Use of human fibrin glue (Tisseel) versus staples for mesh fixation in laparoscopic transabdominal preperitoneal hernioplasty (TISTA): a randomized controlled trial (NCT01641718).

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Abstract:

BACKGROUND: Inguinal hernia repair is one of the most common surgical procedures worldwide. This procedure is increasingly performed with endoscopic techniques (laparoscopy). Many surgeons prefer to cover the hernia gap with a mesh to prevent recurrence. The mesh must be fixed tightly, but without tension. During laparoscopic surgery, the mesh is generally fixed with staples or tissue glue. However, staples often cause pain at the staple sites, and they can cause scarring of the abdominal wall, which can lead to chronic pain. We designed a trial that aims to determine whether mesh fixation with glue might cause less postoperative pain than fixation with staples during a transabdominal preperitoneal patch plastic repair.

METHODS/DESIGN: The TISTA trial is a prospective, randomized, controlled, single-center trial with a two-by-two parallel design. All patients and outcome-assessors will be blinded to treatment allocations. For eligibility, patients must be male, >=18 years old, and scheduled for laparoscopic repair of a primary inguinal hernia. One group comprises patients with a unilateral inguinal hernia that will be randomized to receive mesh fixation with either tissue glue or staples. The second group comprises patients with bilateral inguinal hernias. They will be randomized to receive mesh fixation with tissue glue either on the right or the left side and with staples on the other side. The primary endpoint will be pain under physical stress, measured at 24 h after surgery. Pain will be rated by the patient based on a numeric rating scale from 0 to 10, where 10 equals the worst pain imaginable. A

total of 82 patients will be recruited (58 patients with unilateral inguinal hernias and 24 patients with bilateral hernias). This number is estimated to provide 90% power for detecting a pain reduction of one point on a numeric rating scale, with a standard deviation of one.

DISCUSSION: Patients with bilateral hernias will receive two meshes, one fixed with glue, and the other fixed with staples. This design will eliminate the inter-individual bias inherent in comparing pain measurements between two groups of patients.

TRIAL REGISTRATION: ClinicalTrials.gov: NCT01641718.