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Original article

Gamma nail™ in pertrochanteric fractures in elderly patients: is anatomical reduction necessary? A preliminary study

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Summary. *Aim of the work:* This study analyzes the clinical and radiographic results of 100 patients who underwent osteosynthesis with Gamma nail™, following fracture of the pertrochanteric region. *Methods:* These patients were divided into 2 groups: A, those without anatomical reduction of the fracture and B, those with anatomical reduction. All patients were classified according to the ASA system, pre-injury and follow-up Harris Hip Score and pre-operative/post-operative radiographic evaluation. An univariate analysis has been performed comparing pre-injury and final follow-up Harris Hip Score. Moreover a multivariate analysis has been completed including: age, ASA classification, anticoagulant therapy, cognitive impairment, length of surgical procedure, type of surgical result, length of hospitalization, timing between trauma and surgical procedure. *Results:* The univariate analysis documented no statistical significance (p=0.541). At multivariate analysis resulted as statistically significant only the age, the ASA classification and the timing between trauma and surgical procedure. Patients of group A have obtained rehabilitation time, fracture healing time and long-term functional results similar to patients of group B. *Conclusions:* It is suggested that, compared with anatomic reduction, preoperative ASA, age and the time interval between trauma and surgery are more predictive criteria of patient mortality in the months following the intervention. (www.actabiomedica.it)

Key words: pertrochanteric fractures, Gamma nail™, outcomes, anatomical reduction

Introduction

One of the most widely used methods of intramedullary nailing in treatment of trochanteric fractures in use today is the gamma nail which features a number of perceived advantages, among which its minimal invasiveness and need for smaller skin incisions, compared to other techniques (1-3). Nevertheless in literature there are few studies on the Gamma nail.

However, despite excellent results, its implantation in elderly patients, in whom pertrochanteric fractures occur more frequently, should be carefully considered (1). Indeed, the interruption of the skeletal continuity caused by pertrochanteric fractures often entails the alteration of the delicate balance between the patient's physical health, mental vigour, emotional sphere and overall harmony with the surrounding environment (3). These aspects -and, not least, the low/poor survival rates at follow up in this patient population- are particularly relevant when pondering therapeutic approach and treatment for elderly patients who often arrive in already precarious conditions of health (3).

Considering that operation time should be limited to the least possible, in order to contain surgery-

related risk for the patient as much as possible, our study aimed to evaluate (1) the effectiveness of achieving anatomical reduction in this type of procedure for this type of patient and (2) the reliable predictors of outcome.

Materials and methods

The ethical committee of at our institution approved the study protocol and informed consent was obtained from each patient. In total, 112 consecutive patients were treated by Gamma nail™, between June 2010 and December 2012, following fracture of the pertrochanteric region. Pathological fractures and subtrochanteric fractures were excluded from the study. Of these, 24 were male and 88 female, with a ratio of about 1:4. The affected side was the left in 68 cases, the right in 44. Before the trauma, the condition of the 112 patients was as follows: 56 were walking in their home without the aid of a walking stick, 52 relied on a walking stick for support, and 4 were bedridden. Average time elapsing between injury and surgery was about 38 hours (min. 3 - max 120). For 16 patients receiving oral anticoagulant therapy, waiting time for surgery was extended due to washout period. 90 patients also presented several associated diseases: 18 patients had hypertension, 18 had ischemic heart disease, 16 type II diabetes, 16 chronic atrial fibrillation, 10 previous ischemic cerebral accidents, 8 chronic obstructive pulmonary disease and 4 had been treated for cancer (showing, however, no evidence of bone metastasis). Duration of surgery was on average 45 minutes (min. 20 - max 90).

