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Osteoporotic 3-4 part humeral proximal fractures in the elderly with ASA 3 score: comparison of surgical and non-surgical treatments

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Summary

Objectives. To compare the outcomes of non-surgical treatment and reverse shoulder arthroplasty (RSA) in osteoporotic four-part proximal humeral fracture (PHF) in elderly population with ASA 3 score to determine which interventions are the most appropriate for management.

Methods. Between January 2014 and December 2016, 60 patients aged from 75 to 90 years with osteoporotic four-part PHF were enrolled and were randomly allocated to non-surgical treatment or RSA (n = 30). Clinical indexes for patients in the two groups, such as Constant-Murley score (CMS), Disability of Arm, Shoulder and Hand (DASH) score, individual subject evaluation of the outcomes and plain X-ray were compared at 36 months of follow-up.

Results. CMS, DASH score, activities of daily living (ADL), and range of motion (ROM) were significantly higher in the nonoperative group than in the RSA group at the last follow-up, whereas pain was greater in the RSA group at 12 months. In addition, patients in the nonoperative group had higher abduction, external rotation with elbow (ER 1), strength and satisfactory rating compared with RSA at the last follow-up. There were 2 cases who have suffered from superficial infection and 4 cases from shoulder stiffness in the RSA group.

Conclusions. Conservative treatment is a possible option in elderly patients with ASA 3 score valuation.

Key words: four-part proximal humeral fracture, shoulder arthroplasty, conservative treatment, ASA 3.

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Introduction

Proximal humerus fracture (PHF), the third most common injury among older people, is second to the hip and distal radius fractures and accounts for about 4-5% of whole body bone fractures [1]. The Neer classification suggests that general osteosynthesis is recognized as an effective treatment for two- or three-part fractures [2-5]. Otherwise, four-part fractures, the most severe type of PHF in elderly patients, good favorable clinical and anatomical results may be achieved even if non-operative treatment is performed.

Treatment results are directly related to the functions of shoulder joint, and thus the aim of therapy for PHF is to make the fracture position recover to its former

state and to avoid stiff weak joints and humerus necrosis [6,7]. Even if many surgical options are available for this fracture type [8-10], the results remain controversial [11]. Therefore, it is of interest to investigate the outcomes of non-surgical treatment in elderly patients with ASA score of 3, thus avoiding surgical complications.

Increasing evidence have shown that reverse shoulder arthroplasty (RSA) has an excellent effect on postoperative recovery of PHF patients [12,13]. Although much research has been devoted to the different methods used to treat PHF, the functional and clinical outcomes of PHF still remain controversial in elderly patients.

To date, no randomised controlled trials (RCTs) have directly compared RSA with nonoperative treatment for 3- or 4-part PHFs in elderly patients with ASA score of 3. The high frequency of PHFs, the growing epidemiologic pattern that they follow, and the absence of scientific evidence on their ideal treatment are the reasons why such studies are necessary. The purpose of this study was to perform a prospective evaluation of functional outcomes and quality of life comparing conservative treatment to RSA for the treatment of comminuted PHFs in elderly patients.

Specifically, we compared the outcomes of conservative treatment with RSA in osteoporotic four-part PHF in elderly patients with an ASA anesthesiological score of 3 [14]. We evaluated outcomes according to Constant-Murley score (CMS) [15], Disability of Arm, Shoulder and Hand (DASH) [16] score, individual subjective evaluation of outcomes and plain X-ray at 12 months. Our study may provide basis for the future selection on PHF patients.

Materials and methods

All procedures were conducted with the approval of the institutional review board of San Salvatore Hospital. An informed consent form was obtained from each patient prior to the study. This was a prospective RCT. A total of 60 patients who were diagnosed with a four-part PHF were enrolled in this study between January 2014 and December 2016.

The fracture was diagnosed from an anteroposterior view, a lateral shoulder view in the scapular plane and computed tomography for fracture classification according to Neer criteria. The mean age in each group was 80 years and the ASA anesthesiological assessment was 3. All the patients were randomized to conservative treatment group or RSA using a computer-generated randomization sequence. The nonoperative group comprised 30 patients and the RSA group had 29.

All patients had a minimum follow-up period of 12 months. The patients had to be able to understand the informed consent process of the study. The inclusion criteria were age ≥ 75 years with a 3- or 4-part displaced PHF with an ASA score of 3. The exclusion criteria were: mental disorders including cognitive impairment, open fracture, pathologic fracture, fracture-dislocation or head-splitting fracture according to Neer [17], neurologic disorder, associated ipsilateral or contralateral upper- or lower-limb fracture, prior surgery on the shoulder, or associated comorbidity contraindicating surgery, as well as patients who were not autonomous prior to the fracture.

