Fibrin sealant reduces the duration and amount of fluid drainage after axillary dissection: a randomized prospective clinical trial.

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Publication Date: 2001

Abstract:

BACKGROUND: Patients who have axillary dissections during lumpectomy or modified radical mastectomy for breast carcinoma accumulate serosanguinous fluid, potentially resulting in a seroma. Currently accepted practice includes insertion of one or more drains for fluid evacuation. This multicenter, randomized, controlled, phase II study was undertaken to evaluate whether a virally inactivated, investigational fibrin sealant is safe and effective when used as a sealing agent to reduce the duration and volume of serosanguinous fluid drainage and to determine the dose response of this effect.

STUDY DESIGN: Patients undergoing lumpectomy or modified radical mastectomy were randomized to treatment with 4, 8, or 16 mL of fibrin sealant or control (no agent) at the axillary dissections site. Patients undergoing modified radical mastectomy also received an additional 4 or 8 mL of fibrin sealant at the skin flap site. Efficacy was evaluated by the number of days required for wound drainage and the volume of fluid drainage compared with control. Safety was confirmed by clinical course, the absence of viral seroconversion, and no major complications attributable to the sealant.

RESULTS: The 4-mL axillary dissection dose of fibrin sealant significantly reduced the duration and quantity of fluid drainage from the axilla following lumpectomy ($p < \text{or} = 0.05$). In the modified radical mastectomy patients, a 16-mL axillary dissection dose combined with an 8-mL skin flap dose was

significantly effective in reducing the number of days to drain removal ($p < or = 0.05$) and fluid drainage ($p < or = 0.01$). There were no fibrin sealant patient viral seroconversions and no major complications attributable to the sealant. A number of wound infections were noted, although this may represent a center-specific effect.

CONCLUSIONS: Application of fibrin sealant following axillary dissection at the time of lumpectomy or modified radical mastectomy can significantly decrease the duration and quantity of serosanguinous drainage. The viral safety of the product was also supported.