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# LATE COMPLICATIONS AND FUNCTIONAL OUTCOMES AFTER NONOPERATIVE MANAGEMENT VERSUS SURGICAL STABILIZATION OF RIB FRACTURES IN PATIENTS WITH BLUNT CHEST TRAUMA: A 12-MONTH MULTICENTER STUDY

*Nguyen The May[1], Nguyen Cong Huy[1], Le Minh Sơn[1], Pham Quoc Hoa[1], Trinh Phi Hung[1], Nguyen Viet Phuong[1], Tieu Cong Quyet[1], Nguyen Anh Da[1], Pham Huu Lu[2], Doan Quoc Hung[3], Nguyen Van Dai[1*]*

*[1]Department of Thoracic and Cardiovascular Surgery, Viet Tiep Friendship Hospital - No. 1 Nha Thuong Street, Le Chan Ward, Hai Phong City, Vietnam*
*[2]Division of Cardiovascular and Thoracic Surgery, Department of Surgery, Hanoi Medical University - No. 1 Ton That Tung Street, Kim Lien Ward, Hanoi City, Vietnam*
*[3]Hospital Director, Vinmec Ocean Park 2 International General Hospital, Vinhomes Ocean Park 2 Urban Area - Van Giang District, Hung Yen Province, Vietnam*

## ABSTRACT

***Background:*** Late consequences after multiple rib fractures remain clinically important, especially in patients managed nonoperatively. This study aimed to compare 12-month late complications and functional outcomes between nonoperative management and surgical stabilization of rib fractures (SSRF) in patients with blunt chest trauma.

***Methods:*** This multicenter prospective cohort included 192 eligible patients with blunt chest trauma and rib fractures treated at three Vietnamese trauma centers, comprising 64 patients treated with SSRF and 128 managed nonoperatively. Twelve-month outcomes were assessed in an extended follow-up conducted after completion of the primary study. This complete-case analysis included 155 of the 192 patients: all 64 patients (100%) in the SSRF group and 91 of 128 patients (71.1%) in the nonoperative group; all 37 losses to follow-up occurred in the nonoperative group. Treatment allocation was nonrandomized, and comparisons were unadjusted for baseline differences between groups. The primary outcome was chronic chest wall pain at 12 months. Secondary outcomes included exertional dyspnea, chest wall deformity, clinical symptoms suggestive of rib malunion/nonunion, pulmonary function, EQ-5D-5L, and return to work.

***Results:*** In this unadjusted complete-case comparison, patients who underwent SSRF had lower rates of chronic chest wall pain (10.9% vs. 34.1%, p=0.001), exertional dyspnea (12.5% vs. 31.9%, p=0.006), chest wall deformity (3.1% vs. 16.5%, p=0.012), and clinical symptoms suggestive of rib malunion/nonunion (4.7% vs. 18.7%, p=0.015) than patients managed nonoperatively. Patients who underwent SSRF also had higher 12-month FVC (90.8±9.4% vs. 82.1±12.6% predicted, p<0.001), FEV1 (88.7±10.1% vs. 80.4±13.2% predicted, p<0.001), and EQ-5D-5L index (0.93±0.08 vs. 0.84±0.13, p<0.001). The two groups differed significantly at baseline in injury severity score, admission pain score, and frequency of flail chest and chest wall deformity.

***Conclusion:*** In this multicenter prospective cohort, patients who underwent SSRF had more favorable observed 12-month pain, pulmonary-function, and quality-of-life outcomes than complete-case participants managed nonoperatively. However, these comparisons were unadjusted and were affected by substantial baseline imbalance and differential loss to follow-up. The findings should therefore be considered exploratory and should not be interpreted as establishing a causal treatment effect. Further studies using adjusted analyses, standardized imaging follow-up, and health-economic evaluation are warranted.

***Keywords:*** *Blunt chest trauma; Rib fractures; Surgical stabilization; Nonoperative management; Late complications; Pulmonary function.*

## 1. INTRODUCTION

Rib fractures are common injuries in patients with blunt chest trauma and are associated with pain, impaired cough, restricted ventilation, pulmonary complications, and delayed recovery [1,3]. Although most patients are treated nonoperatively, persistent chest wall pain, dyspnea, impaired pulmonary function, reduced quality of life, and delayed return to work may persist long after hospital discharge [3,4,11].

