Suprapatellar versus infrapatellar intramedullary nailing for tibal shaft fractures

A meta-analysis of randomized controlled trials

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Abstract

Background and Objective: The aim of this study was to compare the outcome of using tibial nails inserted by the suprapatellar approach with tibial nails inserted by the infrapatellar approach in a meta-analysis of randomized controlled trials (RCTs).

Methods: The following electronic databases were searched: PubMed (1966 to January 2018), EMBASE (1974 to January 2018), Cochrane Library (January 2018), Web of Science (1990 to January 2018). We also used Google Search Engine to search more potentially eligible studies until January 2018. The methodological qualities of included studies were assessed in accordance with the guidelines provided by the Cochrane Collaboration for Systematic Reviews. The statistical analysis all of included studies were performed by STATA 13.0 software. The outcomes were total blood loss, postoperative pain, range of motion (ROM), Lysholm knee score, fluoroscopy time, operation time, and postoperative complications.

Results: Four RCTs published between 2015 and 2017 were selected in the meta-analysis. There was a significant difference between suprapatellar and infrapatellar approach surgery in total blood loss, postoperative pain, ROM, Lysholm knee scores, and fluoroscopy times.

Conclusions: The suprapatellar approach for intramedullary nailing appears superior to the infrapatellar approach, with a reduction in total blood loss, improved postoperative pain, shorter fluoroscopy time, and better knee functionality outcomes. There was no increased incidence of postoperative complications between the 2 groups. Further research remains necessary.

Abbreviations: CI = confidence interval, RCT = randomized controlled trials, ROM = range of motion.

Keywords: approach randomized controlled trials, infrapatellar, meta-analysis, suprapatellar, tibia intramedullary nailing

1. Introduction

Tibial shaft fractures are a common traumatic injury with an annual incidence of approximately 75,000 in the United States,^[1] comprising roughly 2% of all fractures in adults.^[2,3] Traditional infrapatellar intramedullary nailing is a popular surgical procedure used in the treatment of tibial shaft fractures, as it is minimally invasive and allows for early functional rehabilitation.^[4] However, this procedure may lead to proximal fracture fragment displacement with the knee in flexion, resulting in valgus and procurvatum.^[5] Additionally, postoperative anterior

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Received: 22 December 2017 / Accepted: 5 May 2018 http://dx.doi.org/10.1097/MD.000000000010917 knee pain is a common postoperative complication after intramedullary nail insertion with a reported incidence ranging from 10% to 80%.^[6]

Recently, the suprapatellar approach has attracted the attention of orthopedists, as it seems to offer fewer complications and re-operations. It is an approach that is modified from the semiextended approach proposed in 2000.^[7] It is shown to facilitate reduction in knee fractures in a semi-extended position, and the extended position of the lower leg allows for easier fluoroscopic imaging. Wang et al^[8] reported that the suprapatellar approach is superior to the infrapatellar approach, as it may reduce blood loss and improve functional recovery. However, intra-articular injury might be a potential complication of this approach. There is no reliable evidence on the incidence of patellofemoral joint damage, limiting its clinical application.

Whether the suprapatellar approach provides a superior clinical outcome for tibial shaft fractures compared with the infrapatellar approach remains controversial. Until now, only a few clinical studies have compared the functional outcomes between the 2 approaches. However, the sample size has been small and follow-up intervals have been short. To our knowledge, no meta-analysis has been reported that compares the efficacy between the suprapatellar and infrapatellar approaches for intramedullary nailing of tibial shaft fractures. Therefore, we have conducted this meta-analysis of randomized controlled trials (RCTs) to determine whether the suprapatellar approach is associated with less postoperative pain and improved functional outcome compared with the infrapatellar approach.

ZG and WH equally contributed to the article.

The authors report no conflicts of interests.

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2. Materials and methods

Ethical approval or patient consent was not required as the present study was a review of previously published articles.

