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Comparative evaluation of the functional results of unstable intertrochanteric fractures treated with osteosynthesis augmented with beta tricalcium phosphate verses treatment with osteosynthesis

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Abstract

Introduction: Unstable intertrochanteric fractures are treated surgically rather than being managed conservatively. It is essential to operate on these patients as fast as possible, and, at the same time, it is pertinent to ensure the operated patients do not go into malunion or implant failure. A study was conducted to check whether beta-tricalcium phosphate added in the void spaces of unstable intertrochanteric fractures could lead to better functional results.

Methods: 40 patients with unstable intertrochanteric fractures were admitted between October, 2020 and October, 2021, and follow-ups were conducted for one year. Out of 40 patients, half of the patients who were operated on were augmented with beta-tricalcium phosphate in the void spaces, which was considered as Group A, and the remainder were operated on with osteosynthesis alone, which was considered as Group B. The parameters used to measure the functional results were the Functional Ambulatory Category (FAC) score and the Harris Hip score (HHS). The patients were followed up radiologically with X-rays.

Results: 38 patients followed up; 19 patients were augmented with beta-tricalcium phosphate, and the remainder i.e., 19, were in the control group. The patients augmented with beta-tricalcium phosphate showed a better FAC score which was significant at six months post-surgery. It was observed that the HHS and the Visual Analogue Scale (VAS) score were better in augmented cases than in cases not augmented with beta-tricalcium phosphate, but were insignificant.

Conclusion: The group of patients augmented with beta-tricalcium phosphate showed better functional results six months post-surgery. This further leads to decreased morbidity and mortality post-surgery.

Introduction

An intertrochanteric fracture is an extracapsular fracture of the proximal femur that occurs between the greater trochanter and the lesser trochanter. The intertrochanteric aspect of the femur is composed of dense trabecular bone [1]. The calcar femoral is the vertical wall of

dense bone that extends from the posteromedial part of the femoral shaft to the posterior portion of the femoral neck. This structure is essential because it determines whether or not the fracture is stable. The fracture occurs in an area just distal to the capsule of the hip joint and proximal to the isthmus [2]. The mode of injury is "fall" which is mainly seen in the elderly, and is primarily due to decreased vision, poor reflexes other pathology like osteoporosis [3]. The force generated by an elderly individual during a fall from an erect posture is 10-15 times more than to create a hip fracture. But all people who fall will result in hip fractures, but it depends upon the mechanics of the fall [4,5].

Intertrochanteric fractures account for about half of all proximal femoral fractures, and one-third of these fractures cause significant morbidity. About 300000 hip fractures occur annually, half of which are intertrochanteric fractures [6]. The incidence is more in women than men. Clinical features include pain in the groin and inability to bear weight, and on examination, the lower limb is found to be externally rotated, shortened and varus [7]. Hip abductors tend to displace the greater trochanter laterally, and iliopsoas pull the lesser trochanter medially and proximally. The hip flexors, extensors and abductors tend to replace the distal fragment proximally.

In stable fracture patterns, the posteromedial cortex remains intact or has minimal comminution, while unstable fractures include comminuted fractures, where the posteromedial cortex is not intact, reverse oblique and subtrochanteric fractures [8]. Surgeons rarely encounter problems like non-union of bone due to cancellous bone and rich blood supply [9].

The clinical application of biologically derived materials engineered to repair or regenerate musculoskeletal tissue is called orthobiologics. There are different ceramic-based bone graft substitutes, such as calcium hydroxyapatite, tricalcium phosphate, calcium sulphate, and a combination of calcium sulphate and calcium phosphate. Ceramics are synthetic scaffolds made from calcium phosphate, and they induce a response similar to that of bone.