Surgical stabilization of rib fractures (SSRF) has increasingly been adopted for selected patients with flail chest, multiple displaced rib fractures, chest wall deformity, or severe pain despite optimal medical treatment [1,2]. Recent recommendations from the World Society of Emergency Surgery (WSES) and the Chest Wall Injury Society (CWIS) support SSRF in appropriately selected patients and highlight its potential benefits in improving pain control, respiratory function, and overall recovery [1].

Several studies have demonstrated improved outcomes after SSRF compared with nonoperative management [2,5,11]. In Vietnam, favorable early results of rib fixation have also been reported by Nguyen Huu Uoc et al. [6], while our previous multicenter study demonstrated superior in-hospital outcomes after SSRF compared with

[1]*Department of Thoracic and Cardiovascular Surgery, Viet Tiep Friendship Hospital - No. 1 Nha Thuong Street, Le Chan Ward, Hai Phong City, Vietnam*
[2]*Division of Cardiovascular and Thoracic Surgery, Department of Surgery, Hanoi Medical University - No. 1 Ton That Tung Street, Kim Lien Ward, Hanoi City, Vietnam*
[3]*Hospital Director, Vinmec Ocean Park 2 International General Hospital, Vinhomes Ocean Park 2 Urban Area - Van Giang District, Hung Yen Province, Vietnam*
**Corresponding author: Nguyen Van Dai*
*Email: vandai.bluesky.kiwi@gmail.com - Tel: 0977086438*
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nonoperative treatment [8].

However, most published studies have focused on short-term outcomes, whereas evidence regarding late complications and functional recovery remains limited, particularly in Asian populations [3,4,11]. Therefore, this multicenter prospective cohort study aimed to compare late complications and functional outcomes at 12 months between patients undergoing SSRF and those managed nonoperatively following blunt chest trauma.

## 2. METHODS

### 2.1. Study design

This multicenter prospective cohort study was conducted at three major trauma centers in Vietnam, including Viet Duc University Hospital, Cho Ray Hospital, and Viet Tiep Friendship Hospital. Consecutive eligible patients were enrolled between October 2020 and October 2023. The original study was designed to evaluate indications, surgical techniques, and short- to mid-term outcomes of surgical stabilization of rib fractures (SSRF). Following completion of the primary study, surviving patients were invited to participate in an extended follow-up program. Long-term outcomes were assessed 12 months after injury to evaluate late complications, pulmonary function, and quality of life.

Treatment decisions were made according to routine clinical practice and were not influenced by study participation.

### 2.2. Ethical considerations

The study protocol was reviewed and approved by the Institutional Review Board of Hanoi Medical University (Approval No. 504/GCN-HĐĐĐNCYSH-ĐHYHN, dated May 5, 2021; IRB-VN01.001/IRB00003121/FWA00004148). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and relevant national regulations.

Written informed consent was obtained from all participants or their legal representatives before enrollment. After completion of the prespecified short- and mid-term assessments, participants were invited to participate in an extended 12-month follow-up program. The extended follow-up was covered by the approved ethical framework of the study, and the informed consent obtained at enrollment covered participation in the follow-up assessments.

### 2.3. Study population

Eligible patients were adults aged 18 years or older who sustained blunt chest trauma with radiologically confirmed rib fractures and underwent either SSRF or nonoperative management.

*Inclusion criteria:*

- Age ≥18 years.

- Blunt chest trauma.

- Rib fractures confirmed by chest computed tomography.

- Treatment at one of the participating centers.

- Availability of complete baseline clinical and radiological data.

*Exclusion criteria:*

- Penetrating chest trauma.

- Death before outcome assessment.

- Severe cognitive impairment precluding follow-up evaluation.

- Incomplete baseline data.

- Refusal to participate in follow-up.

The initial cohort included 192 eligible patients, comprising 64 patients treated with SSRF and 128 patients managed nonoperatively. At 12

months, 155 patients completed follow-up. All 64 patients in the SSRF group were successfully followed, whereas 91 of 128 patients in the nonoperative group completed follow-up. Therefore, 37 patients were lost to follow-up, all from the nonoperative group.

### 2.4. Treatment allocation and indications for surgery

Treatment allocation was based on predefined clinical indications and the judgment of the treating surgical team rather than randomization.