2.1. Search methodology

The following electronic databases were searched: PubMed (1966 to January 2018), EMBASE (1974 to January 2018), Cochrane Library (January 2018), and Web of Science (1990 to January 2018). We also used Google Search Engine to search more potentially eligible studies until January 2018. The following key words were used for these databases: "tibia shaft fracture," "intramedullary nail," "infrapatellar," and "suprapatellar." We did not apply any language and geographical restrictions. References from retrieved articles were also assessed to extend the search strategy.

2.2. Inclusion criteria

The following criteria for the inclusion of studies were used: RCTs that compared the infrapatellar approach intramedullary nailing of tibial shaft fractures with a control group in whom the suprapatellar approach was applied; human studies; the outcomes of each RCT providing adequate information on total blood loss, postoperative pain score, knee functional outcome, fluoroscopy time, operation time, and postoperative complications. Moreover, prospective cohort studies and retrospective comparative studies were excluded. Two reviewers independently scanned titles and abstracts to search for potential studies, finally identifying eligible studies for inclusion based on further review of the full text. Disagreements were resolved by consensus after discussion or by consulting a third reviewer if necessary.

2.3. Assessment of methodological quality

The methodological qualities of the included studies were assessed independently by the two reviewers according to the guidelines provided by the Cochrane Collaboration for Systematic Reviews. This table comprises 7 items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other biases. The methodological quality of each RCT study was assessed as low (low risk of bias), high (high risk of bias), or unclear (unclear risk of bias). Disagreements were resolved by consensus after discussion, and if necessary, a third reviewer was consulted. The evidence grade was determined using guidelines from the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) working group.^[9]

2.4. Data extraction

Data were independently extracted using a standard data form of the first author's name, year of publication, sample size, sex, age, intervention, country, study design, follow-up, and relevant outcomes. The primary outcomes in this meta-analysis included total blood loss, postoperative pain score and knee functional outcome. In addition, we also used fluoroscopy times, operation time, and postoperative complications as secondary outcomes for comparison between the 2 groups. Missing or insufficient information was obtained via e-mail communication with the original author. Any disagreement was resolved via consensus after discussion, and the third reviewer was consulted.

2.5. Data synthesis

The statistical analyses of all included studies were performed by STATA 13.0 software (Version: 5.3, the Cochrane Collaboration, UK). For continuous data, the mean difference and 95% confidence interval (CI) were calculated. For dichotomous data, the risk difference (RD) and 95% CI were calculated respectively. The χ^2 test and I^2 statistic was used to assess statistical heterogeneity. The fixed-effects model was chosen if the χ^2 test >0.1 or the $I^2 < 50\%$. Otherwise, the random-effects model was used.

3. Results

3.1. Search result

Figure 1 shows the process of including studies, in which 359 potentially relevant studies were screened. After scanning titles and abstracts, 349 studies were excluded for duplication, leaving 10 to be read in full. Of those 10, 6 studies were excluded, as they failed to meet certain inclusion criteria. As a result, 4 RCTs^[10–13] published between 2016 and 2017 were selected for the meta-analysis. No gray literature was included.

3.2. Characteristics of included studies

All studies were RCTs that had been published in English with trials sample sizes ranging from 25 to 162, and the mean age of included patients ranged between 40 and 47 years. All RCTs offered complete outcome data and inclusion criteria. Experimental groups were treated using the infrapatellar approach for intramedullary nailing for tibal shaft fractures, and the control groups received the suprapatellar approach. Baseline characteristics of the included studies are shown in Table 1.

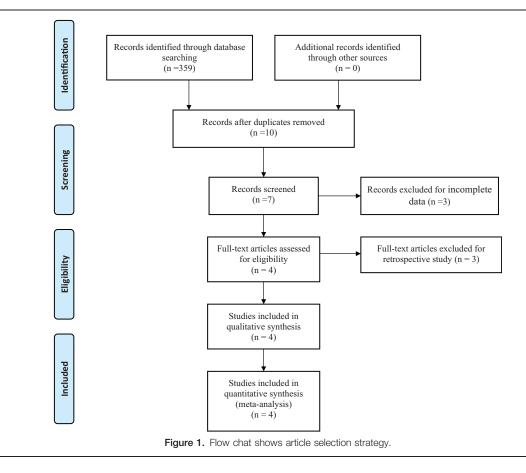
3.3. Risk of bias

Methodological quality assessment of the 4 included studies is presented in Table 2. Each RCT describes the random sequence generation procedure, but 3 studies do not describe allocation concealment. The blinding of participants and personnel was conducted with a high or unclear risk of bias. Only 1 study showed that the assessor was blinded. A low risk of bias due to incomplete outcome data and selective outcome reporting was detected.

