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Randomized controlled trial of surgical rib fixation to non-operative management in severe chest wall injury

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Abstract

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OBJECTIVE: Compare the effectiveness of surgical stabilization of rib fractures (SSRF) to non-operative management in severe chest wall injury

SUMMARY BACKGROUND DATA: SSRF has been shown to improve outcomes in patients with clinical flail chest and respiratory failure. However, the effect of SSRF outcomes in severe chest wall injuries without clinical flail chest is unknown.

METHODS: Randomized controlled trial comparing SSRF to non-operative management in severe chest wall injury, defined as: 1) a radiographic flail segment without clinical flail, or 2) ≥5 consecutive rib fractures, or 3) any rib fracture with bicortical displacement. Randomization was stratified by unit of admission as a proxy for injury severity. Primary outcome was hospital length of stay (LOS). Secondary outcomes included intensive care unit (ICU) LOS, ventilator days, opioid exposure, mortality, and the incidences of pneumonia and tracheostomy. Quality of life (QoL) at 1, 3, and 6 months was measured using the EQ-5D-5L survey.

RESULTS: 84 patients were randomized in an intention-to-treat analysis (Usual Care=42, SSRF=42). Baseline characteristics were similar between groups. The numbers of total fractures, displaced fractures, and segmental fractures per patient were also similar, as were the incidences of displaced fractures and radiographic flail segments. Hospital LOS was greater in the SSRF group. ICU LOS and ventilator days were similar. After adjusting for the stratification variable, hospital LOS remained greater in the SSRF group (RR 1.48, 95%CI 1.17–1.88). ICU LOS (RR 1.65, 95%CI 0.94–2.92) and ventilator days (RR 1.49, 95%CI 0.61–3.69) remained similar. Subgroup analysis showed that patients with displaced fractures were more likely to have LOS outcomes similar to their Usual Care counterparts. At 1 month, SSRF patients had greater impairment in the Mobility (3 [2–3] vs 2 [1–2], p=0.012) and Self Care (2 [1–2] vs 2 [2–3], p=0.034) dimensions of the EQ-5D-5L.

CONCLUSION: In severe chest wall injury, even in the absence of clinical flail chest, the majority of patients still reported moderate to extreme pain and impairment of usual physical activity at one month. SSRF increased hospital LOS and did not provide any QoL benefit up to 6 months.

Abstract

This randomized controlled trial showed that patients with a severe chest wall injury (not including flail chest) who underwent surgical rib fixation (SSRF) had greater hospital length of stay than their non-operative counterparts. Quality of life measured by the EQ-5D-5L was also worse at 1-month follow-up for SSRF patients.

Keywords

rib fractures; rib fixation; SSRF; thoracic trauma

INTRODUCTION

Approximately 350,000 people suffer rib fractures in the United States each year, with more than one-third requiring hospitalization.[1,2] Fractured ribs may result in respiratory failure, prolonged mechanical ventilation, post-traumatic pneumonia, long-term disability, and death. Morbidity and mortality increase with each fractured rib, and an inflection point

is seen at six or more rib fractures.[3] Care of these injuries typically consists of breathing exercises and pain control, often including opioid pain medications. However, despite usual care, patients with rib fractures are more physically disabled at 30 days post-injury than a reference group of chronically ill medical patients, and they lose an average of 70 days of work or normal physical activity.[4]

Surgical stabilization of rib fractures (SSRF) is an adjunct to usual care that has been postulated to improve pain and decrease the incidences of respiratory failure, tracheostomy, pneumonia, and death. SSRF has been shown to improve outcomes in patients with clinical flail chest (three or more segmental rib fractures plus paradoxical chest wall motion) plus respiratory failure requiring mechanical ventilation in four small randomized controlled trials.[5,6,7,8] A fifth trial, which enrolled patients both with and without respiratory failure who had either a clinical flail chest injury or unstable displaced rib fractures and severe chest wall deformity, also showed a modest benefit to SSRF in the subgroup of patients with respiratory failure.[9]

Thanks to improved outcomes in this rather narrow subset of patients with chest wall injury, as well as the recent proliferation of commercially available rib-specific fixation systems, the use of SSRF has increased substantially over the last twenty years.[10] Importantly, application of the procedure has also expanded to include patients with chest wall injuries that do not include flail chest and respiratory failure, despite a lack of data to support the expanded indication. In fact, the role of SSRF in patients with a severe chest wall injury that does not include clinical flail chest and respiratory failure remains unknown. A recent practice management guideline from the Eastern Association for the Surgery of Trauma found insufficient evidence either for or against SSRF in such patients to offer any recommendation.[11] Additionally, few studies of SSRF include patient-reported outcomes, especially following hospital discharge. Accordingly, long-term health status following a severe chest wall injury remains ill-defined.