Indications for SSRF included:

- Flail chest.

- Three or more markedly displaced rib fractures.

- Three or more complex rib fractures.

- Clinically significant chest wall deformity.

- Persistent severe pain despite optimized nonoperative treatment.

Nonoperative management consisted of multimodal analgesia, respiratory physiotherapy, oxygen therapy or ventilatory support when required, pleural drainage when indicated, and standard trauma care according to institutional protocols.

Because treatment decisions were not randomized, patients selected for SSRF generally had more severe injury characteristics at presentation, including higher Injury Severity Scores, higher admission pain scores, and a greater frequency of flail chest and chest wall deformity. For some indications (persistent severe pain and chest wall deformity), allocation was guided by predefined severity thresholds (for example, pain refractory to optimized analgesia, or chest wall volume loss meeting a threshold on computed tomography), such that patients in the nonoperative group generally presented with less severe pain or a lesser degree of chest wall deformity. For patients with symptomatic rib nonunion, allocation additionally depended on patient preference, since some patients who met criteria for SSRF elected not to undergo surgery and were managed nonoperatively instead. The nonoperative group should therefore not be considered a uniform population of patients who met SSRF criteria but declined surgery; rather, it comprised a mixture of patients with inherently milder clinical indications and, for a subset of indications, patients who chose nonoperative management. Consequently, the two treatment groups were not comparable at baseline (Table 2), and this nonrandomized, indication-based allocation must be considered when interpreting all between-group comparisons in this study.

### 2.5. Surgical technique

SSRF was performed using commercially available titanium locking plate systems, including MatrixRIB® (DePuy Synthes, USA) and RibFix Blu® (Zimmer Biomet, USA). Surgical approaches were selected according to fracture location and associated thoracic injuries. Muscle-sparing thoracotomy techniques were preferred whenever feasible. Thoracoscopic assistance was used selectively for assessment and treatment of concomitant intrathoracic injuries.

### 2.6. Follow-up and outcome measures

*Primary outcome:*

The primary outcome was chronic chest wall pain at 12 months.

*Secondary outcomes:*

Exertional dyspnea, chest wall deformity, clinical symptoms suggestive of rib malunion/nonunion, delayed return to work, FVC, FEV1 and EQ-5D-5L.

*Definitions of 12-month outcomes:*

For the extended 12-month analysis, outcomes were operationalized as follows, based

on the variables available in the follow-up dataset and informed by published clinical terminology; they should not be interpreted as externally validated diagnostic criteria. Chronic chest wall pain was defined as pain localized to the previously injured chest-wall region that remained present at the 12-month assessment. Exertional dyspnea was defined as patient-reported shortness of breath during physical exertion at the 12-month assessment. Chest wall deformity was defined as a persistent visible or palpable alteration in chest-wall contour at the site of the previous rib fractures, identified during clinical examination, with imaging used when available; standardized imaging was not performed for all participants. Clinical symptoms suggestive of rib malunion/nonunion were defined as persistent localized pain and/or clinically appreciable instability, abnormal movement, or a clicking sensation at the previous rib-fracture site, considered clinically suggestive of rib malunion or nonunion; this outcome was not confirmed by standardized imaging (computed tomography or radiography) in all participants and should not be interpreted as a radiologically confirmed diagnosis. Delayed return to work was defined as failure to resume pre-injury employment by the 12-month assessment among participants who were employed before injury. Thoracic readmission was defined as any patient-reported unplanned hospital readmission within 12 months attributable to chest-wall injury or a thoracic complication related to the index trauma; this outcome was based on patient report and was not independently verified against hospital records. Health-related quality of life was assessed using the EQ-5D-5L, comprising five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), and the EQ visual analogue scale (EQ-VAS), a self-rated assessment of overall health status; EQ-5D-5L index values were calculated using the Vietnamese value set. Pulmonary function was assessed by spirometry, with FVC and FEV1 expressed as percentages of predicted values; the 12-month assessment followed the same measurement procedure used in the original study. The original study documentation did not specify the spirometer model, patient positioning, number of measurements, reference equations, or acceptability and repeatability criteria, and compliance with a specific technical standard (such as the ATS/ERS spirometry standards) was not documented.