Surgical interventions were performed at turn by each surgeon of the team in turn, according to work shifts. All surgeons were trained for the procedure. Patients were operated on traction table in supine position and spinal anesthesia was used. Image intensifier was used for the important pre-operative maneuvers to reduce the fracture. Stryker's™ instruments were used for surgery following the guidelines of internal fixation with gamma nail. Medical reports were reviewed for epidemiological data such as age, gender, fracture side, comorbidity, time elapsing between injury and surgery, medium hospitalization period and surgery time. Mean follow-up was 23 months (min 12 – max 30). Pre-Injury (PI) and at final follow-up (FFU), clinical evaluation was performed using the Harris Hip Score (HHS) (4). Regarding PI-HHS, 95 of 100 of HHS concerning pain, limb, absence of deformity and daily activity were calculated based on history told by patients concerning hip pre-injury conditions and 5 points concerning range of motion (ROM) were calculated on the contra-lateral site. Two observers were assigned to analyze antero-posterior and lateral radiographs of the hip in preoperative and early postoperative periods, at 30 and 90 days after surgery, and at the final follow-up. Pre-operative X-rays were used to classify the fracture types according to the A.O. (5): twenty fractures were type 3.1.A.1.1, forty fractures type 3.1.A.1.2, eight type 3.1.A.1.3, twenty-four type 3.1.A.2.1, ten type 3.1.A.2.2 and ten were type 3.1.A.3.1. Quality of fracture reduction was assessed on postoperative radiographs. Criteria for considering the reduction to be considered unsatisfactory were: a misalignment on antero-posterior radiograph greater than 10 mm, 10° of varus/valgus angulations, and/or misalignment greater than 20° on the lateral radiograph (6,7). Displacement of the lesser trochanter was disregarded (8).

According to anesthesiology consultation before surgery, all patients were classified according to the A.S.A. (the American Society of Anesthesiologists) system (9). Rehabilitation protocol suggested the patient remained seated in bed on the second day after surgery, started C.P.M. (Continue Passive Motion) and had gait load protected and assisted from the third day after surgery; this protocol was followed for all patients with adequate compliance. Medium hospitalization length was 13 days (3 - 41) and rehabilitation was continued until dismissal. Physiotherapy was continued in rehabilitation facilities up to one month after surgery.

Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (IBM SPSS 20.0). An univariate analysis with Mann-Whitney test was performed comparing pre-injury Harris Hip Score (PI-HHS) and final follow-up Harris Hip Score

(FFU-HHS). Moreover a multivariate analysis was completed including: age, ASA-PS score, anticoagulant therapy, cognitive impairment, length of surgical procedure, quality of surgical result (anatomical vs. no anatomical reduction of the fracture), length of hospitalization, timing between trauma and surgical procedure. This type of analysis was performed in order to identify the predictive power of the different variables in determining the final outcome, evaluated by the use of FFU-HHS.

Results

Of the 112 patients operated, 100 were evaluated at follow-up (12 resulted to be unreachable). These 100 patients were classified into 2 groups: group A (Figure 1), those without anatomical reduction of the fracture at postoperative x-ray control (28 patients) and group B (Figure 2), those with anatomical reduction (72 patients). At the final follow-up clinical and radiographic results were analyzed (Table 1).

An univariate analysis documented no statistical significance between PI-HHS and FFU-HHS (p=0.541). At multivariate analysis, only age, ASA-PS score and timing between trauma and surgical procedure resulted as statistically significant, when compared to FFU-HHS.

No statistical significance was documented for the other parameters evaluated at multivariate analysis (Table 2). Ten patients (10%) experienced a detachment of the lesser trochanter, only two had a reduction of daily activities due to old age. None reported pain on walking, and no patients experienced delayed fracture healing or nonunion. Patients did not have other complications (cut-out, varus consolidation); postoperative serial radiographs did not reveal any loss of the obtained reduction. Classes IV and V of the ASA-PS score proved to be those with a higher risk: in our follow-up no patient of class V and only four of

