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RESEARCH ARTICLE

The use of sliding hip screw versus Targon proximal femoral nail in the treatment of unstable pertrochanteric fractures AO:31-A2. A prospective randomized trial.

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Abstract

Purpose: This study aimed at investigating the functional outcome after using either a Targon proximal femoral nail versus sliding hip screw in the treatment of pertrochanteric fractures with posteromedial comminution AO:31-A2.

Methods: Twenty-six patients were prospectively randomized into either Targon PFN or SHS fixation group. Our primary outcome was the hip function measured by Harris hip score at six months follow up. Secondary outcomes are revision surgery, implant associated complications and limb shortening.

Results: The two groups were similar regarding age, six and side distribution. Both groups had similar AO classification subtypes. At 6 months follow up, the Harris hip score was similar for both fixation methods. The SHS group had 5 patients with excessive fracture collapse and neck screw backing out and this group of patients had significantly shorter lower extremities compared to patients without excessive collapse. The Harris hip score is still similar in both groups.

Conclusion: The Targon PFN might decrease the likelihood of excessive fracture collapse and the resultant limb shortening in cases of unstable pertrochanteric fractures with posteromedial comminution, howeverhip function was similar for both fixation methods and was not affected by excessive fracture collapse.

Introduction

Stable fixation in pertrochanteric fractures that maintains reduction and allows early weight bearing is essential to achieve the best functional outcome.The sliding hip screw has been the implant of choice for stabilizing both stable and unstable intertrochanteric fractures, However, excessive fracture collapse, medialization of the femur, and limb shortening are known complications [1-3]. Complication rates as high as 23% were reported and one of the important causes is excessive fracture collapse in unstable fracture patterns [4, 5].

On the other hand, different versions of intramedullary fixation devices were developed for use in trochanteric fractures [6-9]. Cephalomedullary nails are biomechanically superior for load transfer and have some theoretical biologic advantageslikeminimally invasive surgical techniquewith shorter healing and recovery times and proposed improved functional outcome. The incidence of fracture collapse and medializationshouldas well be lessened by the use intramedullary fixation devices, as the fracture can settle only until the proximal fragment abuts against the

nail.However, iatrogenic fractures and additional fracture comminution during nail insertion are known complications, particularly in earlier designs [6, 10-13].

To date, no evidence supports the use of the more recent designs of intramedullary fixation devices in favor to the classic sliding hip screw [14-16]. In fact, the use of extramedullary sliding hip screw is still more superior with fewer complication rates in stable trochanteric fractures (AO: 31-A1)[14]. On the other hand, intramedullary nails may have some advantages in fractures at the level of lesser trochanter, reversed obliquity fractures (AO: 31-A3) and in subtrochanteric fracture, although the evidence is yet insufficient [14, 17].In case of unstable intertrochanteric fractures with posteromedial comminutionat the area of the lesser trochanter (AO: 31-A2), the evidence to support either fixation devices is even more controversial.

The aim of this study is to compare the use of one of the newer designs of the trochanteric intramedullary fixation devices (Targonproximal femoral nail PFN) with anextramedullary fixation (the sliding hip screw, SHS) in the treatment of unstable intertrochanteric fractures with posteromedial comminution (AO: 31-A2).We would like to investigate the effect of fracture collapse on the ultimate hip functional outcome. Our primary outcome would be the hip function as measured by the Harris hip score at 6 months follow up and the secondary outcomes are revision surgery, implant associated complications and lower extremity shortening.

Materials and methods

This randomized clinical trial was initiated following approval of our local research ethics committee. All patients with the diagnosis of intertrochanteric fractures with postero-medial comminution (AO: 31-A2) admitted to our institution (an academic level I trauma center) were eligible for inclusion in this study[18]. Exclusion criteria were pathological fractures, patients with terminal illness and patients with neurological disease or metabolic bony disease. Patients were randomized into two groups, either the TargonPFN nail fixation group (Egyfix, Cairo, Egypt) versus Sliding Hip Screw 135° group.

The randomization for the method of fixation was done before the start of this study through generating random sequence of integer numbers starting from 1 to in one column. This sequence was then copied to an excel sheet and the even numbers represented the future Targon nail cases and vice versa. This excel sheet was available with the research coordinator of this study (HH). Others authors and surgeons in our institution who would manage new patients were not aware about this sequence and they know the decision of fixation with each new admission directly from our research coordinator.