To address this gap in knowledge, we conducted a single center randomized controlled trial of SSRF compared to usual care in rib fracture patients without a clinical flail chest injury. The study included both inpatient clinical metrics and patient-reported outcomes at 1, 3, and 6 months. We hypothesized that SSRF would improve hospital length of stay.

METHODS

This study was a single center, pragmatic, randomized controlled trial comparing usual care alone to usual care plus SSRF. The protocol was registered with the National Library of Medicine on September 9, 2019 and assigned identifier number NCT04081233. After approval by the university and hospital institutional review boards, study enrollment began on February 18, 2020 and concluded on June 30, 2022. Enrollment was suspended between March 16, 2020 and May 18, 2020 due to the emergence of the SARS CoV-2 (COVID-19) pandemic. Long-term outcomes were collected through December 31, 2022. Originally budgeted to enroll over 24 months, the primary funding mechanism was extended to allow for an additional 6 months of enrollment. However, due to a combination of research shutdowns related to the pandemic and hospital internal disasters,

the exclusion of patients with active COVID infection, and overall low enrollment rates, target enrollment was not achieved during the funding period. Because additional funding mechanisms could not be identified and because nearly 100% of the funding was used to support the research personnel, the authors made the difficult but pragmatic decision to conclude the study. In order to enhance the quality, readability, and value of the prepared manuscript, the CONSORT checklist for parallel group randomized trials published by the Equator network (https://www.equator-network.org/reporting-guidelines/consort/) was utilized.[12] The completed checklist is available as Supplemental Digital Content. The datasets generated during the present study are not publicly available, but are available from the corresponding author on reasonable request.

Study Population

All adult trauma patients (age 16 years or older) who were admitted to the study institution with a severe chest wall injury sustained secondary to a blunt trauma mechanism were screened for eligibility for the trial. Severe chest wall injury was defined as: 1) the presence of a radiographic flail segment (fractures of three or more consecutive ribs where each rib has at least two fracture lines) seen on cross-sectional imaging, or 2) five or more consecutive rib fractures, or 3) any single rib fracture with bicortical displacement. While not necessarily pathologically equivalent, these criteria have been previously identified in observational studies to be associated with worse clinical outcomes, and they present discrete targets for surgical stabilization.[3,13,14,15] In addition to a severe chest wall injury, at least one of the true ribs (rib numbers 1–7) had to be accessible for surgical stabilization. Patients were excluded from the study if they were younger than 16 years, had a clinical flail chest injury (radiographic flail segment plus paradoxical chest wall motion), severe traumatic brain injury (defined as a best resuscitated GCS ≤ 8 as measured at 24h), spinal cord injury, pre-existing congestive heart failure or oxygen-dependent pulmonary disease, lacked equipoise for enrollment (either because they had a severe deformity of the chest wall or were asymptomatic from their injury), or were so severely injured that they were not expected to be able to undergo surgical rib fixation. Finally, the COVID-19 pandemic emerged shortly after study enrollment began. Because of the novel nature of the virus and the potential risk of surgery to COVID-19 patients, especially in the first year of the pandemic, active COVID infection also became an exclusion criterion.

Treatment Groups

Eligible patients who agreed to participate were randomized into either the control arm or the intervention arm. Patients in the control arm received usual care according to the study institution's established protocol for the management of chest wall injury (https://med.uth.edu/surgery/management-of-multiple-rib-fractures/). This protocol consists of pulmonary toilet with incentive spirometry, lung volume expansion exercises using positive expiratory pressure assisted by a respiratory therapist, and a pill-based multimodal approach to pain management. This multimodal pain medication regimen, which utilizes acetaminophen, a non-steroidal anti-inflammatory, a gamma-aminobutyric acid (GABA) analog, and lidocaine transdermal patches as the first line medications for pain management, has been previously validated in the trauma population to be cost-effective and to decrease opioid exposure.[16,17] Oral opioids such as tramadol and oxycodone were only provided for

