

Endoscopic intralesional platelet-rich plasma (PRP) injection after balloon dilation for colonic Crohn's disease strictures: a pilot study

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Abstract

Background and Aims: Fibrostenotic strictures complicate Crohn's disease (CD) and often recur after endoscopic balloon dilation (EBD). Platelet-rich plasma (PRP) promotes wound healing in other fibroproliferative disorders, but its endoscopic application in CD stricture has not been explored. We aimed to assess the safety, feasibility, and preliminary efficacy of intralesional PRP injection after EBD for colonic CD strictures.

Methods: This was a prospective, single-arm pilot study. Between January 2024 and August 2025, 29 patients with colonic CD strictures underwent EBD followed by submucosal injection of autologous PRP (1-2 mL at 3-4 points of the dilated segment). The primary outcome was the restenosis rate at 3 weeks, defined as inability to pass a 10.5-mm endoscope. Secondary outcomes included technical success, adverse events, changes in intestinal ultrasound findings, and the proportion of patients requiring surgery within 1 year.

Results: Technical success was achieved in 100% of patients (29/29). No PRP-related adverse events occurred. Two patients (6.9%) developed delayed hemorrhage attributable to concurrent polypectomy rather than PRP injection, and one patient (3.4%) developed a perforation related to balloon dilation that was successfully managed with endoscopic clip closure. The restenosis rate was 48.2% at the 3-week follow-up and 73.1% at 1 year. Intestinal ultrasound showed no significant changes from baseline in stricture-wall thickness or proximal luminal width at either time point. At 1 year, one patient (3.8%) underwent surgery due to perforation.

Conclusions: Endoscopic intralesional PRP injection after EBD is technically feasible and safe in colonic CD strictures. Although this single-arm study cannot establish efficacy, it provides the first descriptive benchmark of restenosis outcomes with this approach; the favorable safety profile supports further investigation of repeated dosing or combination strategies in this and other fibrostenotic conditions.

Introduction

Crohn's disease represents a chronic, progressive inflammatory disorder affecting the gastrointestinal tract, whose incidence keeps rising with industrialization^{1,2}. In the long-term care of CD, stricture remains a perpetual issue. A Danish population-based cohort followed newly diagnosed patients for seven years and found that the proportion with either stricturing or penetrating phenotypes increased by 7% each³. Epidemiological data indicate that approximately 50% of patients with Crohn's disease will develop clinically apparent fibrostenotic strictures during their lifetime⁴. CD strictures are broadly divided into inflammatory and fibrotic subtypes. Numerous novel biologics have shown good efficacy for inflammatory strictures⁵, yet for fibrotic strictures only a handful of agents are still in pre-clinical development⁶. Endoscopic or surgical intervention is therefore often necessary. Pooled evidence indicates that endoscopic balloon dilation (EBD) is both effective and cost-efficient⁶⁻¹⁰ and it is recommended by the Stenosis Therapy Anti-Fibrotic Research (STAR) Consortium¹¹, and remains the

dominant technique in daily practice. Unfortunately, fibrotic CD strictures might recur after endotherapy, so repeated procedures are sometimes required^{12, 13}. Prolonging the stricture-free time or reducing the number of endoscopic sessions is therefore an unresolved challenge. Intralesional injection of corticosteroids or anti-TNF agents have been proposed^{14–17}, but the results were not in consistency, so the STAR Consortium do not recommend these methods¹¹.

Autologous platelet-rich plasma (PRP) concentrates platelet-derived growth factors and fibrin from the patient's own blood. When the PRP is injected into a target site, it potentiates local repair and regeneration¹⁸. PRP is already widely used in medical fields such as dentistry, surgery, orthopedics, dermatology, and aesthetic medicine^{18, 19}. It is reported that, intralesional PRP after incision reduces restenosis in urethral-stricture²⁰. Animal study showed that, topical PRP treatment decreased stricture development after the experimental corrosive burn in rats²¹, but no study has yet explored PRP for preventing gastrointestinal stricture recurrence in human body. Hence, we conducted this pilot study to assess the safety, feasibility, and preliminary efficacy of intralesional PRP injection after EBD for colonic CD strictures.