In the patients who were allocated to RSA, surgery was performed around 7 days after the trauma by 2 senior shoulder surgeons (F. F., A.D.F.). All patients were operated on under general anaesthesia using also an interscalene block, in the beach-chair position, with a deltopectoral approach. Patients received the SMR Modular Shoulder System (Systema Multiplana Randelli; Lima-LTO, San Daniele del Friuli, Italy). The tuberosities were reattached using 2 horizontal and 2 vertical suture configurations (Ethibond; Johnson & Johnson, New Brunswick, NJ, USA). A cerclage suture was placed circumferentially around the greater tuberosity and through the supraspinatus insertion at the tendon-bone junction, medial to the prosthesis, and through the subscapularis insertion at the tendon-bone junction in cases where the tendon quality allowed it. Prior to suture tying, spaces between the prosthesis, shaft, and tuberosities were packed with cancellous bone graft from the resected humeral head when there was a bone deficit. Next, the lateral portion of the rotator interval was closed with a No. 2 nonabsorbable suture and the arm in 30° of external rotation. Postoperatively, the arm was immobilised in a sling for 3 weeks, allowing elbow, wrist, hand and pendulum shoulder movements from the first day after surgery. From the second week, passive assisted Codman movements with neutral rotation and less than 90° of anteversion were allowed. Active range of motion (ROM) started at 6 weeks and gradually progressed until counter resistance was felt after 12 weeks to strengthen the musculature. Patients randomised to conservative treatment were immobilised in a sling until the second week after their fracture before starting the same rehabilitation program as the patients treated surgically. The patients were reassessed by a different independent physician monthly to assess improvement with physical therapy. When patients had reached the point at which no further improvements were noted between 2 visits, formal physiotherapy in the hospital was discontinued.

Post-operative evaluation

Clinical evaluation. The outcomes of surgery on patients' subjective ratings were recorded as follows: excellent, good, fair and poor. The pain status was assessed based on a visual analogue scale (VAS), which was described as follows: VAS is a 100-mm in length horizontal line, patients who selected the point on VAS line means the point represents the best perception of pain level for one patient. Additionally, functional outcomes were evaluated based on the disability of arm, shoulder and hand (DASH) and Constant-Murley score (CMS).

Radiological evaluation

Post-operative radiographs including standard true anteropos-

terior (AP), axillary and scapular Y views were obtained immediately after operation and at routine follow-up postoperatively at 6 and 12 months. The same radiological checks were performed in the non-surgical group. For the nonoperative treatment, nonunion, malunion, avascular necrosis, and osteoarthrosis were assessed.

Statistical analysis

Continuous variables, shown as the mean ± standard deviation (SD), were compared by Student's t-test to detect the between-group difference. Two-way and three-way analysis of variance (ANOVA) was employed to determine inter- and intra-observer errors, respectively. Qualitative data between groups was compared with the χ^2 test. All of the parameters evaluated were normally distributed. Statistical analysis was performed using SAS Statistical Software 9.1.3. A P value < 0.05 was considered statistically significant.

Results

Clinical characteristics

The mechanism of injury in all patients was fall on the upper extremity. The mean age was 83.5 years for the entire group and 85 years (standard deviation, 4 years) for the nonoperative group *vs* 82 years (standard deviation, 3.4 years) for the RSA group (p = 0.007).

Of all patients, 86.4% were women (86.7% in the conservative treatment group and 86.2% in the RSA group, p = 0.959). Neither lateral nor dominant limb involvement was significantly different between groups. Of the fractures in the nonoperative group, 17% were 3-part fractures and 83% were 4-part fractures, and of the fractures in the RSA group, 13% were 3-part fractures and 87% were 4-part fractures. Therefore, both groups were comparable regarding the epidemiologic results except for age, where the conservative treatment group was an average of 3 years older than the RSA group. All the patents in the two groups underwent anesthesiologic evaluation and categorised as ASA 3. Data are summarized in Table I. The mean follow-up period was 12.3 months.

Patient satisfaction

At 12 months' follow-up, in response to the dichotomous question "Based on the results you have achieved, would you undergo the same treatment again?" all the patients in the in the nonoperative treatment group said yes compared with 87% of those in the RSA group. No significant difference was found between the 2 treatment groups (p = 0.2373).

Radiologic results

The radiographic results are summarised in Table II. Nonanatomic healing or resorption of the tuberosities was not associated with poor Constant and DASH scores. Among the 14 cases of non-anatomic healing or resorption GT, the mean CMS was 74.51 and mean DASH score was 6.9 ($p < 0.5$). The functional results after RSA with anatomic tuberosity healing, RSA, and nonoperative treatment are provided at 3, 6, and 12 months follow-up (Tab. III).