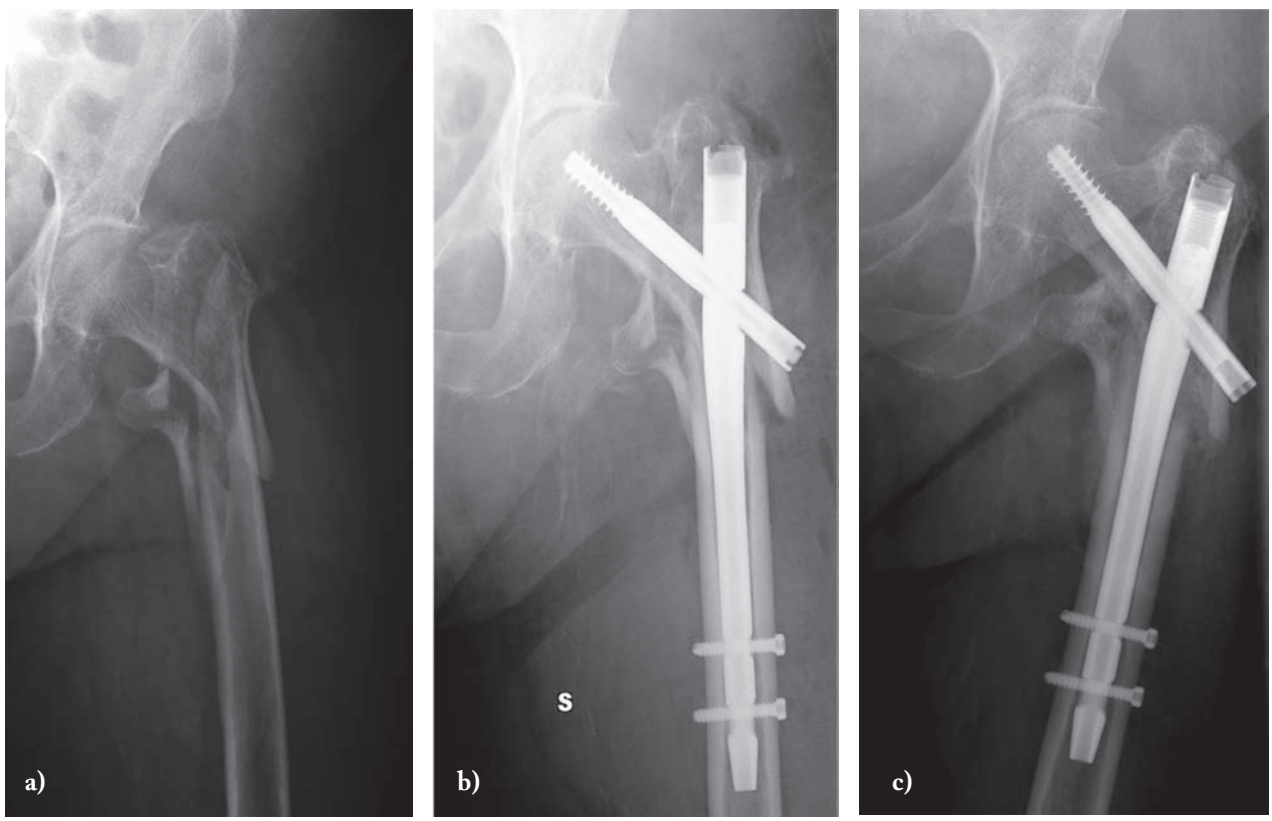

Figure 1. (a) Preoperative X-Ray of patient with proximal femoral fracture type 31-A.2.2. (b) Post-operative X-Ray: the reduction is not anatomical. (c) X-Ray check at three months: healing of the fracture