Hydroxyapatite, alpha-tricalcium phosphate and beta-tricalcium phosphate can all be used to fill void spaces in a cancellous bone [10]. Hydroxyapatite is crystalline, with a high degree of hardness, with similar chemistry to that of hydroxyapatite in the human body [11]. It is osteoconductive and carries osteoinductive growth factors that can act as a graft [12]. However, hydroxyapatite is brittle, undergoes slow absorption, can impart stress to implant materials, and has a risk of inhibiting fracture healing. Hence, it is combined with tricalcium phosphate or the autogenous bone for faster resorption [13-15]. Alpha tricalcium phosphate is osteoconductive and is soluble in body fluids, but absorption takes place for about 24 months. Beta tricalcium phosphate is available in injectable and crystal forms. Its size varies from 1 to 1000 micrometre, and it imitates the trabecular structure of a cancellous bone. Its porosity activates bone-forming cells, nutrients, and growth factors, and it supports their resorption and infiltration [16]. Beta tricalcium phosphate has good biological compatibility and bone compatibility, and after implantation, the material is quickly resorbed [17]. It is absorbed from the surgical site when a new bone is visible at the surgical site.

When a patient who has undergone hip surgery goes into malunion or implant failure while loading, it leads to less mobilisation, which, in turn, increases the morbidity due to deep vein thrombosis, infected bed sore, hypostatic pneumonia, urinary tract infection, etc. It is, thus,

essential to start early mobilisation to reduce post-operative morbidity, which is around 40% one year after the hip fracture.

This study aims to determine if augmenting unstable intertrochanteric fractures with beta-tricalcium phosphate and osteosynthesis can lead to better functional results compared to the control group with no augmentation, which will eventually also affect the morbidity and mortality of the patient.

An intertrochanteric fracture is defined as an extracapsular fracture of the proximal femur that occurs between the greater trochanter and the lesser trochanter. The intertrochanteric aspect of the femur is composed of dense trabecular bone [1]. The calcar femorale is the vertical wall of dense bone that extend from the posteromedial aspect of the femoral shaft to the posterior portion of the femoral neck. This structure is important because it determine whether the fracture is stable or unstable. The fracture occurs in an area just distal to the capsule of the hip joint and proximal to the isthmus [2]. The mode of injury is "fall", and is mostly observed in elderly, mainly due to reasons, such as decreased vision, poor reflexes, and other pathology like osteoporosis [3]. The force that is generated by an elderly individual during a fall from an erect posture is 10 -15 times more than to create a hip fracture. But all the people who fall will result in hip fracture but depends upon the mechanics of the fall [4,5].

Materials and Methods

A prospective, randomised, control study was conducted at Dr. D.Y. Patil Medical College, Pune. 40 patients with unstable intertrochanteric fractures treated with osteosynthesis were included in the study, out of which 38 people followed up (19 augmented with beta-tricalcium phosphate and the remaining 19 in the control group). The augmented group was labelled as Group A, and the non-augmented group as Group B. The mean age of the groups was almost the same i.e., 61.6 in the augmented group and 62.6 in the non-augmented group. The study's inclusion criteria included all unstable intertrochanteric fractures above the age group of 20 years. The exclusion criteria included patients with unstable intertrochanteric fractures aged less than 20 years, all patients with stable intertrochanteric fractures, patients with other fractures which lead to difficulty in weight-bearing in the lower limb, and pathologic fractures. Most of the cases were operated under spinal anaesthesia. 26 out of 40 patients were operated on within one day of admission, and the remainder i.e., 14 patients, within 72 hours.

After anaesthesia, the patient was placed on the traction table in the supine position, with the foot fastened to the traction table. Fracture reduction was made under the C-arm by the Whitman method -Reduction in hip extension-then abduction, traction and internal rotation. Once optimum reduction was obtained, it was further confirmed using the C-arm (fluoroscopy) unit.

Exposure: Lateral approach incision is taken centring over the greater trochanter. Dissect subcutaneous tissue and divide tensor fascia late to reach gluteus medius (superiorly) and vastus lateralis. The guide wire is inserted under C -arm guidance both in AP and lateral view.

The lateral part of the proximal femur is draped correctly, and is ready for the incision. Dissection continues through the iliotibial band (ITB) until the vastus lateralis fascia is seen

and is split longitudinally. The incision is made at the vastus ridge and carried on distally as per the type of implant used. The profunda femoris' perforating arterial branches are recognised and bound after the vastus lateralis is lifted anteriorly from the lateral intermuscular septum. The muscle is sufficiently spaced from the lateral femoral shaft to accommodate the plate placement.

Stabilisation: At the upper level of the lesser trochanter, the guide wire is inserted 2 cm from the greater trochanter's flare. The anteversion guide wire must be engaged first into the femoral head and kept parallel to the femoral neck. The final guidewire is then applied directly parallel to the anteversion guidewire with the aid of an angle guide.

