A prospective, controlled clinical evaluation of surgical stabilization of severe rib fractures

Fredric M. Pieracci, MD, MPH, Yihan Lin, MD, Maria Rodil, Madelyne Synder, MPH, Benoit Herbert, MD, Dong Kha Tran, MD, Robert T. Stoval, MD, Jeffrey L. Johnson, MD, Walter L. Biffl, MD, Carlton C. Barnett, MD, Clay Cothren-Burlew, MD, Charles Fox, MD, Gregory J. Jurkovich, MD, *and* **Ernest E. Moore, MD,** *Denver, Colorado*

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Author Disclosures

Fredric M. Pieracci: research support, DePuy Synthes. Carlton C. Barnett: research support, DePuy Synthes. The remaining authors have nothing to disclose.

Reviewer Disclosures

The reviewers have nothing to disclose.

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Submitted: September 18, 2015, Revised: October 23, 2015, Accepted: November 3, 2015, Published online: November 21, 2015.
From the Trauma, Acute Care Surgery, and Surgical Critical Care, Denver Health Medical Center, University of Colorado School of Medicine, Denver Colorado.
This study was presented at the 74th annual meeting of the American Association for the Surgery of Trauma, September 9–12, 2015, in Las Vegas, Nevada.
Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal's website (www.jtrauma.com).
Address for reprints: Fredric M. Pieracci, MD, MPH, Trauma and Acute Care Surgery, Denver Health Medical Center, University of Colorado Health Sciences Center, 777 Bannock St, MC0206 Denver, CO 80206; email: fredric.pieracci@dhha.org.

DOI: 10.1097/TA.0000000000000925

BACKGROUND: Previous studies of surgical stabilization of rib fractures (SSRF) have been limited by small sample sizes, retrospective methodology, and inclusion of only patients with flail chest. We performed a prospective, controlled evaluation of SSRF as compared with optimal medical management for severe rib fracture patterns among critically ill trauma patients. We hypothesized that SSRF improves acute outcomes.

METHODS: We conducted a 2-year clinical evaluation of patients with any of the following rib fracture patterns: flail chest, three or more fractures with bicortical displacement, 30% or greater hemithorax volume loss, and either severe pain or respiratory failure despite optimal medical management. In the year 2013, all patients were managed nonoperatively. In the year 2014, all patients were managed operatively. Outcomes included respiratory failure, tracheostomy, pneumonia, ventilator days, tracheostomy, length of stay, daily maximum incentive spirometer volume, narcotic requirements, and mortality. Univariate and multivariable analyses were performed.

RESULTS: Seventy patients were included, 35 in each group. For the operative group, time from injury to surgery was 2.4 day, operative time was 1.5 hours, and the ratio of ribs fixed to ribs fractured was 0.6. The operative group had a significantly higher RibScore (4 vs. 3, respectively, $p < 0.01$) and a significantly lower incidence of intracranial hemorrhage (5.7% vs. 28.6%, respectively, $p = 0.01$). After controlling for these differences, the operative group had a significantly lower likelihood of both respiratory failure (odds ratio, 0.24; 95% confidence interval, 0.06–0.93; $p = 0.03$) and tracheostomy (odds ratio, 0.18; 95% confidence interval, 0.04–0.78; $p = 0.03$). Duration of ventilation was significantly lower in the operative group ($p < 0.01$). The median daily spirometry value was 250 mL higher in the operative group ($p = 0.04$). Narcotic requirements were comparable between groups. There were no mortalities.

CONCLUSION: In this evaluation, SSRF as compared with the best medical management improved acute outcomes among a group of critically ill trauma patients with a variety of severe fracture patterns. (*J Trauma Acute Care Surg.* 2016;80: 187–194. Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Therapeutic study, level II.

KEY WORDS: Rib fractures; surgical stabilization of rib fractures; respiratory failure; tracheostomy.