With each new unstable intertrochanteric fracture (AO:31-A2) admission, baseline demographics, mechanism of trauma and surgical history were collected. Associated trauma as well as medical co-morbidities were recorded as well and routine trauma x-ray series were requested.

Interventions

Surgical procedures were performed according to standard protocols for either the Targon PFN or SHS as recommended by each device manufacturer[8, 19]. The TargonPFN (Egyfix, Cairo, Egypt) used in the present study was a Titanium Alloy (Ti-6AI-4V)180 mm in length and 9-11 mm in diameter.It is inserted with reaming of the medullary canal. Proximal fixation is achieved by a neck screw and an anti-rotation screw. The TargonPFN may be distally locked either dynamically or statically (diameter of the locking screws). The neck shaft angle of the implant is 130°. For the second group,four or five-holes, 135° SHS was used.

All procedures were performed on a radiolucent orthopaedic fracture table under spinal anaesthesia. Patients were mobilized starting from the 2nd postoperative day and discharged to home. Postoperative follow up was standardized for both groups.

Study outcomes

The patients were followed up radiologically at 6 weeks, 3 months and 6 months postoperatively. Harris hip score was evaluated at the 6 months follow up visit. Secondary outcomes are excessive fracture collapse with associated lateral migration of the neck screw (neck screw backing out)[20], z-effect or reversed z-effect in case of Targon PFN[21, 22],implant failure with need for revision surgery and shortening of the affected limb (in mm).

Statistical analysis

Independent student t-test was used to compare both groups for continuous data. Comparisons for categorical data were done using Chi square and Fischer exact tests. A p value < 0.05 was considered to be statistically significant. All statistical analyses were performed using SPSS (SPSS 20.0, SPSS Inc., Chicago, IL, USA). All values are presented in the form of mean ± SD (standard deviation).

Results

Twenty-six patients were included in our study (13 patients in each group). Randomization was not followed in 9 patients mainly due individual surgeon's preferences with/or against one fixation method (Table 1). The two groups were similar regarding age, sex and side distribution, mechanism of trauma and the presence of associated trauma (Table 1). Regarding AO classification subtypes, the Targon PFN group had more AO:31-A2.2 while the SHS group had more AO:31-A2.3, however this was not statistically significant. Four patients died shortly postoperatively due to unrelated medical comorbidities and therefore, their follow up results were not recorded.No intraoperative complications were recorded in either group. All fractures were healed at the 6 months follow up visit without cases of loss or failure of fixation that required revision surgery.

Regarding our primary outcome, Harris hip score was similar for both fixation methods at 6 months follow up as well as the magnitude of lower extremity shortening. Excessive fracture collapse and backing out of the neckscrew took place in 5 patients in the SHS group (P= 0.02, Table 2). None of the patients in the Targon group had z-effect or reverse z-effect.

When we compared the group of patientswho had neck screw backing out with patients without this complication, we found that the lower extremities in the first group were significantly shorter (20 mm in average) compared to 5 mm in patients without backing out (P= 0.013, Table 3). Hip function according to Harris hip scorewas not significantly differentbetween both groups (Table 3).

TABLE 1: Demographic data of our patients.

		TargonPFN Group (N= 13)	DHS Group (N=13)	P value
Age		62.9±13.7 y	65.4±11.4 y	0.628
Sex	Male	10	7	0.216
	Female	3	6	
Mechanism of Trauma	Domestic Fall	11	12	0.539
	High energy trauma	2	1	
Side of injury	Right	7	7	1
	Left	6	6	
Associated trauma		Head injury (1 patient) Ipsilateral calcaneal fracture (1 patient)	Head injury (1 patient)	
Randomization	Randomized	10	7	0.216
	Non-randomized	3	6	
AO classification	AO:31-A2.1	2	4	0.059
	AO:31-A2.2	9	3	
	AO:31-A2.3	2	6	

Table 1: Demographic data of our patients.

TABLE 2: The results of our fixation methods in both groups.

