

## **EARLY REMOVAL OF POST-MASTECTOMY DRAINS IS NOT BENEFICIAL: RESULTS FROM A HALTED RANDOMIZED CONTROLLED TRIAL**

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**Background:** Drainage of mastectomy sites with closed suction drainage to avoid seromas is standard in the treatment of breast cancer. The optimal time to remove these drains has not been well defined. This study evaluates whether surgical drains can be removed on post-op day 2 following mastectomy, without increasing the need for seroma treatment.

**Materials and Methods:** Women undergoing mastectomy for malignancy, with either sentinel lymph node biopsy or complete axillary dissection, were enrolled at a single site over a four month period. After mastectomy, patients were randomized to early drain removal two days post-op (Early Removal), or standard drain removal (<30cc drainage in 24 hours or 2 weeks post-op, whichever came first) (Standard Treatment). All medical contacts after discharge were recorded for a period of one month. The Fisher test was used to compare differences between the two groups with regard to number of seroma aspirations, drain re-insertions, infections, and physician visits.

**Results:** Twenty-seven of the anticipated 80 women were recruited before an interim analysis was mandated to address patient safety concerns expressed by enrolling physicians. Of these patients, three withdrew prior to completion of the trial. Of the remaining 24 patients, 14 had been randomized to the Standard Treatment group and 10 were in the Early Removal group. Patients in the Standard Treatment group had significantly fewer seroma aspirations (0 versus 2;  $p=0.0004$ ), fewer drain re-insertions (0 versus 5;  $p=0.004$ ), and fewer physician visits (1.5 versus 3;  $p=0.004$ ). These results demonstrate a significantly higher risk to patients in the Early Removal group and this trial was therefore stopped early due to concerns over patient safety.

**Discussion:** Surgical drains cannot be safely removed on post-op day 2 after mastectomy. Early removal significantly increases the occurrence of seromas requiring additional treatment.