Rib fractures remain one of the most common and debilitating injuries.[1] Surgical stabilization of rib fractures (SSRF) has been practiced sporadically for decades and almost exclusively in patients with flail chest.[2] However, recent data indicate that this operation is used in less than 1% of such patients nationally.[3] In a review of perceived barriers to widespread adoption of SSRF, Mayberry et al.[4] identified lack of clinical trials as the major concern reported by practicing trauma, orthopedic, and thoracic surgeons. Existing literature involving SSRF has been summarized in two recent meta analyses.[5,6] The data remain limited by antiquated fixation systems, lack of prospective study design, small sample sizes, delayed (>72 hours from injury) fixation, inclusion of only patients with flail chest, lack of national (United States) prospective data, and poor follow-up. Our objective was to conduct a clinical evaluation of SSRF that addressed the aforementioned limitations. We hypothesized that early SSRF, as compared with the best medical management, improves acute outcomes among a cohort of trauma patients with diverse rib fracture patterns.

PATIENTS AND METHODS

We conducted a prospective, controlled clinical evaluation from January 2013 through December 2014 at Denver Health Medical Center, a state-certified, American College of Surgeons–verified Level I trauma center. Eligible patients included adults (age ≥ 18 years) with one or more of the following rib fracture patterns: (1) flail chest (three or more contiguous ribs fractured in two or more places); (2) three or more severely displaced fractures, defined as bicortical displacement; (3) 30% or greater volume loss of a hemithorax and quantified using computed tomography of the chest; (4) any fracture pattern with failure of optimal medical management (see Figure, Supplemental Digital Content 1, http://links.lww.com/TA/A700) within 72 hours of injury. Patients were excluded if they were identified 72 hours or greater from injury.

Our study design involved a crossover paradigm, in which all patients presenting in the year 2013 were managed nonoperatively, and all patients presenting in the year 2014 were managed operatively, provided that they or their surrogate decision maker granted informed consent for the procedure. This study design was chosen because it coincided with our operative staff and surgeons familiarizing themselves with the SSRF procedure (during the nonoperative year), including in-services, off-site continuing education courses, and cadaver laboratory skills sessions. Once preparations were complete, the transition was made to the operative year. Because of this timeline, the

TABLE 1. Baseline Demographics

Variable	Operative (n = 35)	Nonoperative (n = 35)	*p*
Age, mean (SD), y	51.0 (15.3)	50.3 (15.1)	0.85
Male	30 (85.7)	24 (68.6)	0.09
Mechanism			0.82
MVC/MCC	14 (40.0)	14 (40.0)	
Auto/pedestrian and bike	13 (37.1)	11 (31.4)	
Fall	8 (22.9)	10 (28.6)	
BMI, mean (SD), kg/m^2	27.8 (5.7)	27.5 (5.9)	0.87
Asthma/COPD	2 (5.7)	4 (11.4)	0.67
Tobacco (current or former)	13 (37.1)	11 (31.4)	0.61

BMI, body mass index; COPD, chronic obstructive pulmonary disease; MCC, motorcycle collision; MVC, motor vehicle collision.

TABLE 2. Associated Injuries

Variable	Operative (n = 35)	Nonoperative (n = 35)	*p*
ISS	21.5 (17.0–26.0)	22.0 (17.0–38.0)	0.69
Intracranial hemorrhage	2 (5.7)	10 (28.6)	0.01
Admission GCS score	15.0 (14.0–15.0)	14.0 (7.0–15.0)	0.03
Facial fractures	3 (8.6)	7 (20.0)	0.17
Clavicle fracture	6 (17.1)	5 (14.3)	0.74
Scapula fracture	8 (22.9)	5 (14.3)	0.36
Spine fracture	11 (31.4)	17 (48.6)	0.09
Pelvic fracture	8 (22.9)	12 (34.3)	0.19
Long bone fracture	1 (2.9)	0	NA
Solid organ injury	9 (25.6)	11 (31.4)	0.60
BCVI	0	2 (5.7)	0.49
BPC 18 score	4.0 (2.0–5.0)	3.5 (2.0–4.0)	0.67
Pneumothorax	28 (80.0)	31 (88.6)	0.51
Hemothorax	18 (51.4)	10 (28.6)	0.09

BCVI, blunt cerebrovascular injury; NA, not applicable.

Colorado Multicenter Institutional Review Board deemed the activity as quality improvement.

