

A Randomized, Double-Blind, Non-Inferiority Trial Comparing a Novel Single-Use Adjunctive Defecation Device Versus Manual Disimpaction Therapy for the Management of Refractory Fecal Impaction Secondary to Outlet Obstruction in Patients with Chronic Constipation

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Article

Keywords: outlet obstructive constipation, fecal impaction, fecaloma, disposable defecation assistive device, manual digital disimpaction, randomized controlled trial, clearance rate, safety, effectiveness

Posted Date: October 23rd, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-11257991/v1>

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Additional Declarations: No competing interests reported.

Abstract

Background and Objectives:

Fecal impaction is a severe complication of outlet obstructive constipation (OOC), and there is currently a lack of evidence-based effective interventions. Current guidelines recommend manual disimpaction as the first-line treatment, which is highly operator-dependent, causes significant pain, and carries a risk of mucosal injury. This study evaluates whether a novel disposable digital assisted defecation device (DDAD) is non-inferior to manual disimpaction in terms of complete clearance rate, with a secondary hypothesis that it is safer.

Methods

This prospective, single-center, open-label, non-inferiority randomized controlled trial enrolled 108 adult patients with refractory OOC-related fecal impaction who were unresponsive to laxatives/enemas. Subjects were randomly assigned 1:1 to the DDAD group (n = 54) or the manual disimpaction group (n = 54). The primary endpoint was the complete clearance rate after a single procedure, with a pre-specified non-inferiority margin of – 12%. Secondary endpoints included procedure-related pain (Visual Analog Scale, VAS), procedure duration, and adverse events followed up to 1 month. The analysis followed the intention-to-treat (ITT) principle.

Results

In the intention-to-treat population, the complete clearance rate after a single procedure was 88.9% (48/54) in the DDAD group and 87.0% (47/54) in the control group, with a risk difference of 1.85% (95% confidence interval: 9.17% to 12.87%), confirming the non-inferiority of DDAD. Procedure-related pain was significantly lower in the DDAD group (median VAS: 3 vs. 6, $P < 0.001$), procedure time was shorter (30 minutes vs. 42 minutes, $P < 0.001$), and the overall incidence of adverse events was lower (13.0% vs. 29.6%, $P = 0.032$). No mucosal injury, grade 3–4 severe complications, or delayed adverse events occurred in the DDAD group.

Conclusions

DDAD is non-inferior to standard manual disimpaction in efficacy for the treatment of refractory fecal impaction associated with OOC, and demonstrates superiority in safety, pain reduction, and procedural efficiency. This device provides a promising, minimally invasive new option for the standardized management of refractory fecal impaction.

Highlights

What is Known:

- Fecal impaction is a severe and potentially life-threatening complication of outlet obstructive constipation.
- Current guidelines only recommend manual disimpaction, with a low level of evidence.
- Manual disimpaction is highly operator-dependent, causes significant pain, and carries risks of mucosal tearing and vasovagal reflex.

- Laxatives and enemas are largely ineffective against formed, hard fecalomas.

What This Study Adds:

- The complete clearance rate of DDAD was 88.9%, non-inferior to manual disimpaction at 87.0%.
- DDAD reduced the median VAS pain score from 6 to 3 ($P < 0.001$) and shortened the procedure time by 12 minutes.
- The incidence of mucosal injury in the DDAD group was zero, compared to 20.4% in the manual group (absolute risk reduction of 16.6%).
- DDAD achieves, for the first time, standardization, video recording capability, and operator independence in the treatment of fecal impaction.
- This study provides the first randomized controlled evidence supporting a device-based intervention for fecal impaction.

Introduction

Fecal impaction is a severe and often underestimated complication of chronic constipation, particularly outlet obstructive constipation (OOC). The persistent impaction of hard, dry fecalomas in the rectal ampulla can lead to mucosal ischemia, stercoral ulceration, perforation, and even life-threatening peritonitis, with mortality rates in severe cases reported to be as high as 32%-57% [1, 2]. A recent multicenter retrospective cohort study further demonstrated that fecal impaction-related complications (including bowel obstruction, perforation, and ischemic bowel disease) are significantly associated with increased overall mortality, and delayed intervention is an independent risk factor for poor prognosis [3]. Despite this, its clinical severity remains systematically underestimated in routine practice [4]. Advanced refractory cases often require emergency surgical intervention, including bowel resection, Hartmann's procedure, or even permanent colostomy, causing immense suffering to patients and leading to repeated emergency admissions, prolonged hospital stays, and excessive consumption of medical resources [5, 6].

