Post-operative benefits of Tisseel()/Tissucol () for mesh fixation in patients undergoing Lichtenstein inguinal hernia repair: secondary results from the TIMELI trial.

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Abstract:

PURPOSE: The Tisseel/Tissucol for mesh fixation in Lichtenstein hernia repair (TIMELI) study showed that mesh fixation with human fibrin sealant during inguinal hernia repair significantly reduced moderate-severe complications of pain 12 months post-operatively compared with sutures. Further analyses may assist surgeons by investigating predictors of post-surgical complications and identifying patients that may benefit from Tisseel/Tissucol intervention.

METHODS: Univariate and multivariate analyses identified risk factors for combined pain, numbness and groin discomfort (PND) visual analogue scale (VAS) score 12 months post-operatively. Variables tested were: fixation method, age, employment status, physical activity, nerve handling, PND VAS score at pre-operative visit and 1 week post-operatively. The effect of fixation technique on separate PND outcomes 12 months post-surgery was also assessed. Analyses included the intention-to-treat (ITT) population and a subpopulation with pre-operative PND VAS > 30 mm.

RESULTS: 316 patients were included in the ITT, with 130 patients in the subpopulation with pre-operative PND VAS > 30. Multivariate analysis identified mesh fixation with sutures, worsening pre-operative PND and worsening PND 1 week post-surgery as significant predictors of 12-month PND in the ITT population; mesh fixation with sutures was a significant predictor of 12-month PND in

the pre-operative PND VAS > 30 subpopulation ($p < 0.05$). Mesh fixation with Tisseel/Tissucol resulted in significantly less numbness and a lower intensity of groin discomfort compared with sutures at 12 months; there was no difference in pain between the treatment groups.

CONCLUSIONS: Pre-operative discomfort may be an important predictor of post-operative pain, numbness and discomfort. Tisseel/Tissucol may improve long-term morbidity over conventional sutures in these patients.