

Study Title: Double-Blinded Randomized Control Trial Comparing Liposomal Bupivacaine and Plain Bupivacaine in Transversus Abdominis Plane For Deep Inferior Epigastric Artery Perforator (DIEP) Flap Breast Reconstruction

NCT # 03700970

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Statistical Analysis

Patient characteristics were summarized as appropriate, using mean (standard deviation [SD]) and median (25th-75th interquartile range [IQR]) for quantitative variables and counts (percentages) for qualitative variables. Unadjusted comparisons of patients between the plain bupivacaine group and the liposomal bupivacaine group were performed using Wilcoxon test or Pearson chi-square test. The effect of the study intervention on daily oral opioid intake in oral morphine equivalents (OME) was examined using linear mixed effects regression model, adjusting for post-operative day (as a categorical variable), intervention status (plain bupivacaine/ liposomal bupivacaine), and their interaction. Since there were repeated measurements of OME for 7 post-operative days, a random intercept indexed by subject number was used in the linear mixed effects regression model. All analyses were performed using the R Programming Language 3.3.0 (R Foundation for Statistical Computing, Vienna, Austria). P<0.05 was considered a statistically significant difference.

Sample size calculations were based on demonstrating superiority of the TAP block with liposomal bupivacaine. A simulation-based power analysis was used to evaluate statistical power under the following assumptions: 1) use of linear mixed effects regression after log transformation of the opioid intake outcome, 2) average opioid consumption on days 0, 1, 2, and

3 is 30, 90, 70 mg mEq under standard of care, 3) use of liposomal bupivacaine will result in a 20% reduction in opioid consumption at each study day, and 4) the between- and within-subjects coefficients of variation are 20% and 60%, respectively (these values are based on standard of care data from our institution). Thus, the minimum-detectable difference is a 20% reduction in average opioid consumption at each study day. Under these assumptions, 60 participants are needed to achieve 80% power.