3.4. Outcomes of meta-analysis

3.4.1. Total blood loss. Four studies reported total blood loss after operation. There was no significant heterogeneity among the studies (χ^2 =3.42, df=3, I^2 =12.3%, P=.331) and a fixed-effects model was adopted. The pooled results of the studies showed that suprapatellar approach was associated with a significant reduction of total blood loss compared with infrapatellar approach (weighted mean difference [WMD]=7.886, 95% CI: 1.129–14.642, P=.022; Fig. 2).

3.4.2. Postoperative pain score. A total of 4 RCTs reported the postoperative pain score after surgical procedure. Heterogeneity testing showed that there was low heterogeneity between the studies ($\chi^2 = 5.10$, df=3, $I^2 = 41.2\%$, P = .164), so the fixed-effect model was used. The overall estimate showed that there was significant difference regarding the postoperative pain score between groups (WMD=0.707, 95% CI: 0.558–0.847, P < .001; Fig. 3).



3.4.3. Lysholm knee score. Three RCTs showed Lysholm knee scors. There was no significant heterogeneity among the studies ($\chi^2 = 0.90$, df=2, $I^2 = 0\%$, P = .638) and a fixed-effects model was adopted. The present meta-analysis revealed that there was significant difference between 2 groups in terms of Lysholm knee score (WMD=-3.212, 95% CI: -4.964 to -1.459, P < .001; Fig. 4).

3.4.4. Range of motion. A total of 3 studies reported the range of motion (ROM). Heterogeneity testing showed that there was low heterogeneity between the studies ($\chi^2 = 1.91$, df=2, $I^2 = 0\%$, P = .385), so the fixed-effect model was used. The overall estimate showed that there was no significant difference regarding the ROM between groups (WMD=-1.284, 95% CI: -3.160 to 0.593, P = .180; Fig. 5).

Table 1

The basic information of included studies.

	Study design	Sample size	Age	Sex ratio (M/F)	Fracture classification	Infrapatellar group	Suprapatellar group	Follow-up
Author		(E/C)	(E/C)	(E/C)				
Sreekumar, 2017 ^[10]		17/21	44/42	8/9 13/8	Open vs. closed fracture = 5:33	Tibial nail	Tibial nail	1 y
Chan et al, 2016 ^[11]	RCT	14/11	43/40	10/4 6/5	Open vs. closed fracture = 3:22	Tibial nail insertion	Tibial nail insertion	1—2 y
Sun et al, 2016 ^[12]	RCT	81/81	47/46	31/16 15/31	Open vs. closed fracture = 21:141	Intramedullary nailing	Intramedullary nailing	2 у
Wang et al, 2016 ^[13]	RCT	30/38	46/42	42/4 39/3	Open vs. closed fracture = 8:60	Intramedullary nailing	Intramedullary nailing	Half year

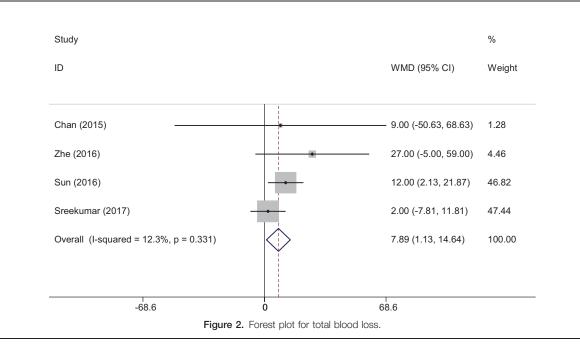
C=control group, E=experimental group, RCT=randomized controlled trial

Table 2

Assessment of the risk of bias in the included RCTs.