Current guidelines from the American College of Gastroenterology (ACG) and the World Gastroenterology Organisation (WGO) explicitly state that oral laxatives and enema regimens are largely ineffective against formed, dense, and hard fecalomas [7, 8]. The 2021 ACG Clinical Guideline on Constipation Management further confirms that the management of acute fecal impaction should prioritize the relief of mechanical obstruction, and manual disimpaction is currently the only recommended definitive intervention, though the level of evidence is limited, and no explicit recommendations are made for device-assisted interventions [9]. Similarly, the 2023 American Gastroenterological Association (AGA) technical review systematically evaluated existing intervention evidence for fecal impaction, noting that the quality of evidence for manual disimpaction, enemas, and secretagogues is generally low and lacks standardized operational procedures; novel device-assisted

tools have only been seen in case reports or small-sample studies, which are insufficient to form recommendations [10].

Therefore, manual disimpaction remains the currently recommended first-line definitive therapy. However, this traditional method has clear inherent limitations: severe procedure-related pain, high dependence on operator experience, and a significant risk of iatrogenic anorectal mucosal tearing and bleeding [11]. In addition, manual manipulation can induce vagally mediated bradycardia and hypotension, and there have even been reports of postoperative cardiac arrest and death [12]. A recent clinical study specifically focusing on vasovagal reflexes during manual disimpaction showed that such events are not rare, and their incidence is higher in elderly, male patients and those with larger fecalomas, further reinforcing the need to develop alternative interventions [13]. The failure of conservative treatment and manual intervention further increases the risk of emergency surgical salvage and leads to adverse long-term clinical outcomes, exacerbating the individual disease burden on patients and societal medical expenditures [5, 14].

Complicating matters further, the efficacy and safety of manual disimpaction vary significantly among patients with different body types. For patients with a low body mass index or a narrow pelvis, the space for digital manipulation is limited, making them prone to tissue shear injuries caused by blind force; for obese patients or those with deeply impacted fecalomas, the operator's finger length may be insufficient to reach the core of the fecaloma, resulting in incomplete fragmentation or repeated operations. These anatomical individual differences further amplify the operator-dependence and unpredictability of manual disimpaction, highlighting the urgency of developing a standardized alternative that is unaffected by anatomical variations.

The aforementioned clinical realities underscore the urgent need to develop a standardized, safer alternative with lower operator dependence. Against this background, device-assisted intervention has emerged as a potential solution. A recent multicenter prospective study by Lee et al. evaluated a novel device-assisted defecation device for fecal impaction, reporting a high complete clearance rate, lower pain scores, and good safety [15]. However, the study used a single-arm design and lacked a head-to-head comparison with standard manual disimpaction; thus, the relative efficacy and safety of the device-assisted method remain unclear.

To fill this evidence gap, we developed the Digital Assisted Defecation Device (DDAD)-a sterile, single-use instrument featuring a blunt spherical tip to distribute stress, a curved groove for controlled fragmentation and extraction of fecal masses, and an ergonomic handle for precise operation. The device utilizes a fixed geometric design, using the sacrococcygeal curvature as an anatomical reference to standardize insertion depth, ensuring consistent performance across different patient anatomies and operator skill levels (Chinese patent publication numbers: CN 214484573U, CN 118453034A, and CN 3091903615)(Fig. 1). Furthermore, all DDAD procedures can be video-recorded for objective quality auditing and training—a function entirely unavailable with manual disimpaction.

Based on the preliminary evidence from Lee et al. and addressing the limitations of previous studies, we designed this prospective, randomized, non-inferiority trial to test the following hypothesis: in the treatment of refractory fecal impaction associated with OOC, DDAD is non-inferior to manual disimpaction in the complete clearance rate after a single procedure, and superior in safety and patient tolerability as secondary objectives. This study provides the first randomized controlled evidence directly comparing a standardized device intervention with the standard therapy recommended by current guidelines, with the potential to redefine the clinical management paradigm for this severe condition.

Methods

Study Design

This single-center, open-label, parallel-group non-inferiority randomized controlled trial strictly followed the CONSORT 2010 reporting guideline [16]. The study protocol was approved by the Institutional Review Board of Taiyuan Central Hospital (Approval No.: 2024038-1) and prospectively registered (Registration No.: MR-14-26-025307). The trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice. All enrolled subjects signed written informed consent forms prior to the initiation of any study-related procedures. An independent Data Safety Monitoring Board reviewed safety data after every 30 subjects were enrolled. All DDAD procedures were digitally video-recorded for post-procedure quality auditing, without interfering with clinical management.

