Prospective randomised controlled trial of an intramedullary nail versus a sliding hip screw for intertrochanteric fractures of the femur

Ioannis Aktselis · Constantine Kokoroghiannis · Evaggelos Fragkomichalos ·
Georgios Koundis · Anastasios Deligeorgis · Emmanouil Daskalakis ·
John Vlamis · Nikolaos Papaioannou

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Abstract

Purpose The purpose of this prospective randomised trial was to assess whether an intramedullary nail is superior to a sliding hip screw in the treatment of multifragmentary intertrochanteric fractures

Methods Eighty patients with a 31-A2.2 or A2.3 Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) intertrochanteric fracture were randomly allocated to fixation with either the Gamma nail or the AMBI sliding hip screw device.

Results All patients were followed up at one, three, six and 12 months postoperatively, except for nine who died. There was no statistical difference in Parker mobility score between groups. The Gamma nail group had significantly higher Barthel Index and EuroQol-5D (EQ-5D) scores than the AMBI group at 12 months. At the same time, the EQ-5D score had returned to its pre-operative values in the Gamma nail group but not in the AMBI group. There were no differences in mortality, radiation time and hospital stay. Duration of the operation, incision length and hip pain occurrence were significantly less in the Gamma nail group.

Conclusions Few failures occur when unstable 31-A2.2 and A2.3 AO/OTA fractures are fixed with a sliding hip screw. Nevertheless, an intramedullary nail seems superior in reconstituting patients to their pre-operative state.

Keywords AMBI sliding screw · AO/OTA 31 A2.2 and A2.3 · Fractured neck of femur · Gamma nail · Intertrochanteric fractures · Intramedullary nail · Randomized trial · Sliding hip screw

Introduction

The use of cephalomedullary nails has overtaken the use of sliding hip screws in the treatment of intertrochanteric fractures during the past decade [5, 15, 17, 26]. This trend seems unjustified, as extensive meta-analyses of randomised trials fail to demonstrate the relative benefit of intramedullary devices [40]. Hence the official recommendation of the United Kingdom National Clinical Guideline Centre to “Use extramedullary implants such as a sliding hip screw in preference to an intramedullary nail in patients with trochanteric fractures above and including the lesser trochanter” [35]. A recent prospective randomised trial failed to show any benefit in using a long intramedullary nail over a sliding hip screw in Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association (AO/OTA) 31-A2 intertrochanteric fractures, which are considered unstable [7]. It has been suggested that the three-part AO/OTA 31-A2.1 fracture differs from the multifragmentary 31-A2.2 and A2.3 fracture because the latter is significantly more prone to failure and re-operation when treated with a sliding hip screw [38]. It has also been suggested that patients treated with intramedullary nails mobilise

I. Aktselis (✉) · C. Kokoroghiannis · E. Fragkomichalos ·
G. Koundis · A. Deligeorgis · E. Daskalakis
‘E Orthopaedic Department, KAT General Hospital,
Athens, Attica, Greece
e-mail: aktselis@hotmail.com

J. Vlamis
3rd Orthopaedic Department, University of Athens, KAT General
Hospital, Athens, Attica, Greece

N. Papaioannou
Laboratory for Research of Musculoskeletal System ‘Theodoros
Garofalidis’, University of Athens, KAT General Hospital,
Athens, Attica, Greece

faster and better compared with those treated with sliding hip screws [16, 22, 36, 45].

The hypothesis tested in this study was that there is no difference between a short intramedullary nail (Gamma nail, Stryker, Schönkirchen, Germany) and a sliding hip screw (AMBI, Smith & Nephew, Memphis, TN, USA) in AO/OTA 31-A2.2 and A2.3 intertrochanteric fractures. The primary outcome measures were mobility assessed by the Parker score, daily function evaluated by the Barthel Index and EuroQual (EQ)-5D assessed by quality of life (QoL) [31, 39, 43]. Secondary outcome measures were mortality, duration of surgery, radiation time, hospital stay and hip pain. Also, mechanical failure was defined as screw cutout from the femoral head, implant breakage, nonunion, intra- or postoperative secondary fracture of the femoral shaft and medialisation of the distal fragment by >90 % of femoral-shaft diameter.

