

A double-blind, randomized, placebo-controlled clinical trial evaluating fibrin sealant in thyroidectomy closure.

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Abstract:

Objectives: Evaluate the advantages and disadvantages of Evicel fibrin sealant when used in thyroid surgery closure, taking into account the following endpoints: postoperative drain output, time to drain removal, length of admission, and adverse events. **Methods:** From June 2010 to January 2014, an institutional review board-approved prospective, randomized, doubleblind study of Evicel versus a saline control was conducted on 70 subjects receiving total thyroidectomy or hemithyroidectomy. Twenty-eight received Evicel and 27 received saline; data from 15 subjects were eliminated due to protocol violations. The mean age was 50.3 (range, 21 to 73). **Results:** Comparisons of baseline characteristics, including age, sex, and type of surgery, revealed successful subject randomization. There was no significant difference in drain output between Evicel (median [interquartile range]: 96.3 mL [73.3-139.3 mL]) and placebo (120.0 mL [68.8-161.5 mL], $P = .334$). Drain time (37.9 hours [25.2-48.7 hours] vs 43.6 hours [37.6-58.1 hours]) and hospital stay (45.5 hours [33.4- 53.8 hours] vs 50.9 hours [44.1-69.4 hours]) were also shorter for Evicel, but again these differences were not significant ($P = .101$ and $.526$, respectively). For the subjects undergoing total thyroidectomy, there was a significant reduction in drain output (103.5 mL [80.0-138.6 mL] vs 150.0 mL [120.0-188.5 mL], $P = .035$) and drain time (40.3 hours [26.2-49.1 hours] vs 47.1 hours [42.0-67.8 hours], $P = .035$) with Evicel. Hospital stay in this subgroup was shorter with Evicel (50.3 hours [43.6-54.9 hours] vs 59.4 hours [48.4-70.6 hours]), but this result was not significant ($P = .246$). No outcomes were significant in the hemithyroidectomy subgroup. Nine adverse events occurred in the Evicel group compared to 3 for placebo ($P = .101$). **Conclusions:** Evicel sealant appears to be a safe, effective

method to reduce serous drain output following total thyroidectomy but has a limited role in hemithyroidectomy due to low levels of baseline drain output.