METHODS: The study was multicenter, randomized and placebo-controlled for up to 48 hours in adult patients undergoing the following outpatient abdominal surgical procedures: abdominoplasty, open tension-free inguinal hernioplasty or laparoscopic abdominal surgery. Following IRB approval and patient informed consent, approximately 180 patients who met all inclusion and none of the exclusion criteria were randomly assigned at a 2:1 ratio to treatment with ST or PT. Efficacy was assessed by patient reports of pain intensity on an 11-point numerical rating scale (0 = no pain, and 10 = worst possible pain) and a five-point pain relief scale (0 = no relief, 4 = complete relief). The primary efficacy variable was the summed pain intensity difference to baseline over the 12-hour study period (SPID12). Safety was assessed via periodic measurement of vital signs, continuous monitoring of oxygen saturation, spontaneously reported adverse events (AEs) and the use of concomitant medications.

RESULTS: A total of 161 (107 ST and 54 PT) patients were randomized and received study drug. Average patient age was 41 years, 68% were female and approximately 50% had undergone abdominoplasty surgery. Statistically significant SPID12 differences were observed in favor of ST over PT (25.8 vs. 13.1; p<0.001) for the entire cohort, demonstrating superiority of sublingual sufentanil 30mcg for management of acute post-operative pain. Subgroup analysis by surgery type, despite much smaller sample sizes, also yielded significantly higher scores for ST over PT for abdominoplasty patients (30.8 vs 17.6; p=0.001). Most AEs were mild to moderate in severity with nausea and headache as the most common across both treatment arms.

DISCUSSION/CONCLUSION: The sufentanil sublingual 30 mcg tablet has shown benefit over placebo across a range of surgical procedures as a non-invasive analgesic modality requiring short-term treatment of acute moderate-to-severe pain.

Racial and Ethnic Variations in Clinical and Patient-Reported Outcomes Following Breast Reconstruction

Nicholas L. Berlin, MD, MPH; Adeyiza O. Momoh, MD; Ji Qi, MS; Jennifer B. Hamill, MPH; Hyungjin M. Kim, ScD; Andrea L. Pusic, MD, MHS; Edwin G. Wilkins, MD, MS

INTRODUCTION: Existing studies evaluating disparities in breast reconstruction have assessed variations in types and rates of reconstruction among racial and ethnic minorities.1-3 However, variations in postoperative outcomes for minority populations remain understudied.4 The objectives of this study are to evaluate racial and ethnic variations in complications and patient-reported outcomes (PROs) following breast reconstruction.

MATERIALS AND METHODS: The Mastectomy Reconstruction Outcomes Consortium is an 11 center, prospective cohort study assessing clinical and patient-reported outcomes following autologous and implant-based breast reconstruction. Race and ethnicity data were available by self-report and medical records. Complications (major or any) and reconstructive failures at one-year post-reconstruction were recorded. PRO measures included BREAST-Q subscales for satisfaction with breasts, sexual, psychosocial, and physical well-being, as well as the PROMIS subscale for physical functioning. Mixed-effects logistic regression models were used to assess clinical outcomes and mixed-effects linear models were used to evaluate patient reported outcomes at one-year postoperatively.

RESULTS: A total of 2,476 women with known race and ethnicity information had one-year follow-up data, including 2,058 (83.1%) White, 146 (5.9%) Black, 133 (5.4%) Hispanic or Latino, and 139 (5.6%) patients from other minority groups. Patient age, body mass index, education, household income, laterality, diabetes status, and indication for mastectomy differed by race and ethnicity. Clinical outcomes were available for all women, but PROs at one-year were completed by 1,456 (response rate = 74.1%) White, 65 (47.4%) Black, 74 (56.9%) Hispanic or Latino, and 80 (59.3%) patients from other minority groups. To account for differential non-response rates across race groups, all PRO analyses were weighted by the inverse of the response probability, in addition to adjusting for baseline covariates. At one-year postoperatively, no differences were noted in clinical outcomes by race or ethnicity, but black women experienced higher psychosocial (P=.001) and sexual well-being (P=.004) relative to white women.
CONCLUSION: Despite a growing body of literature identifying disparities in clinical outcomes for minority populations, differences in complication and failures rates across race following breast reconstruction were not significant. Furthermore, the data suggest that black women experienced a greater increase in psychosocial and sexual well-being from undergoing reconstruction. In the context of a healthcare system increasingly focused on clinical and patient-report outcomes, future studies are needed to investigate loss to follow-up among underserved populations undergoing breast reconstruction.