	Random	Allocation	Blinding of participates	Blinding of outcome	Incomplete	Selective	Other
Study	sequence generation	concealment	and personal	assessment	outcome data	reporting	bias
Chan et al, 2016 ^[11]	Low risk	Low risk	High risk	Unclear risk	Low risk	Low risk	Unclear risk
Sreekumar, 2017 ^[10]	Low risk	Unclear risk	Unclear risk	Unclear risk	Low risk	Low risk	Unclear risk
Sun et al, 2016 ^[12]	Low risk	Unclear risk	High risk	Unclear risk	Low risk	Low risk	Unclear risk
Wang et al, 2016 ^[13]	Low risk	Unclear risk	High risk	Low risk	Low risk	Low risk	Unclear risk

RCTs = randomized controlled trials.

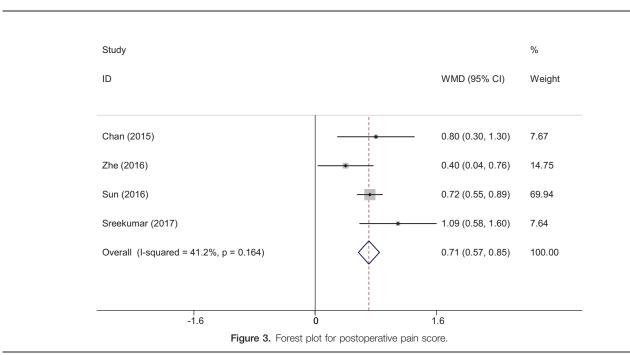


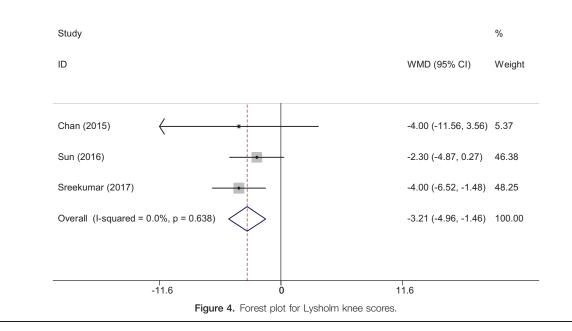
3.4.5. Fluoroscopy time. Fluoroscopy time after operation were reported in 2 RCTs, and pooled result indicated that there was significant difference between groups in terms of the fluoroscopy time (WMD=17.949, 95% CI: 8.320–27.577, P < .001; Fig. 6).

3.4.6. Operation time. Three studies reported the operation time. A fixed-effects model was used ($\chi^2 = 1.17$, df=2, $I^2 = 0\%$, P = .577). There was no significant difference between the 2 groups in terms of operation time (WMD=-7.271, 95% CI: -22.332 to 7.791, P = .344; Fig. 7).

3.4.7. Postoperative complications. Three RCTs reported the postoperative complications. No significant difference was found between groups regarding the incidence of the postoperative complications (RD=0.020, 95% CI: -0.059 to 0.098, P=.624; Fig. 8).

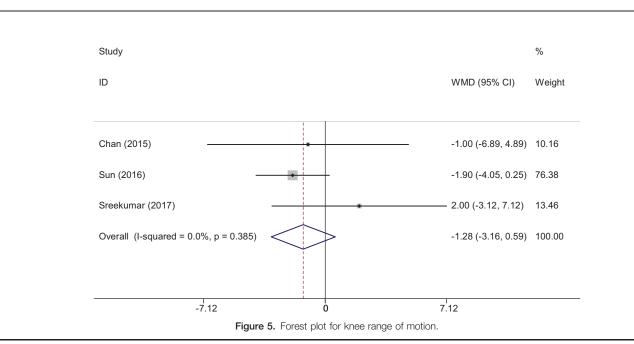
3.4.8. Evidence level. Quality evidence for each result is evaluated by the GRADE system. The overall evidence is moderate, which indicated that further research is likely to significantly change confidence in the effect estimate but may change the estimate (Table 3).

