Suprapatellar versus infrapatellar intramedullary nailing for treatment of tibial shaft fractures in adults

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Abstract
Background: Numerous studies have compared suprapatellar (SP) nailing to infrapatellar (IP) nailing for treatment of tibial shaft fractures; however, the best strategy remains controversial. The aim of this meta-analysis is to assess whether SP or IP nailing is more effective for tibial shaft fractures in adults.

Methods: Literature searches of PubMed, Embase, OVID, Cochrane Library, Web of Science, Chinese Biomedical Literature, Wanfang, Weipu Journal, and CNKI databases were performed up to July 2017. Only randomized controlled trials (RCTs) comparing SP versus IP intramedullary nailing for tibial shaft fractures were included. Data collection and extraction, quality assessment, and data analyses were performed according to the Cochrane standards.

Results: Twelve RCTs were selected for analysis. SP intramedullary nailing reduced knee joint pain, visual analog score, fluoroscopy time, and sagittal angle, resulting in better Harris hip score, Lysholm knee score, short-form 36 questionnaire, range of motion, and rates of “excellent” and “good” outcome. There were no significant differences in operative time, blood loss, length of hospital stay, union time, and coronal angle between groups.

Conclusion: The present meta-analysis indicates that SP intramedullary nailing has obvious advantages over IP intramedullary nailing for treatment of tibial shaft fractures in adults. However, owing to the low-quality evidence currently available, additional high-quality RCTs are needed to confirm these findings.

Abbreviations: HHS = Harris hip score, IP = infrapatellar, IMN = intramedullary nail, RCT = randomized controlled trial, ROM = range of motion, SF-36 = short-form 36, SP = suprapatellar, VAS = visual analog score.

Keywords: infrapatellar intramedullary nailing, meta-analysis, suprapatellar intramedullary nailing, tibial shaft fracture

1. Introduction
Tibial shaft fractures, primarily caused by high-energy trauma,[1] are the most common diaphyseal fractures in adults, accounting for about 13.7% of all fractures.[2] At present, there are several treatment methods for tibial shaft fractures, such as open reduction and internal fixation with plates, external fixation, and intramedullary nailing.[3] The insertion of an intramedullary nail (IMN) with interlocking screws is considered the standard of care for operatively managed tibial shaft fractures.[4] However, IMN insertion through the infrapatellar (IP) approach remains technically challenging due to proximal fracture fragment displacement with knee flexion induced by quadriceps and extensor complex as well as the multiple adjustments made during imaging.[5] Further, postoperative anterior knee pain is a common if not the most frequent complication after IMN insertion, with a reported incidence varying from 10% to 86%.[6–8]

The suprapatellar (SP) approach was developed as an alternative to obviate these potential drawbacks. In the SP approach, the quadriceps tendon is split to obtain access to the SP pouch and retro-patellar space through an incision 2.5-cm proximal to the patella. A cannula system then allows for the standard insertion of the tibial nail. The full or near-full extension position of the leg assists in neutralizing the deforming forces of the quadriceps muscle and maintaining proper alignment of the proximal tibia. In addition, extension also helps align comminuted shaft fractures or highly unstable distal third fractures, cases in which maintaining reduction against gravity in the flexed or hyper-flexed position can be extremely challenging. Also, the extended position of the lower leg allows for easier fluoroscopic imaging.[9]

Recently, a number of prospective randomized trials comparing SP with IP have been conducted.[8–19] However, these studies were limited in sample size and quality of methodology, and failed to draw a definitive conclusion on which operative approach method is optimal for tibial shaft fractures in reducing complications and improving prognosis. To provide a robust...
support for clinical decision, we conducted a meta-analysis to evaluate the efficacy of 2 interventions in treatment of tibial shaft fractures.

2. Materials and methods

2.1. Search strategy

We searched the following electronic databases for studies comparing SP to IP for the treatment of tibial shaft fractures in adults: PubMed, Embase, OVID, the Cochrane Library, Web of Science, Chinese Biomedical Literature database, Wanfang data, Weipu Journal database, and the CNKI database. The key words used were “tibial shaft fracture,” “tibial fracture,” “shaft of tibial fracture,” “suprapatellar approach,” “suprapatellar tibial nailing,” “suprapatellar nailing,” “infrapatellar approach,” “infrapatellar tibial nailing,” “infrapatellar nailing,” “traditional tibial nailing,” “traditional nailing,” and “transpatellar tendon approach.” Articles were searched up to July 2017. Google Scholar was also searched to investigate potentially relevant literature. In addition, the reference lists of included studies and all related review articles were checked for additional trials, published or unpublished. Language and publication status date were not restricted, and gray literature as well as ongoing trials were also investigated.