DISCLOSURE/FINANCIAL SUPPORT: Supported by grants from the National Cancer Institute (1R01CA152192). Andrea Pusic is co-developer of the BREAST-Q, which is owned by Memorial Sloan-Kettering Cancer Center, and receives a portion of licensing fees (royalty payments) when the BREAST-Q is used in industry sponsored clinical trials. No other authors have a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

REFERENCES:
1. Albornoz CR, Bach PB, Pusic AL, et al. The influence of sociodemographic factors and hospital characteristics on the method of breast reconstruction, including microsurgery: A U.S. population-based study. *Plastic and reconstructive surgery.* 2012;129(5):1071–1079.
2. Alderman AK, McMahon Jr L, Wilkins EG. The national utilization of immediate and early delayed breast reconstruction and the effect of sociodemographic factors. *Plastic and reconstructive surgery.* 2003;111(2):695–703.
3. Rubin LR, Chavez J, Alderman A, Pusic AL. ‘Use what God has given me’: Difference and disparity in breast reconstruction. *Psychology and Health.* 2013;28(10):1099–1120.
4. Butler PD, Nelson JA, Fischer JP, et al. African-American women have equivalent outcomes following autologous free flap breast reconstruction despite greater preoperative risk factors. *American Journal of Surgery.* 2015;209(4):589–596.
5. Nelson A. Unequal treatment: confronting racial and ethnic disparities in health care. *Journal of the National Medical Association.* 2002;94(8):666–668.

Histone Deacetylase Inhibitors Enhance Cytotoxicity Towards Breast Tumors While Preserving the Wound Healing Function of Adipose Derived Stem Cells

Kiavash R. Koko, MD; Shaohua Chang, PhD; Ashleigh R. Hagaman, MD; Marc W. Fromer, MD; Ryan S. Nolan, MD; Ping Zhang, PhD; Jeffrey P. Carpenter, MD; Spencer A. Brown, PhD; Martha S. Matthews, MD; Dorothy Bird, MD

INTRODUCTION: Paclitaxel improves pathologic response of breast cancer resections; however, it may negatively affect the wound healing function of human adipose derived stem cells (hASC) and impair reconstructive surgery. Histone deacyethylase inhibitors (HDACi) modify epigenetic regulation of gene expression. HDACi also stabilize microtubules similarly to paclitaxel; therefore, combining these drugs creates a synergistic mechanism of cell cycle arrest. We aim to combine these drugs in order to enhance cytotoxicity towards breast cancer cells, while preserving the wound-healing function of hASCs for downstream reconstructive applications.

METHODS: Triple negative breast cancer cells (MBA-MB-231) and hASCs (IRB approved clinical isolates) were treated with a standard therapeutic dose of paclitaxel [1.0uM] alone or low dose paclitaxel [0.1uM] combined with the HDACi: Suberoylanilide Hydroxamic Acid (SAHA). Cell viability was measured via MTT assay. Gene expression of hASCs was measured by quantitative real-time PCR. Functional wound healing was measured via cell migration in a standardized fibroblast scratch assay.

RESULTS: Cell Viability (%): Standard-Dose Paclitaxel [SP] vs Low-Dose Paclitaxel + SAHA [LP+S]

- Breast Cancer Cells (n=9): [SP: 68% +/- 8.3] vs [LP+S: 60.8% +/- 6.6] p=0.31
- Adipose Stem Cells (n=9): [SP: 76% +/- 7.1] vs [LP+S: 105.7% +/- 16.1] p<0.05

Gene Expression: fold change of pro-inflammatory genes IL-1b, IL-6, and the pro-apoptotic gene FAS decreased in the [LP+S] group vs [SP] group though not statistically significant.

- IL-1b (n=5): [SP: 4.1 +/- 2.2] vs [LP+S: 2.1 +/- 0.8] p=0.27
- IL-6 (n=5): [SP: 1.4 +/- 1.4] vs [LP+S: 0.7 +/- 0.3] p=0.52
- FAS (n=5): [SP: 0.8 +/- 0.03] vs [LP+S: 0.7 +/- 0.1] p=0.53

Wound Healing: Dermal fibroblasts healed 24 hours sooner in the presence of hASCs treated with low-dose Paclitaxel +