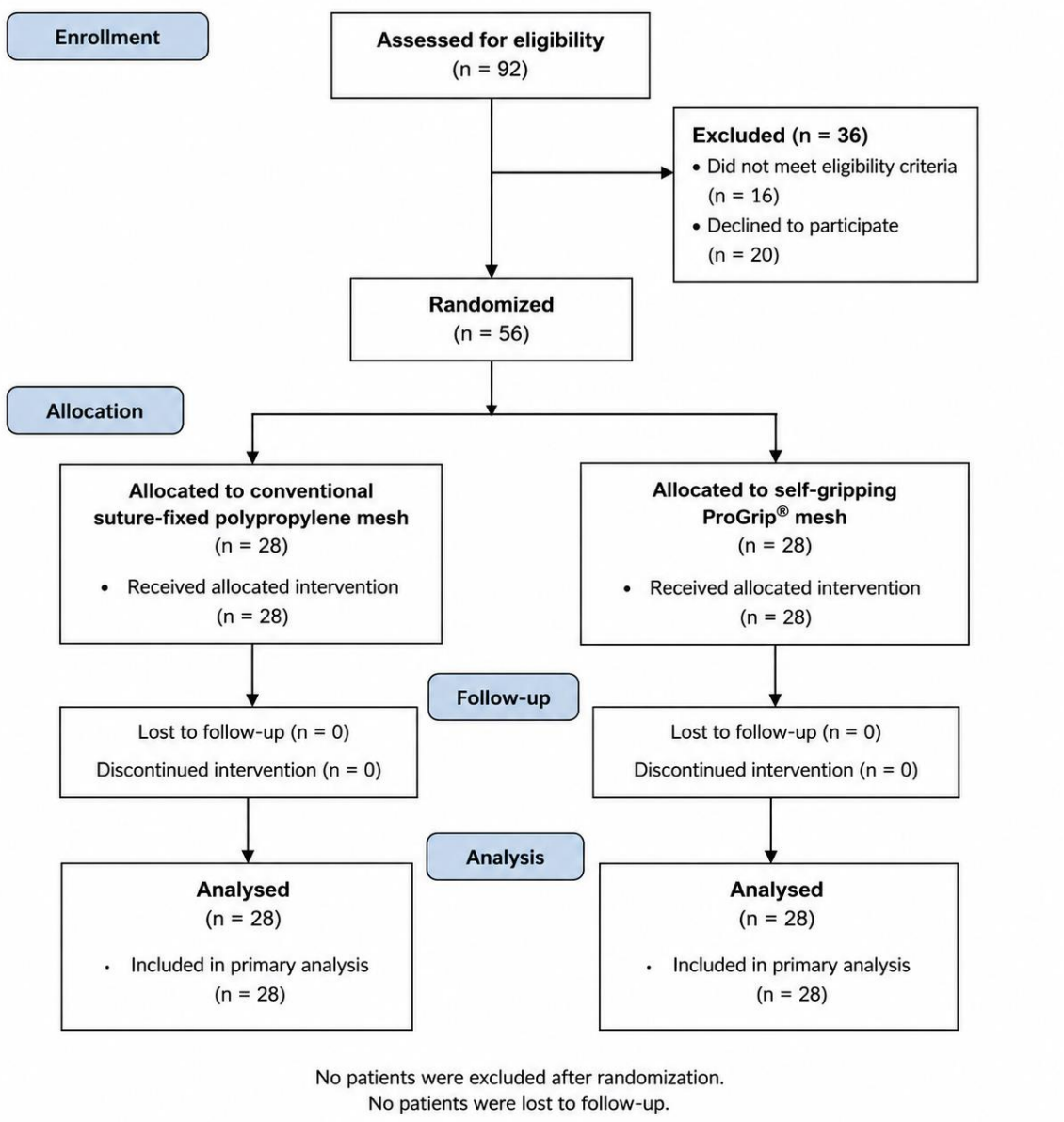
Summary Results Overview

Participant Flow

Between November 2021 and November 2022, 92 patients presenting with primary unilateral inguinal hernias were assessed for eligibility. Sixteen patients did not meet the inclusion criteria, and 20 patients declined participation. A total of 56 patients were randomized in a 1:1 ratio to undergo open Lichtenstein inguinal hernia repair using either a conventional suture-fixed polypropylene mesh (n = 28) or a self-gripping ProGrip® mesh (n = 28). All randomized patients received the allocated intervention. No patient required conversion to general anesthesia, no participant was excluded after randomization, and there were no losses to follow-up. Consequently, all 56 randomized patients completed the 12-month follow-up and were included in the final analysis.



Baseline Characteristics

The study population consisted exclusively of male patients, with a median age of 53 years (range, 27–85 years). The two treatment groups were comparable regarding demographic and preoperative clinical characteristics. Hypertension was present in 19.6% of patients, diabetes mellitus in 12.5%, chronic obstructive pulmonary disease in 7.1%, coronary artery disease in 7.1%, asthma in 1.8%, and heart disease in 3.6%. Most patients were classified as ASA I (71%), while the remaining 29% were ASA II. Right-sided hernias accounted for 57.2% of cases, and indirect inguinal hernias represented 89% of all hernias.

Primary Outcome

The primary outcome was acute postoperative pain assessed during the first postoperative month.

Pain was evaluated on postoperative day 1, postoperative day 7, and at 1 month. No statistically significant differences were observed between the two groups on postoperative day 1 (1 patient in the polypropylene group versus 3 patients in the ProGrip® group; $p = 0.20$) or at 1 month (8 versus 5 patients, respectively; $p = 0.30$).

At postoperative day 7, significantly fewer patients experienced pain after repair with the self-gripping ProGrip® mesh compared with the conventional polypropylene mesh (9/28 [32.1%] versus 19/28 [67.9%]; $p = 0.016$).

Secondary Outcomes

Operative Outcomes

The mean mesh implantation time was significantly shorter in the ProGrip® group than in the polypropylene mesh group (9.9 minutes versus 19.9 minutes; $p < 0.001$).

The direct procedural cost, calculated from the cost of the mesh and fixation materials, was significantly higher in the ProGrip® group (mean 697.23 Tunisian dinars) compared with the polypropylene group (mean 300.00 Tunisian dinars) ($p < 0.001$).

Quality of Life

Quality of life was evaluated using the Physical Functioning and Bodily Pain domains of the SF-36 questionnaire at 2, 3, 6, and 12 months after surgery.

Patients treated with the self-gripping ProGrip® mesh demonstrated significantly better physical functioning at 2 months compared with patients treated with the conventional polypropylene mesh (90.25 versus 84.39; $p = 0.036$). No statistically significant differences were observed at 3, 6, or 12 months.

Hernia Recurrence

One clinical recurrence occurred during follow-up in the polypropylene mesh group. No recurrence was observed in the ProGrip® group.

Adverse Events

No intraoperative complications occurred, and no surgical drains were required.

No mesh infections were reported during follow-up.

Postoperative complications included three parietal hematomas (all in the ProGrip® group), four scrotal hematomas (two in each group), one superficial wound infection (ProGrip® group), and twelve seromas (seven in the polypropylene group and five in the ProGrip® group). None of these differences reached statistical significance.