GM-CSF alone. Intradermal inoculations were given monthly × 6, followed by boosters every 6 months, × 4. LR≥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

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INTRODUCTION: Contralateral prophylactic mastectomy (CPM) in younger women with unilateral breast cancer (BC) has more than doubled. Studies of cost and quality of life of the procedure remain inconclusive.

METHODS: A cost-effectiveness analysis using a decision-tree model in TreeAge Pro 2015 was used to compare long-term costs and quality of life after unilateral mastectomy (UM) with routine surveillance vs CPM for sporadic BC in women younger than 50 years of age. A 10-year risk period for contralateral breast cancer (CBC), reconstruction, wound complications, cost of routine surveillance, and treatment for CBC were used in the model to estimate accrued costs. In addition, a societal perspective was used to estimate quality adjusted life years (QALYs) after either treatment for a period of 20 years. Medical costs were obtained from the 2014 Medicare physician fee schedule and event probabilities were taken from recent literature.

RESULTS: The mean cost of UM with surveillance was $10,185 and CPM was $14,294. Treatment with UM resulted in $4,109 less in costs, yet a gain of 0.21 QALYs when compared with CPM over 20 years of follow-up. The resulting incremental cost effectiveness ratio is a savings of $19,566 per QALY gained when patients undergo UM. Even under worst-case scenario and varying assumptions, UM cost and quality dominated CPM.

Outcomes* after unilateral, sporadic BC treatment with CPM or UM	UM Cost, $	UM QALY†	CPM Cost, $	CPM QALY†
All possible outcomes averaged	10,185	14.75	14,294	14.54
Ideal outcome without reconstruction: no surgical complications; no CBC	8,509	19.71	9,965	19.51
Ideal outcome with reconstruction: no surgical complications; no CBC	13,356	19.69	14,920	19.49
Poor outcome without reconstruction: surgical complications; CBC at 5 years	35,359	17.67	37,041	17.47
Poor outcome with reconstruction: surgical complications; CBC at 5 years	40,404	17.65	42,194	17.45

*Outcomes: Possible outcomes after decision for UM vs CPM with or without reconstruction: initial complications, death at 5 years, CBC at 5 years, death at 10 years, CBC at 10 years, and survival.
†QALY: QALYs are added together for each health state a woman enters over the 20 years of the model; a perfect health state in the model would result in total QALYs of 20. QALYs are based on values from the literature that surveyed women with BC.

CONCLUSIONS: From this refined model, UM costs less and provides a better quality of life. Regardless of expected outcome, patients electing to undergo UM with routine surveillance gain several months of life in optimal health at a lower overall cost when compared with patients choosing CPM.

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

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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.