated with Inj. Teriparatide compared to the patients who did not take teriparatide post operatively, the union was 9.1% at 8 weeks [5]. Lou *et al* has done a review literature proving that patients treated with teriparatide had statistically significant difference in radiological fracture healing time compare to the patients with control group [13]. Kim *et al* also has reported that the patients treated with teriparatide had shown significant improvement approximately within 2-3 weeks [14]. The study done by Prabhakaran *et al* study population didn't take Teriparatide and showed radiologically no signs of union at 4- 8 weeks post operatively (91.6%) and the radiological union was achieved by 16 weeks [2]. In our study we have found that there is an improved functional outcome in the patients when treated with Inj. Teriparatide post operatively. Kim *et al* has proved in his study that patient treated with Inj. Teriparatide has improved functional outcome [14]. Peichl also has reported in his study that patient who took Inj. Teriparatide has accelerated fracture healing and functional outcome [5]. Lou *et al* in his study has said that the osteoporotic patients who suffered fracture had an early return to normal life and were able to work faster and there was decreased medical consumption and chronic morbidity [13]. Borkar *et al* has proved significant shorter time in fracture healing and a better functional outcome in the patients who took Inj. Teriparatide post operatively [15]. Aspenberg et al has manifested in his study that there is characteristic improvement in the functional outcome in the study population who took Inj. Teriparatide post operatively [11]. Singhal *et al* has proved in his study that faster fracture union has enabled the patients for better functional outcome [12]. Our study has also proved that there is the significant decrease in pain scale following the administration of Inj. Teriparatide. Aspenberg *et al* in his study using VAS score has proved that there is significant decrease in the pain following the administration of Inj. Teriparatide in the study group [11]. Huang *et al* also has reported in his study that there is decrease in the pain score using parker and palmer score [6]. Lou *et al* has also mentioned about the decrease in pain following the treatment with Inj. Teriparatide [13].

Limitations:

1. Smaller sample size.
2. Needs a comparative group to assess the better outcomes and the effectiveness of Inj. Teriparatide.

CONCLUSION: Our study proved that daily administration of Inj. Teriparatide 20mcg post operatively for 3 months has yielded a good functional outcome and an improved radiographic signs of fracture union. Patients were able to return to daily routine activities due to faster union of fracture. The faster union time of fracture is important for the geriatric population to enable them to return to daily routine activities, which in turn reduced the morbidity and mortality risk.

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