During both the nonoperative and operative periods, all patients were managed using a standardized protocol involving escalating levels of both analgesia and pulmonary toilet (see Figure, Supplemental Digital Content 1, http://links.lww.com/TA/A700). Our operative technique for SSRF has been described previously[7] and involved early (<72 hours from injury) fixation of fractures of Ribs 3 to 10 through muscle-sparring, fracture pattern–dependent exposures. All operations were performed by a group of five acute care surgeons. Efforts were made to repair both fracture lines in patients with flail chest;[8] however, posterior fractures within 5 cm of the transverse processes were neither exposed nor repaired. Furthermore, fractures of Ribs 3 and 10 that were at the limit of exposure were not plated if the morbidity of additional exposure was believed to outweigh the benefit of fixation. Both tube thoracostomies and percutaneous analgesic catheters were placed routinely following completion of SSRF. Either percutaneous analgesic catheters or thoracic epidural catheters were placed in all patients in the nonoperative arm.

Covariates included patient demographics, comorbidities, and injury patterns. Rib fracture pattern severity was quantified using the RibScore,[9] Rib Fracture Score,[10] and Chest Trauma Score.[11] Presence and severity of pulmonary contusions were quantified using the blunt pulmonary contusion (BPC) 18 score.[12] Acute outcomes included (1) respiratory failure, defined as mechanical ventilation in 24 hours or greater; (2) pneumonia, defined as clinical signs and symptoms with quantitative microbiologic confirmation of a lower respiratory tract culture in ventilated patients (>10^5 colony-forming units per milliliter[13]); (3) tracheostomy, at the discretion of the attending surgical intensivist; (4) ventilator days; (5) intensive care unit (ICU) length of stay (LOS); (6) hospital LOS; (7) in-hospital mortality; and (8) perioperative complications, including superficial surgical site infection, empyema, hardware migration, and hardware failure. In addition to these outcomes, we also abstracted (1) daily best incentive spirometry recording (nonintubated patient) and (2) daily narcotic requirements, calculated using the following equivalence scale: morphine 4 mg PO = hydromorphone 0.2 mg IV = hydromorphine 2 mg PO = oxycodone 10 mg PO = hydrocodone 10 mg PO = fentanyl 50 μg IV.

Data were analyzed with SAS Enterprise Guide 5.1 (SAS Institute, Inc., Cary, NC) and SPSS 17.0 (SPSS, Chicago, IL). Continuous data are presented as median (interquartile range [IQR]); categorical variables are presented as n (%). Unadjusted associations between independent variables selected *a priori* and operative status were assessed using a Student's *t* test or a Wilcoxon rank-sum test for continuous variables depending on the results of normality tests. A χ^2 test was used to assess associations between categorical variables. Covariates were included in multiple linear and logistic regression models describing

TABLE 3. Rib Fracture Pattern

Variable	Operative (n = 35)	Nonoperative (n = 35)	*p*
No. ribs fractured	9.0 (7.0–11.0)	8.0 (6.0–11.0)	0.18
Total no. fractures	13.0 (11.0–17.0)	9.0 (6.0–13.0)	0.01
Three or more rib fractures	30 (85.7)	30 (85.7)	0.93
Bilateral fractures	13 (37.1)	13 (37.1)	1.00
Flail chest	28 (80.0)	11 (31.4)	<0.0001
First rib fracture	16 (45.7)	9 (25.7)	0.08
RibScore	4.0 (3.0–5.0)	3.0 (2.0–4.0)	0.002
Rib Fracture Sore	10 (8–22)	10 (7–24)	0.30
Chest Trauma Score	7 (6–8)	7 (5–8)	0.42

TABLE 4. Unadjusted Outcomes

Outcome	Operative (n = 35)	Nonoperative (n = 35)	*p*
Respiratory failure	17 (48.6)	25 (71.4)	0.05
Tracheostomy	5 (14.3)	16 (45.7)	0.01
Pneumonia	7 (20.0)	11 (31.4)	0.28
Days of mechanical ventilation	0 (0.0–8.0)	5.0 (0–18)	<0.01
Hospital LOS	13.0 (9.0–21.0)	16.0 (10.0–23.0)	0.11
ICU LOS	6.0 (3.0–10.0)	9.0 (4.0–15.0)	0.15