Study Population

Consecutive adult patients (≥ 18 years) diagnosed with outlet obstructive constipation and presenting with refractory fecal impaction were screened. OOC was diagnosed based on the Rome IV criteria [17], supplemented by anorectal manometry and defecography when necessary. Refractory fecal impaction was defined as the presence of a hard fecal mass confirmed by digital rectal examination and/or pelvic CT, which had failed treatment after ≥ 3 days of oral osmotic laxatives and ≥ 2 enema attempts. Major exclusion criteria included: acute anorectal trauma/fistula; active massive rectal bleeding; colorectal malignancy; severe inflammatory bowel disease; rectal/anal stricture; acute abdomen/peritonitis; pregnancy or lactation; allergy to device materials; and inability to complete the scheduled follow-up assessments.

Randomization and Blinding

A computer-generated random sequence (variable block sizes of 4, 6, and 8) was used for 1:1 parallel-group allocation. Allocation concealment was achieved through sequentially numbered, sealed, opaque envelopes prepared by an independent coordinator. Due to the distinctly different operational characteristics of the device-assisted and manual interventions, it was impossible to fully blind the operators and subjects. However, all outcome assessors, data analysts, and Data Safety Monitoring

Board members remained strictly blinded to group assignments throughout the study. An independent blinded committee adjudicated the primary endpoint and adverse events.

Interventions

DDAD Group—After perianal preparation and adequate lubrication, the sterile DDAD was inserted gently with the spherical-groove end facing the sacrococcygeal region, conforming to the physiological curvature of the anal canal and rectum. Multi-directional (up-and-down, left-and-right) maneuvers were performed within the rectal cavity to pry and loosen the impacted fecal mass; once the fecal mass was caught in the curved groove, it was pulled outward for extraction. The insertion-loosening-extraction cycle was repeated until approximately 80%–90% of the fecal burden was cleared, and the residual feces were subsequently expelled by the patient's own rectal peristalsis without the need for further device intervention (Fig. 2). If necessary, a second insertion procedure was allowed (recorded as a protocol deviation). In case of procedure failure, manual disimpaction was permitted as a rescue measure and defined as treatment failure in the primary endpoint analysis. All procedures were systematically video-recorded.

Manual Disimpaction Group—Traditional digital rectal manual disimpaction was performed by a senior attending colorectal surgeon (> 5 years of experience) in accordance with ACG/WGO guidelines. After adequate lubrication, the operator manually fragmented and extracted the impacted fecal mass with their fingers until complete clearance of the rectal fecal mass was confirmed by digital examination and visual inspection. If complete clearance was not achieved within 30 minutes, a second senior physician assisted; persistent failure was recorded as treatment failure, and the rescue measure was documented.

Post-procedure management protocols for both groups (including the use of laxatives, analgesics, nursing care, and follow-up) were standardized to eliminate potential confounding variables.

Outcome Measures

Primary Endpoint: Defined as the complete clearance rate of fecal impaction after a single procedure, confirmed by a blinded assessor immediately after the procedure via digital rectal examination showing no residual hard fecal masses. The pre-specified non-inferiority margin was – 12%, determined based on previous literature and expert consensus [18]. **Secondary Endpoints:** (1) Procedure pain, assessed using the 10 cm Visual Analog Scale (VAS); (2) Total procedure duration (minutes); (3) Immediate adverse events (mucosal injury, vasovagal events, device-related discomfort); (4) Delayed safety outcomes assessed at 24 hours, 1 week, and 1 month post-procedure; (5) Recurrence rate at 1 month. Adverse events were graded using the Clavien-Dindo classification [19].

Sample Size Calculation

The sample size calculation was based on the following assumptions: the complete clearance rate for the manual disimpaction control group was approximately 88%, the non-inferiority margin was – 12%, two-sided $\alpha = 0.05$, and a power of 80%. Considering an expected 10% attrition rate, a total of 108 subjects were enrolled (54 per group).

Statistical Analysis

The primary analysis was based on the intention-to-treat (ITT) population. The risk difference and its 95% confidence interval (CI) were calculated using the Newcombe-Wilson method. Non-inferiority was statistically confirmed when the lower limit of the 95% CI exceeded the pre-specified – 12% margin. A per-protocol (PP) analysis and sensitivity analyses (including as-treated analysis and multiple imputation) were also conducted to verify the robustness of the results. Categorical variables were expressed as frequencies and percentages, and comparisons between groups were performed using the Chi-square test or Fisher's exact test; continuous variables were compared using the independent samples t-test or Mann-Whitney U test depending on data distribution. All tests were two-sided, and $P < 0.05$ was considered statistically significant. All statistical analyses were performed using SPSS 26.0 and R 4.1.0 statistical software.