2.2. Inclusion and exclusion

Study inclusion criteria were as follows:

1. Patients: skeletally mature patients (older than 18 years old) diagnosed with tibial shaft fracture.
2. Intervention: SP intramedullary nailing or IP intramedullary nailing.
3. Outcome: operative time, fluoroscopy time, blood loss, Harris hip score (HHS), Lysholm knee score, short-form 36 (SF-36) questionnaire physical score (SF-36 PCS), SF-36 mental score (SF-36 MCS), visual analog scale (VAS), rate of knee joint pain, range of motion (ROM), “excellent” and “good” outcome ratings, time to union, length of hospital stay, and radiographic results.
4. Study design: prospective, randomized controlled trial (RCT).

Exclusion criteria were as follows: studies including open fractures, intra-articular fractures, or plateau fractures; duplicates or multiple publications of the same study; retrospective studies, single-case reports, reviews, or animal studies; and studies without usable data.

2.3. Quality assessment

The quality of the included studies was assessed independently by 2 reviewers (XC and HTX) using the Cochrane Risk of Bias Tool of Review Manager Version 5.3 (Copenhagen, Denmark, The Nordic Cochrane Centre, The Cochrane Collaboration). Appraisal criteria included random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias. Each of these factors was recorded as low risk, unclear risk, or high risk. If data were unclear, we contacted authors for clarification whenever possible. Disagreements were resolved by third party adjudication (JC).

2.4. Data extraction

Data were extracted for all studies that met the inclusion criteria. For each study, 2 review authors (XC and HTX) independently completed data extraction forms tailored to the requirements of this review. All disagreements were resolved by discussion between the 2 review authors. If consensus could not be made, a third review author (JC) was asked to complete the data extraction form and discuss the paper with the other 2 authors until consensus was reached.

2.5. Statistical analysis

2.5.1. Heterogeneity test and effect value. This study used Review Manager 5.3 software for meta-analysis. Risk ratios (RRs) were calculated for dichotomous variables in each study. Standardized mean difference or weighted mean difference (WMD) was calculated for continuous variables, and 95% confidence intervals (CIs) were determined for all effect sizes. Heterogeneity was analyzed using Chi-squared tests before meta-analysis ($P = .05$). If there was no heterogeneity ($P \geq .05$, $I^2 < 50\%$), a fixed-effects model was used. Otherwise ($P < .05$) a random effect model was used. Sensitivity analysis was conducted by step-wise removal of data sets. Data sets causing significant changes in pooled results when removed were analyzed further to assess the reason. We then judged the results for stability and strength. If the heterogeneity was too large to analyze, descriptive analyses are presented.

2.5.2. Publication bias. Publication bias was analyzed using Begg and Egger tests. A $P \leq .05$ was considered significant.

3. Results

3.1. Search results

The literature search yielded 77 studies. Of these, 37 were duplicates and 25 did not match our inclusion criteria according to title and abstract assessment. No data was obtained from gray literature investigations or ongoing trials (we received no answers from authors we contacted). For the remaining 15 studies, 3 did not meet the inclusion criteria after full-article assessment. Therefore, 12 RCTs (including 2 studies of Master’s degree thesis) with a total of 779 patients were included in this review. The searching process is shown in Figure 1.

3.2. Quality assessment and basic information

According to The Cochrane Collaboration Risk of Bias Tool, the quality of all RCTs was acceptable (Fig. 2), and all reported the method of randomization. Three RCTs were conducted through computer-generated lists, one through sealed envelopes, and 3 reported binding of the surgeons and participants. No study showed an unclear bias due to incomplete outcome data or selective outcome reporting.

3.3. Demographic characteristics

Demographic characteristics are summarized in Table 1. Baseline characteristics SP and IP groups were similar.

3.4. Duration of operation time

Seven studies involving 494 fractures provided data on operation time. There was significant heterogeneity among studies ($\chi^2 = 33.75, P < .00001, I^2 = 82\%$), and the pooled outcome did not differ significantly between groups...
(WMD: 0.23, 95% CI: −2.80 to 3.25, \(P = .88\); Fig. 3). However, sensitive analysis (Fig. 4) excluding the outlier study\(^{[17]}\) revealed a significant difference between SP and IP for the remaining studies (WMD: −1.93, 95% CI: −1.56 to −0.68, \(P = .002\)) with low statistical heterogeneity (\(\chi^2 = 5.90, P = .32, I^2 = 15\%\), Fig. 5).