The presence of osteonecrosis was not associated with poor DASH and Constant scores: 28.9 ± 21.8 and 53.6 ± 13.8, respectively, *vs* 28.8 ± 17.1 and 58.7 ± 9.9, respectively, in patients with no osteonecrosis (p = 0.993 and p = 0.285, respectively).

Complications

At 12 month follow-up, in the RSA group, no additional sur-

Table II. Radiologic results.

Outcome at 36 mo follow-up	Non-operative (n = 30), n (%)	RSA (n = 29), n (%)
Osteonecrosis	17 (58.6)	
Malunion	30 (100)	
Nonunion	1 (3.4)	
GT anatomic healing		15 (52)
GT nonanatomic healing or resorption		14 (48)
Scapular notching		0
Lucent lines		0

Table I. General epidemiologic characteristics of nonoperative and RSA groups.

	Non operative	RSA	P value
Patients	29	30	
Age, mean ± SD, yr	85 ± 4	82 ± 3.4	.007*
Sex, male/female	4 (13)/26 (87)	4 (14)/25 (86)	.959
Dominant/nondominant	20 (67)/10 (33)	13 (45)/16 (55)	.091
Fracture type, 3 part/4 part	5 (17)/25 (83)	5 (17)/25 (83)	.7306

RSA: reverse shoulder arthroplasty; SD: standard deviation
Data are presented as number of patients (percentage) unless otherwise indicated

Table III. Clinical results of the total patients enrolled in this study

Variable	3 months	
	Non-operative	RSA
CMS scores (%)	77.91 ± 9.13	72.1 ± 5.21* p < .05
Pain (%)	8.9 ± 10.11	9.7 ± 8.23
ADL (%)	10.13 ± 4.51	8.21 ± 3.2
ROM (%)	19.3 ± 3.11	11.45 ± 5.11* p < .05
Strength (%)	15.8 ± 8.22	14.3 ± 3.14
DASH (%)	9.32 ± 9.11	10.8 ± 8.32
Variable	6 months	
	Non-operative	RSA
CMS scores (%)	76.84 ± 9.27	75.13 ± 6.11
Pain (%)	11.3 ± 10.21	12.3 ± 10.18
ADL (%)	11.33 ± 5.13	8.78 ± 7.12* p < .05
ROM (%)	18.71 ± 4.12	12.56 ± 3.14
Strength (%)	16.7 ± 7.11	14.9 ± 6.13* p < .05
DASH (%)	10.11 ± 7.11	8.97 ± 9.14* p < .05
Variable	12 months	
	Non-operative	RSA
CMS scores (%)	78.21 ± 11.33	76.14 ± 6.18
Pain (%)	11.9 ± 8.82	12.6 ± 9.43
ADL (%)	11.91 ± 3.11	8.34 ± 3.13* p < .05
ROM (%)	20.13 ± 4.15	13.21 ±10.15* p < .05
Strength (%)	16.4 ± 7.23	15.1 ± 9.23
DASH (%)	9.89 ± 8.57	7.32 ± 3.21

% stands for the score in fracture side comparable to that in unaffected side. Two- and three-way analysis of variance (ANOVA) was used to calculate inter- and intra-observer errors respectively. CMS: Constant-Murley score; ADL: activities of daily living; ROM: range of motion; DASH: the Disability of the Arm, Shoulder and Hand

*Statistically significant difference between groups.

gical procedures were performed, and no other complications such as prosthesis dislocation, periprosthetic fracture, acromial stress fracture, or infection were found. However, there were 2 cases of suprascapular nerve injury confirmed by electromyographic study. These 2 cases were patients with poor pain control.

In addition, comparison of the clinical evaluation for the two groups of PHF patients are shown in Table III; patients who received no treatment demonstrated more excellent activities of daily living (ADL) and range of motion (ROM) with time increasing compared with the RSA group ($p < 0.05$). Also, bone strength, CMS scores and DASH for patients in the conservative treatment group were significantly higher than that in RSA group at later follow-up times (around 12 months) ($p < 0.05$). In addition, pain for these patients was significantly lower than that in the RSA group ($p < 0.05$) at 12 months. The mean active joint amplitude for the two groups at 12 months calculated based on the CMS score is shown in Table IV. The results showed that abduction and external rotation with elbow at side for patients in conservative group were significantly different from that in the RSA group ($p < 0.05$). Otherwise, there were no significant differences in anterior elevation and internal rotation in abduction for patients in the two groups.