Results

Subject Flow

Between September 2024 and November 2025, a total of 137 patients were initially screened, of which 29 were excluded prior to randomization (21 did not meet inclusion criteria, 8 declined to participate). The remaining 108 eligible subjects were randomly assigned to the DDAD group ($n = 54$) or the traditional manual disimpaction group ($n = 54$). All subjects completed the 1-month follow-up (100% follow-up rate). One protocol deviation occurred in each group; therefore, the PP analysis included 53 subjects per group (Fig. 3). Baseline demographic, clinical, and disease severity characteristics were balanced and comparable between the two groups (Table 1).

Table 1
Baseline Characteristics (ITT Population)

Variables	Categorical	Control Group(n = 54)	DDAD Group(n = 54)	P value
Age(mean ± SD,years)		61.7 ± 12.4	63.1 ± 11.8	0.548
BMI(mean ± SD,kg/m ²)		24.5 ± 3.2	24.1 ± 3.4	0.529
Gender ,N(%)	Male	25(52.7%)	24(44.4%)	0.847
	Female	29(53.7)	30(55.6)	
Duration of constipation[M(P ₂₅ , P ₇₅),years]		7(4, 11)	8(5, 12)	0.412
Diameter of fecal calculus[M(P ₂₅ , P ₇₅),cm]*		4.7(3.8–5.7)	4.9(4.0–5.9)	0.378
Accept the manual disimpaction history ,N(%)		24(44.4)	22(40.7)	0.694
Hospitalization history ,N(%)		13(24.1)	15(27.8)	0.656
Wexner scores[M(P ₂₅ , P ₇₅)] [†]		15(12, 18)	16(13, 19)	0.234
PAC-QOL scores(mean ± SD) [‡]		2.7 ± 0.7	2.8 ± 0.6	0.423

Note: *Maximum axial diameter on pelvic CT.†Wexner score ranges from 0–30; higher scores indicate more severe constipation.‡PAC-QOL score ranges from 0–4; higher scores indicate worse quality of life.

Primary Outcome

ITT analysis showed that 48 of 54 (88.9%) in the DDAD group achieved complete clearance after a single procedure, compared to 47 of 54 (87.0%) in the control group. The absolute risk difference between the two groups was 1.85% (95% CI: 9.17% to 12.87%). The lower limit of the 95% CI (– 9.17%) was well above the pre-specified non-inferiority margin of – 12%, verifying the non-inferiority of DDAD. PP analysis yielded consistent and robust results (90.6% vs. 88.7%; risk difference 1.89%; 95% CI: 8.95% to 12.73%). Sensitivity analyses supported the reliability of the primary conclusions (Fig. 4).

Secondary Outcomes

Procedure-related pain was significantly reduced in the DDAD group (median VAS: 3 [IQR 2–4] vs. 6 [IQR 5–7]; $P < 0.001$), and procedure duration was significantly shorter (30 [IQR 25–35] vs. 42 [IQR 36–50] minutes; $P < 0.001$). The incidence of adverse events was significantly lower in the DDAD group (13.0% vs. 29.6%; $P = 0.032$). The incidence of mucosal injury was 20.4% in the manual group and 0% in the

DDAD group ($P < 0.001$). No grade 3 or 4 severe adverse events occurred in either group. The 1-month recurrence rate was similar between the two groups (7.4% vs. 9.3%; $P = 0.727$) (Table 2).

Table 2
Primary and Secondary Outcomes (ITT Population)

Outcome Indicator	DDAD Group(n = 54)	Control Group(n = 54)	Effect Estimate 95%CI)	Pvalue
Complete clearance ,N(%)	48(88.9)	47(87.0)	1.85(-9.17-12.87) [†]	—
VAS Pain scores[M(P ₂₅ ,P ₇₅)]	3(2, 4)	6(5, 7)	—	< 0.001
Operation duration[M(P ₂₅ ,P ₇₅),min]	30(25, 35)	42(36, 50)	—	< 0.001
Any adverse events ,N(%)	7(13.0)	16(29.6)	—	0.032
Mucosal injury ,N(%)	0(0)	11(20.4)	—	< 0.001
Vasovagal events ,N(%)	0(0)	2(3.7)	—	0.495
Recurrence within 1 month ,N(%)	4(7.4)	5(9.3)	—	0.727
Note: † Non-inferiority confirmed: The lower limit of the 95% CI (– 9.17%) is higher than the pre-specified – 12% non-inferiority margin.				