		PFN Group (N= 10)	DHS Group (N=12)	P value
Operative time		67.3±29.8 min	79.2±15 min	0.209
Harris Hip Score		88±10	87±8	0.699
Shortening		6±10 mm	10±10 mm	0.471
HHS Grade	**Excellent**	6	5	0.632
	Good	3	6	
	Poor	1	1	
Backing out of neck screw		*0*	*5*	*0.02**

Table 2: The results of our fixation methods in both groups.

TABLE 3:Patients with backed out neck screw compared to patients without backing out.

		No Backing out (N= 17)	Backing out (N= 5)	P value
Harris Hip Score		88±10	89±7	0.262
Shortening		*5±10 mm*	*20±10 mm*	*0.013**
HHS Grade	Excellent	10	1	0.274
	Good	6	3	
	Poor	1	1	

Table 3: Patients with backed out neck screw compared to patients without backing out.

Figure legends

Figure 1: Excessive fracture collapse was evident in this patient who had SHS fixation at 3 and 6 months follow up radiographs.

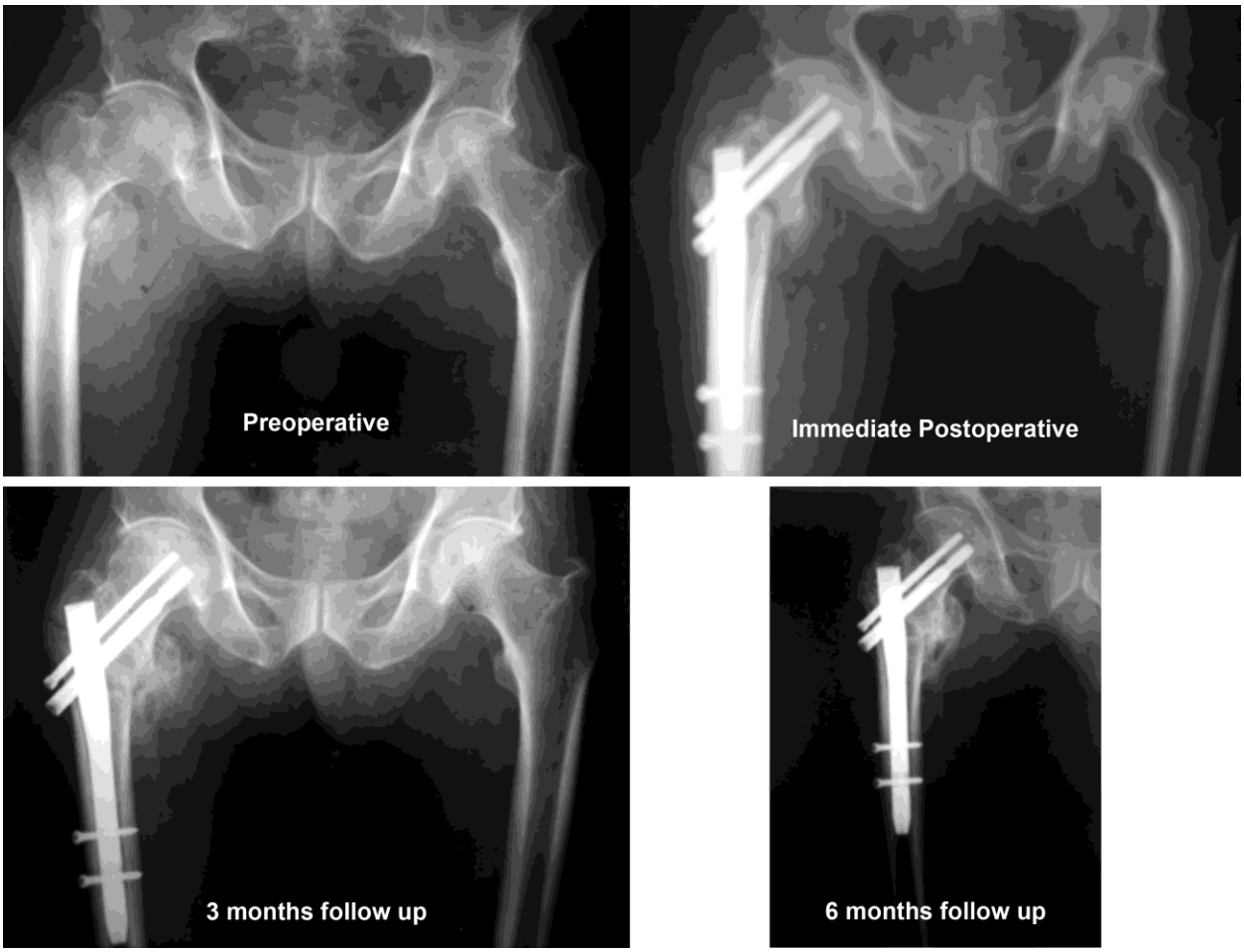

Figure 2: Male patient, 65-year-old who had domestic fall. With the use of Targon PFN, excessive fracture collapse and backing out was lessened until the fractures were fully healed.

