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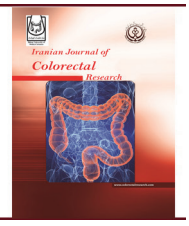

Clinical Evaluation of the Lepu Medical PPH Stapler versus the Golden Stapler (XNY) in Hemorrhoidal Disease and Rectal Mucosal Prolapse: A Regulatory Validation Study

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Abstract

Background: Stapled hemorrhoidopexy (PPH) is a well-established surgical procedure for treating high-grade hemorrhoidal disease and rectal mucosal prolapse. Regulatory clinical validation is essential to ensure the device's safety and performance equivalence.
Methods: In this prospective regulatory evaluation, 23 patients underwent PPH using either the Lepu Medical stapler (n=10) or the XNY (Golden Stapler) device (n=13). Intraoperative technical success, surgeon-reported device fluency (5-point scale), hemostasis, postoperative pain (VAS), and early complications during a 3-month follow-up period were assessed.
Results: Technical success was achieved in all cases, with complete circumferential staple lines. The XNY stapler demonstrated higher mean fluency scores than the Lepu Medical stapler (4.8 vs. 4.1). Minor staple-line overstitching occurred in 20% and 23% of cases, respectively. Postoperative pain was low, and no anal stenosis, infection, or recurrence was observed after three months.
Conclusion: Both staplers provided safe and effective treatment. The XNY stapler demonstrated a statistically significant advantage in fluency scores compared to the Lepu Medical stapler. However, the Lepu Medical stapler met all clinical safety requirements, including pain, recovery, and complication rates, suggesting that its use in routine surgical practice and national healthcare procurement could be as safe as the XNY device.

Keywords: Hemorrhoids; Stapled hemorrhoidopexy; Rectal mucosal prolapse; Surgical staplers; Regulatory evaluation

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Introduction

Hemorrhoidal disease remains a significant burden on healthcare systems and often requires surgery when conservative treatments fail (1, 2). Stapled hemorrhoidopexy (PPH), first described by Longo in 1998, is widely used for grade III and IV hemorrhoids and rectal mucosal prolapse due to its minimally invasive nature and rapid recovery (3). This procedure employs a circular stapler to resect a circumferential ring of redundant rectal mucosa, offering advantages including reduced postoperative pain, shorter operative time, and faster return to daily activities compared to the Milligan-Morgan or

Ferguson techniques (4). A 2026 systematic review and meta-analysis of multiple randomized trials confirmed these short-term benefits (5).

A prospective randomized trial directly comparing triple-row and double-row staplers reported that both devices are safe and effective for treating hemorrhoids. However, complications such as postoperative bleeding, length of hospital stay, use of hemostatic sutures, postoperative pain, and late complications such as recurrence differed significantly between the two groups (6).

The clinical success of PPH critically depends on the performance characteristics of the circular stapler used—specifically, consistent staple formation, appropriate compression height, reliable tissue transection, and adequate hemostasis. Suboptimal stapler performance can lead to serious complications such as anastomotic bleeding, stricture formation, staple-line dehiscence, rectovaginal fistula, and recurrence of prolapse (7).

The increasing availability of staplers from various manufacturers necessitates regulatory evaluation to ensure consistent clinical performance. While this expanded availability may offer cost savings and competitive pricing benefits to healthcare systems, it also raises an important regulatory and clinical question: Do all commercially available circular staplers provide equivalent safety and efficacy profiles when used for PPH? Currently, many devices enter the market through regulatory pathways that rely on demonstrating substantial equivalence to predicate devices, without requiring direct comparative clinical data. This creates a knowledge gap regarding real-world comparative performance. The aim of our study is to evaluate the superiority of newer-generation circular staplers relative to established devices and to assess postoperative complication rates**,** including early complications (bleeding, urinary retention, pain scores) and late complications (urinary incontinence, recurrence, fecal urgency) across different stapler brands.

Materials and Methods

This device validation comparative study was conducted at Shahid Faghihi Hospital, Shiraz, Iran, from April 2024 to October 2025. The study received ethical approval from the institute's committee (approval number is IR.SUMS.REC.1403.316), and written informed consent was obtained from all participants before the commencement of the study.

Study Setting

We prospectively evaluated 23 patients undergoing procedure for grade III/IV hemorrhoids and rectal mucosal prolapse using PPH. Patients were assigned to Group A (Lepu Medical stapler, n=10) or Group B (XNY/Golden Stapler, n=13) according to the device used. The two groups were matched for sex and age, and all patients underwent the standard PPH technique. Group assignment was determined by mutual agreement between the patients and their physicians; the study was not randomized.