TABLE 5. Results from Multivariable Analyses

Categorical Outcomes	Adjusted Odds Ratio	95% CI	*p*
Respiratory failure	0.24	0.06–0.93	0.03
Tracheostomy	0.18	0.04–0.78	0.03
Pneumonia	0.53	0.14–2.00	0.62

Continuous Outcomes	β	SE	*t* Value	Pr > |*t*|	Pr > F	*R*	R^2
No. days on MV	1.26	4.45	0.28	0.78	0.26	0.14	0.04
Hospital LOS	1.87	7.37	0.25	0.80	0.02	0.25	0.16
ICU LOS	−0.46	2.08	−0.22	0.83	0.01	0.28	0.19

All models adjusted for ISS, intracranial hemorrhage, and RibScore.
MV, mechanical ventilation.

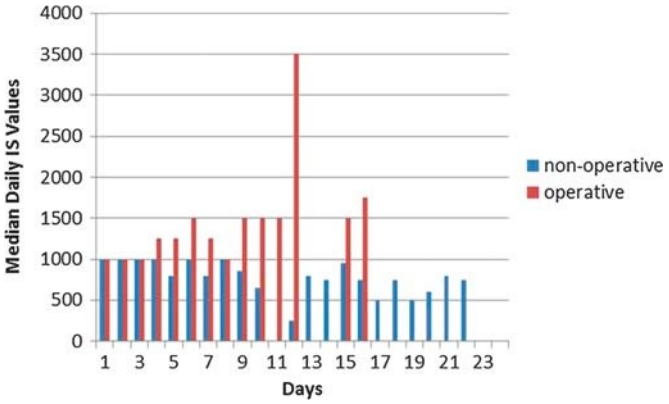

Figure 1. Daily incentive spirometry recordings.

the association between operative status and prespecified acute outcomes based on their status as being clinically significant or having a confounding effect ($p < 0.20$). Adjustment variables were also limited in count with respect to sample size. Unadjusted and adjusted odds ratios with 95% confidence intervals (CIs) are presented. Unadjusted and adjusted β coefficients, β with SEs, *t* statistics, coefficient *p* value, and F statistic *p* value are presented. Statistical significance was defined as $p < 0.05$.

RESULTS

Thirty-five patients met inclusion criteria in the nonoperative year, and 37 patients met inclusion criteria in the operative year. Two patients (5.4%) from the operative year declined SSRF and were excluded from analysis, leaving 35 patients in the operative arm. Baseline demographics for each group are presented in Table 1. There were no significant differences between groups in age, sex, mechanism of injury, body mass index, history of pulmonary diseases, or tobacco use.

Associated injuries are listed in Table 2. Although most injuries occurred with a similar frequency between groups, the nonoperative group, as compared with the operative group, had a significantly higher incidence of intracranial hemorrhage (28.6% vs. 5.7%, respectively, $p = 0.01$), with an associated lower Glasgow Coma Scale (GCS) score (14 vs. 15, respectively, $p = 0.03$). Upon further exploration of this discrepancy, we noted that no patient in either group underwent either invasive intracranial pressure monitoring (e.g., bolt or ventriculostomy) or emergency craniotomy/craniectomy. With respect to pulmonary injury, the operative and nonoperative groups had a similar BPC 18 score, as well as a similar incidence of both pneumothorax and hemothorax. Finally, with respect to spine injuries, one patient in each arm (3%) had a lumbar vertebral body fracture; the remainder of spine injuries involved isolated transverse and spinous process fractures.

Details regarding rib fracture pattern are shown in Table 3. In general, the operative group seemed to have a more severe fracture pattern as compared with the nonoperative group, as evidenced by a higher RibScore (4 vs. 3, respectively, $p = 0.002$), more total fractures (13 vs. 9, respectively, $p = 0.01$), and a higher incidence of flail chest (80.0% vs. 31.4%). The most common inclusion criterion for both groups was three or more severely displaced fractures (n = 30, 85.7%).