Discussion

The incidence of pertrochanteric fractures has increased considerably during recent years because of the worldwide increase in life expectancy[23].The Sliding hip screw (SHS) gained widespread acceptance as the fixation method of choice and is currently considered the standard device for comparison of outcomes[6, 24], however complications are frequent, particularly in unstable pertrochanteric fractures [1, 25].

The gamma nail (GN) has been available for use since 1988 and was designed specifically for the treatment of these fractures in order to combine the advantages of semi-closed intramedullary nailing technique, a dynamic femoral neck screw [26].Unfortunately, serious implant-related complications have been reported as fractures of the femoral shaft in up to 17%[25],failure of fixation in up to 7% [6]and complications of distal locking in up to 10%, [25].Newer designs proximal femoral nails were developed to lessen implant associated complications of the earlier designs [14]. In our study, we had used a new PFN design (Targon PFN).To our knowledge,only two prospective randomized studies compared the use of SHS versus Targon PFN in treatment of pertrochanteric fractures[9, 27].

In the current study, we were interested mainly in studying the behavior of extramedullary fixation (SHS) versus one of the newer designs intramedullary fixation devices (Targon PFN) in the treatment of the more controversial unstable intertrochanteric fracture type with posteromedial comminution in the area of the lesser trochanter (AO:31-A2). We did found that the Targon PFN was superior in the prevention of excessive fracture collapse and neck screw backing out. Moreover, the group of patients who had backing out of the neck screw had significantly shorter lower extremities compared to patients without backing out (Table 3). No statistically significant difference could be foundregarding our primary outcome which is the ultimate function as measured by Harris hip score between either the Targon PFN versus SHS groups or between patients with backing out of the neck screw compared to patients without backing out.

The Primary function of fixation devices used for treating pertrochanteric fractures is to produce a controlled fracture impaction through sliding of the neck screw with torsional stability. SHS offers sliding capacity with minimal torsional stability. Rotational stability requires a contact between head fragment and lateral cortex, which may not be available in unstable trochanteric fractures and therefore fracture collapse occurs with subsequent lateral migration of neck screw "backing out" and limb shortening. Intramedullary devices would allow more controlled impaction until the proximal fragment abuts the intramedullary nail and therefore, nails would substitute for deficient lateral support and lateral bony cortex. Moreover, intramedullary nails merely suspend the proximal fragment until healing ensues [10, 28].

Leung et al found thatpertrochanteric fractures collapsed along the axis of the dynamic neck screw in average of 5.3mm and15.7mm for the stable and unstable fracture patterns respectively [29]. Another study found that excessive sliding was the major reason for fixation failure and claimed sliding of more than 15mm was associated with higher incidence of failure of the fixation [30].

Despite those theoretical mechanical advantages, randomized clinical trials as well as the current study failed to detect better functional outcome for the use of intramedullary fixation devices in favor to the more classic sliding hip screws. In fact, in the Cochrane reviews by Parker and Handoll[14] for randomized trials comparing the two fixation methods concluded that SHS has lower complication rates.

Reports comparing Targon PFN with extramedullary sliding hip screw device have shown that SHS has fewer intraoperative difficulties and lower blood loss as well as lower cost [9, 27]. However, according to Park et al [9], revisions and conversion to arthroplasty were fewer with superior recovery of mobility with the Targon PFN. Lower limb shortening, hip flexion and residual pain were similar for both fixation devices [9].

Conclusion

In summary, Targon PFN appears to decrease the likelihood of excessive fracture collapse and the resultant lower limb shortening in cases of unstable pertrochanteric fractures with posteromedial comminution (AO:31-A2). However, this was not translated into better hip function as measured by Harris hip score at the final follow up.

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