Inclusion criteria: Male and female patients aged between 18 and 90 years. Patients with mucosal prolapse, with or without Grade 3 or Grade 4 hemorrhoids. Exclusion criteria: Pregnant female patients; patients with necrosis or inflammation of the anal tissue caused by multiple injections for hemorrhoids; patients with active infections; patients who have received antibiotics or anticoagulant therapy within 30 days prior to the planned surgery date; or those who have undergone preoperative therapy.

Data collection was conducted, recording patients' demographics, clinical symptoms, examination findings, and preoperative investigations. Patients were discharged the following day after ensuring there was no discharge from the operative site. They were advised to follow up at one week, during which pain scores (VAS), any complaints or symptoms, and examination findings were documented. Monthly follow-ups were conducted for three months. A questionnaire assessed whether the patient had passed gas or stool, as well as the degree of pain, leakage, or anal stricture experienced three months after the operation.

Secondary outcomes included intraoperative hemostasis, assessed by the accuracy and cleanliness of sutures, defects, and bleeding to evaluate blood loss reduction; postoperative pain measured using the VAS; and adverse events monitored during a three-month follow-up. Additionally, urinary and fecal incontinence were evaluated. Patients completed the questionnaire again three months after surgery.

The study was neither blinded nor randomized due to the nature of the intervention. Device fluency refers to a surgeon's proficiency and ease in using specialized circular stapling devices and was assessed on a 5-point scale. Device fluence is graded from 0 to 5 based on the surgeon's comfort with the device, and a comparison between the two devices was conducted by a single surgeon.

Statistical Analysis

The sample size is limited by the availability of new devices and volunteers for the observational study. Descriptive variables are presented as means and standard deviations. Intergroup comparisons of normally distributed continuous variables will be performed using the independent samples t-test, with a significance level set at $P < 0.05$ (SPSS version 19; Chicago, IL, USA).

Results

A total of 23 patients underwent PPH stapler hemorrhoidopexy, with 10 patients in the Lepu Medical group (Group A) and 13 patients in the Golden Stapler/XNY group (Group B). Technical

success was achieved in all cases (Tables 1 and 2). The mean age of patients was 52.30±17.46 years in Group A and 60.00±15.13 years in Group B, with no statistically significant difference between the groups (P=0.270, Table 3).

Postoperative pain, as measured by the VAS, did not differ significantly between Group A (2.20±1.13) and Group B (1.85±1.14; P=0.469). The duration of pain in days also showed no significant difference (Group A: 2.50±2.12 days vs. Group B: 3.38±2.72 days; P=0.407; see Table 3). Operative time did not differ between the two groups (P=0.745).

The XNY stapler demonstrated significantly higher fluency scores (mean 4.77±0.44) compared to the Lepu Medical stapler (mean 4.20±0.63), and this difference was statistically significant (P=0.019; 95% CI: −1.03, −0.10; see Table 3).

Minor overstitching to control bleeding was required in 20% of cases in the Lepu Medical group (2 out of 10 patients—one case requiring a single stitch at the 10 o'clock position and another requiring two stitches at the 6 o'clock position). In the XNY group, overstitching was required in 23% of cases (3 out of 13 patients), involving bleeding sites at the 4, 7, and 11 o'clock positions. Urinary retention requiring catheterization occurred in two patients in the XNY group (one for 12 hours and one for one day), while no urinary retention was observed in the Lepu Medical group (Tables 1 and 2).

Transient gas incontinence was reported in both groups: 3 patients (30%) in the Lepu Medical group, lasting from 3 days to 2 weeks, and 2 patients (15%) in the XNY group, lasting from 2 to 7 days. No urinary or fecal incontinence was observed (Tables 1 and 2).

Postoperative recovery was uneventful in all patients. No cases of anal stenosis or infection were observed in either group at the 3-month follow-up.

Table 1: Results in patients who underwent surgery using the PPH stapler No. 34, Lepu Medical Company brand

Sex	Diagnosis	Accuracy and cleanliness of sutures/defects/bleeding	Urinary/fecal/gas incontinence
Male	Mucosal prolapse	Bleeding/one stitch at 10 o'clock	No
Female	Mucosal prolapse	No	Gas/three days
Female	Mucosal prolapse	No	Gas/ one week
Male	Mucosal prolapse	No	No
Female	Mucosal prolapse	Bleeding/two stitches at 6 o'clock	No
Female	Mucosal prolapse+ Hemorrhoide	No	Gas/8days
Female	Mucosal prolapse	No	No
Male	Mucosal prolapse+Hemorrhoide	No	Gas/2weeks
Female	Mucosal prolapse	No	No
Female	Mucosal prolapse+Hemorrhoide	No	No

Table 2: Results in patients who underwent surgery using the Golden Stapler brand PPH stapler No. 34