Methods

Patients

Patients with CD in our hospital were recruited for this study between April 2024 and August 2025. Written informed consent was obtained from all participants prior to enrollment.

The inclusion criteria were as follows: ♂ diagnosed as CD; ♂ stenosis of the colon was found during colonoscopy, and surgery was not considered for the time being; ♂ narrow length <5cm; ♂ the patients agreed to undergo EBD and voluntarily signed the informed consent to participate in this study, and were capable of complying with the agreement. The exclusion criteria were as follows: ♂ the patient has contraindications for endoscopic therapy, such as coagulation disorder, severe cardiopulmonary dysfunction, active bleeding, and inability to cooperate; ♂ deep and large active ulcer was found in the stenosis; ♂ < 18 years old; ♂ foreign patients; ♂ patients with a history of malignant tumors, including melanoma (except local skin cancer); ♂ pregnant or nursing patients; ♂ patients who could not be followed at all nodes of the primary outcome indicator; ♂ other diseases that researchers believe could put patients at risk.

Study design

This study reports the pilot phase of the ongoing trial NCT06165289, which was registered in the ClinicalTrials.gov on January, 14, 2026. Recruitment was temporarily suspended after this feasibility analysis; the decision to resume accrual will be made pending feasibility review and resource confirmation. Participants were randomly assigned to the PRP low-concentration group, and PRP high-

concentration group in a 1:1 ratio. This study implemented a single-blind design in which outcome assessors remained unaware of group assignments.

Before the procedure, the patients' basic information, Harvey-Bradshaw Index (HBI), and laboratory results (blood routine, liver function, C-reaction protein) were obtained. Intestinal ultrasound was performed by experienced ultrasonographers.

PRP preparation

Approximately 30 mL of blood was taken from the patients' peripheral vein using blood collection tubes, and the baseline platelet count was checked. Two-step centrifugation was used to remove the red blood cells and prepare PRP. The concentration of PRP in the low-concentration group was $1 \times 10^6/\mu\text{L}$, and $2 \times 10^6/\mu\text{L}$ in the high-concentration group. The detailed procedure is presented in the **Supplementary materials**.

Endoscopic procedures

All endoscopic procedures were performed by experienced endoscopists, who has experience of more than 100 cases of EBD. After dilation of the stricture, 1–2 mL of PRP was injected submucosally at 3–4 points of the wound site of the stricture (Fig. 1 shows the endoscopic procedure). The detailed procedure is presented in the Supplementary materials, and was detailed as reported previously²¹.

Follow-up

Patients return for reassessment at 3 weeks post-procedure. If the endoscope sized 10.5mm can traverse the stricture at that visit, follow-up is scheduled 1 year later. If passage is not possible, repeat dilation is performed at 3 weeks post-procedure. The explicit study schedule is presented in Figure S1.

Outcome measures

The primary outcome parameter was the restenosis rate at 3 weeks post-procedure: restenosis was defined as the endoscopy with size of 10.5mm cannot pass the stricture. The secondary outcome measures were technical success, adverse events, changes in intestinal ultrasound (including the thickness of the stricture intestinal wall, and the width of the proximal intestinal cavity, and the proportion of surgery due to stricture or perforation in 1 year post-procedure.

Statistical Analysis

Continuous, normally distributed variables are presented as mean $\pm$ standard deviation (SD). Non-normally distributed continuous variables are reported as median (inter-quartile range, IQR). Categorical data are given as n (%). All analyses were performed with SPSS version 22 (IBM Corp., Boston, MA, USA).

Stricture-free survival was defined as the interval from the first endoscopic intervention until endoscopic restenosis (inability to pass a 10.5-mm colonoscope) or surgical resection for colonic stricture. Surgery-free survival was defined as the interval from the first endoscopic intervention until surgery due to stricture or perforation.

Results

Patients and basic characteristics

Between January 2024 and August 2025, 29 patients (15 low-concentration and 14 high-concentration PRP) were enrolled in the pilot trial (the flow chart of the study is presented in Fig. 2). Mean age of the patients was 31.1 ± 7.7 years and 23 (79.3%) were male. Median HBI was 2 (IQR 2). Seventeen patients (58.6%) showed penetrating disease behavior, one (3.4%) had extraintestinal manifestations and 20 (69%) had perianal disease. Baseline demographic and clinical characteristics are presented in Table 1. The laboratory results are provided in Supplementary Table S1.