Method 1: After fixing the implant, using the help of a drill bit of 4.5 mm, a hole was made in the lateral cortex such that the posteromedial portion of the femur was reached, and 5-10 ml of beta-tricalcium was injected. Here the proximal hole can also be used [18].

Method 2: Another technique involved using a syringe and a trephine biopsy needle. The beta-tricalcium phosphate paste was prepared in a plastic cup and loaded into a syringe later. The guide wire was inserted through the P2 holes, and the trephine biopsy needle cap was removed. With the help of a guide wire directed to the void space, 5-10 ml of tricalcium phosphate paste was injected into the fracture site, and the trephine biopsy needle was slowly withdrawn [Figure 1].

Method 3: This was used in cases where the fracture site was open. Beta-tricalcium phosphate was added to the void spaces with the help of a long scoop and abgel was applied over it.

Post-operatively all patients were stable, and an X-ray of the pelvis with both hips and cross-table lateral of the operated side was taken. Intravenous antibiotics were given and were followed up radiologically and functionally at two months and six months, respectively, with the help of the HHS, VAS score for pain, and the FAC score [Table 1]. Full weight bearing in the operated limb was done in both groups at six weeks post-operatively.

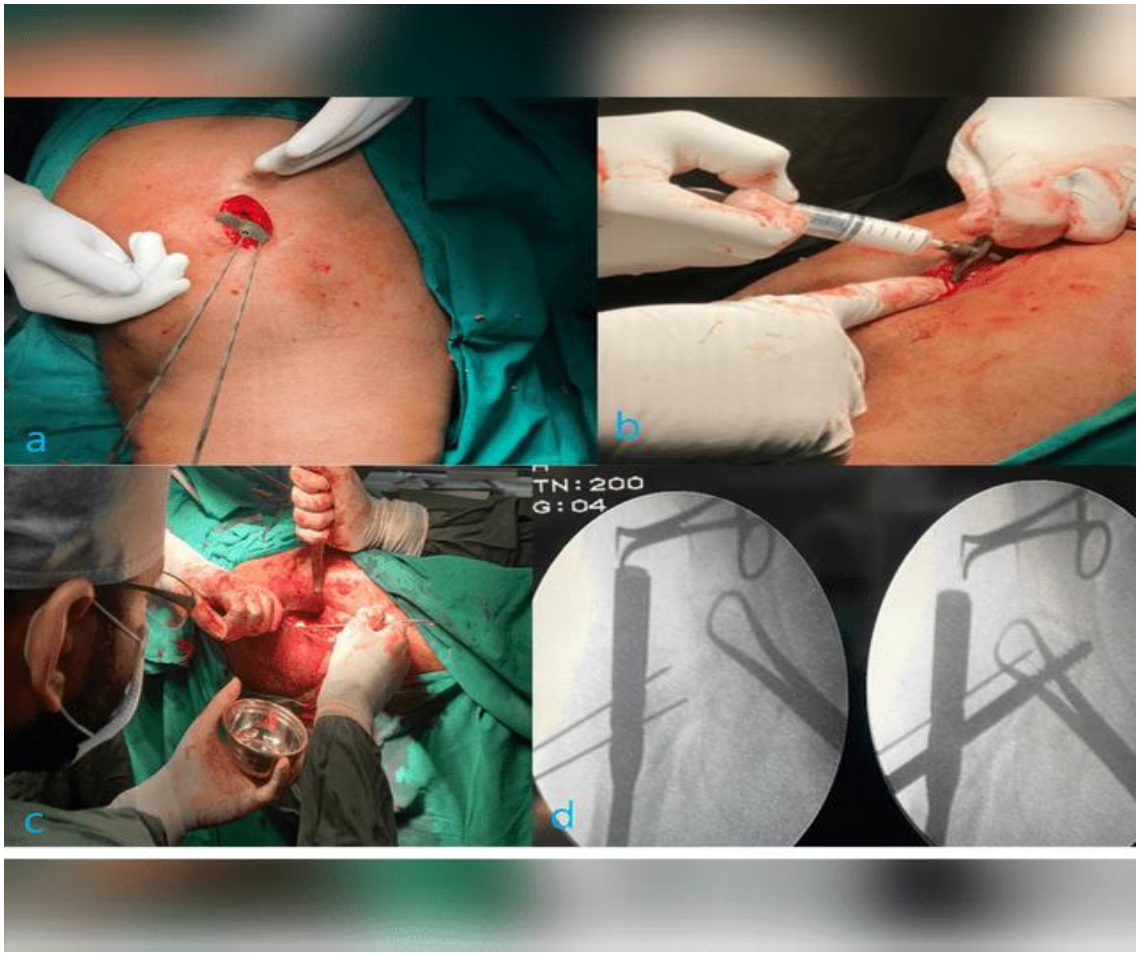

Figure 1: Figure 1(a) depicts a guide wire being inserted into jamshidi trephine biopsy needle for directing beta-tricalcium phosphate to the void space; Figure 1(b) shows an intraoperative image of the injection of beta-tricalcium phosphate to the void space with the help of a syringe and trephine biopsy needle; Figure 1(c) shows beta-tricalcium phosphate insertion to the void space with use of a long scoop; and Figure 1(d) is the intraoperative C-arm image of the same patient as shown in Figure 1(b) after injecting beta-tricalcium phosphate paste to the void space.

The data were entered in Microsoft Excel 2019 (Part of Microsoft Office Professional Edition) [computer program]. Microsoft; 2019) and analyzed using EpiInfo v7.2 (Dean AG, Arner TG, Sunki GG, Friedman R, Lantinga M, Sangam S, Zubieta JC, Sullivan KM, Brendel KA, Gao Z, Fontaine N, Shu M, Fuller G, Smith DC, Nitschke DA, and Fagan RF. Epi Info™, a database and statistics program for public health professionals. CDC, Atlanta, GA, USA, 2011.) and MedCalc v18.2.1 (MedCalc Statistical Software version 18.2.1 (MedCalc Software, Ostend, Belgium; http://www.medcalc.org; 2018).

