A Randomized Control Trial for Negative Pressure Therapy on Preoperatively Irradiated Pelvis and Lower Extremity Soft Tissue Sarcoma Wounds

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INTRODUCTION: Wound healing after oncologic resection in the pelvis and lower extremity is often challenging due to patient host and local treatment factors. Patients with soft tissue sarcomas who receive neoadjuvant radiation therapy are at an increased risk of post-operative wound complications. The purpose of this study was to determine whether incisional negative pressure wound therapy (INPWT) would reduce the rate of post-operative wound complications among pelvis and lower extremity sarcomas treated with neoadjuvant radiation therapy.

METHODS: This prospective, multicenter, randomized controlled trial evaluated the risk of wound complications following surgical resection of extremity soft tissue sarcomas in patients who had undergone preoperative external beam radiation. Participants were randomized to the INPWT or standard dry gauze dressing arm. Outcomes were collected at pre-op, 2 week post op, 6 week post op, 3 month post op and 6 month post op. Data were maintained in a longitudinal centralized database from each of the nine participating sites. Patients were eligible for enrollment if they had undergone resection of a soft tissue sarcoma of the pelvis or lower extremity following neoadjuvant external beam radiation therapy and closed by primary closure. Patients were excluded for flap coverage or skin graft, amputations, unplanned or “non-oncologic” resections, and recurrence. The primary endpoint was the 6-month wound complication rate, defined as the proportion of participants who did not experience a return to the operating room, superficial infection, deep infection, or wound packing for more than two weeks by the 6-month post-operative follow-up. Data collected preoperatively included radiation type and dose, use of chemotherapy, VAS pain score, MSTS score, PROMIS Global Health score, medical comorbidities, tumor location, and any use of pain medicines.

RESULTS: A total of 163 participants were enrolled across nine different sites, with 150 evaluable for the primary endpoint. Of these, 77 were assigned to the INPWT arm, and 73 to the standard gauze dressing arm.

Participants assigned to the INPWT arm experienced a wound complication rate of 41.6% (95% CI: 30.4–53.4; p-value=0.171), while those in the standard gauze dressing arm had a wound complication rate of 39.7% (95% CI: 28.5–51.9; p-value=0.101). No statistically significant difference in wound complication rates between the two groups was observed, with an odds ratio of 0.93 ($p = 0.87$). Additionally, when adjusting for potential confounding factors such as treatment center, no significant difference in complication rates was observed (Odds Ratio = 0.91, $p = 0.98$). Similarly, even when controlling for tumor location, there was still no meaningful difference between the two arms in terms of wound complications (Odds Ratio = 0.80, $p = 0.53$). At the six month follow-up there was no statistical difference between the two groups in PROMIS Global Health (Physical or Mental), MSTS score, or VAS results.

DISCUSSION AND CONCLUSION: The use of INPWT over primarily closed incisions for soft tissue sarcoma resection after neoadjuvant radiation therapy did not confer substantial improvement on the incidence of wound complications. There are also no differences seen in these cohorts in patient reported outcomes or pain scores.