**Supplemental Digital Content 1**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Differences in Pain Scores 3 and 12 Months After Total Knee Arthroplasty in the Spinal and General Anesthesia and in the No-tourniquet and Tourniquet Groups | | | | | | |
|  | | **Spinal vs. general anesthesia**  **Difference (95% CI)** | ***P* Value** | **No tourniquet vs. tourniquet**  **Difference (95% CI)** | ***P* Value** | **Anesthesia x tourniquet interaction effect**  ***P* Value** |
| **3 months after operation** | | **(n = 391)** |  | **(n = 391)** |  |  |
|  | Average pain | -0.3 (-0.7 to 0.1)7 | 0.165 | 0.1 (-0.3 to 0.5)7 | 0.669 | 0.658 |
|  | Worst pain in 24 hours | -0.2 (-0.7 to 0.3)4 | 0.376 | 0.0 (-0.5 to 0.5)4 | 0.996 | 0.799 |
|  | Least pain in 24 hours | -0.1 (-0.4 to 0.2)5 | 0.440 | -0.01 (-0.3 to 0.3)5 | 0.916 | 0.352 |
|  | Current pain | -0.2 (-0.6 to 0.2)7 | 0.262 | 0.1 (-0.2 to 0.5)7 | 0.455 | 0.563 |
|  | Pain severity | -0.2 (-0.5 to 0.1)5 | 0.212 | 0.1 (-0.3 to 0.4)5 | 0.651 | 0.649 |
|  | Pain interference | -0.6 (-1.0 to -0.1)9 | 0.012 | 0.2 (-0.2 to 0.6)9 | 0.359 | 0.786 |
| **12 months after operation** | | **(n = 387)** |  | **(n = 387)** |  |  |
|  | Average pain | -0.3 (-0.7 to 0.1)5 | 0.140 | 0.3 (-0.1 to 0.7)5 | 0.191 | 0.705 |
|  | Worst pain in 24 hours | -0.4 (-1.0 to 0.1)3 | 0.099 | 0.4 (-0.1 to 0.9)3 | 0.143 | 0.273 |
|  | Least pain in 24 hours | -0.3 (-0.6 to -0.03)4 | 0.031 | 0.2 (-0.04 to 0.5)4 | 0.102 | 0.904 |
|  | Current pain | -0.3 (-0.7 to 0.1)4 | 0.136 | 0.4 (-0.02 to 0.8)4 | 0.061 | 0.643 |
|  | Pain severity | -0.4 (-0.7 to 0.00)4 | 0.051 | 0.3 (-0.02 to 0.7)4 | 0.063 | 0.521 |
|  | Pain interference | -0.6 (-1.0 to -0.2)8 | 0.003 | 0.2 (-0.2 to 0.6)8 | 0.243 | 0.574 |
| Results are from the analysis of covariance, with the main effects for anesthesia (spinal vs. general) and tourniquet (no tourniquet vs. tourniquet), an interaction effect of anesthesia × tourniquet, and preoperative pain score of the respective postoperative score as a covariate. Patients assessed pain and pain interference using a numerical rating scale (0 = no pain/interference, 10 = worst imaginable pain/interference). Pain severity is an arithmetic mean of four variables: average pain, worst and least pain in the last 24 hours, and current pain. Pain interference is an arithmetic mean of seven variables: general activity, mood, walking, relations with others, working, sleep, and enjoyment of life during the last 24 hours. Superscript numbers present the number of missing values. | | | | | | |

Authors’ comments concerning the chosen method for main analyses:

The main analyses of this study concerning the Brief Pain Inventory-short form change scores were conducted using the two-way analysis of variance, and the normality assumptions of residuals were met for all outcomes. However, this approach did not consider the baseline imbalances between the no-tourniquet and tourniquet groups in the scores concerning average pain, worst pain in the last 24 hours, and the arithmetic mean of the four pain severity variables.

We recognized that the analysis of covariance would have been a preferable model for analyzing differences between the study groups 3 and 12 months after operation.1 However, the assumptions for this method (the normality and homogeneity of regression slopes) were not met for all outcomes.

Depending on the pain variable, 13%–51% of the scores at 3 months and 29%–59% of the scores at 12 months were zero, and the residuals of the analysis of covariance model were not normally distributed (evaluated by visual inspection of histograms and skewness > 1) for variables concerning least pain in the last 24 hours and current pain at 3 and 12 months and for pain interference at 12 months.

The assumptions concerning the homogeneity of regression slopes were checked with scatter plots between the pre- and postoperative pain scores. The regression slopes for different groups crossed for variables concerning average pain, worst and least pain in the last 24 hours, current pain, and the mean of four pain severity variables at 3 months. Similarly, the regression slopes crossed for average pain, worst pain in the last 24 hours, current pain, and the means of four pain severity and seven pain interference variables at 12 months. The assumptions concerning the homogeneity of regression slopes were also tested with the interaction effect between preoperative pain score and group. The interaction was significant for least pain in the last 24 hours at 3 months (anesthesia group × preoperative pain score, *P* = 0.017), for average pain at 12 months (tourniquet group × preoperative pain score, *P* = 0.037), and for worst pain at 12 months (anesthesia group × preoperative pain score, *P* = 0.042).

Nevertheless, we explored our data using the analysis of covariance as post hoc sensitivity analysis. The results are presented in the table above. Due to problems with the assumptions, the results from this analysis may not be valid for all outcomes and should be interpreted carefully. Eventually, neither of the statistical methods demonstrated differences that would be interpreted as clinically important (difference between groups ≥ 1.0 by numerical rating scale).

Reference

# Vickers AJ, Altman DG. Statistics notes: Analysing controlled trials with baseline and follow up measurements. *BMJ* 2001; 323: 1123–4