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# Acute compartment syndrome in tibial fractures: a meta-analysis

Bo Cong<sup>1</sup> and Haiguang Zhang<sup>1\*</sup>

## Abstract

**Purpose** Acute compartment syndrome (ACS) is a severe complication associated with tibial fractures, which can result in irreversible muscle and nerve damage if not promptly identified and treated.

**Method** This study systematically searched PubMed, EMBASE, the Cochrane Library, and Web of Science. Data on demographics, fracture attributes, injury mechanisms, and biomarkers were extracted. Meta-analyses were performed using both fixed- and random-effects models, depending on the degree of heterogeneity.

**Result** A total of 17 studies were included. Younger adult age and older age in pediatric populations were both linked to higher ACS risk, depending on the age group. Male sex was strongly associated with ACS. High-energy trauma and polytrauma were also associated with a heightened risk. Delayed external fixation also showed a protective effect, albeit based on limited evidence. Biomarkers, including elevated monocyte count and creatine kinase-MB levels, were also significant predictors.

**Conclusion** Younger adult age, male sex, high-energy trauma, and polytrauma were identified as critical risk factors for ACS in tibial fractures. Findings emphasize the need for standardized definitions and prospective investigations. Further research addressing pediatric age ranges, fracture location, and biomarker validation is essential to refine risk assessment and optimize early interventions.

**Keywords** Tibial fractures, Acute compartment syndrome, Risk factors, Meta-analysis

## Introduction

Acute compartment syndrome (ACS) is a potentially devastating complication associated with tibial fractures. It is characterized by increased pressure within a closed muscle compartment, leading to impaired circulation, muscle and nerve ischemia, and, if left untreated, irreversible tissue damage, contractures, or even limb amputation [1]. Among orthopedic emergencies, ACS represents one of

the most time-sensitive conditions, requiring prompt diagnosis and surgical intervention to prevent long-term disability [2]. Given the potentially severe consequences, early recognition and intervention are critical to preserving limb function and preventing adverse outcomes. Tibial fractures, particularly those resulting from high-energy trauma, are the most common injuries associated with ACS, with reported incidences ranging from 2 to 9% depending on fracture type and severity [3]. Currently, the specific risk factors contributing to ACS in patients with tibial fractures remain incompletely understood, necessitating a comprehensive investigation.

Identifying risk factors for ACS is essential for improving patient management, as it enables clinicians to recognize high-risk cases and implement timely monitoring

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and intervention strategies. Several factors, such as age, sex, fracture classification, and mechanism of injury, have been proposed as contributors to ACS development [4–6]. However, reported findings in the literature have been inconsistent, and no consensus has been reached on the precise predictors of ACS. This lack of clarity highlights the need for more robust statistical analyses to provide definitive evidence regarding ACS risk factors. Although previous studies have explored risk factors for ACS in patients with tibial fractures, several limitations remain. A systematic review investigated this topic but did not conduct a meta-analysis, failing to provide a quantitative synthesis of the evidence [4]. Another meta-analysis attempted to analyze risk factors for ACS but primarily focused on comparing mean values or proportions between ACS and non-ACS groups [3]. However, simple group comparisons of means or proportions cannot adequately quantify the strength of association between specific risk factors and ACS risk. Moreover, these methods do not sufficiently account for potential confounders, making them prone to bias when pooling heterogeneous data.

Therefore, this study adopts odds ratios (ORs) as the primary effect measure, as ORs allow for the estimation of the independent effect of each risk factor after adjusting for potential confounders. In addition, ORs directly quantify the strength of association between exposure and outcome, which is particularly important when baseline risk varies across populations. By synthesizing data from multiple studies and applying standardized statistical techniques, this meta-analysis aims to provide a quantitative assessment of associations between specific risk factors and ACS in patients with tibial fractures.

## Methods

### Data sources and search strategy

The study was performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and was registered with PROSPERO (CRD420250654457) [7]. Literature search was performed across four databases: PubMed, EMBASE, Cochrane Library, and Web of Science. The search included articles published from database inception until November 27, 2024. Keywords and Medical Subject Headings (MeSH) terms, as well as Emtree terms, related to “tibial fractures,” “acute compartment syndrome (ACS),” and “risk factors” were combined using Boolean operators (AND/OR) to identify relevant studies on tibial fractures and ACS risk factors. We also searched the reference lists of included studies and relevant reviews to identify additional studies.