Sex	Diagnosis	Accuracy and cleanliness of sutures/defects/bleeding	Urinary/fecal/gas incontinence	Urinary retention/ time
Male	Mucosal prolapse+Hemorrhoide	No	No	No
Female	Mucosal prolapse	No	No	No
Male	Mucosal prolapse+Hemorrhoide	Bleeding/two stitches at 7 o'clock	No	One day
Female	Mucosal prolapse	No	No	No
Male	Mucosal prolapse	No	No	No
Male	Mucosal prolapse	Bleeding/one stitch at 4 o'clock	No	No
Female	Mucosal prolapse	No	Gas/ one week	No
Female	Mucosal prolapse	No	Gas/3 days	No
Female	Mucosal prolapse	No	No	No
Male	Mucosal prolapse	No	No	No
Female	Mucosal prolapse	No	No	No
Male	Mucosal prolapse	Bleeding/two stitches at 11 o'clock	No	12 hours
Female	Mucosal prolapse+Hemorrhoide	No	Gas/2days	No

Table 3: Comparison of data between two groups

	Group A (Mean±SD)	Group B (Mean±SD)	p-value*	95% CI (lower, upper)
Age (Y/O)	52.30±17.46	60.00±15.13	0.270	-21.84,6.44
Fluency	4.20±0.63	4.77±0.44	0.019	-1.03, -0.10
Pain (VAS)	2.20±1.13	1.85±1.14	0.469	-0.64, 1.35
Pain/day	2.50±2.12	3.38±2.72	0.407	-3.06, 1.29

*Independent sample t-test

Discussion

PPH has been widely adopted for the treatment of advanced hemorrhoidal disease and rectal mucosal prolapse due to its favorable recovery profile. Objective evaluation of device performance and safety is increasingly important for regulatory approval and institutional procurement.

In our results, both staplers demonstrated equivalent accuracy and cleanliness of sutures, defects, and bleeding, as well as comparable outcomes regarding urinary, fecal, and gas incontinence, urinary retention, and time to complete technical success. These findings support the safety equivalence of the two groups over this limited time period. All data were collected using a questionnaire completed by the attending physician.

The XNY stapler was associated with smoother firing mechanics and higher fluency scores. These differences do not affect patient safety but may influence surgeon comfort and procedural flow (8). No increase in operative time or pain was observed during this short-term follow-up.

Careful attention to purse-string placement and resection depth resulted in appropriate mucosal excision and sphincter preservation in both groups, with no anal stenosis or ischemic complications observed at the 3-month follow-up.

In a study by Giuratrabocchetta et al., patients with grade III hemorrhoids underwent PPH using two types of staplers. The EEA® stapler (Covidien) demonstrated superior hemostatic properties compared to the PPH® stapler (Ethicon EndoSurgery), potentially reducing the recurrence rate of hemorrhoid prolapse. Additionally, the EEA® stapler was able to resect a larger mucosal area with fewer bleeding complications than the PPH stapler (9).

The modified tissue-selecting therapy (TST) staplers, which use an asymmetrically positioned cartridge to preserve healthier mucosa, are associated with reduced anal stenosis and incontinence, less persistent post-stapler pain, and a minimal risk of rectovaginal fistula (10).

A 2023 randomized controlled trial demonstrated that a modified TST technique combined with complete preservation of the anal canal epithelium provided greater efficacy and safety than conventional PPH for circumferential mixed hemorrhoids, resulting in lower pain scores and fewer recurrences (11).

From a regulatory perspective, these results demonstrate that the Lepu Medical stapler meets established safety standards. However, this study was limited by a small sample size, short follow-up duration, and unequal investigator familiarity favoring the established PPH device.

Conclusion

While two evaluated PPH staplers demonstrated acceptable safety and efficacy for PPH in treating high-grade hemorrhoidal disease and rectal mucosal prolapse, ergonomic differences favored the XNY device. However, specific performance metrics—particularly bleeding, incontinence, and postoperative pain—were comparable, suggesting that the use of either device in selected patients does not result in significant differences according to this short-term study.

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Authors' Contribution

KH.G. and H.KH. have read and approved the final version of the manuscript. KH.G. and H.KH. were involved in conceptualization; H.KH. was involved in literature search and drafting and writing of the manuscript. KH.G. and H.KH. were involved in writing and reviewing of the manuscript. KH.G. was involved in supervision and project management.

Ethics and Regulatory Statement

Conducted under Ministry of Health oversight, written consent obtained, per Declaration of Helsinki. Institute ethical committee approval number is IR.SUMS.REC.1403.316

Conflict of Interest

The authors declare no conflicts of interest related to this study.

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