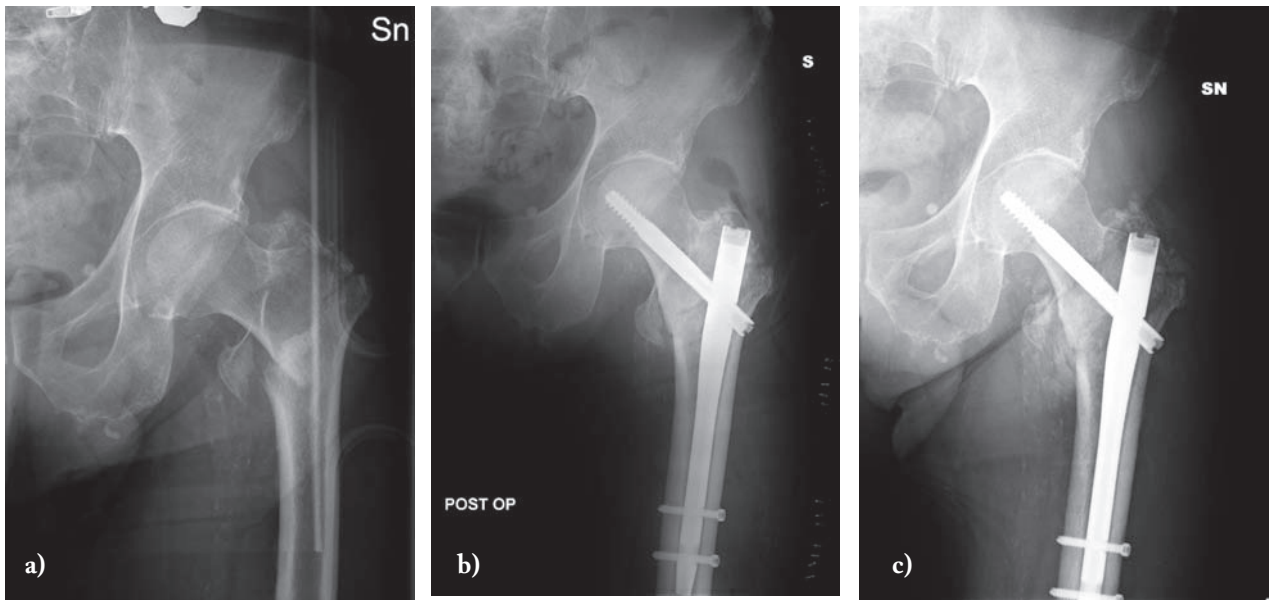

Figure 2. (a) Preoperative X-Ray of patient with proximal femoral fracture type 31-A.2.1. (b) Post-operative X-Ray: the reduction is anatomical. (c) X-Ray check at three months: healing of the fracture

Table 1. Patient data Group A and Group B

	GROUP A (no anatomical reduction)	GROUP B (anatomical reduction)
Number of patients	28	72
Mean age (std dev)	83+/-7	80+/-13
Mean time of surgery (std dev)	46+/-19	45+/-20
Mean time injury/surgery (std dev)	40+/-33	38+/-27
Mean length of hospitalization (std dev)	13+/-5	13+/-5
Mean PI-HHS (std dev)	72+/-20	71+/-20
Mean FFU-HHS(std dev)	72+/-24	72+/-20
Classification ASA-PS scale	II:6 III: 17 IV: 5	II:12 III:46 IV:14

Legend: PI-HHS: Pre-injury Harris Hip Score ; FFU-HHS: Final follow-up Harris Hip Score

lass IV survived up to the moment of our observation. Mortality rate was 23% among class III patients, 50% among class IV patients, and 50% among patients in class V.

Table 2. Multivariate analysis investigating the predictive power of the different variables for outcome

Variables	p
Age	<0.001
Time injury/surgery	<0.001
Length of surgical procedure	0.313
Length of hospitalization	0.065
Classification ASA-PS scale	0.005
Surgical outcome (Anatomical vs. no anatomical reduction)	0.173
Anticoagulant therapy	0.169
Cognitive impairment	0.251

Discussion

The results of this study indicate that long-term functional results (FFU-HHS) do not necessarily depend on reduction quality but on many other variables (comorbidity, age, elapsed time from trauma to surgery) that should also be taken into account. Mortality for these fractures during the first year after the event is 15%-20%; these figures are partially justified by the

fact that post-operatory recovery is not facilitated by the presence of co-morbid conditions (3,10,11).

We used the ASA-PS score for classifying pre-injury comorbidity in our series of cases (12,13). Although the ASA-PS score has been criticized for its subjective nature as a measure of clinical severity, in several studies it proved to be a powerful predictor of mortality/survival after hip fracture (3,10,11,12,14).

ASA-PS score can also be used as a good predictive criterion for patient functional recovery in the months following the hip surgery (13), and our results confirmed this hallmark. (p = 0.005 -Table 2)

In fact, patients with low ASA-PS score and high PI-HHS had a better rehabilitation pathway compliance and a better quality of life at follow up. Patients that had a high PI-HHS maintained the same score after surgery independently from anatomical reduction of the fracture (Table 1) while patients with high ASA-PS score and low PI-HHS had a worse rehabilitation pathway compliance and a worse patient life quality in follow up.

Overall, the risk is higher for male patients over 80 years of age and having an ASA-PS score IV or higher and in the period from injury to 3 months after the surgery (3,10). According to our results classes IV and V of the ASA-PS score are those with higher risk: in fact, no patient of class V, and only 1 patient of class IV reached follow-up.

Sexson and Lehner correlate mortality rate to the number of associated diseases, arguing that mortality decreases from 30% to 15% in patients with fractures without associated diseases, but increases from 22% to 33% in those with three or more major diseases. Hence, having all patients undergo geriatric consultation and intensive care assessment in the very first hours after admission is obviously of paramount importance (15).

Moreover, we found a significant correlation between FFU-HHS and interval time between trauma and surgical procedure ($p<0.001$ – Table 2). This datum is in accordance with most of the literature and international guidelines. Indeed several Authors report that co-morbidity/mortality can be significantly reduced by early surgery in trauma hip surgery (3,16-21).