### Inclusion and exclusion criteria

Studies were included if they met the following criteria: (1) involved patients with tibial fractures, (2) specifically investigated risk factors associated with ACS in this population, and (3) reported odds ratios (ORs) and 95% confidence intervals (CIs) or sufficient data to calculate them. Exclusion criteria were as follows: (1) non-original research articles, including abstracts, letters, comments, reviews, and case reports; (2) studies with duplicate data or overlapping populations; (3) studies that failed to report outcomes related to ACS or its risk factors; (4) non-English; (5) conference proceedings and unpublished studies.

### Study selection and data extraction

Study selection and data extraction were performed by two independent reviewers. Any discrepancies were resolved through discussion between the two reviewers without involving a third reviewer. The extracted data included detailed study characteristics such as the author, publication year, country, and study design. Patient demographics, including sample size, age, and site of fracture studied, were also recorded. Information on risk factors for ACS was collected, including ORs and their corresponding 95% CIs.

### Quality assessment

The methodological quality of included studies was assessed using the Newcastle-Ottawa Scale (NOS). Each study was evaluated across three domains: selection of study groups, comparability, and ascertainment of outcomes. Studies scoring 7 or higher were considered high quality.

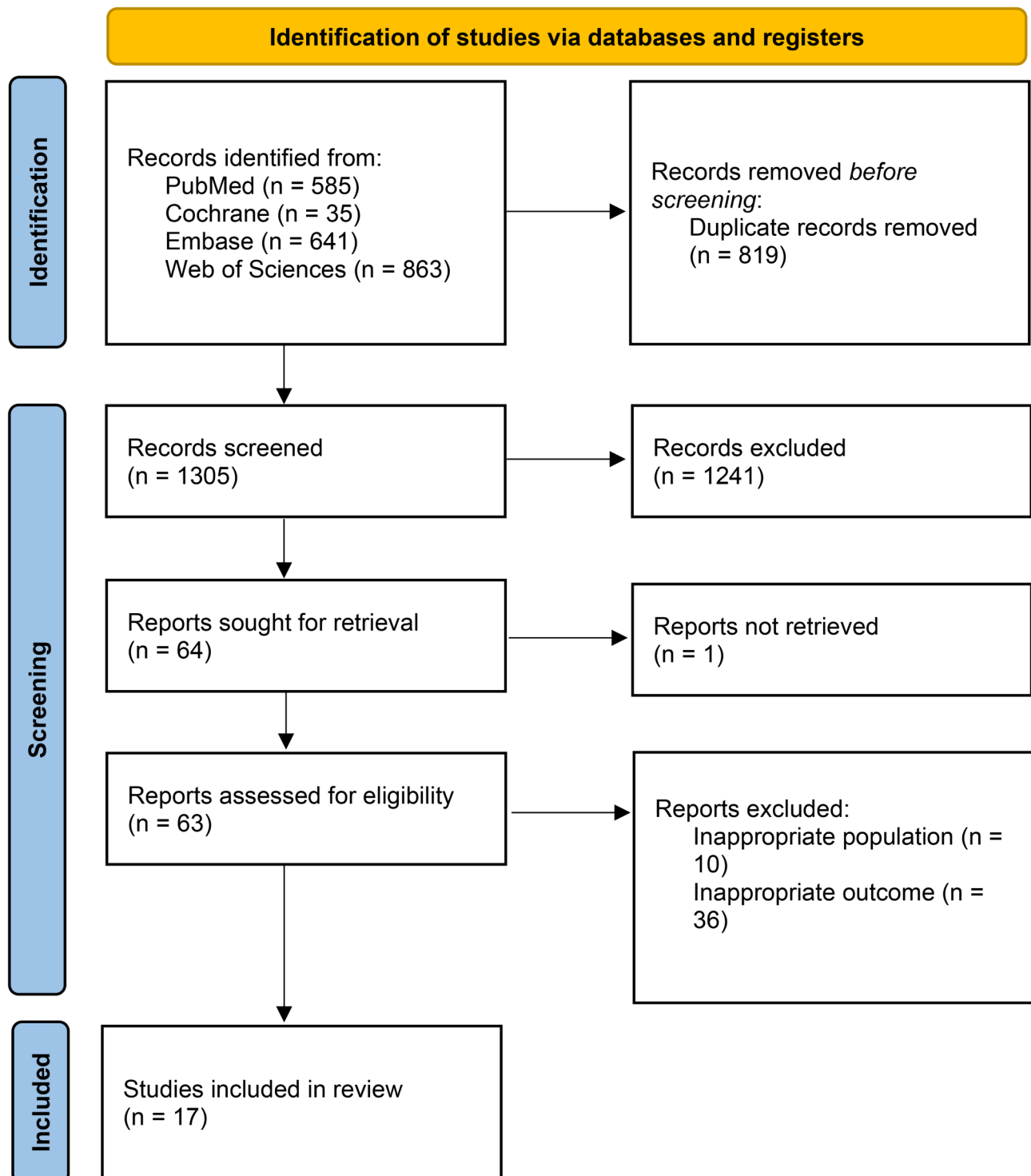
### Statistical analysis

Meta-analysis was performed using Review Manager (RevMan) version 5.4. Adjusted ORs were prioritized for inclusion in the meta-analysis. For studies that did not report adjusted ORs, unadjusted ORs obtained through simple logistic regression were used. Both random-effects and fixed-effects models were considered based on heterogeneity, as assessed using the  $I^2$  statistic. When  $I^2$  was below 50%, a fixed-effects model was applied; otherwise, a random-effects model was used. For studies reporting relative risks (RRs), values were converted to ORs using standard formulas prior to pooling [8]. In cases where ORs reflected opposite meanings, logarithmic transformation was performed to standardize the interpretation. Publication bias was evaluated using funnel plots since the number of included studies was limited.

## Results

A total of 2,124 articles were initially identified for this systematic review. After screening, 63 studies remained, of which 10 were excluded due to mismatched study populations and 36 due to incompatible results. Ultimately,

17 retrospective studies were included (Fig. 1) [9–25]. Most of the studies originated from the United States, collectively involving 23,853 participants, among whom 10,019 cases of ACS were reported. Patient age varied widely across studies. The most frequently reported