Patients and methods

From October 2008 until January 2011, 223 patients with an intertrochanteric fracture admitted in our department were considered for inclusion in this study. Inclusion criteria were an unstable 31.A2.2 or 31.A2.3 (but not 31.A2.1) fracture type according to the AO/OTA classification in a patient >65 years

old [34]. Exclusion criteria were bilateral fractures, pathologic fractures, previous chemotherapy and/or radiotherapy, rheumatic diseases, polytrauma, a previous operation in the same hip/femur and American Society of Anesthesiologists (ASA) score IV or V [3]. Patient selection was performed upon admission. All intertrochanteric fractures were categorised according to the AO/OTA classification by at least two consultants [43]. From 123 patients with a 31-A2.2 or A2.3 fracture, 80 were enrolled in the study (Fig. 1).

Patients were randomised to fracture fixation with either the Gamma nail or the AMBI sliding hip screw device, each group comprised 40 patients. For convenience, these groups are referred to as the Gamma nail group and the AMBI group. Randomisation was performed using 80 sealed, opaque envelopes picked from a box in the presence of three surgeons. Written consent was obtained from all patients. The study received ethical board permission and was registered to the National Organization for Drugs. Study design and reporting were based on the CONSORT principles [33]. All operative procedures were supervised by four consultant orthopaedic surgeons experienced in both techniques of fixation.

Spinal anaesthesia was used in all patients. Longitudinal traction was applied to the fractured limb on a fracture table. Closed reduction was sought. If not successful, open reduction was performed. Gamma nail was inserted through a small

Fig. 1 Patient flow through the trial

Fig. 1 Diagram depicting the flow of patients through the trial.

incision proximal to the greater trochanter under image intensifier. Reaming was performed up to 15.5 mm proximally. The angle of the Gamma nail was 125°, except for three cases in which it was 130. In the case of the AMBI device, AMBI was applied onto the femur through a standard lateral approach. Angles were 135° in 21 cases and 130° in 14. Three-hole plates were used in 28 patients, four-hole plates in four and five-hole plates in three. There were no additional antirotational screws in the neck and the head of the femur in any patient. Suction drain was not used, and one dose of a second-generation cephalosporin was administered preoperatively and continued for 48 hours postoperatively. The head screw was placed in keeping with Baumgartner's suggestion that tip apex distance (TAD) should be <25 mm to minimise the risk of cutout and in the middle-middle or middle-inferior position [4, 5, 8, 18, 25]. Operative time, radiation time and incision length were recorded.

Postoperatively, patients were mobilised with a walker and weight bearing, as tolerated. Weight bearing differed in cases of medialisation of the distal femoral fragment by >90 % of its diameter on postoperative X-rays, as this would lead to mechanical failure [41]. Patients were followed up at one, three, six and 12 months postoperatively. Anteroposterior and lateral X-rays were obtained at each follow-up visit. Fracture union was defined as the presence of visible bone trabeculae between bone fragments in both views, accompanied by pain-free walking [24]. Patients' postoperative state was evaluated at each follow-up visit and compared with pre-injury status using the Parker score, Barthel Index and EQ-5D. Parker score is a pure mobility score, with a maximum of nine points and a minimum of zero. Barthel Index ranges from 0 to 100 and assesses the ability of patients to carry out activities of daily living. EQ-5D questionnaire was used to evaluate QoL. The EQ-5D is composed of two elements: a five-numbered score concerning patient lifestyle which then, with the use of an algorithm, gives an outcome score from −0.200 (minimum) to 1.000 (maximum) [40, 44].

Statistical analysis

Continuous variables are presented with mean and standard deviation (SD) or with median and interquartile range (IQR). Quantitative variables are presented with absolute and relative frequencies. For comparison of proportions, chi-square and Fisher's exact tests were used. For comparison of study variables between groups, nonparametric Mann–Whitney test was computed for nonnormal variables and Student's *t* test for normal variables. Differences in changes in Barthel, EQ-5D and Parker scores during the follow up period between groups were evaluated using repeated measurements analysis of variance (ANOVA). Parker score was log-transformed for the ANOVA due to its skewed distribution. All *p* values reported are two tailed. Statistical significance was set at *p* 0.05, and

analyses were conducted using SPSS statistical software (version 18.0). Power analysis methodology represents a design, with two levels of the between-patient factor of two study groups and five levels of the within-patient factor of time. Effect size for this calculation used the ratio of the SD of effects for a particular factor or interaction and the SD of within-patient effects. Power analysis was conducted for a single, two-group between-patient factor, and a single within-patient factor assessed over five time points. For this design, 71 participants achieves a power of 0.95 for the between-patient main effect at an effect size of 0.45; a power of 0.95 for the within-patient main effect at an effect size of 0.17; and a power of 0.96 for the interaction effect at an effect size of 0.17.

