HSSJ (2016) 12:287–290
DOI 10.1007/s11420-015-9479-z

HSS Journal®
The Musculoskeletal Journal of Hospital for Special Surgery

Displaced Proximal Humerus Fractures: is a Sling as Good as a Plate?

Michael E. Steinhaus, MD · David M. Dare, MD · Lawrence V. Gulotta, MD

Received: 7 September 2015/Accepted: 20 October 2015/Published online: 20 January 2016

Abstract The treatment of displaced proximal humerus fractures is challenging and complex, as its success is predicated on multiple factors. While it is clear that a majority of proximal humerus fractures may be treated nonoperatively, it is less clear which patients benefit from surgical management. The PROFHER trial, a randomized controlled study, used patient-reported outcomes to compare surgical to nonsurgical management of displaced proximal humerus fractures. The purpose of this review is to highlight the strengths and weaknesses of the PROFHER trial and to assess the validity of its conclusion in the context of existing literature. The authors found no difference in the Oxford Shoulder Score (OSS) between the surgical and nonsurgical groups. Additionally, no difference was found between groups in any of the secondary outcomes, which included the Short-Form 12 (SF-12) health survey, surgical and fracture-related complications, additional surgery or therapy, inpatient medical complications, and mortality. They concluded that the recent increase in surgical management of proximal humerus fractures is perhaps unwarranted. While the randomization was successful and the pragmatic design may enable greater generalizability, this study possesses numerous flaws inherent in such an ambitious endeavor, including an inability to identify specific factors which explain the lack of superiority of surgical management. Despite its weaknesses, this study is a valuable datapoint which encourages surgeons to reexamine their surgical indications for this injury.

Keywords proximal humerus fracture · outcomes

Introduction

In patients over 65 years old, the incidence of proximal humerus fractures in the USA is 250 per 100,000, making it the third most common fracture in the elderly [2]. First classified by Neer [14], proximal humerus fractures most commonly occur as a result of low-energy falls in elderly, osteoporotic women [10]. A majority of proximal humerus fractures in the elderly are stable injuries and are thus amenable to nonsurgical management [14]. Nevertheless, there are many challenges in the treatment of proximal humeral fractures and the variety of fracture patterns makes classification difficult.

Humeral head vascularity, bone quality, fracture pattern, and degree of comminution, in addition to patient-specific variables, such as age and functional status [15], are important factors to consider when evaluating proximal humerus fractures. While Neer's system focuses on the number of fracture parts, the AO-ASIF classification [12] considers the likelihood of disruption to humeral head vascularity, which helps predict the risk of osteonecrosis and influences clinical decision-making [15].

Nonsurgical management with sling immobilization followed by early range of motion is typically recommended for patients with non- or minimally displaced fractures, in addition to valgus-impacted and some displaced two-part fractures. Generally, however, surgical treatment should be considered in head-to-shaft displacement of greater than 50% of the diaphyseal diameter and in varus or valgus deviation of greater than 20° from the normal 130° head-to-shaft angle [3, 13].

A recent Cochrane review of 23 small, randomized trials examined the evidence supporting various treatments for

Work performed at Hospital for Special Surgery, New York, NY.

Electronic supplementary material The online version of this article (doi:10.1007/s11420-015-9479-z) contains supplementary material, which is available to authorized users.

M. E. Steinhaus, MD (✉) · D. M. Dare, MD · L. V. Gulotta, MD
Department of Orthopaedic Surgery,
Hospital for Special Surgery,
New York, NY, USA
e-mail: steinhausm@hss.edu

M. E. Steinhaus, MD · D. M. Dare, MD · L. V. Gulotta, MD
Hospital for Special Surgery,
535 East 70th Street,
New York, NY 10021, USA

proximal humerus fractures. The authors concluded that there was insufficient evidence to inform the management of these fractures [8]. There are major challenges in analyzing this data. There is substantial variation in definitive treatment practices (i.e., ORIF vs. hemiarthroplasty vs. reverse total shoulder arthroplasty) [7] and the criteria for selecting patients for surgery is often subjective [8]. Although no clear consensus exists regarding the treatment of these fractures, operative management increased by 25% from 1999 to 2005, while the incidence of fractures remained unchanged. Correspondingly, the rate of revision surgical procedures showed a proportional increase [2].

The article by Rangan et al. discussed here reports up to 2 years of follow-up on a cohort randomized to surgical or nonsurgical management for displaced fractures of the proximal humerus involving the surgical neck. In this randomized trial of 231 patients with displaced fractures of the proximal humerus, the investigators' primary research question was the following: What are the differences in patient-reported outcomes between the surgical and nonsurgical groups? The authors also sought to examine the differences in complication rates, subsequent therapy, and mortality. The purpose of this review is to identify the strengths and weaknesses of the PROFHER trial, to interpret its outcomes in the context of existing literature, and to evaluate the validity of its conclusions.