**Fig. 1** Study selection flow diagram

fracture sites included tibial diaphyseal fractures, tibial plateau fractures, and fractures of the proximal, middle, or distal tibia. NOS scores ranged from 4 to 8, indicating moderate to high methodological quality for the majority of studies (Table 1).

### Patient characteristics

In this study, age, sex, occupation, and race have been identified as significant risk factors for ACS in patients with tibial fractures. Six studies reported age-related findings [10, 17, 20, 21, 25]. Among patients over 18 years old, younger age was associated with a higher risk of ACS (OR: 0.98, 95% CI: 0.96–0.99,  $P=0.008$ ), although there was substantial heterogeneity ( $I^2=86\%$ ) (Fig. 2A). The funnel plot appeared symmetric, suggesting that no significant publication bias was present in the included studies (Figure S1 A). Conversely, in patients under 18 years old, older age was linked to an increased ACS risk (OR: 1.157, 95% CI: 1.032–1.297,  $P=0.0126$ ) [26]. Six studies examined sex as a risk factor, revealing that male patients had a significantly higher risk of ACS compared to females (OR: 2.27, 95% CI: 1.64–3.14,  $P<0.001$ ), with moderate heterogeneity ( $I^2=70\%$ ) (Fig. 2B) [10, 14, 17, 18, 20, 25]. Funnel plot analysis for these two factors suggested the presence of underlying heterogeneity and slight publication bias (Figure S1 B). Notably, one study [22] reported that the higher incidence of ACS in males could be partially attributed to their younger average age compared to females.

Regarding occupational risk, one study found that patients in blue-collar professions involving physical labor had a significantly higher risk of ACS compared to those in other occupations (OR: 1.95, 95% CI: 1.33–2.86). Similarly, one study reported a race-related disparity, showing that non-African American patients had a significantly higher ACS risk than African Americans (OR: 2.238, 95% CI: 1.08–4.638). In terms of obesity, one study [15] found no significant impact of obesity on ACS risk, regardless of whether the ACS occurred in the tibial tubercle or tibial shaft. Another study [18] similarly reported no significant association between BMI and ACS risk.

### Fracture type and mechanism of injury

Three studies investigated the impact of open versus closed fractures on the risk of ACS in tibial fracture patients [9, 12, 20]. The association between fracture type and ACS was weak (OR=0.93, 95% CI: 0.40–2.19,  $P=0.87$ ), with substantial heterogeneity ( $I^2=71\%$ ) (Fig. 3A). The visually symmetrical funnel plots suggested that small studies were not systematically missing, and publication bias was low (Figure S1 C). Two studies provided insights into the role of fracture location. Using tibial plateau fractures as the reference category, diaphyseal