Categorical variables were expressed in frequency and percentages; continuous variables were expressed as mean and standard deviation (SD). Normal distribution was verified by the Shapiro-Francia test. Independent t-test/Mann-Whitney test (where applicable) was used to check for the significance of observations between the two groups. Furthermore, Chi-square and Fisher's exact test (wherever applicable) were conducted to prevent the independence of attributes. $P < 0.05$ was considered statistically significant in all the tests performed.

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Results

Out of 40 patients, 38 patients were able to adequately follow up. In total, 19 patients were treated with osteosynthesis augmented with beta-tricalcium phosphate, and 19 patients were treated with osteosynthesis alone. Group A contained 63.2 % males and 36.8% females, while Group B contained 57.9% males and 42.1% females, respectively [Figure 2].

Malunion was observed in one case in Group B. There were other postoperative complications, of which serous discharge was observed in Group A augmented with beta-tricalcium phosphate, while the other non-augmented, Group B demonstrated difficulties like bed sores and wound gaping. The mode of injury was more commonly "slip and fall at home or workplace" compared to a road traffic accident. FAC score, HHS, and VAS score for pain were calculated at follow-up at two and six months for both sets of patients. The HHS averaged at 86.47 in Group A compared to 84.26 in Group B at six months post-surgery. At two months post-surgery, the FAC score was 3.7 and 3.36, whereas it was 4.79 and 4.36 at 6 months post-surgery, for Group A and Group B, respectively [Table 2].

Furthermore, all patients were made to walk without support at six weeks postoperatively. There was no loss of reduction while weight bearing in Group A [Figure 3]. There was a case of malunion in Group B.

VAS pain score averaged at 0.84 in Group A, compared to 1.74 in Group B. The duration of hospital stay was 14.57 for Group A and 15.57 for Group B. Moreover, operative time was less in Group A, averaging at 66 minutes, whereas it averaged at 65 for Group B.

Out of all the parameters, only the FAC score at six months was found to be statistically significant.