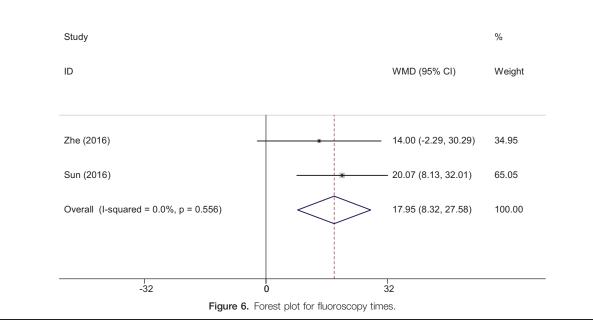




4. Discussion

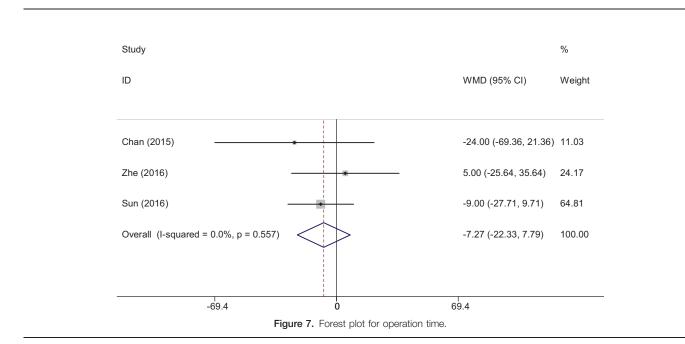
In our study, we compared the infrapatellar and suprapatellar approaches for nailing of tibial shaft fractures. This was the initial systematic review of RCTs to determine the optimal approach for tibial nail insertion. We demonstrate that the suprapatellar approach for intramedullary nailing is superior to the infrapatellar approach in terms of reduced total blood loss, postoperative pain, and improved knee functional outcome. No significant difference in operation time or incidence of postoperative complications was discovered. The quality of the evidence for each result was evaluated by the GRADE system and the overall evidence is moderate. Tibial shaft fractures are common and comprise about 2% of all fractures in adults.^[2,3] With the advantages of stable internal fixation and less damage to surrounding tissue, intramedullary nailing is considered the criterion standard for the treatment of tibial shaft fractures.^[14] Some experts indicated that the infrapatellar approach to intramedullary nailing is associated with patellar tendon injury.^[15] The suprapatellar approach involves an incision proximal to the patella, and the intramedullary nail passes through the trochlear groove. Theoretically, this approach could reduce the risk to both the patellar tendon and infrapatellar nerve damage, as well as decrease perioperative blood loss. Currently, there is no reliable evidence for the comparison of the 2 approaches; therefore, we performed this

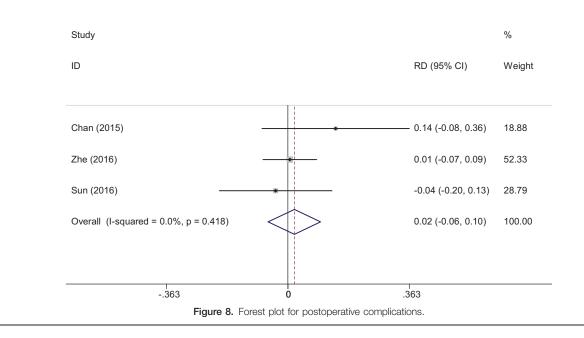




meta-analysis of RCTs. We found that the suprapatellar intramedullary nailing can significantly reduce total blood loss.