breakthrough pain as needed. For severe pain not responding to oral therapy, intravenous infusions of lidocaine or ketamine were added at the discretion of the treating physician. Regional analgesia techniques such as epidural analgesia, myofascial plane blockade, and intercostal nerve blockade were also considered. The pain medication regimen was deescalated as pulmonary status and pain control allowed. Patients in the intervention arm received the same treatments as the control arm plus surgical stabilization of their fractured ribs. Since stabilization of all fractures is not always possible due to anatomic constraints or the locations of specific fractures, the surgeon was required to stabilize at least one true rib (due to their greater contribution to chest wall volume and mechanical respiratory function). In order to maintain a pragmatic approach, surgical stabilization was performed using any commercially available rib fixation system at the discretion of the operating surgeon. Likewise, surgical technique was not explicitly specified, other than to minimize the size and number of incisions and to use muscle-sparing techniques whenever possible. The use of regional analgesia at the time of SSRF was not permitted, since routine use of regional analgesia in one treatment group might systematically bias the primary and secondary outcomes. Patients in the control arm who had refractory respiratory failure or refractory chest wall pain were permitted to cross over to the intervention arm and receive surgical stabilization after agreement between the treating physician and the primary investigator.

Screening, Randomization, and Blinding

Screening was conducted at presentation to the hospital. Randomization occurred after obtaining informed consent from the patient or a legally authorized representative. Patients were randomized with a 1:1 allocation ratio using permuted blocks of 4 or 6 to ensure an equal number of patients in each group. Study data were collected and managed using Research Electronic Data Capture (REDCap) tools hosted at the study institution. REDCap is a secure, web-based software platform designed to support data capture for research studies by providing an interface for validated data capture, audit trails for tracking data manipulation and export procedures, automated export procedures to common statistical packages, and procedures for data integration and interoperability with external sources.[18,19] Randomization was performed using the REDCap randomization module and stratified by unit of admission as a proxy for injury severity. If randomized to SSRF, the procedure was performed as early as possible after admission, given competing/concomitant injuries and the need for more critical surgical procedures. Given the nature of the intervention, the patients and treating physicians were not blinded to the allocation group.

Primary and Secondary Outcomes

The primary outcome was hospital length of stay (LOS) in days. This outcome was selected because it is clinically meaningful and because prior observational studies have shown an association between SSRF and decreased LOS in rib fracture patients without clinical flail chest.[14] Additionally, the use of a continuous outcome allowed for greater statistical power at smaller sample sizes. LOS estimates were abstracted from a retrospective cohort study of patients with a similar pattern of chest wall injury for use in the sample size calculation.[19] Assuming a median LOS of 10 days (IQR 6–15) in the control group and two-sided alpha of 0.05, a sample size of 150 patients (75 per group) was calculated to provide 85% power to detect a difference of 3 days (*i.e.*, a median LOS of 7 days in intervention group).

Secondary clinical outcomes included the traditional metrics common to surgical rib fixation studies: mortality, intensive care unit (ICU) LOS, ventilator days, hospital-free days, ICU-free days, ventilator-free days, opioid exposure, and the incidences of respiratory failure requiring mechanical ventilation, tracheostomy, pneumonia, and the need for regional analgesia. Pneumonia was defined as >10,000 cfu/mL cultured bacteria from a bronchioalveolar lavage or the clinical diagnosis of pneumonia with subsequent antibiotic treatment. Hospital-free days were defined as 30 minus the number of hospital days. Patients who died in the hospital were assigned a value of zero. The same method of calculation was used to define ICU-free days and ventilator-free days. Re-intervention rates for surgical complications, including bleeding, seroma, and surgical site infection were also collected.

Long-Term Outcomes

Patients were asked to complete the EQ-5D-5L health status questionnaire at 1, 3, and 6 months after admission. The questionnaire was completed either in person (if the patient was scheduled for a routine clinic visit at those time points) or via telephone. Patients were also asked to report the date they had returned to work, the date they had returned to normal physical activity, and the date their rib fracture pain had resolved. Research team members conducting these questionnaires were blinded to the allocation group. Patients who died were assigned a score of 5 (the most adverse score) for each dimension of the EQ-5D-5L and a 0 for the Visual Analog Score. The EQ-5D-5L Index scores (a summary score based on societal preference weights for the cumulative health states measured by the five different dimensions) were calculated using the 2017 United States time trade-off valuation dataset.[22]

Statistical Analysis

The primary and secondary outcomes were analyzed by intention to treat. Two patient subgroups were defined prior to the start of the trial: those patients with radiographic flail segments and those with bicortically displaced fractures. Tests of interaction were performed on the *a priori* subgroups to evaluate for heterogeneity of treatment effect. All statistical analyses were performed using R© (The R Foundation) and STATA® (version 15.1; StataCorp; College Station, TX) commercially available software.