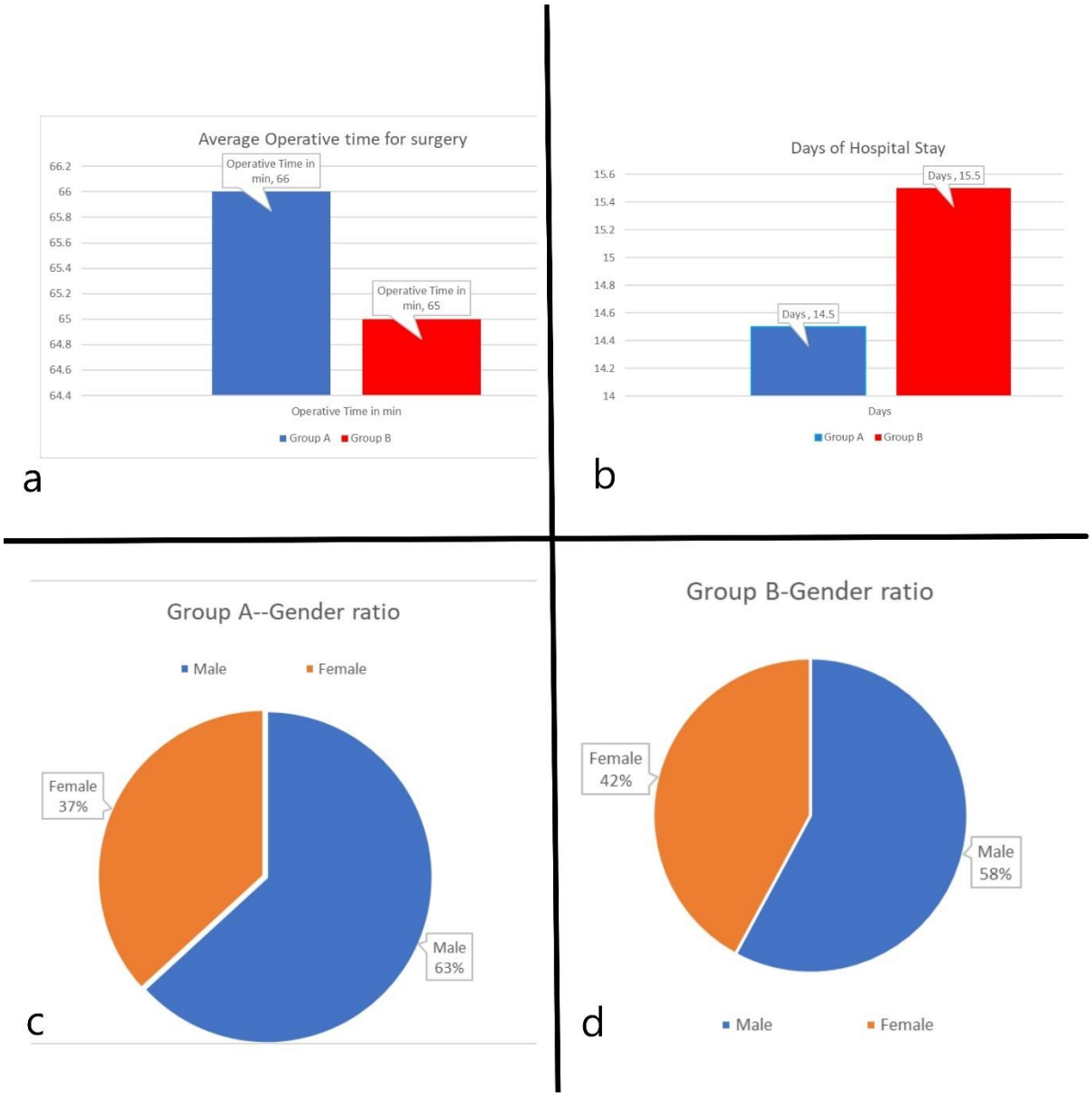

Figure 2: Figure 2(a) shows a bar diagram of operative time in minutes for surgery in Group A and Group B; Figure 2(b) shows the bar diagram of hospital stay in days for Group A and Group B; Figure 2(c) depicts a pie chart representing the gender ratio involved in the study in Group A; and Figure 2(d) represents a pie chart illustrating the gender ratio involved in the study in Group B.