fractures were associated with a significantly lower ACS risk (OR=0.23, 95% CI: 0.11–0.48,  $P<0.001$ ), and pilon fractures showed an even lower risk (OR=0.16, 95% CI: 0.07–0.37,  $P<0.001$ ) [24]. Interestingly, another study reported higher but statistically nonsignificant ACS risks for tibial plateau and pilon fractures compared to other types (OR=5.24, 95% CI: 0.77–35.46) [12]. One study found no significant association between ACS risk and multisegment or bilateral tibial injuries [20]. However, meta-analysis results highlighted polytrauma as a key risk factor for ACS in tibial fractures. Three studies confirmed that patients with polytrauma had a significantly higher risk of ACS compared to those without (OR=3.11, 95% CI: 1.97–4.91,  $P<0.001$ ), with low heterogeneity ( $I^2=13\%$ ) (Fig. 3B) [12, 15, 18]. Funnel plot analysis supported these findings (Figure S1 D).

High-energy trauma was another prominent risk factor, as reported in six studies [9, 10, 12, 16, 17, 25]. Patients with tibial fractures caused by high-energy mechanisms had a significantly increased risk of ACS (OR=1.97, 95% CI: 1.65–2.35,  $P<0.001$ ), with moderate heterogeneity ( $I^2=30\%$ ) (Fig. 3C). The asymmetry in the funnel plot, with a lack of studies on the left side, might have indicated selective reporting (Figure S1 E). Conversely, low-energy injuries were associated with a significantly lower ACS risk (OR=0.334, 95% CI: 0.152–0.737) [17]. Interestingly, delayed external fixation was found to reduce ACS risk, as demonstrated by two studies (OR=0.44, 95% CI: 0.23–0.84,  $P=0.010$ ) [13, 14]. This finding exhibited low heterogeneity ( $I^2=20\%$ ) (Fig. 3D), and funnel plot analysis revealed no significant publication bias (Figure S1 F). These results underscore the complex interplay between fracture characteristics, injury mechanisms, and ACS risk, with high-energy trauma and polytrauma emerging as critical determinants.

### Fracture severity

One study [12] evaluated the influence of fracture severity indicators on the risk of ACS in tibial fractures. The severity indicators included: ratio of fracture length to tibial length, distance from the talar dome to the center of the tibial fracture  $\geq 15$  cm, fracture segment overriding  $\geq 8$  mm, total translation  $\geq 40\%$ , total angulation  $\geq 5^\circ$  and distance between the fibular and tibial fractures  $< 3$  cm. Among these, only the distance from the tibial fracture center to the talar dome  $\geq 15$  cm was significantly associated with an increased risk of ACS (OR=3.54, 95% CI: 1.59–7.87).

