Evaluation of the topical hemostatic efficacy and safety of TISSEEL VH S/D fibrin sealant compared with currently licensed TISSEEL VH in patients undergoing cardiac surgery: a phase 3, randomized, double-blind clinical study.

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Abstract:

AIM: TISSEEL VH is the only commercially available fibrin sealant indicated as an adjunct to conventional methods of hemostasis during cardiac surgery. A next generation fibrin sealant (TISSEEL VH S/D) has been developed in frozen, ready-to-use form with an added virus inactivation step (solvent/detergent [S/D] treatment) to provide added safety and convenience to the currently licensed product. This study was performed to compare efficacy and safety of the two products.

METHODS: Phase 3, prospective, randomized, double-blind, multicenter study to compare TISSEEL VH S/D to TISSEEL VH during cardiac surgery. The primary efficacy endpoint was the proportion of patients who achieved hemostasis at the primary treatment site within 5 min, and maintained hemostasis until surgical closure.

RESULTS: The proportion of patients who achieved hemostasis at the primary treatment site within 5 min, and maintained hemostasis until surgical closure was 88.2% for TISSEEL VH S/D and 89.6% for TISSEEL VH in the intent-to-treat population. The difference in proportions, TISSEEL VH S/D minus TISSEEL VH, was 1.4% with a standard error of 3.70%. The lower 97.5% confidence bound of this difference was 8.6%, which is above the predefined noninferiority margin of 15%. Therefore,

TISSEEL VH S/D is at least as efficacious as TISSEEL VH. The safety profile of TISSEEL VH S/D was very similar to that of currently licensed TISSEEL VH as assessed by the safety endpoints.

CONCLUSION: TISSEEL VH S/D is safe and effective for use as an adjunct to hemostasis in patients undergoing cardiac surgery.