Discussion

Increasing evidence has demonstrated that the difficulty in treating the elderly displaced four-part PHF is related to poor bone quality, tuberosity fragment comminution and medial strut comminution that are associated with cuff tearing and implant mispositioning, or defective tuberosity reduction or fixation, resulting in controversial outcomes for different treatments [18-21]. Moreover, there is no clear consensus or guidelines on the best treatment for PHFs, specifically in elderly patients. However, despite the lack of scientific evidence [22]. There is a growing trend toward treating these fractures surgically, which has increased since RSA became available [22,23]. Notwithstanding, it must be considered that not all elderly patients can undergo surgery and for this reason there are no scientific studies that link the type of fracture with the general condition of the patient.

In order to try to standardize treatment based on the patient's clinical condition, we use anaesthesiological evaluation, i.e. as discriminant we consider ASA 3: a patient with a severe systemic disease that is not life-threatening. As example, these include patients with some functional limitations as a result of disease (e.g., poorly treated hypertension or diabetes, morbid obesity, chronic renal failure, a bronchospastic disease with intermittent exacerbation, stable angina, implanted pacemaker).

Table IV. Functional results according to the constant-Murley score in the two groups at the 12 months follow-up.

Variable	Non-operative group	RSA group
Abduction	6.8	5.3*
Anterior elevation	7.3	6.7
External rotation with elbow at the side	7.2	5.6*
Internal rotation in abduction	7.6	7

*Statistically significant difference between the two groups.

When we performed a literature review of the results of RSA or conservative treatment in elderly patients, we realised that the main problem was the definition of "elderly patient". Although there are authors who regard patients aged 65 years as elderly, there are others who only include patients older than 80 years [23,24]. Although the concept of the elderly patient is very broad and does not encompass age alone but also implies associated comorbidities, we need to define what we consider "elderly" to be able to compare the results, given that the demands of life, life expectancy, and improved perceived quality of life after interventions are very different for a patient aged 65 years vs. a patient aged 80 years [24].

No studies have directly prospectively compared nonoperative management with RSA for the treatment of 3 and 4 part PHFs in elderly patients in accordance with general health conditions, and for this reason ASA evaluation is an excellent parameter to understand if the patient with ASA 3 has valid results with surgical treatment or if the surgical risk does not justify the treatment itself. The present study is the first RCT to assess the treatment of 3 or 4 part PHFs in geriatric patients with ASA 3. Chivot et al. recently published a multicentre retrospective comparative study between RSA and nonoperative treatment in patients older than 70 years. They found no significant differences in the mean scores for the short version of the DASH (QuickDASH), activities of daily living, or VAS for pain in either group at last assessment, and found a relatively small clinical difference in the Constant score (56.5 points *vs* 50.5 points, p = 0.03) for surgical vs. conservative treatment, respectively [25]. They concluded that RSA should be proposed only to patients with significant functional demands. Our study suggests that there are no benefits of RSA over nonoperative treatment for 3- and 4-part PHFs in elderly patients in terms of functional outcomes.

Surgical treatment of PHFs gives a relatively wide range of results depending on the population selected and the treatment applied. This study analysed a homogeneous population, not only in fracture type and age but also in associated comorbidities measured using ASA valuation. This index, apart from enabling us to quantify the comorbidities of patients, informs us on the life expectancy of the study population.

The follow- up period in this study was 1 year, a period that could be criticised as being too short to provide reliable results. However, as mentioned earlier, in light of the ASA valuation for this elderly population and patient survival, it is a priority to determine their functional situation and short-term quality of life rather than long-term complications such as implant loosening or scapular notching. This is why we consider 12 months follow-up sufficient for this objective for this particular population. Regarding the clinical situation, various studies have highlighted that for fractures treated conservatively or treated with RSA, there is not usually any functional improvement at 1 year following the fracture [23,26], and long-term complications related to nonoperative treatment, such as osteonecrosis, have been indicated as rare and well tolerated by other authors [27,28]. Our main finding in the nonoperative group was that the majority of 4-part fractures, even severely displaced fractures, showed union (97%), although they healed with malpositioning of the humeral head and greater tuberosity, more specifically malunion in 30 cases and nonunion in 1 case.

However, there are some limitations in the current study. First, it was a single-centre study. Second, the number of cases enrolled in our study was relatively small because it was hard to obtain four-part PHF patients. Third, the multi-surgeon design was often an inevitable limitation.

The strength of our study is the prospective randomised design in a well-defined study population in terms of age and fracture, with appropriate procedures to prevent observer bias (blinding) both in the randomisation process and in evaluation of results.

Ethical consideration

This study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Authors' contributions

The Authors contributed equally to the work.

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Conflict of interest

The Authors declare no conflict of interest.

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