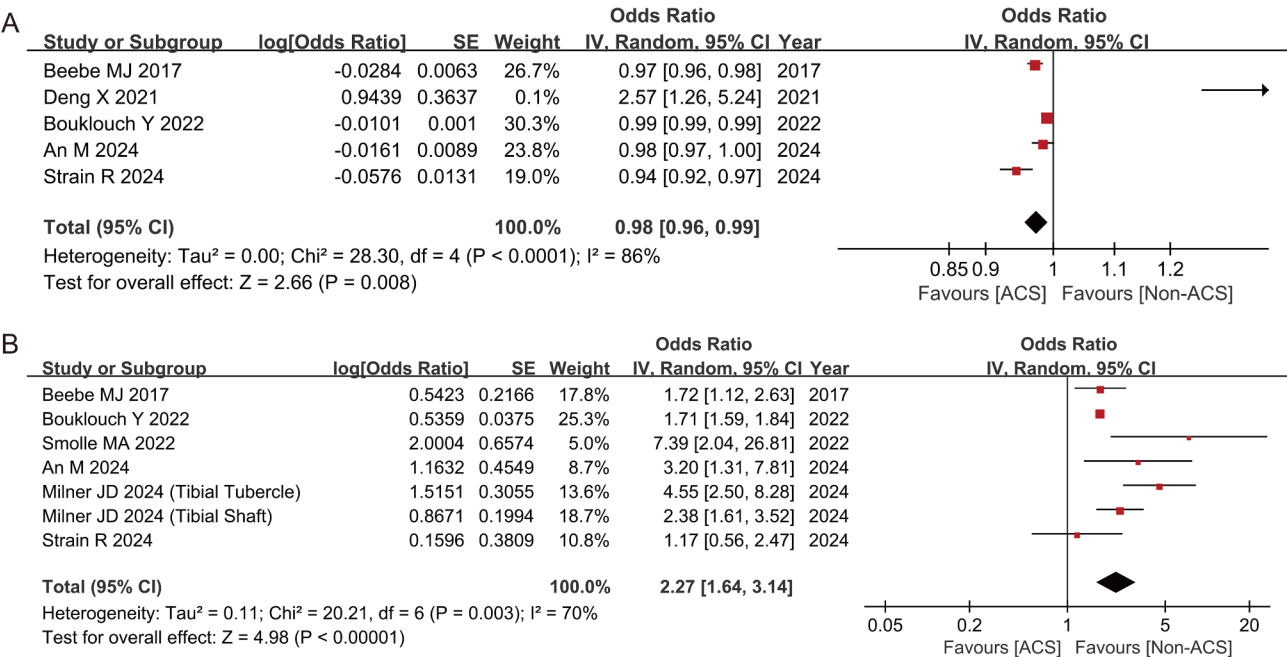
### Biomarkers

A study [19] investigated the relationship between various blood biomarkers and the risk of ACS. The findings identified three significant risk factors: monocyte count (OR=3.352, 95% CI: 1.266–8.873,  $P=0.015$ ), systemic

**Table 1** General characteristics of included studies

Study	Country	Study design	ACS/non-ACS	Age	Site of fracture studied	NOS score
Ziran BH et al. 2013	USA	Retrospective	CS: $n = 18$ non-CS: $n = 141$	CS: $42 \pm 11.6$ non-CS: $48 \pm 15.5$	plateau fractures	6
McQueen MM et al. 2015	UK	Retrospective	ACS: $n = 160$ non-ACS: $n = 1228$	12–98	tibial diaphyseal fractures	5
Allmon C et al. 2016	USA	Retrospective	CS: $n = 56$ non-CS: $n = 922$	$\geq 18$	plateau, shaft or pilon fractures	7
Haller J M et al. 2016	USA	Retrospective	CS: $n = 14$ non-CS: $n = 145$	$\geq 18$	high-energy tibial plateau and plafond fractures	6
Beebe MJ et al. 2017	USA	Retrospective	ACS: $n = 136$ non-ACS: $n = 2749$	$42.9 \pm 18.0$	fractures involved the proximal segment (OTA/AO 41): 952 fractures involved the middle segment (OTA/AO 42): 1262 fractures involved the distal segment (OTA/AO 43): 834	5
Gamulin A et al. 2017	Switzerland	Retrospective	ACS: $n = 28$ non-ACS: $n = 2749$	$> 16$	tibial plateau fractures	7
Wuarin L et al. 2020	Switzerland	Retrospective	ACS: $n = 31$ non-ACS: $n = 239$	$> 16$	tibial shaft fractures	6
Deng X et al. 2021	China	Retrospective	ACS: $n = 35$ non-ACS: $n = 1084$	18–80	tibial plateau fractures	6
Bouklouch Y et al. 2022	USA	Retrospective	ACS: $n = 8748$ non-ACS: $n = 194,752$	Male: $40.2 \pm 18.1$ female: $49.2 \pm 20.7$	Proximal tibial fractures: 38% midshaft fractures: 30% distal fractures: 32%	8
Gamulin A et al. 2022	Switzerland	Retrospective	ACS: $n = 67$ non-ACS: $n = 658$	$> 16$	an intra- or extra-articular proximal tibia fracture (AO/OTA classification codes 41A2, 41A3, 41B, 41 C), a tibial shaft fracture (AO/OTA 42), or an intra- or extra-articular distal tibia fracture (AO/OTA 43)	6
Smolle MA et al. 2022	Austria	Retrospective	ACS: $n = 23$ non-ACS: $n = 230$	50.7 (18.0–85.0)	tibial plateau fractures	4
Ahmed N et al. 2023	USA	Retrospective	CS: $n = 49$ non-CS: $n = 4443$	$< 18$	Open tibia fx: 352 Proximal tibia fx: 1018 Proximal tibia fx extra-articular: 1409 Proximal tibia fx_complete articular_bicondylar_open: 127 Tibia fracture, proximal, complete articular; plateau; bicondylar: 1081 Tibia fracture, proximal, extra-articular, open: 35 Tibia fracture, proximal, partial articular: 470	6
An M et al. 2024	China	Retrospective	ACS: $n = 86$ non-ACS: $n = 619$	ACS: 32.5 (24.8–53.0) non-ACS: 43.0 (30.0–56.0)	diaphyseal tibial fractures	6
Milner JD et al. 2024	USA	Retrospective	ACS: $n = 296$ non-ACS: $n = 50,670$	10–18	Tibial Tubercle & Tibial Shaft	7
Strain R et al. 2024	UK	Retrospective	ACS: $n = 58$ Non-ACS: $n = 1089$	$\geq 18$	diaphyseal fractures (AO/OTA type 42)	5
Wang T et al. 2024	China	Retrospective	ACS: $n = 127$ non-ACS: $n = 127$	$\geq 18$	NR	6
Wier J et al. 2024	USA	retrospective	CS: $n = 87$ non-CS: $n = 3098$	$\geq 18$	tibial plateau fractures	6

