

Reamed compared with unreamed nailing of tibial shaft fractures: Does the initial method of nail insertion influence outcome in patients requiring reoperations?

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Background: Patients with a tibial shaft fracture experiencing their first postoperative complication following treatment with intramedullary nails may be at greater risk of subsequent complications than the whole population. We aimed to determine whether the initial method of nail insertion influences outcome in patients with a tibial shaft fracture requiring multiple reoperations.

Methods: Using the Study to Prospectively Evaluate Reamed Intramedullary Nails in Tibial Shaft Fractures trial data, we categorized patients as those not requiring reoperation, those requiring a single reoperation and those requiring multiple reoperations, and we compared them by nail insertion technique (reamed v. unreamed) and fracture type (open v. closed). We then determined the number of patients whose first reoperation was in response to infection, and we compared other clinical outcomes between the reamed and unreamed groups.

Results: Among 1226 patients included in this analysis, 175 (14.27%) experienced a single reoperation and 44 patients (3.59%) underwent multiple reoperations. Nail insertion techniques (reamed v. unreamed) did not play a role in the need to perform multiple reoperations. Seventy-five percent of patients requiring multiple reoperations had open tibial shaft fractures. An equal number of these were reamed and unreamed insertions. The majority of patients had their course complicated by infection and almost 50% of patients whose first reoperation was for infection required more than 2 reoperations for management. The rest required multiple procedures for nonunion or bone loss.

Conclusion: Our findings corroborate those of other studies, in which open fracture type rather than nail insertion technique was found to be the cause of morbidity following intramedullary nailing of tibial fractures.

Clinical trial registration: www.ClinicalTrials.gov, no. NCT00038129

Contexte : Les cas de fracture de la diaphyse tibiale qui présentent une première complication postopératoire après un enclouage centromédullaire pourraient être exposés à un risque plus grand de complications ultérieures comparativement à la population générale. Nous avons voulu déterminer si la technique initiale d'enclouage a une influence sur les résultats lorsqu'une fracture de la diaphyse tibiale requiert plusieurs réinterventions.

Méthodes : À partir de l'essai intitulé Study to Prospectively Evaluate Reamed Intramedullary Nails in Tibial Shaft Fractures pour l'évaluation prospective de l'enclouage alésé des fractures de la diaphyse tibiale, nous avons établi les catégories suivantes : aucune réintervention, 1 seule réintervention et multiples réinterventions, et nous les avons comparées aux plans de la technique d'enclouage (avec c. sans alésage) et du type de fracture (ouverte c. fermée). Nous avons ensuite établi le nombre de cas pour lesquels la première réintervention découlait d'une infection, et nous avons comparé d'autres paramètres cliniques entre les groupes avec et sans alésage.

Résultats : Sur les 1226 cas inclus dans cette analyse, 175 (14,27 %) ont subi 1 seule réintervention et 44 (3,59 %) en ont subi plusieurs. Les techniques d'enclouage (avec c. sans alésage) n'ont joué aucun rôle dans le recours à de multiples réinterventions. Soixante-quinze pour cent des cas soumis à de multiples réinterventions étaient des fractures ouvertes. Parmi ceux-ci, il y avait autant d'enclouages alésés que non alésés. Dans la majorité des cas, la complication était une infection et près de 50 % dont la première réintervention découlait d'une infection ont eu besoin de 2 réinterventions pour en venir à bout. Dans les autres cas, les multiples interventions étaient justifiées par des fractures non consolidées ou une perte osseuse.

Conclusion : Nos observations confirment les conclusions d'autres études selon lesquelles la cause de la morbidité suivant l'enclouage centromédullaire des fractures tibiales est le type de fracture ouverte plutôt que la technique d'enclouage.

Enregistrement de l'essai : www.ClinicalTrials.gov, no. NCT00038129

In the management of tibial shaft fractures, postoperative complications, specifically those that result in a reoperation, are a very important outcome to consider. The likelihood of experiencing a postoperative complication may be increased dramatically owing to the complexities of the injury and procedure. Tibia fractures may have high-energy mechanisms of injury with increasing soft-tissue damage and severity of comminution, which have been associated with greater likelihood of reoperation.¹

Reported reoperation rates in closed and open tibial shaft fractures have varied between 17% and 50%.²⁻⁴ Common postoperative complications include infection, compartment syndrome, malunion and nonunion.^{3,5-9} Each complication may result in subsequent surgeries as standard of care. Reoperation not only exposes patients to perioperative risks associated with surgery, but also provides no guarantee that additional complications will not occur.^{3,10} Patients experiencing their first postoperative complication may be at a greater risk of a subsequent complication than the whole population. Thus, it is important to identify factors that are associated with multiple reoperations.