For the operative group, the median number of ribs stabilized was 5 (range, 3–6), and the median ratio of ribs stabilized to ribs fractured was 0.6 (IQR, 0.4–0.7). The mean (SD) time from injury to SSRF was 2.4 (0.78) days, and the mean (SD) surgery length was 1.5 (1.2) hours. There was one case of hardware infection requiring hardware removal on postoperative Day 24 following SSRF. The patient presented to an outside facility with signs of infection and was not managed by our team. Furthermore, a second patient was noted to have a single screw dislodged from a posterior plate on a routine chest radiograph on postoperative Day 5. This finding was inconsequential clinically. The median time from SSRF to tracheostomy was 5 days (IQR, 3–5 days).

Unadjusted outcomes for the operative and nonoperative groups are presented in Table 4. As compared with the nonoperative group, the operative group had a lower incidence of respiratory failure (48.6% vs. 71.4%, respectively, $p = 0.05$), was less likely to undergo tracheostomy (14.3% vs. 45.7%, respectively, $p = 0.01$), and had a shorter duration of mechanical ventilation (median, 0 day vs. 5 days, respectively, $p < 0.01$). No differences were observed in the incidence of pneumonia, hospital LOS, or ICU LOS.

Based on our *a priori* clinical relevance determination as well as univariate associations with study group, we included the following three variables in our multivariable analysis: Injury Severity Score (ISS), intracranial hemorrhage, and RibScore. The results of multivariable logistic regression analyses are shown in Table 5. Adjusting for RibScore, ISS, and intracranial hemorrhage, the odds of respiratory failure among patients undergoing SSRF was 0.24 (95% CI, 0.06–0.93; $p = 0.03$) times the odds of those who did not have the operation. Adjusting for RibScore, ISS, and intracranial hemorrhage, the odds of having a tracheostomy among patients who had SSRF was 0.18 (95% CI, 0.04–0.78; $p = 0.03$) times the odds of those who did not receive the operation. Adjusted for RibScore, ISS and intracranial hemorrhage, patients undergoing SSRF in comparison with those who did not had a positive association with the number of days a patient spent receiving mechanical ventilation ($Pr > F = 0.26$, $R = 0.14$, $R^2 = 0.04$).

Daily incentive spirometry recordings are depicted in Figure 1. The median incentive spirometry recording per hospital day was significantly higher for the operative as compared with the nonoperative group (1,250 mL [983–1,500] vs. 1,000 mL [783–1,083], respectively; $p = 0.04$). No significant differences were observed in median narcotic requirements per hospital day between the operative group (12 [7–25]) and nonoperative group (9 [3–17]) ($p = 0.15$).

DISCUSSION

In this clinical evaluation, we found that SSRF, as compared with the best medical management, was associated independently with a 76% decreased likelihood of respiratory failure and an 82% decreased likelihood of tracheostomy as well as 5-day decreased duration of mechanical ventilation and significantly improved spirometry readings among extubated patients. As compared with previous prospective studies of SSRF, our sample included more patients, a quicker time to operation

(median, 2.4 days), and a wider variety of fracture patterns, with the most common one being three or more displaced fractures. Our study also represents the first prospective, controlled evaluation of SSRF from the United States.

Surgical stabilization of severe rib fractures offers several theoretical advantages. Basic orthopedic principle mandates early reduction and immobilization of fractures to decrease both pain and inflammation as well as prevent nonunion. In the case of long bone and spine fractures, a variety of nonoperative therapies, including splinting, bracing, casting, and external fixation, achieve this goal. However, because of their involvement in respiration, it is nearly impossible to immobilize rib fracture fragments nonoperatively. Continual motion of fracture fragments exacerbates pain, inflammation, bleeding, and malalignment, leading to respiratory failure and chronic pain. In addition to effective reduction and fixation, SSRF offers an opportunity to undertake additional invasive maneuvers, such as bronchoscopy, assessment and potential drainage of the pleural space, and insertion of analgesic catheters under direct vision and general anesthesia. In general, SSRF may be accomplished with minimal operative time, muscle division, and morbidity; in this evaluation, perioperative morbidity for SSRF was relatively low, with a 3% incidence of serious infectious complications.