The Article

Surgical vs. Nonsurgical Treatment of Adults with Displaced Fractures of the Proximal Humerus: The PROFHER Randomized Clinical Trial

Amar Rangan, Helen Handoll, Stephen Brealey, Laura Jefferson, Ada Keding, Belen Corbacho Martin, Lorna Goodchild, Ling-Hsiang Chuang, Catherine Hewitt, David Torgerson, for the PROFHER Trial Collaborators. (JAMA 2015;313:1037–47. March 10).

This randomized, multi-center, superiority study compared surgical to nonsurgical treatment of displaced proximal humerus fractures in 231 adults. Eligible patients were aged 16 years or older, presented within 3 weeks of sustaining the fracture, and possessed a degree of displacement sufficient for the treating surgeon to consider surgical intervention. Patients with shoulder dislocation, open fracture, difficulty understanding the trial or post-operative instructions, comorbidities precluding surgery or anesthesia, a clear indication for surgery, multiple injuries, a non-osteoporotic pathological fracture, terminal illness, or residence outside the catchment area were excluded. A computer program was used for randomization with 1:1 allocation and block sizes of 4, 8, and 12, with patients stratified by tuberosity involvement. Those allocated to surgery received either internal fixation (i.e., with plate and screws) or hemiarthroplasty, while nonsurgical patients underwent sling immobilization. All patients underwent a standardized physiotherapy regimen.

The 250 enrolled patients had a mean age of 66 years, 92 were female, and 249 were white. Of the 125 patients in the surgical group, 16 were ultimately treated nonsurgically. Of the 125 patients in the nonsurgical group, 2 underwent surgery shortly after allocation. Patient questionnaires were administered at 6, 12, and 24 months. The primary outcome measure was the Oxford Shoulder Score (OSS). Secondary outcomes included the Short-Form 12 (SF-12) health survey, surgical and fracture-related complications, subsequent surgery or therapy, inpatient medical complications, and mortality. Ultimately, 231 patients were included in the primary analysis—114 patients in the surgical group and 117 in the nonsurgical group.

The authors found no statistically significant differences between the two treatment groups at 2 years or at any individual time point for the OSS. Additionally, there was no statistically significant difference in OSS between groups when stratified by age (<65 vs. ≥ 65) or fracture type. Furthermore, no statistically significant differences were found between surgical and nonsurgical treatment for any of the secondary outcome measures.

The authors concluded that there was no significant difference between surgical and nonsurgical treatment of displaced proximal humerus fractures involving the surgical neck, as measured by patient-reported outcomes over 2 years.

Commentary

The PROFHER trial suggests that the trend toward surgical management of displaced proximal humerus fractures is not warranted. This is a valuable addition to the literature which aims to guide the treatment of this complex and multifactorial problem.

This study has numerous strengths. First, it attempts to answer a question of substantial clinical relevance with a randomized clinical trial. Randomization was successful, as evidenced by well-balanced baseline characteristics, and although there was crossover between groups, the analytics were sound. The investigators performed an intention-to-treat analysis and controlled for potentially confounding variables such as age, sex, tuberosity involvement, baseline health status, smoking, clustering by center, and patient treatment preference. Patients in both groups had similar physiotherapy use, and follow-up was excellent, with the vast majority of patients having ≥ 1 follow-up available for analysis. As a *pragmatic* randomized controlled trial, this study aimed to test the effectiveness of an intervention in a broad routine clinical practice, which may make the results more generalizable.

There are also several important limitations of this study. While pragmatic trials may produce more generalizable results, the heterogeneity of the study design may have obscured the outcomes. The 109 patients allocated to surgery underwent procedures by 66 surgeons at 30 different centers, which raises a concern about consistency in treatment. Geographic variation in operative treatment and surgical expertise in fractures of elderly patients has been established [20]. With a median 3 patients treated at each center, it is likely that experience and surgical technique were quite varied. In fact, nearly 10% of the surgeries were performed by senior residents who are, if not less skilled, certainly less experienced. Gardner et al. [6] and Hardeman et al. [9] both showed that an anatomic reduction

with restoration of the medial calcar resulted in superior outcomes. The quality of the reduction and fixation is not reported in this study. Additionally, several factors including fracture type and impact on vascularity are known to influence outcomes and management strategies but were not accounted for in this study's analysis. For example, Hardeman et al. found that increased displacement, type C (AO/OTA) fractures, varus fractures, and fractures with compromised humeral head vascularity were associated with inferior outcomes [9]. Similarly, the authors notably excluded patients with a "clear indication for surgery." Although they are right to focus on patients for which the optimal treatment strategy is equivocal, this determination is ill-defined and subjective and could be biasing their results in favor of nonoperative management.