ACS: acute compartment syndrome; CS: compartment syndrome; NOS: Newcastle-Ottawa scale; NR: not reported



**Fig. 2** General factors affecting ACS in patients with tibial fractures. **A:** age; **B:** sex

immune-inflammation index (SII) (OR=1.001, 95% CI: 1.000–1.002,  $P=0.011$ ) and creatine kinase-MB (CK-MB) (OR=1.097, 95% CI: 1.071–1.124,  $P<0.001$ ). These results suggest that elevated monocyte levels, higher SII, and increased CK-MB concentrations are associated with a greater likelihood of developing ACS.

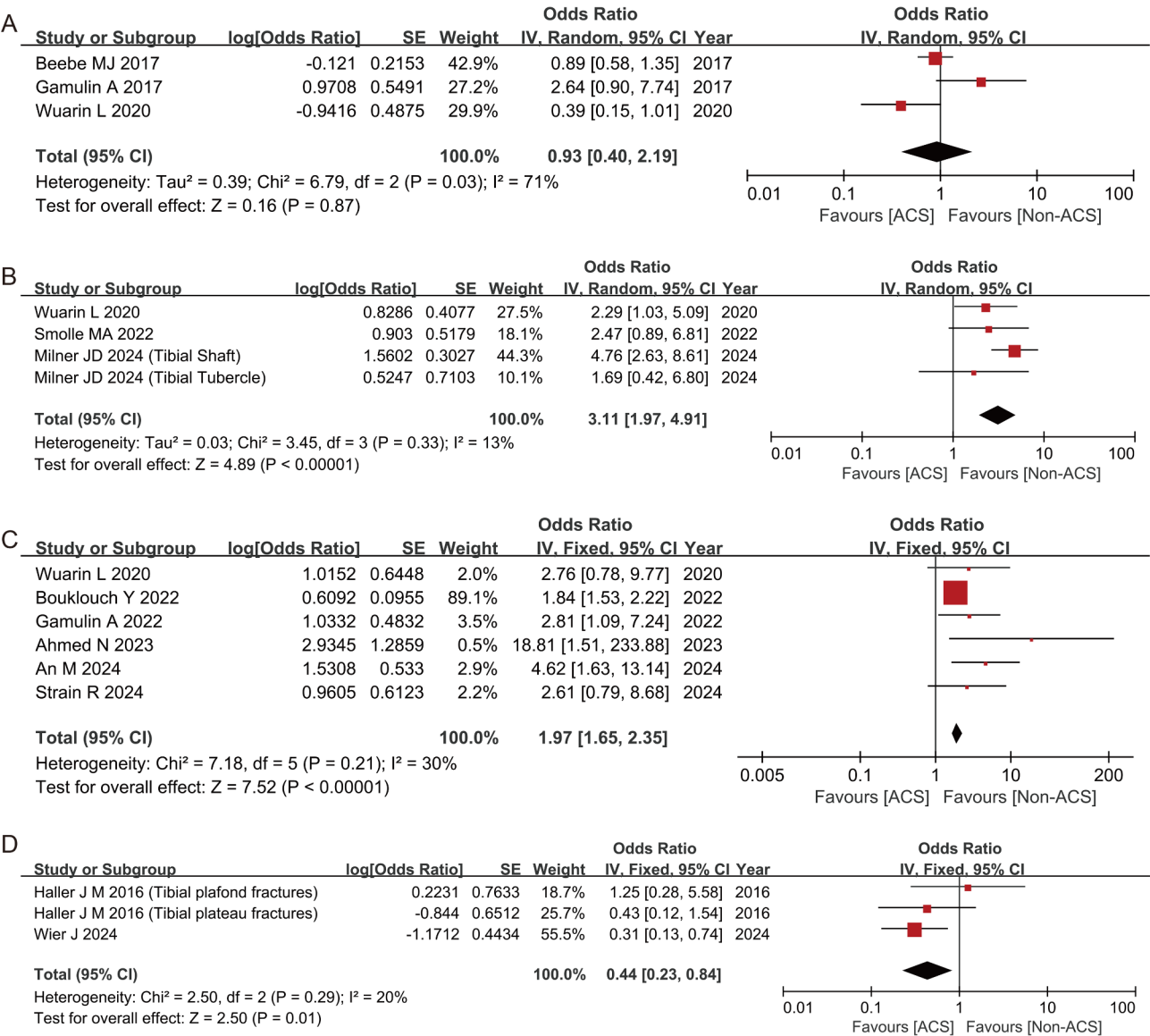
Discussion

In this meta-analysis of 17 studies, we aimed to identify and quantify the risk factors associated with ACS in patients with tibial fractures. Our findings provide several insights regarding demographic characteristics, fracture patterns, injury mechanisms, and biomarkers.