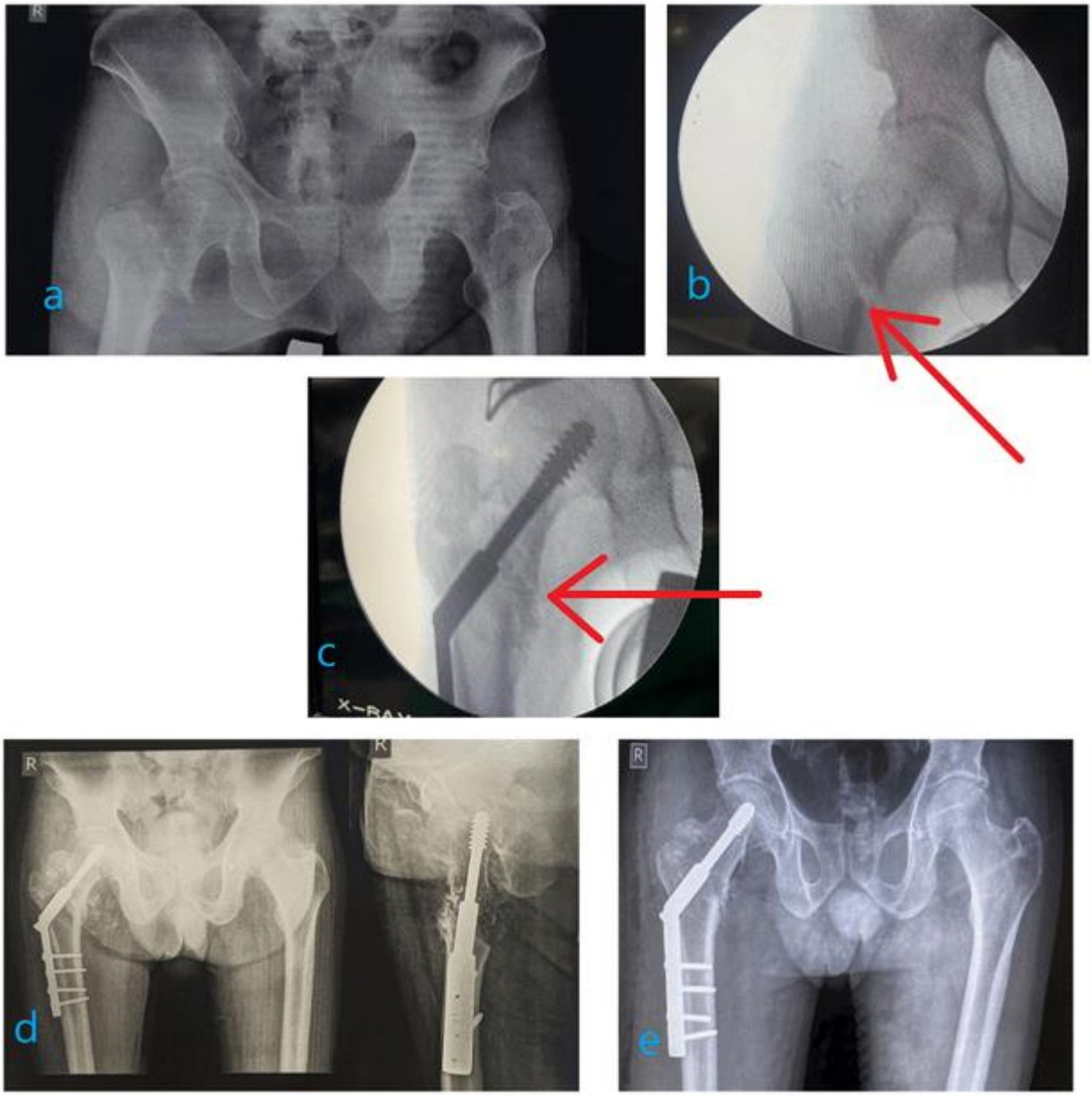

Figure 3: Figure 3(a) shows a pre-operative image of an X-ray of the pelvis with both hips showing a right intertrochanteric fracture; Figure 3(b) is an intraoperative C-arm image of a right, unstable, intertrochanteric fracture after reduction with void space marked by the arrow; Figure 3(c) shows an intraoperative photograph of the right, unstable, intertrochanteric fracture after the insertion of beta-tricalcium phosphate, as observed by the arrow; Figure 3(d) presents a follow-up X-ray of the patient two months post-surgery; and Figure 3(e) shows a follow-up X-ray of the same patient six months post-surgery.