Frequentist Analysis—Generalized linear models (GLMs) were used to analyze all outcomes and included the treatment group and unit of admission (stratifying variable) as covariates. For LOS outcomes, negative binomial or zero-inflated negative binomial regression models were used. Relative risks or group differences and their 95% confidence intervals were also reported.

Bayesian Analysis—Bayesian statistics were used to detect differences in treatment effects overall and in the *a priori* subgroups. The same generalized linear models used in the Frequentist analysis were used for the Bayesian analysis. For LOS outcomes, neutral priors centered at a relative risk of 1.0 with 95% prior interval of 0.33–3.0 (0.5–2 for binary outcomes) were used for the treatment effects. A normal (0, 10) prior was used for the intercept term. Normal (0, 1) priors were used for all other variables in the model. For all Bayesian analyses, posterior medians and 95% credible intervals were reported for group comparisons and probabilities of benefit or harm from the intervention.

RESULTS

During the enrollment period, 2,603 patients with rib fractures were screened at the study institution. Of these, 473 had a severe chest wall injury that met inclusion criteria for the study, and 84 (18%) were enrolled in the trial. After randomization, 42 patients were assigned to the Usual Care (control) group, and 42 patients were assigned to the SSRF (intervention) group. The flow of patients through the trial is presented in FIGURE 1. A total of four patients crossed over to the alternate treatment group. In the SSRF group, one patient suffered a severe clinical decompensation after randomization and was deemed too critically ill to safely undergo the procedure, and two otherwise stable patients ultimately declined to undergo the SSRF procedure. In the Usual Care group, one patient with refractory chest wall pain and respiratory failure underwent SSRF after agreement between the treating physician and the primary investigator.

All comparisons and statistical analyses were performed based on the intention to treat. Baseline characteristics were similar between treatment groups (TABLE 1). Injuries were primarily sustained due to motor vehicle collisions, motorcycle collisions, and falls. Patients in both groups were severely injured. The median injury severity score (ISS) was 22 (IQR 15–27) in the Usual Care group and 22 (17–32) in the SSRF group, and the median chest abbreviated injury score (AIS) was 3 (3–3) in the Usual Care group and 3 (3–4) in the SSRF group. At admission, patients in both groups were similarly distributed among ward, intermediate care, and intensive care levels of acuity. Chest wall injury patterns and characteristics are summarized in TABLE 2. The numbers of total fractures (7 [IQR 6–10] vs 8 [7–10]), displaced fractures (2 [0–2] vs 1 [0–2]), and segmental fractures (2 [0–4] vs 1 [0–4]) per patient were similar, as were the incidences of displaced fractures (25 [60%] vs 24 [57%]) and radiographic flail segments (17 [40%] vs 15 [36%]). Nearly all patients (39 [93%] vs 40 [95%]) had five or more consecutive fractures, and two-thirds of patients had more than one severe chest wall injury criterion.

Unadjusted hospital outcomes are presented in TABLE 3. The primary outcome, hospital LOS, was greater for the SSRF group from admission to discharge (9.9 [±9.8] days vs 14.5 [±10.7] days; $p = 0.046$) and from randomization to discharge (7.6 [±9.4] vs 12.4 [±10.7] days; $p = 0.035$). After adjusting for the unit of admission (the stratifying variable), hospital LOS from admission to discharge (RR 1.46, 95% CI 1.17–1.83; $p = 0.001$) and from randomization to discharge (RR 1.69, 95% CI 1.27–2.24; $p < 0.001$) remained greater in the SSRF group. By Bayesian analysis, the probability of greater hospital LOS in the SSRF group was 99.9%, and there was a 99.7% probability of an increase of at least 10%. Tests for interaction in the *a priori* subgroups showed that patients with displaced fractures had LOS outcomes that were more similar to their Usual Care counterparts (p value for the interaction = 0.142). This benefit was not observed in patients with radiographic flail segments.