Table 1
The basic demographic and clinical characteristics of the patients

Sex (male), n (%)	All (n = 29)	Low-concentration (n = 15)	High- concentration (n = 14)
	23 (79.3)	10 (66.7)	13 (92.9)
Age (yrs), mean $\pm$ SD	31.1 $\pm$ 7.7	31.9 $\pm$ 9.0	30.4 $\pm$ 6.3
Smoking, n (%)	5 (17.2)	2 (13.3)	3 (21.4)
Time from diagnosis to this endotherapy (months), median (IQR)	44 (73)	55 (87)	31 (73.25)
BMI (kg/m ²), mean $\pm$ SD	20.3 $\pm$ 2.8	20.3 $\pm$ 3.0	20.2 $\pm$ 2.7
Harvey-Bradshaw Index, median (IQR)	2 (2)	2 (3)	2 (2)
Penetrating behavior, n (%)	17 (58.6)	9 (60)	8 (57.1)
Extraintestinal manifestations, n (%)	1 (3.4)	0	1 (7.1)
Perianal diseases, n (%)	20 (69)	11 (73.3)	9 (64.3)
Montreal classification for location, n (%)			
L3	24 (82.8)	12 (80)	12 (85.7)
L3 + L4	5 (17.2)	3 (20)	2 (14.3)
Obstructive symptoms score, n (%)			
0	19 (65.5)	12 (80)	7 (50)
1	7 (24.1)	1 (6.7)	6 (42.9)
2	3 (10.3)	2 (13.3)	1 (7.1)
Medication history, n (%)			
Exclusive enteral nutrition	19 (65.5)	10 (66.7)	9 (64.3)
Immunosuppressant	14 (48.3)	8 (53.3)	6 (42.9)
PRP, platelet-rich plasma, SD, standard deviation; IQR, inter-quartile range; IFX, Infliximab; ADA, Adalimumab; VDZ, Vedolizumab; UST, Ustekinumab; UPA, Upadacitinib			

Sex (male), n (%)	All (n = 29)	Low-concentration (n = 15)	High- concentration (n = 14)
	23 (79.3)	10 (66.7)	13 (92.9)
Glucocorticoid	11 (37.9)	5 (33.3)	6 (42.9)
Biologics	24 (82.8)	13 (86.7)	11 (78.6)
IFX	13 (44.8)	6 (40)	7 (50)
ADA	9 (31)	6 (40)	3 (21.4)
VDZ	5 (17.2)	5 (33.3)	0
UST	13 (44.8)	7 (46.7)	6 (42.9)
UPA	3 (10.3)	3 (20)	0
PRP, platelet-rich plasma, SD, standard deviation; IQR, inter-quartile range; IFX, Infliximab; ADA, Adalimumab; VDZ, Vedolizumab; UST, Ustekinumab; UPA, Upadacitinib			

Endoscopic procedures and adverse events

The stricture involved the ileocecal valve in 25 patients (86.2%), the ileocolic anastomosis in 1 (3.4%), the sigmoid colon in 2 (6.9%), and the transverse colon in 1 (3.4%). Mean stricture diameter was 3.6 ± 1.8 mm and mean length 1.2 ± 0.6 cm. Balloon catheters of 14 mm, 16 mm and 18 mm were used in 2 (6.9%), 6 (20.7%) and 21 (72.4%) patients, respectively. In 7 patients (24.1%), there were many pseudopolyps around the stricture, polypectomy was also performed. The technical success rate was 100%, 2 patients (6.9%) had delayed hemorrhage (the hemorrhage was related to polypectomy, not dilation or PRP injection), and 1 patient (3.4%) had perforation (the perforation was related to dilation, nor PRP injection, and was treated with metal clip closure). Endoscopic details are summarized in Table 2.