Current evidence shows that intramedullary nails are the most efficacious implant for the management of tibial shaft fractures.^{1,11-13} However, the characteristics of patients with tibial shaft fractures who undergo intramedullary nailing and require multiple reoperations have not been described. Evaluation of this subset of patients compared with those who do not require multiple operations is important to address potential differences in outcomes. Furthermore, a comparison of the initial method of nail insertion (reamed v. unreamed) has not been performed in this subset of patients. The Study to Prospectively Evaluate Reamed Intramedullary Nails in Patients with Tibial Fractures (SPRINT) was a large, multicentre randomized clinical trial comparing reamed and unreamed intramedullary nails in patients with tibial shaft fractures. This study suggested a benefit for reamed intramedullary nail insertion in patients with closed tibial shaft fractures, largely owing to fewer dynamizations.^{2,14} Using data from SPRINT evaluating reamed and unreamed nail insertion, we conducted an analysis to determine if there was a difference in the number of patients requiring multiple reoperations, or their injury characteristics.

METHODS

SPRINT study

The standardized protocol for the SPRINT study was approved by the relevant research ethics boards (REB #99-077). The methodological details and the results of the primary SPRINT analysis of reamed compared with unreamed nails have been published.^{2,14}

The SPRINT study involved 29 clinical centres in Canada, the United States and the Netherlands. The surgical protocols for reamed and unreamed nailing were standardized, and all patients underwent the same perioperative protocol. There were 1226 patients who met the eligibility criteria and completed the full 1-year follow-up.

Inclusion criteria for the SPRINT study were skeletal maturity, open or closed tibial shaft fracture (Tschernie classification, grade 0 to 3; Gustilo–Anderson classification, type I–IIIB),¹⁵⁻²⁰ amenability of fracture to surgical repair with an intramedullary nail and informed consent. Exclusion criteria were tibial shaft fractures not amenable to reamed or unreamed nailing, pathologic fractures, loss to follow-up and nonconsent.

In the SPRINT study, the primary outcome was a composite resulting in reoperation that included bone grafting, implant exchange or removal, debridement of bone and soft tissue owing to deep infection, fracture dynamization owing to locking screw removal, removal of locking screws owing to implant fracture or loosening, autodynamization (fracture of a locking screw that resulted in settling of the tibia), fasciotomy, failure of the construct (broken nail) and hematoma drainage. Patients were followed for 1 year postinjury, and we documented the reoperations that were planned after the 12-month follow-up period.

The SPRINT study found that there was a significant interaction between the randomized intervention (reamed v. unreamed) and open and closed fractures. In patients with closed fractures, SPRINT investigators found a significant decrease in risk for patients who received a reamed nail compared with those who received an unreamed nail. This effect was not seen in patients with open fractures.^{2,14}

Study design and methods

Using the SPRINT data, we categorized patients in to the following 3 groups: patients who did not require a reoperation, patients who required a single reoperation and patients who required multiple reoperations, where reoperation is defined as the composite for the SPRINT study, during the 12-month follow-up period. We then determined if there were differences in the number of patients in these categories in the reamed compared with the unreamed treatment group, and in patients with open fractures compared with those with closed fractures. We compared patient and fracture characteristics across the 3 categories, including type of injury. High-energy injuries were defined as motor vehicle accidents, pedestrian–motor vehicle accidents, motorcycle accidents, snowmobile accidents, crush injuries and direct blunt trauma. We further investigated patients whose first reoperation was in response to infection and other clinical outcomes.

Table 1. Intramedullary nail and fracture characteristics among patients with single v. multiple reoperations

Characteristic	Total n = 1226	No. (%)	
		Patients with a single reoperation n = 175	Patients with multiple reoperations n = 44
Randomized group			
Reamed	622	84/622 (13.5)	21/622 (3.4)
Unreamed	604	91/604 (15.1)	23/604 (3.8)
Closed fractures			
Reamed	416	42/416 (10.1)	3/416 (0.7)
Unreamed	410	60/410 (14.6)	8/410 (2.0)
Open fractures			
Reamed	206	42/206 (20.4)	18/206 (8.7)
Unreamed	194	31/194 (16.0)	15/194 (7.7)

Table 2. Reasons for the first reoperation among patients requiring multiple reoperations, by group*

Reason for first reoperation	Total	No. (%)	
		Patients with 2 reoperations	Patients with > 2 reoperations
All patients			
Any	44	27 (61.4)	17 (38.6)
Infection	26	14 (53.8)	12 (46.2)
Other†	18	13 (72.2)	5 (27.8)
Reamed			
Any	21	11 (52.4)	10 (47.6)
Infection	15	7 (46.7)	8 (53.3)
Other†	6	4 (66.7)	2 (33.3)
Unreamed			
Any	23	16 (69.6)	7 (30.4)
Infection	11	7 (63.6)	4 (36.4)
Other†	12	9 (75.0)	3 (25.0)

*There were no statistically significant differences between reamed and unreamed groups ($p > 0.05$) for any of the variables assessed.
†“Other” includes nonunion and bone loss.