### 2.7. Statistical analysis

Continuous variables were summarized as mean ± standard deviation and categorical variables as frequencies and percentages. Between-group comparisons were performed using the Student's t-test or Mann–Whitney U test for continuous variables and the chi-square test or Fisher's exact test for categorical variables, as appropriate. Crude risk ratios were calculated for categorical 12-month outcomes. The 12-month analyses were based on available complete cases and were not adjusted for baseline differences or other potential confounders. No propensity score matching, multivariable regression, or multiple imputation was performed. Given the nonrandomized treatment allocation, baseline imbalance, and differential loss to follow-up, the analyses should be considered exploratory.

## 3. RESULTS

### 3.1. Follow-up profile

Among 192 eligible patients, 155 completed

12-month follow-up, corresponding to an overall follow-up rate of 80.7% and a loss-to-follow-up rate of 19.3%. The follow-up rate was 100% in the SSRF group and 71.1% in the nonoperative group.

**Table 1. Follow-up profile at 12 months**

| Variable | Total cohort (n=192) | SSRF (n=64) | Nonoperative (n=128) | p value |
|---|---|---|---|---|
| Completed 12-month follow-up | 155 (80.7%) | 64 (100%) | 91 (71.1%) | < 0.001 |
| Lost to follow-up | 37 (19.3%) | 0 (0%) | 37 (28.9%) | < 0.001 |
| Included in 12-month analysis | 155 | 64 | 91 | - |

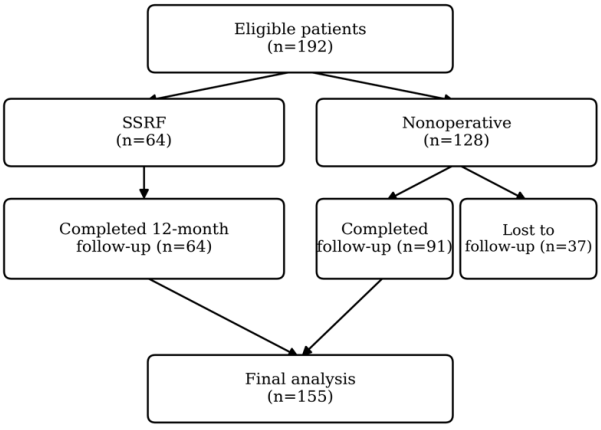


**Figure 1. Study flow diagram and 12-month follow-up profile**

### 3.2. Baseline clinical characteristics of patients with 12-month follow-up

The SSRF and nonoperative groups differed significantly at baseline (Table 2), including higher Injury Severity Score, higher admission Visual Analogue Scale pain score, and greater frequency of flail chest, chest wall deformity, and three or more displaced rib fractures in the SSRF group. These differences reflect the nonrandomized, indication-based treatment allocation described in Section 2.4, and the two groups should not be considered comparable at baseline.

**Table 2. Baseline characteristics of patients who completed 12-month follow-up**

| Variable | SSRF (n=64) | Nonoperative (n=91) | p value |
|---|---|---|---|
| Age, years | 48.6 ± 13.9 | 50.2 ± 15.1 | 0.51 |
| Male sex | 52 (81.3%) | 70 (76.9%) | 0.52 |
| ISS | 11.2 ± 3.1 | 10.1 ± 2.8 | 0.026 |
| Admission VAS score | 6.2 ± 1.4 | 4.5 ± 1.6 | < 0.001 |
| Flail chest | 16 (25.0%) | 6 (6.6%) | 0.002 |
| Chest wall deformity | 24 (37.5%) | 3 (3.3%) | < 0.001 |
| Three or more displaced ribs | 31 (48.4%) | 18 (19.8%) | < 0.001 |

### 3.3. Late complications at 12 months

In this unadjusted complete-case comparison, late complications were observed more frequently in the nonoperative group. Chronic chest wall pain was reported in 34.1% of patients managed nonoperatively compared with 10.9% of patients who underwent SSRF. Exertional dyspnea, chest wall deformity, and clinical symptoms suggestive of rib malunion/nonunion were also observed more frequently in the nonoperative group.

