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Use of both short musculoskeletal function assessment questionnaire and short form-36 among tibial-fracture patients was redundant

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Abstract

Objective: To compare the Short Musculoskeletal Function Assessment Dysfunction Index (SMFA DI) and the Short Form-36 Physical Component Summary (SF-36 PCS) scores among patients undergoing operative management of tibial fractures.

Study Design and Setting: Between July 2000 and September 2005, we enrolled 1,319 skeletally mature patients with open or closed fractures of the tibial shaft that were managed with intramedullary nailing. Patients were asked to complete the SMFA Questionnaire and SF-36 at discharge and 3, 6, and 12 months post−surgical fixation.

Results: The SMFA DI and SF-36 PCS scores were highly correlated at 3, 6, and 12 months post−surgical fixation. The difference in the mean standardized change scores for SMFA DI and SF-36 PCS, from 3 to 12 months post−surgical fixation, was not statistically significant. Both the SMFA DI and SF-36 PCS scores were able to discriminate between healed and nonhealed tibial fractures at 3, 6, and 12 months postsurgery.

Conclusion: In patients with tibial-shaft fractures, the SMFA DI offered no significant advantages over the SF-36 PCS score. These results, along with the usefulness of SF-36 for comparing populations, recommend the SF-36 for assessing physical function in studies of patients with tibial fractures.

Keywords: Tibia; Fracture; Quality of life; Randomized controlled trial; Short Form-36; Short Musculoskeletal Function Assessment Questionnaire

1. Introduction

The Short Musculoskeletal Function Assessment (SMFA), based on the longer, 101-item Musculoskeletal Function Assessment Questionnaire, is a two-part, 46-item, self-reported health-status questionnaire [1]. One part, the Dysfunction Index (DI), is designed to detect differences in the functional status of patients who have a broad range of musculoskeletal disorders that are commonly seen in community practices. The second part, the Bothersome Index, allows patients to evaluate how bothered they are by functional problems. Both SMFA indexes are scored from 0 to 100, and higher scores indicate poorer function.

The Short Form-36 (SF-36) is a widely accepted, well-validated functional-status measure that was developed from the Medical Outcomes Study [2−4]. It is a self-administered, 36-item questionnaire that measures health-related quality of life in eight domains that can be aggregated into a physical and a mental summary score. Each summary score is scored

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What is new?

- The Short Musculoskeletal Function Assessment Dysfunction Index (SMFA DI) and the Short Form-36 Physical Component Summary (SF-36 PCS) scores were highly correlated among tibial-fracture patients.
- Both the SMFA DI and the SF-36 PCS scores were able to discriminate between radiographically healed and nonhealed tibial fractures.
- Orthopedic trialists often report functional recovery with both the SMFA DI and the SF-36 PCS scores.
- In patients with tibial-shaft fractures, SMFA DI offered no important advantages over the SF-36 PCS score.
- Given its more extensive validation and ability to compare with other populations, SF-36 should be the instrument of choice to assess functional recovery in tibial-fracture patients.

separately from 0 to 100, and lower scores indicate poorer function.

Evidence suggests that, in general, disease-specific instruments (such as SMFA) are able to detect small but important change—that is, they are more responsive—than are generic measures [5]. Generic measures (such as SF-36) facilitate comparisons with other populations. These considerations provide the rationale for the common use of both SMFA and SF-36 in current orthopedic trials [6,7]. Use of both instruments, however, increases the burden on both patients and researchers, and may, therefore, adversely impact on trial feasibility. This study was designed to assess what is gained by adding SMFA to SF-36 in clinical trials of patients with tibial fractures.

2. Materials and methods

From July 2000 to September 2005, we enrolled 1,319 patients with open (Gustilo types I–IIIB) and closed (Tscherne types 0–3) tibial-shaft fractures amenable to operative fixation with an intramedullary nail in a multicenter, randomized controlled trial, the eponym for which is SPRINT (Study to Prospectively evaluate Reamed Intramedullary Nails in Tibial fractures). Each institution's ethics review board approved the study, which was registered at *Clinicaltrial.gov* (identifier: NCT00038129); readers can obtain details of the study design elsewhere [8].

At discharge from hospital, patients rated their preinjury status using SMFA and SF-36. We have previously shown that patients undergoing lower-limb orthopedic surgery recall their preoperative quality of life, function, and general health at 2 weeks postsurgery with sufficiently high accuracy to warrant substituting prospectively collected baseline data with recalled ratings [9]. Patients completed the SMFA and SF-36 again at 3, 6, and 12 months postsurgery. Patients completed all questionnaires under the supervision of personnel trained to facilitate instrument completion without influencing responses. The role of supervising personnel was limited to reviewing respondents' questionnaires after completion to confirm that each item was answered, to draw attention to any contradictory responses, and to provide respondents with the opportunity to make changes if they saw fit. The attending surgeons of the patients assessed fracture healing at each follow-up time on the basis of lateral and anterioposterior radiographs of patients' fractures.

2.1. Statistical analysis

Our analyses, at each time point, were restricted to only those patients who provided completed SMFA and SF-36 questionnaires. When follow-up time differed from that specified in the protocol, we used follow-up to the scheduled time point closest to the actual follow-up. If two actual follow-up times were nearest to a single scheduled time point, we used data from the actual follow-up closest to the scheduled time. We evaluated differences in patient characteristics between time points with a *t*-test for normally distributed data and a chi-square test for proportional data; we set our level of statistical significance at $P < 0.05$. At each time point, we calculated the Pearson correlation coefficient and associated 95% confidence interval (CI) between the SMFA DI and SF-36 Physical Component Summary (PCS) scores for all respondents. We explored the ability of the SMFA DI and SF-36 PCS scores to discriminate between patients who had, or had not, healed radiographically at each follow-up point with a paired *t*-test.

We calculated instrument responsiveness through a standardized response mean (SRM)—the mean score change divided by the standard deviation (SD) of the score change [10]. We compared the difference in standardized change scores for SMFA DI and SF-36 PCS from 3 to 12 months with a paired *t*-test. We also tested whether the differences in SRMs between SF-36 PCS and SMFA DI were significant using the modified jack knife procedure [11,12]. In this analysis, each patient's SRM was calculated as his or her individual change in score divided by the SD of change in the whole cohort. We centered the SRM value for each instrument by subtracting the mean SRM score from each individual SRM score. Using linear regression, we predicted the differences in SRMs between two different scales by including the centered SRM value of one of the two instruments of interest as a predictor in the model; the dependent variable assures that the choice of either of the instruments as a predictor will yield the same intercept. A