		Group			
		Group A		Group B	
		Count	Column N %	Count	Column N %
AGE	41 - 50	3	15.8%	3	15.8%
	51 - 60	6	31.6%	5	26.3%
	61 - 70	7	36.8%	6	31.6%
	Above 70	3	15.8%	5	26.3%
GENDER	FEMALE	7	36.8%	8	42.1%
	MALE	12	63.2%	11	57.9%
SIDE	LEFT	9	47.4%	8	42.1%
	RIGHT	10	52.6%	11	57.9%
SURGERY	DHS	3	15.8%	2	10.5%
	PFN	16	84.2%	17	89.5%
MODE OF INJURY	FALL AT HOME	10	52.6%	11	57.9%
	RTA	9	47.4%	8	42.1%
CLASSIFICATION	1C	8	42.1%	4	21.1%
	1D	9	47.4%	11	57.9%
	1E	2	10.5%	4	21.1%
CO MORBIDITY	Present	12	63.2%	11	57.9%
	Absent	7	36.8%	8	42.1%
CO MORBIDITY	Absent	7	36.8%	8	42.1%
	DIABETES	4	21.1%	5	26.3%
	DIABETES AND HTN	3	15.8%	2	10.5%
	HTN	5	26.3%	3	15.8%
	HYPERTENSION	0	0.0%	1	5.3%
POST OPERATIVE COMPLICATIONS	Present	5	26.3%	6	31.6%
	Absent	14	73.7%	13	68.4%
POST OPERATIVE COMPLICATIONS	Absent	14	73.7%	13	68.4%
	BED SORE	1	5.3%	3	15.8%
	SEROUS DISCHARGE	1	5.3%	2	10.5%
	WOUND GAPING	3	15.8%	1	5.3%

Table 2.1: Parameters, such as age, duration of hospital stay, VAS score, FAC score at 2 and 6 months, and HHS.

Group		Mean	Std. Deviation	Median	IQR		Mannwhitney test p value	
					Lower	Upper		
Harris Hip Score	Group A	86.47	3.580	86.00	83.00	90.00	0.146	NS
	Group B	84.26	4.747	84.00	82.00	87.00		
VAS SCORE	Group A	0.84	0.688	1.00	0.00	1.00	0.006	HS
	Group B	1.74	1.195	2.00	1.00	2.00		

Table 2.2 Showing Harris Hip score, VAS score via Mann Whitney test

	Group A			Group B			
		IQR			IQR		Comparison between the groups - Mann Whitney test p value
	Median	Lower	Upper	Median	Lower	Upper	
Functional ambulatory score at 2 months	4.00	3.00	4.00	3.00	3.00	4.00	0.234, NS
Functional ambulatory score at 6 months	5.00	4.00	5.00	4.00	4.00	5.00	0.043, sig

To compare within the group-Wilcoxon signed rank test p	0.000, HS	0.000, HS	

P value for the above comparison

Table 2.3 Showing Functional ambulatory score p value in Mann Whitney score at 2 and 6 months

Discussion

Intertrochanteric fracture occurrences are increasing since people's life spans are increasing daily due to better health care. This type of fracture is primarily seen in the elderly due to falling from a height. In the younger age group, it happens due to high-energy trauma, like road traffic accidents [19].

Due to intersecting cancellous bone compression tensile lamellae networks and weak cortical bone, as in the elderly and forces acting on the hip from a different set of muscle groups, it creates a fracture in the proximal metaphyseal junction of the femur. Intertrochanteric femoral fractures are operated on since they have a high chance of post-fracture morbidity. In a retrospective cohort study with patients aged 60 years or more, consisting of 9000 patients, of which 1500 patients showed postoperative complications, it was observed that most complications were cardiac and pulmonary, constituting around 12 percent of the total [20]. Other combined complications noted were gastrointestinal bleeding, venous thromboembolism and stroke. Additionally, psychosocial complications may also arise, like the fear of falling again, and long periods of bed rest/immobilisation may affect patients mentally. Therefore, patients must be mobilised to develop better functional movements.

Furthermore, Zimmermann et al. concluded that using calcium phosphate in 22 unstable distal end radius fractures led to superior functional results postoperatively after two years. The control group patients were treated with K-wiring [21].