**Table 3. Late complications at 12 months**

| Complication | SSRF (n=64) | Nonoperative (n=91) | Crude risk ratio (SSRF/NOM) | p value |
|---|---|---|---|---|
| Chronic chest wall pain | 7 (10.9%) | 31 (34.1%) | 0.32 | 0.001 |
| Exertional dyspnea | 8 (12.5%) | 29 (31.9%) | 0.39 | 0.006 |
| Chest wall deformity | 2 (3.1%) | 15 (16.5%) | 0.19 | 0.012 |
| Clinical symptoms suggestive of rib malunion/nonunion | 3 (4.7%) | 17 (18.7%) | 0.25 | 0.015 |
| Delayed return to work* | 9/56 (16.1%) | 28/78 (35.9%) | 0.45 | 0.010 |
| Thoracic readmission | 3 (4.7%) | 8 (8.8%) | 0.53 | 0.37 |

**Calculated among patients employed before injury. Values represent unadjusted complete-case comparisons and were not adjusted for baseline injury severity or other potential confounders*

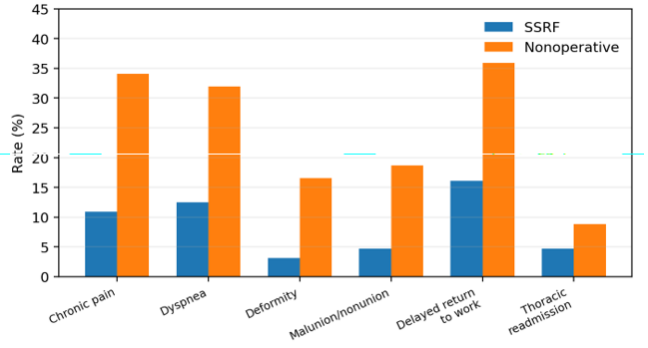


**Figure 2. Late complications at 12 months by treatment group**

### 3.4. Pain, pulmonary function and quality of life

Patients who underwent SSRF had lower VAS pain scores and higher FVC and FEV1 percentages of predicted values at 12 months than patients managed nonoperatively. EQ-5D-5L index and EQ-VAS scores were also higher after SSRF. These findings represent unadjusted between-group differences observed in this complete-case cohort.

**Table 4. Functional outcomes at 12 months**

| Outcome | SSRF (n=64) | Nonoperative (n=91) | p value |
|---|---|---|---|
| VAS pain score | 0.8 ± 1.1 | 2.0 ± 1.6 | < 0.001 |
| FVC, % predicted | 90.8 ± 9.4 | 82.1 ± 12.6 | < 0.001 |
| FEV1, % predicted | 88.7 ± 10.1 | 80.4 ± 13.2 | < 0.001 |
| EQ-5D-5L index | 0.93 ± 0.08 | 0.84 ± 0.13 | < 0.001 |
| EQ-VAS | 86.5 ± 9.7 | 76.2 ± 14.8 | < 0.001 |

Values represent unadjusted complete-case comparisons and were not adjusted for baseline injury severity or other potential confounders.

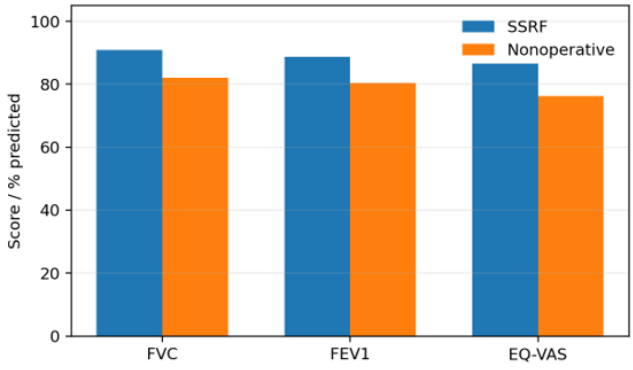


**Figure 3. Pulmonary function and EQ-VAS at 12 months by treatment group.**

## 4. DISCUSSION

In this unadjusted complete-case analysis, patients who underwent SSRF had lower rates of chronic chest wall pain, exertional dyspnea, chest wall deformity, and clinical symptoms suggestive of rib malunion/nonunion at 12 months after injury than patients managed nonoperatively. Patients who underwent SSRF also had higher pulmonary function and quality-of-life scores. However, the SSRF and nonoperative groups differed substantially at baseline, follow-up was incomplete and asymmetric between groups, and no adjustment for confounding was performed. These findings should therefore be interpreted as exploratory, unadjusted observations rather than evidence of a causal treatment effect of SSRF.