For the secondary clinical outcomes, inpatient opioid exposure was greater in the SSRF group. This difference was driven primarily by opioid exposure in the operating room, though SSRF patients also had a greater opioid exposure outside of the operating room due to their longer lengths of hospital stay. The daily rates of non-anesthesia opioid exposure,

however, were similar, as was the opioid exposure prior to randomization. The proportions of patients discharged with opioid prescriptions were also similar. Most patients were discharged to home, and there were no inpatient mortalities in either group.

Patients randomized to SSRF underwent their rib fixation procedure a median of 67 (IQR 51–88) hours after hospital presentation and 23 (19–46) hours after randomization. A median of 4 (4–5) ribs were stabilized at each procedure. Surgical complications of seroma (1 [2%]) and surgical site infection (1 [2%]) were rare but occurred only in the SSRF group.

At 1 month, SSRF patients had greater impairment in the Mobility (3 [IQR 2–3] vs 2 [1–2]; $p = 0.012$) and Self Care (2 [1–2] vs 2 [2–3]; $p = 0.034$) dimensions of the EQ-5D-5L. Usual Activities, Pain, and Anxiety scores were similar, as were Index and Visual Analog Scores (TABLE 4). The proportions of patients in each treatment group with no impairment or minor impairment (scores of 1–2) are compared to those with moderate, severe, or extreme impairment (scores of 3–5) in FIGURE 2. One patient in the SSRF group died before their 3-month follow-up and was assigned maximum adverse scores for the 3-month and 6-month surveys. Despite this penalty, the differences in the Mobility and Self Care dimensions seen at 1 month were no longer observed at 3 months and 6 months. There were no differences in the proportions of patients who had returned to work or normal physical activity at any of the follow-up surveys. While more than one-third of respondents in each treatment group still had not returned to work or normal physical activity at 6 months, most were limited by issues other than chest wall pain.

DISCUSSION

Contrary to our hypothesis, this single center randomized controlled trial demonstrated that SSRF patients had greater hospital LOS and worse health status at 1 month compared to their Usual Care counterparts. Other inpatient clinical metrics were similar between groups. Differences in health status seen at 1 month were no longer present at the 3- and 6-month follow-ups. Regardless of treatment group, most patients with a severe chest wall injury experienced moderate to severe pain and impairment of usual activity at 1 month, and only half were back to work or normal activity by 3 months.

Interestingly, some or all of the differences observed in hospital LOS may be related to artifact from the trial design. Outside of this randomized controlled trial, SSRF would typically be performed at the study institution on hospital day #1 or #2 for patients with a severe chest wall injury. However, because of the invasive nature of the SSRF intervention and the need for thoughtful informed consent, it took patients an average of two days to agree to participate in the study. Accordingly, SSRF was often not performed until hospital day #3 or #4 for those people who were randomized to the intervention arm. Recovery following surgery typically took another 1–2 days, making discharge unlikely before day 5 or 6. However, randomization to the Usual Care group imposed no additional need for hospitalization outside of meeting pain control, incentive spirometry, and physical therapy goals, potentially making patients eligible for discharge sooner than those in the SSRF group. While every effort was made to decrease the time from presentation to study consent and from consent to SSRF, the study itself may have contributed to the differences observed

in the primary outcome. Importantly, however, SSRF did not *decrease* hospital LOS. With a median effect size of +4.6 days, it is unlikely that hospital LOS would be decreased in the SSRF group even if study consent were obtained immediately after presentation.

Despite any artifact from the informed consent process, the results are congruent with those of two recent studies of severe chest wall injury not including clinical flail chest. The first, a prospective multicenter observational study of 110 patients with three or more displaced (≥50% displacement, not necessarily bicortical) rib fractures, showed no difference in hospital LOS, ICU LOS, inpatient opioid exposure, or overall quality of life at 2-, 4-, or 8-week follow-up.[15] The second, a multicenter randomized controlled trial of 124 patients with three or more consecutive rib fractures without respiratory failure showed no difference in in hospital LOS, ICU LOS, inpatient opioid exposure, or quality of life at 3- or 6-month follow-up.[23]