Schildhauer et al., who performed surgery on 36 calcaneum fractures which were depressed, found that the patients who were augmented with calcium phosphate cement could bear weight at three weeks without losing reduction. Additionally, no significant difference in the functional outcomes was observed [22].

Civinini et al. reported an increase in hip score from just below 70 to above 85 in 29 cases of osteonecrosis of the head of the femur, which was treated with decompression in the early stages of development [23]. The patients were allowed full weight bearing at six weeks.

Moreover, beta-tricalcium phosphate reduces the donor site morbidity replacing the use in conditions where only osteoconductivity is needed. Beta-tricalcium phosphate is of great importance where there is a comminuted fracture or a non-union. It, thereby, decreases the rate of transmission of disease. However, it doesn't possess osteoinductive properties, therefore, it should be combined with bone grafts. It can incorporate other materials due to its biochemistry, which further increases its mechanical strength [24].

Furthermore, beta-tricalcium phosphate is porous and can cooperate with osteogenic growth factors to increase bioactivity. Since it is osteoconductive, there is formation of trabecular bone. Since it acts as a scaffold, it gives good strength to fixation in less operating time [25].

Moreover, beta-tricalcium phosphate has an appropriate degradation rate favourable for bone healing. It is available and can be kept in sterile conditions for years.

Beta-tricalcium phosphate can't replace the function of implants, but it can increase their mechanical strength, making them stiffer, thus, preventing them from failing even in cases of early weight bearing. It can indirectly help in deciding the type of implant to be used since it provides biomechanical strength to the construct. Therefore, it helps in reducing operating time. But the primary reduction and stabilisation of the fracture via osteosynthesis remain a significant part of fracture stability. Furthermore, lesser operating time reduces the chances of infection.

Calcium phosphate is 4-5 times harder than cancellous bone, and it can affect the process of bone healing. Consequently, beta-tricalcium phosphate is a better bone graft substitute compared to calcium phosphate. However, there are no studies where beta-tricalcium phosphate is used in unstable intertrochanteric fractures.

In 2009, Chao Shen et al. conducted a study by analyzing 124 cases of tibia plateau fractures after augmentation with beta-tricalcium phosphate and concluded that it could give good functional outcomes and satisfactory results [26].

Disadvantages of beta-tricalcium phosphate include the cost, less osteoinductivity, and lack of strength in load-bearing areas.

Early mobilisation of hip fractures decreases the chance of morbidity and mortality [27]. It is also essential that the mobilisation doesn't lead to implant failure.

The study was done on 30 individuals, of which only 28 were available for follow-up. The FAC score averaged at 4.79 at two months and 3.71 at six months in Group A compared to 3.36 at two months and 4.36 at six months in Group B, respectively. FAC score at six months was the only statistically significant parameter. Early ambulation helps in fewer morbidity chances since it helps in preventing complications leading to morbidity and mortality.

Even though the HHS and VAS score were not statistically significant, the average scores gave better results in Group A compared to Group B. In general, the functional outcome was better in Group A compared to Group B. If the study had been done in a larger group, the other parameters could have been significant. However, this was not feasible since the cost of beta-tricalcium phosphate is high.

Moreover, a single surgeon did not do all the surgeries, and additionally, the fracture types mildly varied from case to case. Still, no malunion was reported in the 14 patients of Group A, while one malunion was reported in Group B. However, in that case, other parameters, like fixation, should have been considered. How sound the reduction was is also a factor contributing to the outcome.

The disadvantage of the study was that the number of patients available for the study was less.

There are very few studies where beta-tricalcium phosphate has been used. Instead, most studies have utilized calcium phosphate. While calcium phosphate is also bioabsorbable, it takes 26-80 weeks to resorb. Consequently, it is usually combined with calcium sulphate for faster resorption.

Conclusion

Unstable intertrochanteric fractures in Group A produced statistically significant results with regards to the FAC score at six months compared to Group B.

It is concluded that unstable, intertrochanteric fractures treated with osteosynthesis augmented with beta-tricalcium phosphate produce better functional results than treatment with osteosynthesis alone. It further helps decrease post-operative complications in unstable, intertrochanteric fractures, and also assists in reducing morbidity and mortality.

Further studies with more patients must be conducted to get better information on the clinical outcomes of similar fractures.

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