One of the most important findings of the present study is the notably lower rate of chronic chest wall pain observed in patients who underwent SSRF. At 12 months, chronic pain was observed in only 10.9% of patients undergoing SSRF compared with 34.1% of those treated nonoperatively. Persistent pain after rib fractures is increasingly recognized as one of the most important determinants of long-term disability and impaired quality of life. Prins et al. reported that thoracic pain frequently persists long after radiographic fracture healing and remains strongly associated with reduced physical functioning and patient satisfaction [3]. Similarly, a recent systematic review and meta-analysis by Zhu et al. demonstrated that SSRF was associated with lower chronic pain rates and superior patient-reported outcomes compared with nonoperative treatment [11]. The unadjusted findings of the present study are consistent with these observations; however, because treatment allocation was not randomized, a causal role of SSRF in preventing chronic pain cannot be established from the present data.

The improvement in pulmonary function observed in the SSRF group is another clinically relevant finding. Patients who underwent SSRF had significantly higher FVC and FEV1 values at 12 months in this unadjusted comparison. Restoration of chest wall stability may improve respiratory mechanics by reducing paradoxical chest wall motion, preserving thoracic volume, and facilitating more effective respiratory muscle function. The WSES-CWIS Position Paper published in 2024 emphasized that SSRF may improve both short-term respiratory outcomes and long-term pulmonary recovery through restoration of chest wall integrity [1]. Similar conclusions were reported by Pieracci et al. in a prospective multicenter trial, where patients undergoing SSRF experienced superior functional recovery compared with nonoperative management [2]. Our unadjusted findings are consistent with these recommendations in a Southeast Asian population, although the nonrandomized design of the present study limits causal interpretation.

Exertional dyspnea was less frequently reported in the operative group, an observed unadjusted difference between groups. Dyspnea remains one of the most common complaints among survivors of multiple rib fractures, even after fracture healing has occurred. Prins et al. demonstrated persistent respiratory symptoms in a substantial proportion of patients several months after injury [3]. Likewise, Peuker et al. reported that patients managed conservatively continued to experience functional limitations and respiratory complaints at one-year follow-up [4]. In the present study, exertional dyspnea was more than twice as common in the nonoperative group; this exploratory association may be consistent with, but does not establish, a beneficial effect of chest wall stabilization on long-term respiratory performance.

Chest wall deformity and clinical symptoms suggestive of rib malunion/nonunion were also observed less frequently after SSRF in this unadjusted comparison. Although most rib fractures ultimately heal, healing in a displaced or non-anatomical position may result in chronic pain, cosmetic deformity, impaired respiratory

mechanics, and reduced quality of life. Restoration of rib alignment and maintenance of stability throughout the healing process may in part explain the lower observed rates of these late structural complications, although this mechanism cannot be confirmed by the present unadjusted comparison. Recent international guidelines increasingly support considering SSRF not only in patients with flail chest but also in selected patients with multiple displaced rib fractures, chest wall deformity, or symptomatic instability [1]. Our findings are consistent with this evolving treatment paradigm.

Quality-of-life outcomes represent an additional exploratory association observed in the present study. Patients who underwent SSRF had significantly higher EQ-5D-5L and EQ-VAS scores than those managed nonoperatively in this unadjusted comparison. These findings are consistent with the observations of Raza et al., who reported improved pain control and quality-of-life measures following rib fixation [5]. Similarly, Zhu et al. demonstrated superior long-term quality-of-life outcomes after SSRF in their meta-analysis [11]. As trauma care increasingly focuses on patient-centered outcomes rather than solely mortality and complication rates, quality-of-life assessment has become an essential component of evaluating treatment effectiveness.

The findings of the present study are also consistent with previous Vietnamese experiences. Nguyen Huu Uoc and colleagues reported favorable early outcomes after rib fixation using plate systems at Viet Duc University Hospital [6]. More recently, Duong Duc Hung et al. highlighted the expanding indications for SSRF in patients with displaced rib fractures and chest wall instability [7]. Our previous multicenter prospective cohort study demonstrated superior in-hospital outcomes after SSRF compared with nonoperative treatment [8], while an early retrospective case series from Viet Tiep Friendship Hospital described the indications and operative technique of plate-and-screw fixation in a small cohort of patients [9]. The present study extends these observations by showing that observed unadjusted differences favoring SSRF persist at 12 months after injury; these exploratory, hypothesis-generating findings cannot establish a causal treatment effect and may be affected by baseline selection and differential attrition.