Table 2
The endoscopic characteristics of the patients

Stricture location, n (%)	All (n = 29)	Low-concentration (n = 15)	High-concentration (n = 14)
Ileocecal valve	25 (86.2)	12 (80)	13 (92.9)
Anastomosis	1 (3.4)	0	0
Sigmoid colon	2 (6.9)	2 (13.3)	0
Transverse colon	1 (3.4)	1 (6.7)	0
Stricture with ulceration, n (%)	1 (3.4)	0	1 (7.1)
Diameter of stricture (mm), mean $\pm$ SD	3.6 $\pm$ 1.8	3.8 $\pm$ 1.8	3.7 $\pm$ 1.9
Diameter $\geq$ 3mm, n (%)	20 (69)	12 (80)	8 (57.1)
Length of stricture (cm), mean $\pm$ SD	1.2 $\pm$ 0.6	1.2 $\pm$ 0.6	1.3 $\pm$ 0.6
Length $\geq$ 2cm, n (%)	8 (27.6)	4 (26.7)	4 (28.6)
Diameter of the balloon catheter, n (%)			
14mm	2 (6.9)	2 (13.3)	0
16mm	6 (20.7)	3 (20)	3 (21.4)
18mm	21 (72.4)	10 (66.7)	11 (78.6)
Polypectomy, n (%)	7 (24.1)	3 (20)	4 (28.6)
Technical success, n (%)	29 (100)	15 (100)	14 (100)
Adverse events, n (%)			
Hemorrhage	2 (6.9)	0	2 (14.3)
Perforation	1 (3.4)	0	1 (7.1)
Subsequent endotherapy			
0	18 (62.1)	8 (53.3)	10 (71.4)
PRP, platelet-rich plasma, SD, standard deviation			

Stricture location, n (%)	All (n = 29)	Low-concentration (n = 15)	High-concentration (n = 14)
1	7 (24.1)	3 (20)	4 (28.6)
2	4 (13.8)	4 (26.7)	0
PRP, platelet-rich plasma, SD, standard deviation			

Follow-up

Two patients (6.9%) were lost to follow-up at the 3-week post-procedure visit, and 3 patients (10.3%) got lost at the 1-year post-procedure visits. The endoscopic restenosis rate was 48.2% at the 3-week post-procedure visit, and 73.1% at the 1-year post-procedure visit. Intestinal ultrasonography showed that, at 3 week and 1 year there were no statistically significant changes from baseline in either stricture-wall thickness (3-week post-procedure visit: -0.3 ± 1.1 mm; 1-year post-procedure visit: -0.7 ± 1.6 mm) or proximal luminal width (3-week post-procedure visit: -1.6 ± 3.0 mm; 1-year: -1.3 ± 5.2 mm). At 1-year post-procedure visit, 1 patient (3.8%) received surgery due to perforation.

Discussion

This pilot study is the first human trial to evaluate the safety and feasibility of a single intralesional injection of autologous PRP immediately after EBD for fibrostenotic colonic CD. As a single-arm, proof-of-concept study without a control group, its primary contribution is to establish the technical feasibility and safety profile of this novel endoscopic adjunct, while providing preliminary descriptive efficacy data that can inform the design of subsequent controlled trials.

The rationale for PRP was grounded on its ability to deliver supra-physiological concentrations of platelet-derived growth factors (PDGF, TGF- β , VEGF) and fibrin scaffolding that accelerate wound remodeling and reduce fibrosis in orthopedic, urological and dermatological models^{20, 23, 24}. The application of PRP in gastrointestinal stricture disease remains limited.. Oztan et al. demonstrated that PRP ameliorates oxidative stress, promotes mucosal healing, and attenuates stricture formation in experimental corrosive esophageal injury²¹. They further established that PRP modulates esophageal motility and reduces contractile responses, effects that may contribute to its anti-stenotic properties²⁴. More recently, Xu et al. reported that submucosal PRP injection prior to autologous skin graft transplantation significantly enhances graft survival and decreases mucosal contraction compared with grafting or stenting alone in a porcine model of extensive esophageal defects, positioning PRP as a promising biological adjunct to prevent postoperative stricture²⁶. Albahrawy et al. showed that leukocyte-platelet-rich fibrin accelerates collagen deposition, re-epithelialization, and angiogenesis while reducing adhesions and stenosis severity in a rabbit colonic anastomosis model²⁷. Collectively, these

preclinical studies provide mechanistic rationale for exploring PRP in human fibrostenotic disorders. However, these investigations were confined to animal models, and no human trials had explored PRP for gastrointestinal stricture prevention prior to our study. Herein, we report the first-in-human experience of intralesional PRP injection combined with EBD for fibrostenotic colonic CD, establishing preliminary safety and feasibility in a clinical setting.