### 3.5. Blood loss

Five studies reported data on intraoperative blood loss,\(^{[8,15–17,19]}\) including 198 patients in the SP group and 205 in the IP group. There was no significant difference in blood loss between SP and IP (WMD: 0.10, 95% CI: −1.24 to 1.43, \(P = .89\)) with no statistical heterogeneity among studies (\(\chi^2 = 1.26, P = .87, I^2 = 0\%\), Fig. 6).

### 3.6. Radiation time

Two articles including 207 fractures provided data on radiation time.\(^{[8,13]}\) A fixed-effects model was applied because no statistical heterogeneity was found among studies (\(\chi^2 = 0.06, P = .81, I^2 = 0\%\)). The pooled results indicated significantly lower radiation time using SP compared to IP (WMD: −38.76, 95% CI: −49.35 to −28.18, \(P < .00001\); Fig. 7).

### 3.7. Hospital stay

Four studies with 351 patients provided data on length of hospital stay.\(^{[8,11,15,19]}\) There was no statistical heterogeneity (\(\chi^2 = 1.78, P = .62, I^2 = 0\%\)) and no significant difference in outcome between groups (WMD: 0.09, 95% CI: −0.13 to 0.31, \(P = .41\); Fig. 8).

### 3.8. Harris hip score of the last follow-up

The HHS at last follow-up was documented in 2 studies.\(^{[17,19]}\) A random-effects model was applied because significant statistical heterogeneity was found between the studies (\(\chi^2 = 6.23, P = .01, I^2 = 84\%\)). The results indicated that the HHS at last follow-up significantly favored SP (WMD: 9.39, 95% CI: 4.29–14.49, \(P = .0003\); Fig. 9). A sensitivity analysis found no significant change when any 1 study was omitted.
3.9. “Excellent” and “good” outcome ratings

Four studies reported the outcome ratings for both SP and IP groups.[11,16,18,19] In the pooled analysis, “excellent” and “good” ratings were more frequent in the SP group at last follow-up (RR: 1.18, 95% CI: 1.08–1.30, P = .0003). A fixed-effects model analysis was adopted to compare the RR between groups. In the pooled results, rate of knee joint pain was lower in the SP group than the IP group (RR: 0.49, 95% CI: 0.34–0.71, P = .0002, Fig. 11).

3.11. Union time

Six studies involving 344 fractures provided data on union time.[11,12,14,16,17,19] The heterogeneity test indicated significant heterogeneity (χ² = 14.35, P = .01, I² = 65%), and the outcome showed no significant difference between 2 groups (WMD: −1.26, 95% CI: −3.53 to 1.01, P = .28, Fig. 12). Excluding the outlier study[14] did not alter significance (WMD: −0.40, 95% CI: −1.60 to 0.79, P = .51), suggesting that the pooled results are reliable.

3.12. Other outcomes

Pooled results for Lysholm knee score, SF-36 questionnaire, VAS, and radiographic results are summarized in Table 2.

3.13. Publication bias

The large sizes of some pooled samples, such as for surgery time,[8,11,13,15–17,19] allowed for the application of Begg test and Egger test for analysis of publication bias. However, no significant bias was found across the studies included in this meta-analysis (Begg test, P = .368, Fig. 13; Egger test, P = .892, Fig. 14).

4. Discussion

Intramedullary nailing using the SP approach was first applied to tibial shaft fractures by Tornetta et al[20] and Cole et al.[21] Many clinicians have since reported substantial advantages of the SP approach, resulting in enhanced popularity. For example, it significantly reduced the incidence of anterior knee pain and other complications, and improved knee joint function.[22] However, there was still no consensus on the better approach, IP or SP, as several RCTs failed to draw a unanimous conclusion. To facilitate a clinical decision, we conducted a meta-analysis to compare the advantages and disadvantages of the 2 methods for tibial shaft fractures in adults.

We found no significant difference in several parameters (surgery time, intraoperative blood loss, length of hospital stay, union time, and coronal angle) between SP and IP groups. However, SP nailing significantly reduced the rate of knee joint pain, VAS, radiation time, and sagittal angle, while improving HHS, Lysholm knee score, SF-36, ROM, and the frequencies of “excellent” and “good” clinical ratings compared to IP nailing.