The improved pulmonary outcomes observed in our evaluation mirror those reported in the three existing clinical trials of SSRF.[14–16] The effect of SSRF on the development of pneumonia has been more variable, which may in part be due to inconsistent definitions. Decreased duration of mechanical ventilation, ICU LOS, and hospital LOS as well as improved spirometry, whether significant or trending, have also been consistently observed.

Despite random assignment to study group by year, important differences in baseline characteristics were observed between groups in our study. Specifically, whereas the nonoperative group had a higher incidence of intracranial hemorrhage, the operative group had a more severe rib fracture pattern. Both of these covariates are known to effect pulmonary outcomes irrespective of SSRF.[9] However, after controlling for these variables, SSRF remained independently associated with improved pulmonary outcomes. With regard to the disparities in the incidence of intracranial hemorrhage, the clinical degree of difference in neurologic status between groups seemed minor as evidenced by a one point median difference in GCS score. Furthermore, the incidence of emergency interventions was similar. With regard to the difference in rib fracture severity, a more severe fracture pattern in the operative group would, if anything, underestimate any benefit of SSRF on pulmonary outcomes.

Randomization by year of presentation may have introduced bias if patient management patterns changed substantially during the study period. We attempted to mitigate this phenomenon by standardizing staff, inclusion criteria, and management protocols. Accordingly, we did not observe a significant difference in the frequency or types of interventions (e.g., thoracic epidural catheter) used between the nonoperative and operative years. Furthermore, other methods of randomization, such as alternating assignments between operative and nonoperative, have been associated with extremely high rates of consent declination and would have almost certainly precluded meaningful enrollment. Similarly, lack of blinding may have influenced provider behavior; however, it would not have been possible to conceal study group assignment. By studying a group of five acute care surgeons, we attempted to balance standardizing the operation with generalizability of our results. Although our study represents the largest to date, samples sizes were nonetheless too small to conduct subgroup analyses to identify which specific fractures patterns benefitted most from SSRF. The ratio of ribs fixed to fractured in our study was 0.6; this number most likely reflects a combination of high ipsilateral rib fractures (i.e., Ribs 1–3) and any contralateral rib fractures that were deemed stable and thus not addressed surgically. Finally, our study is limited by a lack of long-term outcomes. These outcomes, including pulmonary function testing and quality of life assessments, are currently being abstracted among our cohort of study patients.

With the addition of this evaluation to the prospective literature on SSRF, it is our contention that the direction of research involving this operation should shift from whether there is benefit to SSRF toward a refinement of indications, timing, and technique. Although this study is the first to include patients without flail chest, others have recently published survey results of patients following SSRF for a variety of nontraditional fracture patterns.[17] Our group is currently conducting a trial of early versus late SSRF, further limiting the early window to less than 24 hours from injury. Finally, subsequent trials of SSRF should incorporate newly described, minimally invasive techniques, including totally thoracoscopic, intrapleural fixation.[18]

In conclusion, in this evaluation comparing SSRF to the best medical management, we observed improved pulmonary outcomes for those patients undergoing the operation. These improvements persisted after controlling for baseline differences in both associated injuries and fracture patterns. We recommend considering SSRF in all patients who meet one or more inclusion criteria from this study and well as further prospective research into the optimal patient population, timing, and technique of this operation.

DISCLOSURE

This study was funded by an investigator-initiated research grant from DePuy Synthes.

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DISCUSSION

Dr. Charles Adams, Jr. (Providence, Rhode Island): It is always a pleasure to review a paper that supports some of your biases and that you have an interest in. Every trauma surgeon in this room knows that blunt chest trauma and rib fractures are a huge problem. As the population ages, it seems like the incidence of this is increasing.

Eileen Bulger and several others in this room have published about the cost in terms of morbidity and mortality of blunt chest trauma and rib fractures. It's a known driver of inflammation and it's actually used in basic science models because of its systemic effects.

As Dr. Pieracci mentioned, there is some paucity of controlled trials, prospective data to guide our patient selection. But there is increasing enthusiasm across the nation in many trauma centers to embrace rib fixation in order to modify this disease state.