There are several limitations to the present study. First, the rate of enrollment of eligible patients was lower than anticipated at the outset of the trial (FIGURE 1). Although 8% of eligible patients were well enough to be discharged from the hospital prior to screening despite their severe chest wall injury, this loss was anticipated. Such patients were not expected to benefit from SSRF, making them unsuitable candidates for the study. Another 3% of eligible patients lacked faculty equipoise for enrollment, which was also anticipated. The biggest losses to enrollment, however, were because of patient preferences either for or against undergoing a surgical procedure (42%). While most of these patients strongly preferred to avoid surgery and were unwilling to potentially be randomized to the SSRF group, some strongly preferred to undergo SSRF and were unwilling to potentially be randomized to the Usual Care group. However, it is important to note that although an underpowered study would have a lower probability of detecting differences between the treatment groups, observable differences were still apparent despite the smaller sample size. Second, the study was conducted at a single center, which limits its generalizability. While the exact surgical technique was not specified as part of the study protocol, surgeons generally limited the size of incisions and used muscle-sparing techniques whenever possible. Thoracoscopic SSRF approaches were not evaluated. Finally, patients in this study were severely injured and had median Injury Severity Scores that were higher than most previous studies of SSRF patients. Although injury severity was similar between the treatment groups, it is possible that the overall burden of the polytrauma may have diluted any potential benefit of SSRF.

In conclusion, even in the absence of clinical flail chest and respiratory failure, the majority of patients still experienced moderate to severe pain and impairment of usual physical activity at 1-month follow-up. SSRF did not decrease hospital length of stay or improve health status up to 6 months following injury. The use of SSRF outside of the clinical flail chest population should be carefully considered, given the potential harms of the procedure and unclear benefit.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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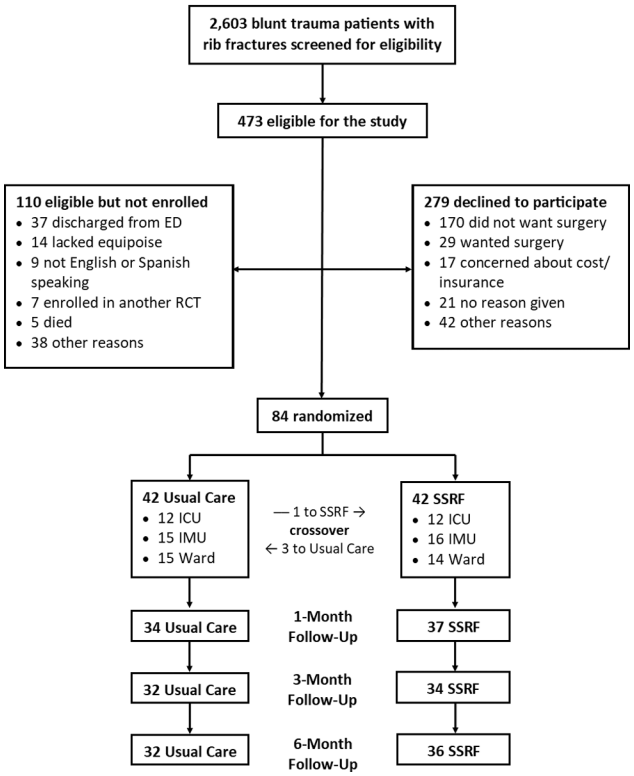

FIGURE 1.

Flow of patients through the surgical stabilization of rib fractures for severe chest wall injury randomized control trial.