These exploratory, hypothesis-generating findings may have clinical relevance, although they cannot establish a causal treatment effect. Historically, SSRF was primarily reserved for patients with flail chest requiring ventilatory support. However, accumulating evidence suggests that selected patients with multiple displaced rib fractures, severe pain, chest wall deformity, or impaired respiratory mechanics may also benefit from operative stabilization [1,2,10]. The present study's exploratory findings are consistent with this broader indication strategy and suggest that chronic pain and functional impairment may warrant consideration alongside traditional short-term outcomes when selecting treatment strategies, pending confirmation in studies with adjusted analyses.

From a health-system perspective, titanium locking plate systems used for SSRF (e.g., MatrixRIB and RibFix Blu) represent a considerable direct cost in the Vietnamese healthcare setting. The present study was not designed as a cost-effectiveness analysis, and the available data are insufficient to draw conclusions regarding the economic efficiency of SSRF or its implications for health insurance coverage policy in Vietnam. Future studies incorporating direct treatment costs, time to return to work, patient affordability, and health insurance reimbursement policies are needed to inform economic and policy decisions regarding the broader adoption of SSRF.

Several limitations should be acknowledged. First, treatment allocation was not randomized and was based on predefined clinical indications and surgeon judgment, introducing confounding by indication: patients selected for SSRF

generally had more severe injury characteristics at baseline, and the two groups differed substantially in Injury Severity Score, admission pain score, and frequency of flail chest and chest wall deformity (Table 2). Second, no adjustment for these baseline differences was performed; no propensity score matching, multivariable regression, or other confounding-adjustment method was used, and all between-group comparisons represent crude, unadjusted associations. Third, the 12-month analysis was a complete-case analysis restricted to patients with available follow-up data and may not represent the full initial cohort. Fourth, follow-up was incomplete and asymmetric between groups: 37 of 128 patients (28.9%) in the nonoperative group were lost to follow-up, compared with none of the 64 patients in the SSRF group. The reasons for loss to follow-up were not systematically recorded; geographic and logistical barriers are plausible explanations, but this remains speculative in the absence of collected data, and differential attrition may have biased the observed between-group differences in either direction. Fifth, the diagnosis of clinical symptoms suggestive of rib malunion/nonunion was not confirmed by standardized imaging (computed tomography or radiography) in all participants at 12 months, and some diagnoses relied on clinical assessment alone. Sixth, pre-existing chronic pulmonary disease (such as chronic obstructive pulmonary disease or asthma) was not a study exclusion criterion, and baseline pulmonary status was not systematically documented; this represents a possible source of unmeasured confounding for the pulmonary function comparisons. Seventh, this study did not include a formal health-economic analysis, and no conclusions regarding cost-effectiveness or health insurance policy can be drawn from the present data. Finally, the study was conducted at tertiary trauma centers in Vietnam and may not be fully generalizable to other healthcare systems or settings with different resources for implant availability and follow-up infrastructure.

Despite these limitations, the present study represents one of the largest prospective multicenter cohorts from Vietnam evaluating outcomes at 12 months after SSRF. However, given the asymmetric loss to follow-up between groups, the 12-month findings should be interpreted as hypothesis-generating rather than confirmatory. Our exploratory, unadjusted findings suggest that SSRF may be associated with less chronic pain, better pulmonary function, fewer late chest wall complications, and higher quality of life among complete-case participants with blunt chest trauma, findings that warrant confirmation in studies with adjusted analyses and more complete follow-up.

## 5. CONCLUSION

In this multicenter prospective cohort, patients who underwent SSRF had more favorable observed 12-month pain, pulmonary-function, and quality-of-life outcomes than complete-case participants managed nonoperatively. However, these comparisons were unadjusted and were affected by substantial baseline imbalance and differential loss to follow-up. The findings should therefore be considered exploratory and should not be interpreted as establishing a causal treatment effect. Further studies using adjusted analyses, standardized imaging follow-up, and health-economic evaluation are warranted.

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