It is against this background that he and his colleagues at Denver General undertook this study to better define the patient population. The results of this study demonstrated that rib fixation is associated with significantly lower incidence of respiratory failure, tracheostomy, and days on mechanical ventilation.

And while this study is considered a cross-over in its management paradigm from all non-operative to all-operative, I think it is probably better to classify this as a "before and after" study. Indeed, the institutional IRB classified this as a quality improvement program, not a prospective study. The results are very compelling, though, and worth discussing.

I have three questions for Dr. Pieracci.

First, your standard medical management consisted of a regimen of oral narcotics, escalating to intravenous narcotics, PCA, and, finally, epidural for those patients that were performing poorly and getting into trouble.

To me this strategy seems a little bit backwards because once respiratory failure is established atelectasis sets in and once secretions have developed it's very hard to reverse that degree of respiratory failure.

So my first question is, do you think your results would be the same if you used a more aggressive approach to managing pain in the non-operative group? Perhaps if you started every patient on PCA, if possible, plus epidurals in those you deem at high risk and then convert them to oral would you get different results?

Second, and you noted this in the presentation as well as in the manuscript, the non-operative group had a significantly higher incidence of head injury compared to the operative group. And, as you note in the manuscript, none of these patients, despite their head injury, required a craniotomy, craniectomy, or intracranial pressure monitor which tells me that they all would fall into the category of mild traumatic brain injury. Indeed, the GCS of this group was 14 compared to 15 in the operative group. And while that one point seems trivial, I really think that it's a huge factor in the management of patients with blunt chest trauma and rib fractures. Those patients will protect their airway but what they won't do is follow commands, use an incentive spirometer, cough on command, hit the PCA button.

I think insipient respiratory failure in that group of patients is very, very common. And I think that actually leads to increased rates of tracheostomy and mechanical ventilation. So my question to you is did you look at the data excluding head injury completely? I know you tried to control for it in a multiple regression analysis but I wonder what your results would be if you excluded head injury.

Lastly, the topic of tracheostomy needs to be addressed. We all know that the timing of tracheostomy is a very subjective decision. And as you note, because it's up to the discretion of the surgical intensivist, there is some bias associated and it's impossible to control for that. I think it would be helpful for the audience if you would elucidate your center's practice regarding tracheostomy. What is your classification? Are you early-trachers? Are you late-trachers? What typically post injury day do you trach? And how is that decision made? And, finally, how is the presence or absence of head injury factored into that decision to whether you are going to perform a tracheostomy?

In conclusion, I think Dr. Pieracci and his colleagues have made significant strides in further defining the role of rib stabilization. I wholeheartedly agree with their contention that we should move from discussing whether there is a benefit of rib fixation to actually defining, refining the indications, the management and the technique. I think we are at that stage now.

I applaud their efforts and I think that this paper will contribute to the evolution of how we care for blunt chest trauma and rib fractures. Thank you.

Dr. Richard Miller (Nashville, Tennessee): Very nice study. Three quick questions.

Since we developed a comprehensive pain service that was very expeditious in putting in epidurals, our ventilator days and narcotic use went down exponentially, so I think you have to include that, like Chuck said, in involving your comparison by having a very robust pain service involved in getting patients mobilized and extubated.

The other thing is, did you look specifically where these ribs are fractured? Some people say ribs one through four don't necessarily need to be plated and this is mostly for areas between the fourth and eighth ribs and then, of course, the lower ribs probably don't need to be plated as well. So did you look where you are doing your plating?

And, lastly, how many of these patients that underwent operative fixation also underwent a VATS at the same time? And did that improve their ventilatory support and their overall outcome? Thank you.

Dr. Hasan B. Alam (Ann Arbor, Michigan): Very nicely done study. Very provocative. I've got two interrelated questions addressing your study designs.

Every time you do a pre/post study you are prone to it, so how did you control for the Hawthorne Effect? I mean you are studying these patients. You are looking at them. Your performance is going to be better because you are studying these patients.