Generally speaking, the number of deaths is related to the patient's age, with a peak in males in the ninth and tenth decade of life (3,22-24). Mortality rate is lower among patients living at home and higher in those living in retirement homes or hospitals (22-23). The significant correlation Age-FFU-HHS ($p<0.001$ – Table 2) obtained from multivariate analysis substantially agrees with expected results from literature (24).

Between the non significant correlations, in particular we emphasize that the outcome of surgery (anatomical vs. no anatomical reduction) does not influence the FFU-HHS ($p=0.173$ – Table 2). This is also the answer to our primary query. We divided our cohort of population in two groups based on surgical results in order to show the homogeneity of the groups. Of the variables reported in Table 1 none shows a statistically significant difference between the two groups. However our multivariate analysis suggests that it is not correct to consider the surgical result as a significant variable to study the outcome of this type of patients.

It is important to underline that a proper implant technique is necessary in order to prevent hardware failure (6-8,28). Pre-operative maneuvers are fundamental in order to achieve fracture reduction (which should be as anatomical possible), and nail implantation should aim to stabilize the fracture while restricting surgery time to the least required by the criteria of fracture fixation (6-8,25).

In order to reduce the fracture, it is important to pull and abduct the limb in order to correct varus. Stability is obtained with the synthesis and not with anatomical reduction as with DHS. The screw must pass through in the centre of the basis of the femoral neck, no matter the position of the screw in the head, in lateral radiographic view. In A-P view the screw in femoral neck must pass through "calcar" and the tip of the screw must be in the lower part of the femoral head with an angle of 120° or 125° (6-8,25).

The importance of a central placement of the screw in lateral radiograph to avoid cut-out has been emphasized in the literature. Central placement of the screw reduces the risk of rotation of the femoral head and neck around the screw that can occur with eccentric placement. However, according to Bojan, it was not possible to define a single optimal zone (inferior, central or even slightly superior) on the A-P view (6,8).

Although indirect reduction cannot be as precise as that obtainable by open surgery, from a biomechanical point of view there are many advantages of using

an intramedullary implant in the long bone, such as the insertion of the nail in the medullary canal which produces a strong primary stability while minimizing the "bypass" of the cortical bone forces ("shield effect") that may occur when applying a plate (26-28). This is explained by the fact that the nail is located near the neutral axis (anatomical axis) of the skeletal segment, acting as a true "central guardian" capable of maintaining an harmonious load distribution, especially in compression with eutrophic stimulation of the restorative osteogenesis mineralization (26-28).

Following international guidelines and recommendations enabled us to obtain a good positioning of the implant and similar long-term functional results both in patients who had an anatomical reduction of the fracture and in those who did not, over comparable surgical times. In literature there are a number of studies on the importance of anatomical reduction in patients operated with DHS or about DHS vs Gamma nail™ but very few studies on Gamma nail™ procedures and results (29-30).

We do recognize this study was subject to some limits. The two groups were not homogeneous and the one with the anatomical reduction was larger; however, this is predictable and, actually, desirable since we always aimed to obtain an anatomical reduction through pre-operative maneuvers. Again, the number of patients at follow-up was scarce.

Another limit of this study could be the significance of HHS. The data collection of the subjective part of HHS (95/100) regarding pre-injury conditions of the hip is based on a questionnaire compiled by the patient after the trauma: there could be some doubts about the reliability of this method.

Moreover, obviously, we were not able to make a clinical examination of the operated limb before surgery so the clinical values (5/100) were calculated on the contra-lateral site before surgery if there wasn't orthopaedic limitation, and on operated limb at follow-up.

Lastly, results are based on a basic, standard treatment, which was therefore performed by several consultant surgeons on our team, including both senior and junior members.

However, despite such limitations, comparison of the two groups suggests that rehabilitation time, fracture healing time, and long-term functional results in patients in whom an X-ray anatomical reduction of the fractures had not been achieved were comparable to those in patients with anatomical reduction, with similar mean age, pre-operative ASA-PS scale, the time interval between injury and surgery, and surgical time.

Therefore, our results confirm that in the treatment of pertrochanteric fractures -compared to anatomical reduction- pre-operative ASA-PS score, age and time interval between injury and surgery are better predictive criteria for rehabilitation pathway compliance, patient's quality of life, and mortality in the months following intervention. To confirm our impressions further studies are needed with a larger sample of patients.

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