Our results indicate that younger age is associated with a higher risk of ACS in adult patients. Supporting this, previous studies have suggested that younger age is a significant risk factor for ACS in adult patients, potentially due to higher physical activity levels and robust musculature [4, 25]. The higher muscle mass in younger adults may contribute to elevated intracompartmental pressures following trauma, as well-developed musculature has limited capacity for expansion within the confined fascial compartments. On the other hand, in pediatric patients with tibial fractures, older age, rather than younger age, has been associated with higher ACS risk, which may be attributed to differences in growth rates and biomechanical stress during adolescence [5, 27]. Adolescents experience rapid musculoskeletal growth, which can result in altered tissue compliance and increased susceptibility to ACS, particularly as muscle hypertrophy outpaces fascial expansion. These apparent discrepancies could stem from

variations in muscle mass, growth patterns, and physical activity levels across different stages of life. Notably, a large retrospective cohort study identified age as the strongest predictor of ACS, with the highest prevalence observed in individuals aged 12–29 years, aligning with the heightened physical demands and increased compartmental pressures in this age group [22]. This underscores the complexity of the relationship between age and ACS risk, which appears to vary across demographic and clinical settings [28–30]. Meanwhile, the association between race and ACS risk remains an intriguing finding. Studies have highlighted disparities in orthopedic outcomes broadly, influenced by socioeconomic status, access to healthcare, and systemic inequities [31]. However, as only one study specifically addressed race-related disparities, this finding should be interpreted with caution, and more robust evidence is needed to draw definitive conclusions. Besides, future investigations could further determine whether genetic predispositions, socioeconomic factors, or healthcare-access inequalities contribute to potential differences in ACS risk across broader clinical and demographic contexts. In addition, male sex was found to significantly elevate the risk of ACS, echoing earlier findings that men may be at greater risk due to higher engagement in high-impact sports or labor-intensive occupations. Previous studies have documented a strong association between ACS and factors prevalent in men, such as participation in rigorous physical activities and employment in manual labor industries [22, 25]. Notably, one study indicated that the higher incidence of ACS in males could be partially attributed to their younger average age





**Fig. 3** Fracture type and mechanism of injury affecting ACS in patients with tibial fractures. **A:** Open fractures; **B:** Polytrauma; **C:** High-energy trauma; **D:** Delayed external fixation

compared to females, potentially magnifying the impact of risk factors such as muscular mass and activity levels [22]. Pediatric studies have shown a higher incidence of ACS among boys despite their lower likelihood of participating in physically demanding activities compared to adult males, suggesting that activity-related injuries and sex-specific physiological factors may contribute to this disparity [5]. It should be noted that the heterogeneity of age and sex in this study was high, which may also be due to the differences in patient selection, diagnostic criteria and treatment strategies among different studies. Moreover, our meta-analysis further revealed that individuals employed in blue-collar jobs have a significantly higher risk of ACS. This elevated risk is likely attributable to the physically strenuous nature of these roles,

which often involve repetitive heavy labor, prolonged exposure to awkward postures, and increased likelihood of workplace injuries. A study has shown that blue-collar occupations are associated with higher incidences of musculoskeletal injuries, potentially predisposing workers to conditions such as ACS due to cumulative trauma and acute high-energy injuries [22]. However, it is worth noting that most studies have not identified blue-collar work as a significant independent risk factor for ACS. This suggests that confounding factors, such as the severity of injury or biomechanical variations, may contribute to the observed association. Further research is needed to explore whether blue-collar employment itself constitutes an independent risk factor for ACS.

