Title: Incidence and Risk Factors Associated with Infection after Intramedullary Nailing of Femoral and Tibial Diaphyseal Fractures: Prospective Study

Document date: 05/31/2018

NCT 03148067

BACKGROUND: Diaphyseal fractures of femur and tibia are prominent due to its high incidence and high economic and social impact. Intramedullary nailing (IN) is the surgical procedure of choice. Surgical site infection (SSI) related to this procedure is considered a difficult to treat complication. AIMS: Determine the incidence of SSI after IN of femoral and tibial diaphyseal fractures and evaluate possible risk factors. METHODS: Prospective observational cohort study. SSI was defined according to CDC-NHSN criteria and surveillance period for the occurrence of infection was 12 months. Incidence of SSI was calculated as the ratio between the number of patients with SSI and total number of patients. Analysis of potential risk factors included patients-related factors (age, gender, body mass index, active foci of infection, immunosuppressive conditions, ASA score, alcohol or illicit drug abuse, smoking, polytrauma, etiology of fracture, type of fracture if closed or open, classification of fracture according to Müller AO, Tcherne classification for closed fractures, Gustilo-Anderson classification for open fractures, previous surgical manipulation, use of blood products); environmental and surgical-related factors (surgical wound classification, duration of surgery, hair removal, intraoperative contamination, antimicrobial use, presence of drains, hypothermia or hypoxia in the perioperative period, type of IN used, reaming, need for soft tissue reconstruction, use of negative pressure therapy) and microbiota-related factors (cultures of nasopharyngeal swabs

for *Staphylococcus aureus* and axillary/inguinal/perineal swab for *Acinetobacter baumannii*).

STATISTICAL ANALYSIS: The studied factors were described and compared according to the occurrence of infection using Mann-Whitney or Student's t-tests for the quantitative variables and using chi-squared or exact tests (Fisher's exact test or likelihood ratio test), for the qualitative variables. The odds ratio of each variable was studied for the occurrence of infection, and the respective 95% confidence intervals were estimated by unadjusted logistic regression. Multiple logistic regression model was estimated to simultaneously assess the characteristics that affected the occurrence of infection, selecting the variables with significance levels lower than 0.10 ($p < 0.10$) in the bivariate tests, maintaining only the variables with a significance level equal to or lower than 0.05 ($p \leq 0.05$) in the final model. Software IBM-SPSS for Windows version 20.0 was used to perform the analyses, and the data were tabulated using software Microsoft Excel 2003. Tests were performed with a 5% significance level.

RESULTS: 221 patients were included and completed the 12-month follow-up period. Incidence of SSI was 11.8%. In the initial analysis by unadjusted logistic regression, following factors were associated SSI: Müller AO classification of the fracture morphology groups 2 or 3, previous use of external fixator, presence of drains, use of negative pressure therapy and need for muscle or skin flap repair. In the multiple logistic regression-adjusted analysis, previous use of external fixator and need for muscle or skin flap repair remained associated with SSI. CONCLUSIONS: Incidence of SSI associated with IN for femoral and tibial diaphyseal fractures was 11.8%. Previous use of external fixators and need for muscle or skin flap repair were factors associated with occurrence of infection.