Technical success was achieved in all patients, with no procedure-related perforations or PRP-attributed adverse events. The two delayed hemorrhages were unequivocally linked to concurrent polypectomy rather than PRP injection or dilation. This safety record is noteworthy given the theoretical risks of submucosal injection in inflamed, strictured intestinal walls—namely perforation, bleeding, and infection. The absence of such complications supports the procedural feasibility of intralesional PRP in the colonic setting.

Regarding efficacy, the observed restenosis rates at 3 weeks (48.2%) and 1 year (73.1%), together with the low 1-year surgery rate, provide a descriptive benchmark for this patient population. However, in the absence of a control group, no efficacy conclusion can be drawn: the natural history of fibrostenotic CD strictures after EBD is highly variable, and whether PRP modifies this trajectory remains unknown. Several mechanistic considerations may explain why only limited benefit was observed. Intestinal fibrosis in CD is driven by persistent immune activation, myofibroblast proliferation, and irreversible collagen cross-linking within a transmural inflammatory milieu^{3, 28}. Unlike acute injuries where PRP has demonstrated benefit—such as corrosive esophageal burns—the fibrotic process in CD is self-perpetuating and only partially reversible. A single exposure to platelet-derived mediators may be insufficient to interrupt this loop, and repeated injections, controlled intestinal inflammation, or combination with anti-fibrotic strategies may be required to achieve a meaningful effect.

Despite the inconclusive efficacy signal in this specific indication, our study proposes several principles transferable to other gastrointestinal applications, such as prevention of stricture formation after extensive endoscopic submucosal dissection (ESD), management of corrosive esophageal injury, and treatment of postoperative anastomotic strictures. In these settings, the fibrotic process is typically more acute and potentially more amenable to regenerative modulation. Whether PRP proves efficacious in these alternative applications awaits rigorous prospective validation.

This study has several limitations. First, the single-arm design without any control group precludes any assessment of efficacy, and all outcome data should be interpreted as purely descriptive. Second, the sample size is small, and the 3-week primary endpoint may have captured predominantly subclinical luminal narrowing rather than clinically significant stricture. Consequently, the true impact of PRP on long-term patient-centered outcomes—cumulative surgery rates, obstructive symptom burden, and perforation risk—remains uncertain. Future trials should adopt a randomized, controlled design with adequate statistical power, protocol-driven and standardized follow-up schedules, and longer observation periods to delineate whether PRP delays clinically meaningful complications rather than merely transient endoscopic stenosis.

In conclusion, this first-in-human pilot study establishes that intralesional PRP injection following EBD is safe and technically feasible in patients with fibrostenotic colonic CD, providing the first clinical benchmark of restenosis outcomes with this approach. While the single-arm design does not permit efficacy conclusions, the favorable safety profile and proof-of-concept for endoscopic delivery support exploration of PRP in alternative gastrointestinal applications—particularly prevention of ESD-related strictures, management of corrosive esophageal injury, and treatment of anastomotic strictures. Larger, mechanistically informed trials with repeated injections or combination strategies are warranted to determine whether the potential of PRP to prevent restenosis can be unlocked in selected clinical settings.

Declarations

Data Availability

The data described in this manuscript may be made available upon reasonable request to Min Zhi (zhimin@mail.sysu.edu.cn).

Ethics Statement

The study was approved by the Institutional Review Board of the Sixth Affiliated Hospital, Sun Yat-sen University (Approval Number: 2022ZSLYEC-511). This study reports the pilot phase of the ongoing trial NCT06165289, which was registered in the ClinicalTrials.gov on January, 14, 2026.

Author contributions

YL, TY, LSS, JCS and MZ designed the study. LSS, JCS and MZ supervised the study. YL, TY, JL, JD, WW, QQJ, HSM, ZYG, MX, and XQY administrated the study and collected the data. YL, TY, JD, WW, and LSS performed the statistical analysis. JL, QQJ, HSM, ZYG, MX, and XQY helped to prepare the PRP. YL, TY, and LSS drafted the manuscript. All authors revised and approved submission of the manuscript.