Anterior knee pain is the most common complication of intramedullary nail insertion for tibial fracture,[10] and there are many studies on associated factors due to its high incidence.[23,24] Incidence of knee pain and VAS were significantly lower following SP compared to IP. Both Jones et al[5] and Courtney et al[13] found that the VAS score of the SP group was equivalent to the IP group. However, there was still no consensus on the better approach, IP or SP, as several RCTs failed to draw a unanimous conclusion. To facilitate a clinical decision, we conducted a meta-analysis to compare the advantages and disadvantages of the 2 methods for tibial shaft fractures in adults.

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decline in both incidence of knee pain and VAS score following SP compared to IP (2-year incidence: 13.6% vs 43.5%; VAS score: 0.29 ± 0.41 vs 0.79 ± 0.68). According to Morandi et al.,\textsuperscript{[26–28]} postoperative knee pain may be related to cartilage injury, patellar ligament injury, iatrogenic damage to the IP nerve, and the protruding nail end at the tibial plateau.\textsuperscript{[29]} These effects may be more severe using the IP approach. First, the knee is flexed to 90° to 100° to assure the desired nail entry point using the conventional IP approach, which may injure the inferior pole of the patella, meniscus, anterior intermeniscal ligament, and tibial plateau. Second, incision of the patella ligament and the protruding nail end at the tibial plateau could result in an aseptic inflammatory response postoperatively.\textsuperscript{[30]} Third, surgeons often cutoff the IP nerve intraoperatively.\textsuperscript{[31]} All of these procedures may contribute to knee pain in patients treated with IP nail insertion. Alternatively, all of these effects may be avoided by using the SP approach. It reduces injury to the patellar ligament by splitting the quadriceps tendon, and the lower knee flexion (approximately 15°)\textsuperscript{[32]} avoids damage to articular cartilage, meniscus, and the inferior pole of patella.\textsuperscript{[33]}

Recovery of knee joint function undoubtedly depends on amelioration of postoperative knee pain. Patients receiving treatment by the IP approach may start rehabilitation exercises much later due to the higher incidence and severity of knee pain caused by injury to the patella ligament or soft tissues. On the contrary, patients have reported better functional scores following the SP approach due to earlier resumption of exercise. Wang et al.\textsuperscript{[25]} reported that the HHS and Johner–Wruhs score were significantly better in the SP group than in the IP group at 9 months after operation ($P = 0.005, P = 0.005$). A RCT found that SP

| Study, y | Country | comparisions | No of patient | Age, y | M/F | Follow-up, mo | Outcome |
|----------|---------|--------------|---------------|--------|------|---------------|---------|
| Shi, 2013 | China | SP | 26 | 19–64 | 46/22 | NS | (4) |
| Yang, 2015 | China | SP | 23 | 43.7 ± 12.5 | 32/14 | 14 ± 3.5 | (1) (9) (11) (12) (13) |
| Wang, 2015 | China | SP | 39 | 32–63 | 40/32 | NS | (10) (11) |
| Courtney, 2015 | USA | SP | 81 | 38.5 (18–68) | 26/19 | 11.8±25.2 | (1) (2) (12) |
| Yan, 2016 | China | SP | 15 | 28–62 | 17/13 | NS | (10) (11) |
| Nie, 2016 | China | SP | 22 | 45.47 ± 12.06 | 31/14 | 24 | (1) (3) (5) (6) (7) |
| Liu, 2016 | China | SP | 28 | 43.0 ± 2.3 | 32/24 | NS | (1) (3) (9) (10) (11) |
| Huang, 2016 | China | SP | 18 | 38.9 (19–67) | 31/11 | 18.7 | (1) (3) (4) (10) (11) |
| Sun, 2016 | China | SP | 81 | 47.47 ± 11.06 | 131/31 | 24 | (1) (2) (3) (5) (6) |
| Chen, 2016 | USA | SP | 23 | NS | NS | 15.55 | (6) (9) (13) |
| Liang, 2017 | China | SP | 37 | 31.27 ± 4.71 | 39/35 | NS | (9) |
| Fu, 2017 | China | SP | 49 | 47.8 ± 2.4 | 59/39 | 12 | (1) (3) (4) (5) (9) |

Outcome: (1) operative time, (2) fluoroscopy time, (3) blood loss, (4) Harris hip score (HHS), (5) Lysholm knee score, (6) Short-form 36 questionnaire (SF-36), (7) visual analog score (VAS), (8) range of motion (ROM), (9) “excellent” and “good” outcome ratings, (10) the rate of knee joint pain, (11) union time, (12) radiographic results, (13) length of hospital stay.

