GM-CSF alone. Intradermal inoculations were given monthly $\times$ 6, followed by boosters every 6 months, $\times$ 4. LR $\geq$ 100 mm prompted GM-CSF DR. Recurrence rates were compared using chi-square or Fisher exact test, as appropriate.

RESULTS: Of 180 enrolled patients, 89 were randomized to GP2 (VG) vs 91 to GM-only (CG). Arms were well matched clinicopathologically. Toxicities were mild and evenly distributed. Study-wide, 24.4% of the patients required DR. This compares to published rates of 17.9% and 18.9% for E75 and AE37 trials, respectively. Dose reduction occurred in 27% VG vs 22% CG (p=0.49). In ITT analysis, the RR in DR vaccinated patients is 8.3% vs 16.9% (p=0.35) in non-DR vaccinated patients, a 50% reduction in relative RR.

CONCLUSIONS: In a randomized phase II trial of GP2+GM-CSF, robust LR prompting GM-CSF DR trended toward lower RR. The DR rate is similar to the reported rates in other peptide+GM-CSF vaccine trials and confirms the correlation with better outcomes reported in those trials. Overall, these consistent findings suggest GM-CSF should be dosed to produce large LR to enhance the clinical benefit of adjuvant peptide vaccines.

Cost-Effectiveness Analysis of Contralateral Prophylactic Mastectomy Compared to Unilateral Mastectomy with Routine Surveillance for Unilateral, Sporadic Breast Cancer

Robert C Keskey, Andrew S LaJoie, PhD, Amanda Roberts, MD, MPH, Kevin D Frick, PhD, In K Kim, MD, MBA, Brad S Sutton, MD, MBA, William G Cheadle, MD, FACS, Nicolas Ajkay, MD, FACS

University of Louisville School of Medicine, Louisville, KY, Johns Hopkins University, Baltimore, MD, University of Toronto, Toronto, ON

INTRODUCTION: Contralateral prophylactic mastectomy (CPM) in younger women with unilateral breast cancer (BC) has more than doubled. Studies of cost and quality of life after unilateral mastectomy (UM) has more commonly been performed in women younger with unilateral breast cancer (BC) compared to contralateral breast cancer (CBC) treatment with CPM or UM. Recurrence rates were compared using chi-square or Fisher exact test, as appropriate.

RESULTS: Of 180 enrolled patients, 89 were randomized to GP2 (VG) vs 91 to GM-only (CG). Arms were well matched clinicopathologically. Toxicities were mild and evenly distributed. Study-wide, 24.4% of the patients required DR. This compares to published rates of 17.9% and 18.9% for E75 and AE37 trials, respectively. Dose reduction occurred in 27% VG vs 22% CG (p=0.49). In ITT analysis, the RR in DR vaccinated patients is 8.3% vs 16.9% (p=0.35) in non-DR vaccinated patients, a 50% reduction in relative RR.

CONCLUSIONS: In a randomized phase II trial of GP2+GM-CSF, robust LR prompting GM-CSF DR trended toward lower RR. The DR rate is similar to the reported rates in other peptide+GM-CSF vaccine trials and confirms the correlation with better outcomes reported in those trials. Overall, these consistent findings suggest GM-CSF should be dosed to produce large LR to enhance the clinical benefit of adjuvant peptide vaccines.

Efficacy and Long-Term Outcomes after Cryo-Assisted Lumpectomy for Breast Cancer

Suzy X Sun, MD, Katherine VanHise, Sudhir Kunchala, Erin K Greenleaf, MD, Christopher S Hollenbeak, PhD, JS Smith, Jr., MD, FACS

Penn State Hershey Medical Center, Hershey, PA

INTRODUCTION: Cryo-assisted lumpectomy (CAL) has been explored as a potential alternative to wire-localized lumpectomy for breast cancer; however, outcomes after CAL have not been widely reported. We assessed the efficacy and long-term outcomes of CAL for patients with breast cancer.

METHODS: An institutional database of 120 consecutive patients who underwent CAL from 2005 to 2015 was reviewed for factors that may influence outcomes after CAL. Patient factors, tumor characteristics, disease recurrence, and survival were compared between those who underwent re-excision for positive margins and those who did not need re-excision. Survival was analyzed using the Kaplan-Meier method.