Conflict of interest

None.

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Figures

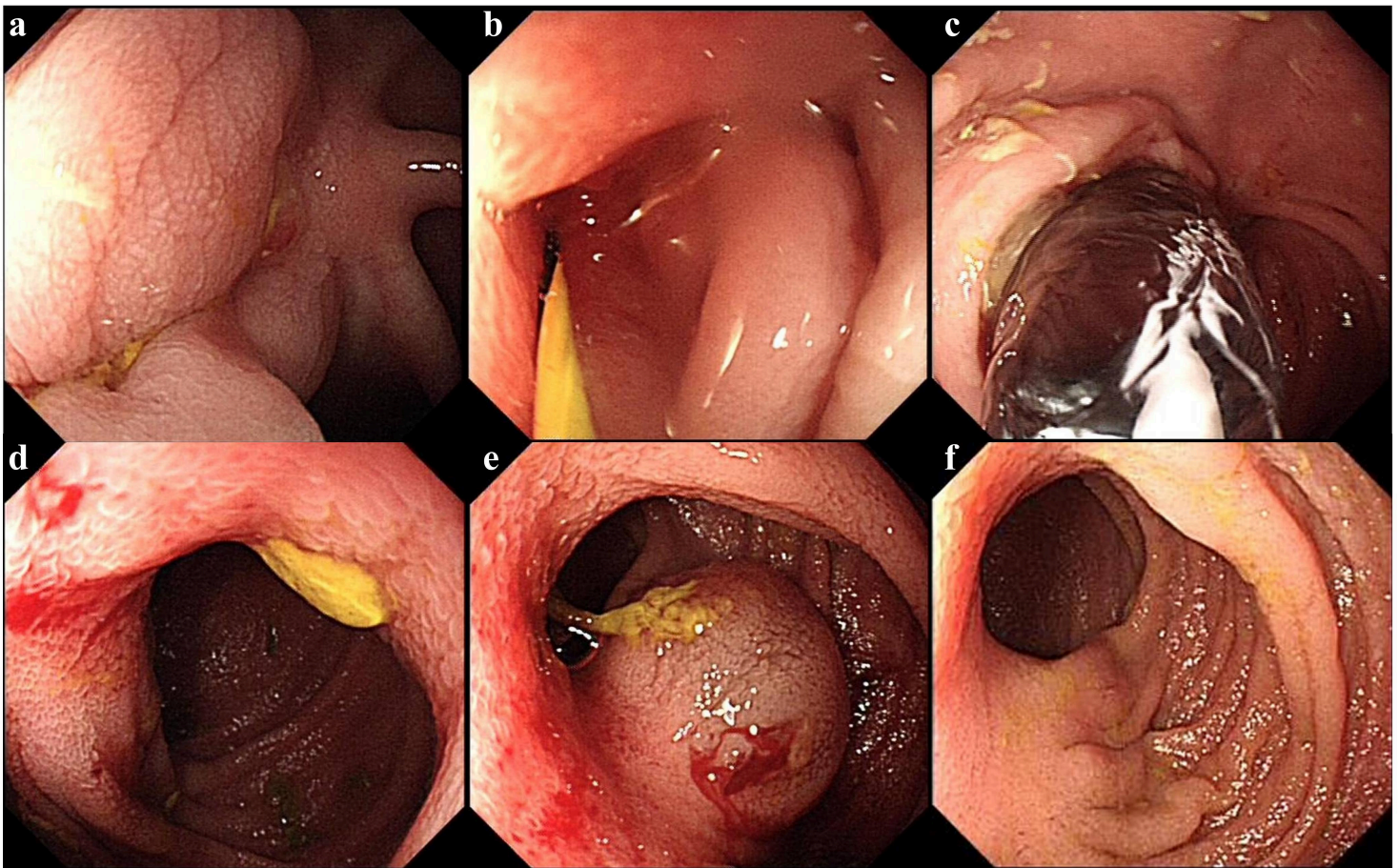


Figure 1

The endoscopic procedure: a. colonoscopy showed ileocecal valve stenosis; b. a guidewire was inserted through the stenosis; c. balloon dilation of the stenosis; d. the stenosis was dilated; e. submucosal injection of platelet-rich plasma (PRP); f. follow-up colonoscopy at 3 weeks showing no restenosis, with the endoscope traversing the previously stenotic segment without difficulty