While the majority (82.6%) of surgeries involved locking plates, the remaining patients received hemiarthroplasty, intramedullary nails, or "other surgery." The inclusion of ORIF by varying technique and hemiarthroplasty in a single group further confounds the data. Solberg et al. retrospectively compared ORIF with hemiarthroplasty in the treatment of three- and four-part proximal humerus fractures [19]. After 3 years, patients who received ORIF had significantly higher outcome scores. Within the hemiarthroplasty group, the patients with healed tuberosities performed better than those with tuberosity non-union. ORIF by locked plating compared to intramedullary nailing or hemiarthroplasty is associated with disparate outcomes, and including patients with different procedures confounds data when analyzed as a single group. In addition, reverse shoulder arthroplasty, an increasingly common arthroplasty treatment for proximal humerus fractures, was not included.

Furthermore, it is unclear if the OSS is a valid instrument for assessing the outcomes of proximal humerus fractures. The questionnaire was designed for patients undergoing elective surgery for degenerative or inflammatory conditions and specifically did not include patients with fractures [4]. Although a study by Baker et al. found a strong correlation between the OSS and Constant Scores in patients treated nonsurgically for non- or minimally displaced proximal humerus fractures, the authors highlight that subjective scoring systems, such as the OSS, are limited in traumatic injuries, in which patient perception of his/her problem is particularly influential [1]. The tight clustering reported by Rangan et al. (SD, 0.89 and 0.88 for the surgery and nonsurgery groups, respectively) contrasts with the wider spread (SD, 12.7) found by Baker et al., further suggesting that the OSS may not be a valid measure in this trial [1].

In general, it is accepted that the majority of proximal humerus fractures are best treated nonoperatively, but indications for operative treatment are less clear, with recent studies of more complex fracture patterns showing mixed results [11]. In a retrospective study of displaced greater tuberosity fractures, Platzer et al. reported that patients who underwent reduction (open or closed) and internal fixation had significantly better functional results than the nonoperative group [18]. Three recent randomized trials compared surgical with nonsurgical treatment [5, 16, 17]. Olerud et al. compared ORIF with sling immobilization in 60 patients with displaced three-part surgical neck fractures and found a trend toward improvements in function and health-related quality of life in the surgical group at 2 years [17]. In a separate study of 55 patients with four-part fractures undergoing hemiarthroplasty or sling immobilization, Olerud et al. showed a significant improvement in quality of life, in addition to improvements in function and pain at 2 years, in the hemiarthroplasty group [16]. Both of these studies reported no differences in range of motion. In contrast, Fjalestad et al. randomized 50 patients with three- or four-part fractures to ORIF or immobilization/closed reduction and demonstrated no difference in functional outcomes [5]. Reflecting the equivocal results published in prior literature, a recent Cochrane review of 23 small, randomized trials found insufficient evidence to recommend surgical or nonoperative management of displaced proximal humerus fractures [8].

In line with prior literature, this trial suggests that surgery is not necessarily superior to nonsurgical treatment in displaced proximal humerus fractures. As a pragmatic randomized controlled trial, the PROFHER trial attempts to inform on the overall performance of this treatment but is unable to identify the specific components or factors that explain the absence of superiority compared to nonsurgical treatment. The surgical treatment of these fractures is technically demanding and depends on surgeon experience and skill, which perhaps explains why this trial that included surgeons at various stages of training found the intervention to lack superiority to no intervention at all.

Despite some weaknesses, this study is a valuable contribution to the literature. Evidence comparing operative and nonoperative management of proximal humerus fractures is varied and when considered collectively neither intervention has been shown to be superior. In their study subjects, the PROFHER trial demonstrates the non-superiority of surgical management and provides an additional datapoint in this ongoing debate. Given the equivocal data surrounding treatment of this injury and the deficiency in our knowledge about which factors most influence future outcomes, surgeons should be particularly thoughtful and deliberate when making treatment decisions in this group.

Compliance with Ethical Standards

Conflict of Interest: Michael E. Steinhaus, MD and David M. Dare, MD have declared that they have no conflict of interest. Lawrence V. Gulotta, MD reports consulting and speaking fees from Biomet, Inc., outside the work.