F = females, IP = infrapatellar, M = males, NS = not stated, RCT = randomized controlled trial, SP = suprapatellar.
nailing resulted in a higher Lysholm knee score compared to IP nailing at last follow-up ($P = 0.034$). According to Avikucea (AAOS annual meeting 2016), SP nailing can also reduce the incidence of malalignment or angular deformity, as only 3.8% exhibited an angular deformity $>5^\circ$ following SP compared to 26.1% after IP. Our meta-analysis leads to a similar conclusion.

The following limitations of our meta-analysis should be acknowledged. First, all the patients included were Chinese or American, so the results cannot be extended to all populations. Second, many trials in our study included both stable and unstable fractures, and we were unable to obtain adequate information from the included studies to distinguish outcomes.
between these subgroups. This may cause an over- or underestimation of the true differences. Therefore, we will consider presenting a summary of the evidence according to fracture type in our next meta-analysis. Last, we failed to assess the heterogeneity of populations regarding age of autonomy and gender between studies. To compensate for this deficiency, we will assess the heterogeneity of these 2 factors in our next meta-analysis.

Based on this meta-analysis, we propose that SP nailing is the better choice over IP nailing for treatment of unstable tibial shaft fractures in adults due to lower postoperative knee pain and better functional recovery of the knee joint. However, this choice is based on mainly studies with relative small samples, short follow-up, and little subgroup analysis. Therefore, additional RCTs with larger samples, longer follow-up, and more precise classification of injury are required to confirm our findings.
Table 2

| Outcome of interest | Subgroup     | No of studies | F^2 | WMD or RR | 95% CI | P    |
|---------------------|--------------|---------------|-----|-----------|--------|------|
| Lysholm knee score[^8,15] | 1 mo         | 2             | 0%  | 2.60      | 1.05–4.16 | .001 |
|                     | 3 mo         | 2             | 0%  | 1.61      | 0.19–3.04 | .03  |
|                     | 6 mo         | 2             | 0%  | 6.77      | 4.93–8.61 | <.0001|
|                     | 12 mo        | 2             | 0%  | 7.87      | 5.63–10.10| <.0001|
|                     | 24 mo        | 2             | 0%  | 5.40      | 4.15–6.62 | <.0001|
| SF-36 MCS[^8,15]    | 6 mo         | 2             | 8%  | 0.33      | -1.37 to 2.02 | .71  |
|                     | 12 mo        | 2             | 58% | -0.21     | -2.97 to 2.55 | .88  |
|                     | 24 mo        | 2             | 57% | 3.38      | 1.03–5.73 | .005 |
| SF-36 PCS[^8,15]    | 6 mo         | 2             | 0%  | 3.57      | 1.55–5.60 | .0005|
|                     | 12 mo        | 2             | 0%  | 6.18      | 4.44–7.91 | <.0001|
|                     | 24 mo        | 2             | 64% | 6.98      | 3.91–10.04| <.0001|
| Visual analog score[^8,15] | 1 mo         | 2             | 0%  | -0.15     | -0.36 to 0.07 | .18  |
|                     | 3 mo         | 2             | 0%  | -0.38     | -0.61 to -0.15 | .001 |
|                     | 6 mo         | 2             | 21% | -0.73     | -0.91 to -0.54 | <.0001|
|                     | 12 mo        | 2             | 0%  | -0.75     | -0.92 to -0.59 | <.0001|
|                     | 24 mo        | 2             | 0%  | -0.60     | -0.76 to -0.43 | <.0001|
| Range of motion[^8,15] | 1 mo         | 2             | 0%  | 2.16      | 0.84–3.48 | .001 |
|                     | 3 mo         | 2             | 0%  | 5.63      | 4.68–6.58 | <.0001|
|                     | 6 mo         | 2             | 0%  | 4.30      | 2.85–5.75 | <.0001|
|                     | 12 mo        | 2             | 0%  | 2.34      | 0.44–4.24 | .02  |
|                     | 24 mo        | 2             | 0%  | 2.85      | 0.94–4.75 | .003 |
| Radiographic results[^11,13] | Coronal angle | 2       | 0%  | -0.34     | -1.25 to 0.58 | .47  |
|                     | Sagittal angle | 2       | 0%  | -2.06     | -3.15 to -0.97 | .0002|

CI = confidence interval, RR = risk ratio, SF-36 PCS = short-form 36 questionnaire physical score, WMD = weighted mean difference.
Figure 13. Begg test funnel plot of operative time. WMD = weighted mean difference.

Figure 14. Egger test funnel plot of operative time.

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