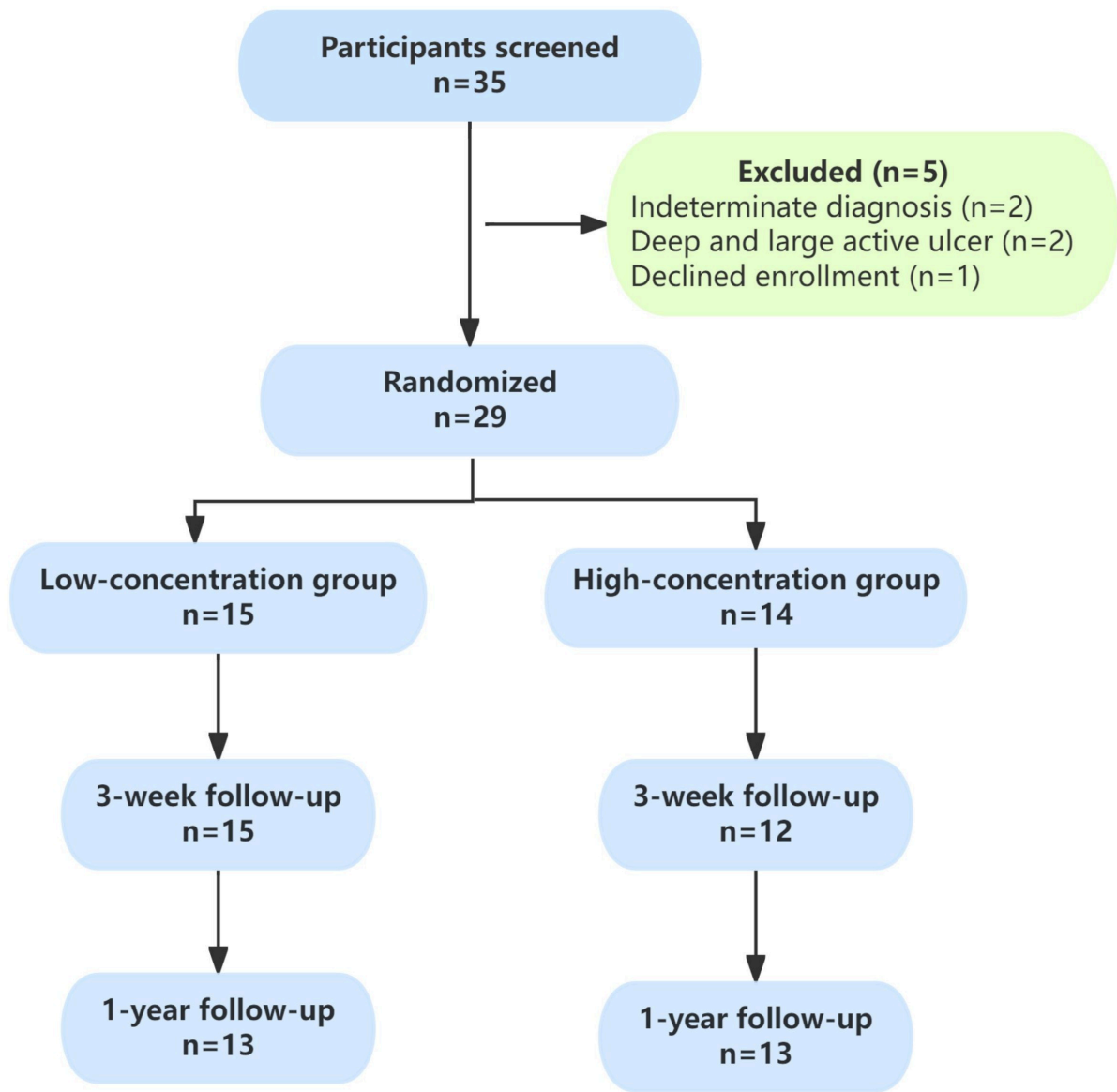


Figure 2
Flow chart of the study

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