And the second is the unintentional bias because you are looking at end points such as tracheostomy, extubation, and those are variables that we control. So now these are patients that you invested time in. It's a quality improvement project. You fix the ribs. You have a built-in incentive to extubate them quickly and maybe not do tracheostomy. These are subjective things, especially if they are not driven by objective protocols.

So it's not that you do a trach because of an objective protocol or extubation is completely and entirely driven by an objective protocol. How did you control for this unintentional bias?

Dr. Jose Diaz (Baltimore, Maryland): I always like to stand up and applaud those who do studies that actually match my bias.

Two specific questions. One is how did you define ammonium? Are you guys' identifiers or non-identifiers, as we tend to be?

And the other is did you look at any laboratory values? One of the things that I have noted anecdotally is that some of these patients with big chest walls may have an abatement of their SIRS response once stabilized, similar to what a bad femur fracture might be.

Very nice study.

Dr. W. Slate Wilson (Portland, Oregon): I notice you are using all metal plates, probably titanium—have you considered using absorbable plates? At OHSU, John Mayberry did develop some vicryl plates but they only last for about three or four weeks and I am wondering what you think about that.

And my other question is, who should we take lessons from?

Dr. Frederic Pieracci (Denver, Colorado): Thank you, Dr. Adams, and others for your questions. The first one was regarding our standardized analgesic control regime. And all of the patients in both of the arms had either a thoracic epidural or a paravertebral catheter placed basically on admission.

I do wonder if there is a benefit to when we would take the patients to the operating room to fix their ribs we would take out the paracostal catheter and put a new one in under direct visualization.

And I do hypothesize that that may provide better pain control as compared to the percutaneously placed ones. But that would just be another benefit of the operation.

The second question was about controlling for patients with traumatic brain injury. We did repeat the analysis excluding those patients which took our sample size down into the 20s. And we saw the same signal. But we lost statistical significance, in my opinion, because of being underpowered.

I hope that by controlling for it in multivariable logistic regression as well as delving into the patients and showing that they had relatively minor TBI that that argues that there was not serious confounding going on by that variable.

Our tracheostomies are performed at the discretion of our surgical intensivists. There is a fair amount of variability but I would say in general we are early-trachers.

The mean time from admission to rib fixation was two days. And the mean time from admission to tracheostomy was five to six days. So there was a two-to-four day window between the surgery and the decision to perform the tracheostomy.

The next question related to which ribs do we fix. We routinely fix ribs three through nine. We have learned that there is not a lot of benefit from fixing one and two. And the exposure required almost always involves muscle division and probably causes more pain than benefit. So ribs three through ten were routinely fixed.

There was a question about how many patients had VATS and the time of rib fixation. No patients had VATS at the same time; but we do routinely leave 19 French Blake drains. And we irrigate through those as reported by the group at Intermountain Medical Center.

And they had some nice data at the Southwestern last year showing that they had a decreased incidence of retained hemothorax in patients who underwent rib fixation. So I do believe that is an additional benefit to the operation, separate from fixing the ribs.

The next question related to the Hawthorne Effect and that is almost impossible to control for, unfortunately. I will mention that when I proposed this idea of doing this pre/post comparison all of our surgeries were performed by a group of five acute care surgeons. And three of them were biased against it working. So for what it's worth they did it anyway, and I appreciate that.

The next question related to our outcomes being subjective, such as the decision to perform a tracheostomy. And that is a valid criticism. We are performing longterm follow-up on our patients, including quality-of-life questionnaires and pulmonary function tests. However, enough time has not elapsed for the operative group to present that data. And I hope to abstract that within the next few months.

The next question related to whether or not we collected any markers of inflammation in these patients and we did not.

And then the final question was about absorbable plates which I know Dr. Mayberry has advocated. I don't have any personal experience with them. I know they are a lot more expensive. I do believe that the function of the plates is just to stabilize the fracture while the body heals it so after probably four to six weeks the plates are unnecessary.

We did have to ex-plant the hardware in one of our 35 patients. He presented to an outside hospital three weeks post-operatively. We were not involved in the decision making but the surgeons took him back to the OR and according to their operative note he had an empyema and a plate infection so that puts our incidence of infection at about 3%, which is still relatively low.

Thank you.