Statistical analyses

We performed 2-tailed Student *t* tests on continuous data and χ^2 tests on categorical data to analyze all comparisons, with a *p* value of less than 0.05 considered statistically significant. All analyses were performed using SAS version 9.2 (SAS Institute).

RESULTS

Among the 1226 patients included in the analysis of the SPRINT trial, 44 patients (3.59%) underwent multiple reoperations, 75% of which were for open fractures (Table 1). Sex, ethnicity, smoking history and leg fracture were similarly distributed among all 3 outcome categories. Furthermore, the nail insertion technique (reamed v. unreamed) had no effect on the number of reoperations (> 1 postindex procedure; $p = 0.66$).

A total of 11 closed tibial fractures required more than 1 reoperation (0.9%). Tscherne classification fracture type

was similar across the 3 outcome categories ($p = 0.06$). Open fractures were more commonly associated with multiple reoperations than closed fractures ($p < 0.001$). The 33 patients with open fractures requiring multiple reoperations also had a higher Gustilo–Anderson classification type than the 73 patients with open fractures who had a single reoperation ($p = 0.01$). We did not find any differences in Orthopaedic Trauma Association classification between patients who had a single reoperation and those who had multiple reoperations ($p = 0.31$).¹⁵ In addition, the number of patients with open fractures who had bone loss was similar across all 3 outcome categories ($p = 0.28$).

Among the 44 patients with multiple reoperations, 26 had their initial reoperations to treat infection (Table 2). Of the remaining 18 patients who had their initial reoperation for a reason other than infection (nonunion or bone loss), 6 subsequently developed an infection; 32 of 44 (72.7%) patients with multiple reoperations had their course complicated by infection. Among patients with multiple reoperations, there was no difference between

reamed and unreamed groups with respect to infection as the indication for the initial reoperation ($p = 0.14$). Finally, 12 of 44 (27.3%) patients had an additional reoperation planned after 12 months to achieve either union or treat infection. After 12 months, there were 7 patients with planned operations in the reamed group and 5 in the unreamed group ($p = 0.50$).

DISCUSSION

The SPRINT trial randomized patients with tibial shaft fractures to insertion of an intramedullary nail with either a reamed or unreamed technique. In patients with closed fractures, patients who received reamed nail insertion had a lower risk of reoperation than those who received unreamed nail insertion. This was not the case in patients with open fractures. However, no distinction was made between patients who required a single reoperation and those who required multiple reoperations.

The number of patients in the SPRINT study who underwent multiple reoperations within the first 12 months after primary intervention was relatively small (3.6%). Among patients with at least 1 reoperation before 12 months, 15% had an additional reoperation planned after 12 months, which is indicative of an extended recovery period. Patients who had multiple reoperations were more likely to have high-energy mechanisms of injury and open fractures. These findings are consistent with those of prior studies.^{3,4,21}

Limitations

Our study had several strengths, including the large sample size of 1226 patients with tibial shaft fractures from 29 clinical centres from Canada, the United States and the Netherlands, which increased the generalizability of our results. To ensure uniformity, a Central Adjudication Committee consisting of 5 orthopedic surgeons adjudicated all of the outcomes, including reoperation.

The major limitation of this particular analysis is that we were unable to collect data beyond the 1-year follow-up period. Since tibial shaft fractures are associated with considerable complications following initial surgery, it is not uncommon for problems to exist beyond the first 12 months postsurgery, especially for open fractures and cases of nonunion or bone loss. Therefore, any additional reoperations that participants underwent after the study follow-up period would not have been captured in our analysis. This drawback introduces some bias in that the study period was not long enough to completely answer our research question.

Despite this limitation, our findings showed that nail insertion technique (reamed v. unreamed) did not play a role in the need for multiple reoperations. Seventy-five percent of patients requiring multiple reoperations had

open tibial shaft fractures. An equal number of these patients received reamed and unreamed insertions. The majority of patients had their course complicated by infection, and almost 50% of patients whose first reoperation was for infection required more than 2 reoperations for management. The rest required multiple procedures for nonunion or bone loss. These data corroborate the findings of previous studies, that open fracture type rather than the technique of nail insertion is the main cause of morbidity following intramedullary nailing of tibia fractures.

CONCLUSION

In the subset of patients who require multiple reoperations after intramedullary nailing of tibial shaft fractures, nail insertion technique does not appear to influence the likelihood of requiring multiple reoperations 1-year postoperatively.

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