Postoperative pain is an important surgical outcome after orthopedic surgery. A majority of patients complained of moderate to severe pain, which may delay functional rehabilitation and increase opioid consumption. Although its etiology is unclear, this pain may be associated with injury of the knee structure and saphenous nerve.^[16,17] Moreover, it is also caused by the surgical stress response, including inflammatory components. Whether the suprapatellar approach contributes to pain relief remains controversial. Leliveld et al^[18] showed that an infrapatellar incision is more likely to cause chronic knee pain because of iatrogenic damage to the infrapatellar nerve after intramedullary nailing. Courtney et al^[19] reported that the infrapatellar nerve is well protected when using the suprapatellar approach; however, they found no significant difference in knee pain scores between the suprapatellar and infrapatellar approaches for intramedullary nailing. Wang et al^[8] demonstrateed that that the overall incidence of articular structure injury is lower when using the suprapatellar approach than it is with the infrapatellar approach, suggesting that suprapatellar nailing achieves a significantly improved pain score. Metaanalysis is used as the main statistical method in our study, enhancing its statistical power. The present meta-analysis





indicates that the suprapatellar group is associated with a significant reduction in knee pain.

The Lysholm knee scale was first introduced in 1982^[20] and contained eight measurements of the function and symptomatology of the knee. The Lysholm knee scoring scale has been used frequently in outcome studies of knee injuries, such as those related to patellofemoral pain. The present meta-analysis demonstrates that there is an improvement in Lysholm knee score in suprapatellar group when compared with infrapatellar group.

Tibial nail insertion for tibial shaft fractures may result in a reduction of the ROM of the affected knee joint.^[21,22] Various factors may influence that reduced ROM, including damage to

the vascularity and soft tissue. Lefaivre et al^[23] showed that the knee ROM is equivalent to the unaffected side when using the infrapatellar approach. However, some authors hold the opposite view point. Chan et al^[11] reported an improved range of motion with the suprapatellar approach; however, there was no significant difference. The present meta-analysis provides similar results. More RCTs are required. Fluoroscopy time is shown to be significantly shorter with the suprapatellar insertion compared with the infrapatellar insertion. The semiextended position may facilitate manipulation of the knee during the surgical procedure.^[24] This position may simplify the reduction of the fracture and make it easier to maintain during nailing.

Table 3

Evidence level by GRADE.

Quality assessment								
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Effect	Quality	Importance
Total blood loss								
4	RCT	Serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	WMD=7.886, 95% Cl: 1.129–14.642, <i>P</i> =.022	High	Important
Postoperative pa	in score							
4	RCT	Serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	WMD=0.707, 95% Cl: 0.558–0.847, P <.001	High	Critical
Lysholm knee so	ores							
3	RCT	Serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision	WMD = -3.212, 95% Cl: -4.964 to -1.459, <i>P</i> <.001	Moderate	Critical
Range of motion			-					
3	RCT	Serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	WMD=-1.284, 95% Cl: -3.160 to 0.593, <i>P</i> =.180	High	Critical
Fluoroscopy time	S							
2	RCT	Serious limitations	Serious inconsistency	No serious indirectness	No serious imprecision	WMD=17.949, 95% Cl: 8.320-27.577, P <.001	Moderate	Important
Operation time								
3	RCT	Serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	WMD=-7.271, 95% Cl: -22.332 to 7.791, <i>P</i> =.344	High	Important

CI = confidence interval, RCTs = randomized controlled trials, WMD = weighted mean difference.

The limitations of this study were as follows: only 4 RCTs were included, the small sample size might lower the reliability of the conclusions; methodological weakness existed in all RCTs which may influence the results; the heterogeneity for included outcomes cannot be avoided because of objective differences existed among patients; short-term follow-up may cause underestimation of complications; publication bias is an inherent weakness that exists in all meta-analyses.

Despite the limitations above, this is the first meta-analysis from RCTs to determine the efficacy of suprapatellar versus infrapatellar approach for tibia intramedullary nailing. More quality RCTs with long-term follow-up are necessary.

5. Conclusion

The suprapatellar approach for intramedullary tibial nailing may be superior to the infrapatellar approach, with a reduction in total blood loss, reduced postoperative pain, shorter fluoroscopy time, and better knee functionality outcomes. There is no increased incidence of postoperative complications between the 2 groups. Further research remains necessary.

Author contributions

Haigang Jia designs the study. Zhixue Gao and Wei Han collects the data and finishes the manuscript. All authors read and approved the final manuscript.

Conceptualization: Haigang Jia.

Writing - original draft: Zhixue Gao, Wei Han.

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