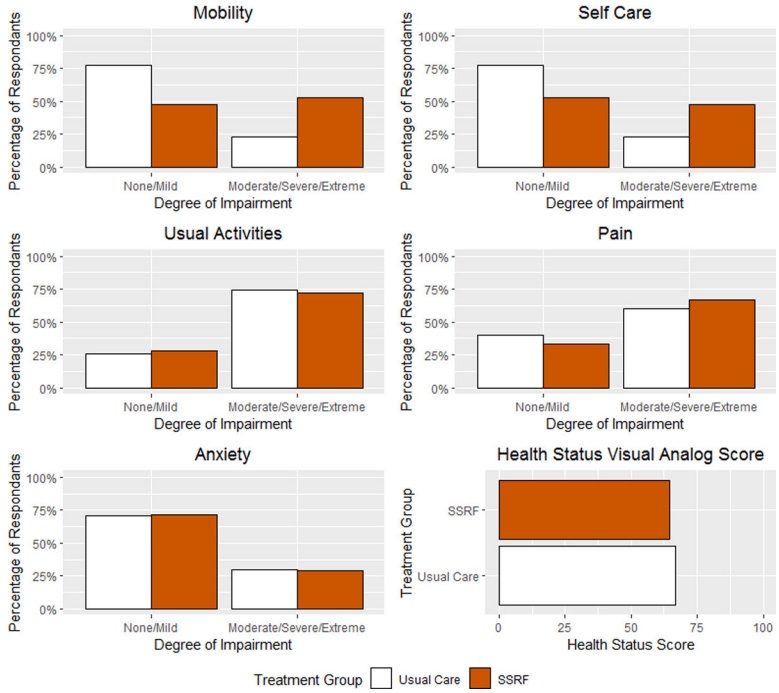

FIGURE 2.

EQ-5D-5L scores at 1-month follow-up. The proportion of patients in each treatment group with no impairment or minor impairment (scores of 1 or 2) are compared to those with moderate, severe, or extreme impairment (scores of 3, 4, or 5) for each dimension. The visual analog score (VAS) for each group is also presented.

TABLE 1.

Baseline characteristics by treatment group. Continuous data are presented as mean (±SD). Non-parametric data are presented as median (IQR). Categorical data are presented as n (%). SSRF = surgical stabilization of rib fractures; ED = emergency department.

	Usual Care (n = 42)	SSRF (n = 42)
Age, years	49 (15)	50 (15)
Male gender	31 (74%)	28 (67%)
White race	25 (60%)	29 (69%)
Motor vehicle collision	19 (45%)	24 (57%)
Motorcycle collision	5 (12%)	7 (17%)
Fall	6 (14%)	3 (7%)
Height, cm	175 (10)	174 (10)
Weight, kg	93 (22)	95 (25)
Body Mass Index, kg/m^2	30 (6)	31 (6)
ED heart rate, bpm	93 (18)	93 (22)
ED respiratory rate, breaths/min	20 (5)	21 (5)
ED systolic blood pressure, mmHg	127 (35)	125 (30)
ED diastolic blood pressure, mmHg	79 (16)	79 (19)
ED Glasgow Coma Scale score	15 (15–15)	15 (14–15)
Injury Severity Score	22 (15–27)	22 (17–32)
Abbreviated Injury Score Head	1 (0–2)	1.5 (0–3)
Abbreviated Injury Score Face	0 (0–1)	0 (0–1)
Abbreviated Injury Score Chest	3 (3–3)	3 (3–4)
Abbreviated Injury Score Abdomen	0 (0–2)	1 (0–2.75)
Abbreviated Injury Score Extremity	2 (1–2)	2 (1–2)
Abbreviated Injury Score External	0 (0–0)	0 (0–0)
Transferred from other institution	19 (45%)	15 (36%)
Allocation Unit: Intensive Care	12 (29%)	12 (29%)
Allocation Unit: Intermediate Care	15 (36%)	16 (38%)
Allocation Unit: Ward	15 (36%)	14 (33%)
Crossover	1 (2%)	3 (7%)
Time from arrival to randomization, h	54 (28)	50 (22)

TABLE 2.

Chest wall injuries by treatment group. Non-parametric data are presented as median (IQR). Categorical data are presented as n (%). SSRF = surgical stabilization of rib fractures.

	Usual Care (n = 42)	SSRF (n = 42)
Number of fractured ribs	7 (6–10)	8 (7–10)
Incidence of ≥5 consecutive fractures	39 (93%)	40 (95%)
Incidence of bicortically displaced fractures	25 (60%)	24 (57%)
Number of bicortically displaced fractures	2 (0–2)	1 (0–2)
Incidence of flail segments	17 (40%)	15 (36%)
Number of segmentally fractured ribs	2 (0–4)	1 (0–4)
Incidence of clavicle fracture	10 (24%)	5 (12%)
Incidence of scapula fracture	5 (12%)	9 (21%)
Patients with one severe injury criterion	12 (29%)	14 (33%)
Patients with two severe injury criteria	21 (50%)	19 (45%)
Patients with three severe injury criteria	9 (21%)	9 (21%)

TABLE 3.

Hospital outcomes by treatment group. Continuous outcomes are presented as mean (±SD). Discrete data are presented as median (IQR). Categorical data are presented as n (%). SSRF = surgical stabilization of rib fractures; ICU = intensive care unit.