Human/Animal Rights: This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed Consent: N/A

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

References

1. Baker P, Nanda R, Goodchild L, Finn P, Rangan A. A comparison of the Constant and Oxford shoulder scores in patients with conservatively treated proximal humeral fractures. *J Shoulder Elbow Surg*. 2008; 17(1): 37-41.

2. Bell JE, Leung BC, Spratt KF, et al. Trends and variation in incidence, surgical treatment, and repeat surgery of proximal humeral fractures in the elderly. *J Bone Joint Surg Am*. 2011; 93(2): 121-131.
3. Court-Brown CM, Cattermole H, McQueen MM. Impacted valgus fractures (B1.1) of the proximal humerus. The results of non-operative treatment. *J Bone Joint Surg Br*. 2002; 84(4): 504-508.
4. Dawson J, Fitzpatrick R, Carr A. Questionnaire on the perceptions of patients about shoulder surgery. *J Bone Joint Surg Br*. 1996; 78(4): 593-600.
5. Fjalestad T, Hole MO, Hovden IA, Blucher J, Stromsoe K. Surgical treatment with an angular stable plate for complex displaced proximal humeral fractures in elderly patients: a randomized controlled trial. *J Orthop Trauma*. 2012; 26(2): 98-106.
6. Gardner MJ, Boraiah S, Helfet DL, Lorich DG. Indirect medial reduction and strut support of proximal humerus fractures using an endosteal implant. *J Orthop Trauma*. 2008; 22(3): 195-200.
7. Guy P, Slobogean GP, McCormack RG. Treatment preferences for displaced three- and four-part proximal humerus fractures. *J Orthop Trauma*. 2010; 24(4): 250-254.
8. Handoll HH, Ollivere BJ, Rollins KE. Interventions for treating proximal humeral fractures in adults. *Cochrane Database Syst Rev*. 2012;12:Cd000434.
9. Hardeman F, Bollars P, Donnelly M, Bellemans J, Nijs S. Predictive factors for functional outcome and failure in angular stable osteosynthesis of the proximal humerus. *Injury*. 2012; 43(2): 153-158.
10. Lee SH, Dargent-Molina P, Breart G. Risk factors for fractures of the proximal humerus: results from the EPIDOS prospective study. *J Bone Miner Res*. 2002; 17(5): 817-825.
11. Maier D, Jaeger M, Izadpanah K, Strohm PC, Suedkamp NP. Proximal humeral fracture treatment in adults. *J Bone Joint Surg Am*. 2014; 96(3): 251-261.
12. Muller M. Appendix A: The comprehensive classification of fractures of long bones. In: Müller MEAM, Schneider R, Willenegger H, eds. *Manual of Internal Fixation: Techniques Recommended by the AO-ASIF Group*. Berlin, Germany: Springer; 1991: 118-125.
13. Murray IR, Amin AK, White TO, Robinson CM. Proximal humeral fractures: current concepts in classification, treatment and outcomes. *J Bone Joint Surg Br*. 2011; 93(1): 1-11.
14. Neer CS 2nd. Displaced proximal humeral fractures. I. Classification and evaluation. *J Bone Joint Surg Am*. 1970; 52(6): 1077-1089.
15. Nho SJ, Brophy RH, Barker JU, Cornell CN, MacGillivray JD. Innovations in the management of displaced proximal humerus fractures. *J Am Acad Orthop Surg*. 2007; 15(1): 12-26.
16. Olerud P, Ahrengart L, Ponzer S, Saving J, Tidermark J. Hemiarthroplasty versus nonoperative treatment of displaced 4-part proximal humeral fractures in elderly patients: a randomized controlled trial. *J Shoulder Elbow Surg*. 2011; 20(7): 1025-1033.
17. Olerud P, Ahrengart L, Ponzer S, Saving J, Tidermark J. Internal fixation versus nonoperative treatment of displaced 3-part proximal humeral fractures in elderly patients: a randomized controlled trial. *J Shoulder Elbow Surg*. 2011; 20(5): 747-755.
18. Platzer P, Thalhammer G, Oberleitner G, et al. Displaced fractures of the greater tuberosity: a comparison of operative and nonoperative treatment. *J Trauma*. 2008; 65(4): 843-848.
19. Solberg BD, Moon CN, Franco DP, Paiement GD. Surgical treatment of three and four-part proximal humeral fractures. *J Bone Joint Surg Am*. 2009; 91(7): 1689-1697.
20. Sporer SM, Weinstein JN, Koval KJ. The geographic incidence and treatment variation of common fractures of elderly patients. *J Am Acad Orthop Surg*. 2006; 14(4): 246-255.