Results

All patients completed follow-up, except for nine who died. Therefore, the sample consisted of 71 patients (35 in the AMBI group and 36 in the Gamma nail group). There was no significant difference in one year mortality rate between two groups. Demographics and clinical characteristics of the two study groups are presented in Table 1; groups were similar in terms of age, sex, side of fracture and pre-operative ASA classification. Table 2 shows changes over the follow-up period for Barthel, EQ-5D and Parker scores for the Gamma nail and AMBI group.

From the first to the 12th month, there was a significant improvement in Barthel Index (*p* < 0.05), EQ-5D (*p* < 0.05) and Parker score (*p* < 0.001), when each time point was compared with the previous one in both groups. With the exception from 3 months to 6 months, where QoL remained unaltered in the AMBI group (*p* = 0.253). At the 12-month follow-up, the Gamma nail group had significantly better daily functioning than the

Table 1 Demographics and clinical characteristics by study group

	AMBI [<i>n</i> (%)]	G3 [<i>n</i> (%)]	<i>P</i> value
Age (years), mean (SD)	83.1 (6.5)	82.9 (5.8)	0.892*
Sex			
Men	7 (20.0)	8 (22.2)	0.819**
Women	28 (80.0)	28 (77.8)	
Side of fracture			
Right	20 (57.1)	19 (52.8)	0.712**
Left	15 (42.9)	17 (47.2)	
ASA (preoperative)			
I	2 (5.7)	2 (5.6)	0.134***
II	27 (77.1)	20 (55.6)	
III	6 (17.1)	14 (38.9)	

AMBI sliding screw, G3 Gamma nail, SD standard deviation, ASA American Society of Anesthesiologists

*Student's *t* test; **chi-square test; ***Fisher's exact test

Table 2 Changes in primary outcome measures during the follow-up period for the two study groups

	Preoperatively (mean (SD))	First month (mean (SD))	3 months (mean (SD))	6 months (mean (SD))	12 months (mean (SD))	Change 1 (mean (SD))	Change 2 (mean (SD))	<i>P</i> value**	<i>P</i> value***	<i>P</i> value****
Barthel										
AMBI	91.9 (12.1)	52.6 (20.5)	70.7 (19.4)	77.9 (19.3)	81.1 (18)	28.5 (17.5)	−10.8 (13.9)	<0.001	<0.001	0.037
G3	92.6 (14.1)	59.6 (22.6)	73.6 (22.2)	82.9 (17.4)	89.7 (15.8)	30.1 (14.4)	−2.9 (8.3)	<0.001	0.043	
<i>P</i> value*	0.803	0.176	0.560	0.250	0.036					
EQ-5D										
AMBI	0.90 (0.14)	0.59 (0.26)	0.72 (0.24)	0.75 (0.25)	0.78 (0.27)	0.19 (0.19)	−0.12 (0.21)	<0.001	0.001	0.012
G3	0.92 (0.14)	0.66 (0.24)	0.76 (0.21)	0.83 (0.19)	0.90 (0.16)	0.25 (0.13)	−0.02 (0.06)	<0.001	0.172	
<i>P</i> value*	0.586	0.232	0.438	0.176	0.018					
Parker										
AMBI	7.8 (2.1)	2.1 (1.4)	3.8 (1.9)	4.9 (2.2)	5.7 (2.2)	3.7 (1.7)	−2.1 (1.6)	<0.001	0.001	0.011
G3	7.5 (2.4)	2.8 (1.5)	4.6 (2.1)	5.7 (2.1)	6.5 (2.3)	3.7 (1.4)	−1.0 (1.3)	<0.001	0.001	
<i>P</i> value*	0.644	0.061	0.095	0.146	0.305					

AMBI sliding screw, G3 gamma nail, SD standard deviation, *Change 1* mean change from first month to 12 months, *Change 2* mean change from baseline to 12 months

p* value for group effect, *p* value for change from first month to 12 months, ****p* value for change from baseline to 12 months, **** effects reported include differences between the two groups in the degree of change in each particular variable (repeated measurements analysis of variance)