Our meta-analysis underscores the critical role of polytrauma and high-energy mechanisms in the development of ACS. These findings align with prior clinical observations that patients with multiple severe injuries often experience significant systemic stress, inflammatory responses, and tissue swelling, all of which elevate compartment pressures [32, 33]. Similarly, high-energy traumas are commonly linked to extensive bone and soft tissue damage, further elevating the risk for ACS. These injuries typically result in increased compartment pressures due to significant vascular compromise, tissue swelling, and inflammatory responses, which are hallmark features of ACS progression [34, 35]. Our meta-analysis also identified noteworthy findings related to management and clinical parameters. Delayed external fixation appeared to have a protective effect, with a significantly lower ACS risk, suggesting that certain surgical timing strategies, such as allowing sufficient soft tissue stabilization prior to definitive fixation, may help mitigate compartment pressure elevation in selected cases [36]. In addition, one study reporting that fracture severity indices were significantly associated with ACS risk, highlighting the potential value of specific radiographic measurements in guiding surveillance for ACS [37]. Contrary to earlier reports linking open fractures to an elevated ACS risk due to high-energy trauma and soft-tissue compromise, the present meta-analysis found no statistically significant difference between open and closed fractures. This contrasts with earlier study suggesting that open fractures might predispose patients to ACS due to higher-energy mechanisms and severe soft-tissue trauma [4]. The lack of significant association in our meta-analysis could be attributed to variability in definitions of open fracture severity or differences in the timing of surgical interventions. Regarding fracture locations, one study suggested that both tibial shaft and pilon fractures exhibited a lower ACS risk compared with tibial plateau fractures [24]. Another study reported an opposite trend without statistical significance [37]. The contradictory results between fracture site and ACS risk may be due to the fact that different studies used different fracture classification methods (such as AO classification and traditional anatomical classification), resulting in a lack of comparability of the results. In addition, the study design and the different fixation strategies adopted for fractures in different medical institutions may have affected the incidence of ACS. These inconsistencies highlight the importance of standardized classifications and the need for robust prospective cohort studies to better delineate the relationship between fracture location and ACS risk.

Lastly, emerging evidence for biomarkers such as monocytes and creatine kinase-MB, suggests that systemic inflammatory and muscle injury markers could help in early ACS detection [38]. Additionally, although

this meta-analysis did not include these parameters due to the lack of sufficient studies meeting our inclusion criteria for quantitative synthesis, emerging diagnostic approaches, such as pH monitoring, oxygen saturation levels, and glycocalyx integrity markers, are increasingly recognized as potential tools for ACS assessment. Ischemic tissue damage in ACS has been linked to alterations in pH and oxygen saturation levels, with worsening tissue hypoxia leading to intracellular acidosis and muscle necrosis [39, 40]. Recent studies suggest that degradation of the glycocalyx layer, reflected by increased circulating levels of syndecan-1, heparan sulfate, and hyaluronan, may serve as biomarkers for endothelial injury and capillary leakage, both of which are hallmarks of ACS progression [1, 41, 42]. While these biomarkers and physiological parameters show promise in ACS detection, their clinical utility remains under investigation. Large-scale prospective trials are required to establish their role in ACS risk stratification.

Our findings should be interpreted in light of several limitations. First, the majority of included studies were observational in nature, which could introduce inherent confounding and selection bias. Second, substantial heterogeneity existed for some parameters (e.g., age), reflecting differences in study populations, clinical protocols, and outcome definitions. Third, publication bias may remain an issue despite funnel plot evaluation, given the relatively small number of studies for certain analyses. Fourth, there are few literatures included clinically relevant factors, such as postoperative complications or detailed rehabilitation programs, or pre-existing vascular diseases. Future research should focus on collecting and analyzing these data to refine ACS prevention and management strategies. In addition, the lack of standardized ACS diagnostic criteria between studies may lead to inconsistent reported ACS incidence and risk factors. Finally, this study found that there may be regional differences in ACS risk, which also needs to be confirmed in future studies.

## Conclusion

This meta-analysis underscores the multifactorial nature of ACS risk in patients with tibial fractures. Younger adult age, male sex, and high-energy trauma emerged as key predictors, while data on open versus closed fractures and fracture location remain inconclusive. ACS prediction models enhanced by specialized prospective studies and standardized risk assessment tools are needed in future research.

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12891-025-08586-z>.



# Supplementary Material 1

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Not applicable.

## Author contributions

All authors have accepted responsibility for the entire content of this manuscript and consented to its submission to the journal, reviewed all the results and approved the final version of the manuscript. BC designed the study, wrote the first draft of the article, collected the data, performed the data analysis and prepared the figures. HZ contributed to the revision of the manuscript.

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## Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

## Declarations

## Ethical approval

Not applicable.

## Competing interests

The authors declare no competing interests.

## Clinical trial number

Not applicable.

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