	Usual Care (n = 42)	SSRF (n = 42)	p value
Hospital days	6 (3–11)	9 (6–20)	0.005
Hospital-free days (up to 30 days)	24 (19–27)	21 (10–24)	0.005
ICU days	0 (0–1)	0 (0–10)	0.410
ICU-free days (up to 30 days)	30 (29–30)	30 (20–30)	0.416
Ventilator days	0 (0–0)	0 (0–1)	0.264
Opioid exposure (pre-randomization), mg	79 (30–169)	80 (50–167)	0.629
Opioid exposure (all), mg	177 (76–387)	349 (218–686)	0.001
Opioid exposure (anesthesia), mg	0 (0–90)	149 (92–266)	<0.001
Opioid exposure (non-anesthesia), mg	125 (62–279)	203 (89–477)	0.088
Daily non-anesthesia opioid exposure, mg	19 (9–34)	20 (9–43)	0.869
Tramadol prescription at discharge	24 (60%)	22 (53%)	0.637
Other opioid prescription at discharge	4 (10%)	3 (7%)	0.946
Discharge to home	34 (81%)	33 (79%)	1.000
Regional analgesia for refractory pain	3 (7%)	7 (17%)	0.312
Surgical drainage of retained hemothorax	2 (5%)	5 (12%)	0.430
Tracheostomy	2 (5%)	7 (17%)	0.158
Deep vein thrombosis	0 (0%)	1 (2%)	1.000
Pulmonary embolism	3 (7%)	1 (2%)	0.609
Pneumonia	5 (12%)	9 (21%)	0.380
Mortality	0 (0%)	0 (0%)	1.000

TABLE 4.

Follow-up outcomes by treatment group at 1, 3, and 6 months. Health status was measured using the EuroQOL-5D-5L instrument. Continuous data are presented as mean (±SD). Nonparametric data are presented as median (IQR). Categorical data are presented as n (%). SSRF = surgical stabilization of rib fractures.

	Usual Care (n = 42)	SSRF (n = 42)	p value
1-Month Follow-Up Survey			
Number of respondents	35 (83%)	37 (88%)	0.755
Mobility dimension	2 (1–2)	3 (2–3)	0.012
Self-Care dimension	2 (1–2)	2 (2–3)	0.034
Usual Activities dimension	3 (2.5–5)	3 (2–5)	0.919
Pain dimension	3 (2–3)	3 (2–3)	0.327
Anxiety dimension	2 (1–3)	2 (1–3)	0.838
Visual Analog Score	67 (18)	65 (22)	0.691
Index Score	0.53 (0.27)	0.44 (0.34)	0.193
Back to work or normal physical activity	5 (15%)	5 (15%)	1.000
3-Month Follow-Up Survey			
Number of respondents	32 (76%)	34 (81%)	0.790
Mobility dimension	1 (1–3)	2 (1–3)	0.185
Self-Care dimension	1 (1–3)	1 (1–2.5)	0.688
Usual Activities dimension	2 (1–3.25)	3 (2–3)	0.342
Pain dimension	2 (2–3)	3 (2–3)	0.378
Anxiety dimension	2 (1–2)	2 (1–3)	0.569
Visual Analog Score	73 (23)	69 (24)	0.523
Index Score	0.61 (0.36)	0.56 (0.32)	0.595
Back to work or normal physical activity	17 (50%)	14 (40%)	0.553
6-Month Follow-Up Survey			
Number of respondents	32 (76%)	36 (86%)	0.405
Mobility dimension	1 (1–2)	1 (1–2)	0.788
Self-Care dimension	1 (1–1)	1 (1–1)	0.751
Usual Activities dimension	1.5 (1–3)	2 (1–3)	0.734
Pain dimension	2 (1–3)	2 (2–3)	0.052
Anxiety dimension	1 (1–2)	1 (1–2)	0.772
Visual Analog Score	77 (20)	74 (23)	0.530
Index Score	0.77 (0.26)	0.69 (0.32)	0.380
Back to work or normal physical activity	19 (61%)	19 (58%)	0.962
Time to return to work, days	43 (35–55)	48 (35–89)	0.361
Time to return to normal activity, days	67 (52–112)	92 (77–119)	0.425
Time to resolution of chest wall pain, days	54 (25–73)	76 (35–104)	0.207