AMBI group, as defined by Barthel Index ($p=0.036$) and EQ-5D ($p=0.018$). At 12 months, the Gamma nail group approached but did not normalise to its pre-operative Barthel Index values ($p=0.043$). In contrast, AMBI group values at 12 months lagged significantly to pre-operative values ($p<0.001$). At 12 months, EQ-5D scores in the Gamma nail group were not significantly different to pre-operative values ($p=0.172$) in contrast to the AMBI group, whose health-related QoL remained significantly lower ($p=0.001$). At 12 months, Parker mobility scores remained significantly lower to pre-operative values in both groups ($p<0.001$). Overall change at 12 months relative to pre-operative values was significantly lower in the Gamma nail than the AMBI group for Barthel Index ($p=0.037$), EQ-5D ($p=0.012$) and Parker score ($p=0.011$). Comparison of secondary outcome measures between groups is shown in Table 3. Mean duration of surgery and median incision length were significantly lower in the Gamma nail group; amount of radiation and length of hospital stay were similar. The percentage of patients that had hip pain was significantly higher in the AMBI group at one, three and six but not at 12 months (Table 4).

No cutouts necessitating re-operation were observed in either group. Three cases in the AMBI group were considered fixation failures: In two patients, uncontrollable medialisation by >90 % of shaft width was observed on X-rays of the first postoperative visit (Fig. 2). Failure was impending, and further mobilisation was discontinued. Both fractures eventually healed at the three month follow-up visit and mobilisation recommenced. In the third patient, the method of fixation was intraoperatively changed to a long gamma nail because of extensive comminution extending 3 cm distal to the lesser

trochanter, which occurred during reaming for AMBI head screw insertion. Nevertheless, failure rates did not reach statistical significance between groups. All fractures eventually healed in both groups. No cases of intra-operative or postoperative secondary fractures around the tip of the Gamma nail were noted. Open reduction was deemed necessary to obtain reduction in two AMBI patients but in none in the Gamma nail group. No additional stabilisation methods, e.g. circlage wires, were used in either group.

Discussion

Numerous prospective randomised trials have proved that sliding hip screw devices can successfully treat the majority of

Table 3 Comparison of secondary outcome measures between study groups

	AMBI Mean (SD)	G3 Mean (SD)	<i>P</i> value
Duration of surgery (min)	75.5 (21.9)	45.7 (22.7)	<0.001*
Amount of radiation	24.4 (15.5)	28.9 (11.7)	0.174*
Hospital stay (days)	16.4 (5.0)	16.6 (6.3)	0.859*
Length of incision, median (IQR)	15 (13–17)	4 (4–4)	<0.001**
Failure of fixation [<i>n</i> (%)]			
No	32 (91.4)	36 (100.0)	0.115***
Yes	3 (8.6)	0 (0.0)	

IQR interquartile range, AMBI sliding screw, G3 gamma nail, SD standard deviation

*Student's *t* test, **Mann–Whitney test, ***Fisher's exact test

Table 4 Change in pain referred to the hip region from the first to the final assessment

Postoperative pain in the hip region.		Fischer's exact test				<i>P</i> for group effect
		AMBI (sliding hip screw)		G3 (Gamma nail)		
		<i>n</i> (%)	<i>P</i> for time effect	<i>n</i> (%)	<i>P</i> for time effect	
1 month	No	12 (34.3)	—	25 (69.4)	—	0.003
	Yes	23 (65.7)		11 (30.6)		
3 months	No	21 (60)	0.031	32 (88.9)	0.045	0.005
	Yes	14 (40)		4 (11.1)		
6 months	No	28 (80)	0.068	35 (97.2)	0.172	0.028
	Yes	7 (20)		1 (2.8)		
12 months	No	32 (91.4)	0.173	36 (100)	0.319	0.115
	Yes	3 (8.6)		0 (0)		
Change (%) from 1 month to 12 months		−57.1	<0.001	−30.6	<0.001	

intertrochanteric fractures, with implant failures occurring in <5 % of cases [1, 2, 7, 16, 23, 28, 29, 32, 42]. Parker and Handoll compared extramedullary to intramedullary devices in a meta-analysis of >3,500 patients and found no significant differences in mortality rates, nonunion, infection, cutout, blood loss, operation duration and radiation time [40]. The study reported here confirms that sliding hip screws seldom fail, even in multifragmentary 31-A2.2 and A2.3 intertrochanteric fractures, as shown by the absence of cutouts and re-operations.

Although not statistically significant, all failures in this study occurred in the AMBI group. These were the result of intra-operative fracture of the lateral trochanteric wall leading to excessive medialisation of the distal femoral fragment and necessitating discontinuation of weight bearing, as mechanical failure was impending [41]. It has been suggested that multifragmentary fractures run a significantly higher risk of this complication relative to two- (AO/OTA 31-A1) and three-

part (AO/ OTA 31-A2.1) fractures. When it happens, failure and re-operation occurs in one of five patients [37]. Fracture of the lateral trochanteric wall is the result of large-diameter drilling necessary for to insert the head screw and barrel of sliding hip screws [19, 20]. This can lead to uncontrollable medialisation of the distal fragment exceeding the sliding capability of the device, loss of contact of the bone ends and eventual mechanical or clinical failure [19, 21, 27, 41]. An exaggerated form of this complication was subtrochanteric propagation of the fracture, recognised intra-operatively in one of our patients and subsequently treated with a long nail. Intramedullary nails can compensate for an incompetent lateral trochanteric wall by acting as a buttress due to their centromedullary position [22, 30, 37].

Mortality at one year was not significantly different between compared groups. Overall, it was <15 %, which is low in comparison with large series reporting rates >30 % [12, 14].

Fig. 2 **a** Intertrochanteric 31-A2.2 Arbeitsgemeinschaft für Osteosynthesefragen/ Orthopaedic Trauma Association (AO/OTA) fracture of right femur, anteroposterior (AP) X-ray. **b** AP projection at 1 month postoperatively showing excessive medialisation of the distal fragment (90 %) and possible rotation

This discrepancy could be attributed to the exclusion of unfit, ASA IV and V patients from our series. Operative time proved to be significantly shorter in the Gamma nail group in this technically demanding group of fractures. There are series showing comparable or even shorter operative times with sliding hip screws, probably reflecting the unfamiliarity in the 1990s with nails [23, 42, 45]. Fixation with a sliding hip screw is a straightforward and fast operation in stable intertrochanteric fractures. However, when unstable fractures are considered separately, nail fixation seems to be faster [9]. Radiation time was not different between groups in our study, averaging <30 seconds per operation. Some series show that nails necessitate less radiation [28, 45]. Series showing significantly more radiation time for nailing are to be viewed with caution, as they report average times between two and seven minutes, which are unacceptably high and reflect surgeon inexperience [16, 42].

Although a short Gamma nail was used in our series, no secondary fractures around the tip of the nail were noted. Secondary fractures were a significant risk in earlier series, reflecting poor nail design and/or insertion technique [6, 10, 13, 23]. A meta-analysis by Bhandari et al. showed that the risk of secondary fracture after nailing became nonsignificant in reported series after 1997 [11].

The functional status of patients in our study was assessed with three different instruments: namely, the Parker Mobility Score, the Barthel index and EQ-5D, which have seldom been used in other randomised trials [7, 9, 32]. Our study revealed no difference in postoperative mobility of patients regardless of fixation method, although change from pre-operative baseline Parker score values was significantly less in the Gamma nail group. There was significant improvement from one follow-up visit to the next, but patients had not recovered their pre-operative walking ability, as assessed by the Parker score, at one year. Nevertheless, there are randomised trials showing significantly better Parker scores, both early and at one year, in patients treated with intramedullary nails when unstable fractures are considered separately [22, 45]. This has been attributed to the significant femoral-neck and overall limb shortening that occurs in unstable fractures and impedes mobilisation in this frail population [22, 36].

Despite similar postoperative mobility between groups in our study, the Gamma nail group was more able to cope with everyday living, as shown by better Barthel Index scoring, than the AMBI group throughout the follow-up period. These differences became significant only at the final one year assessment. The Gamma nail group approached their pre-operative status, which the AMBI group failed to do. This trend is further emphasised in EQ-5D results in which the Gamma nail group were reconstituted to their pre-operative QoL, whereas the AMBI group did not. It is difficult to explain how the use of nails positively affects eventual function and QoL of patients. This is not merely a mobility issue,

as shown by comparable Parker scores between groups. The comparatively less postoperative pain shown in the Gamma nail group could partially explain this. Differences in hip geometry and leg length could also play a role. There were no wound infections in either group postoperatively, despite a longer incision in the AMBI group.

Our study scores high in criteria of a valid methodology set by Parker and Handoll [40]. Most randomised trials to date consider fractures of variable stability, which masks any differences that fixation may have in certain subgroups. It is surprising that patients with an unstable intertrochanteric fracture can regain their pre-injury QoL when an intramedullary nail is used. Probably, this should be also attributed to the strict selection criteria of our study, which excluded ASA IV and V patients who comprise up to 34 % of the population in other studies [12, 22, 36, 42]. The benefit of this selection is emphasised by preoperative Barthel Index and EQ-5D mean scores corresponding to healthy and highly functional patients, who stand the best chance of recovery [9].

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Conflict of interest None.

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