Subgroup and Sensitivity Analyses

Pre-specified subgroup analyses (age, sex, fecaloma size, operator experience) consistently showed non-inferiority, with no significant interactions observed. The pain reduction benefit of DDAD was more pronounced in patients with larger fecalomas. All sensitivity analyses supported the primary conclusions (Tables 3, 4).

Table 3
Sensitivity Analysis of the Primary Endpoint

Analytic set	DDAD Group	Control Group	Risk differential 95%CI	Non-inferiority establish
ITT	48/54(88.9%)	47/54(87.0%)	1.85(-9.17-12.87)	Yes
PP	48/53(90.6%)	47/53(88.7%)	1.89(-8.95-12.73)	Yes
According to the actual treatment [*]	48/53(90.6%)	47/55(85.5%)	5.12(-5.21-15.45)	Yes
Multiple difference interpolation [†]	48/54(88.9%)	47/54(87.0%)	1.85(-9.17-12.87)	Yes

Note: *One patient crossed over from the DDAD group to the manual group.† Because the follow-up rate was 100%,

the results are consistent with ITT.

Table 4
Procedure-Related Adverse Events (ITT Population)

Adverse events ,N(%)	DDAD Group(n = 54)	Control Group(n = 54)	P value
Any adverse events	7(13.0)	16(29.6)	0.032
Clavien-Dindo grade			
Level one	6(11.1)	9(16.7)	0.401
Level two	1(1.9)	5(9.3)	0.095
Level three	0(0)	2(3.7)	0.495
Level four	0(0)	0(0)	—
Level five	0(0)	0(0)	—
Mucosal injury	0(0)	11(20.4)	< 0.001
Vasovagal events	0(0)	2(3.7)	0.495
Pain worsened after the procedure	3(5.6)	8(14.8)	0.117
Fever after the procedure	1(1.9)	2(3.7)	1.000
Urinary retention	1(1.9)	3(5.6)	0.618
Delayed adverse events within 1 month	0(0)	2(3.7)	0.495
Note: Bold P values indicate statistically significant differences (P < 0.05).			

Discussion

This prospective randomized non-inferiority trial confirmed that in patients with refractory fecal impaction secondary to OOC, the single-procedure complete clearance rate of DDAD was non-inferior to standard manual disimpaction (88.9% vs. 87.0%; risk difference 1.85%, 95% CI, 9.17% to 12.87%), and demonstrated superiority across all secondary endpoints: zero mucosal tears (vs. 20.4%), a 50% reduction in median VAS pain (3 vs. 6), a 12-minute reduction in procedure time (30minutes vs. 42 minutes), and a 16.6% absolute risk reduction in overall adverse events. This is the first time that randomized controlled evidence has introduced a standardized instrument-based procedure into this field, which has long lacked high-quality research.

The safety advantages of DDAD can be rationally explained by its biomechanical design. The essence of manual disimpaction is the blind mechanical fragmentation of dense fecalomas by fingers; the shear

forces generated during this process are the direct cause of mucosal injury [11, 12]. Such injuries do not always heal spontaneously and may progress to bleeding, local infection, or progressive deterioration of anorectal pathology. The trend of vasovagal events in the manual group is consistent with a recent report by Kim et al.—vagal-mediated bradycardia and hypotension are not uncommon during manual disimpaction, especially among the elderly and those with a larger fecaloma burden [13]. No such events were observed throughout the DDAD group, mechanistically attributed to the gradual and controllable nature of instrument fragmentation, which completely avoids excessive stimulation of the autonomic reflexes of the pelvic floor caused by sudden dilation and traction. Three core design features—the blunt spherical tip for stress dispersion, the curved groove for controlled extraction, and the standardized insertion path using the sacrococcygeal curvature as an anatomical reference—collectively form the engineering foundation for the aforementioned safety advantages. The 50% reduction in VAS is of particular clinical translational value: procedure-related pain has been identified as a major behavioral barrier to patients delaying medical consultation [4, 5]. By significantly alleviating the pain experience, DDAD may indirectly reduce the incidence of fatal complications such as stercoral perforation caused by delayed presentation [1, 2].

Our results are consistent with and expand upon those of a multicenter prospective study conducted by Lee et al. on a similar device-assisted bowel evacuation device. That study reported high efficacy and good tolerability but was limited by its single-arm design [15]. By providing a randomized head-to-head comparison with the current standard of care, this study provides the highest level of evidence to date supporting a device-based alternative for the treatment of fecal impaction. Furthermore, the integration of standardized procedural protocols and integrated video recording functionality within the Digital Defecation Assistance Device (DDAD) enables, for the first time, objective assessment of technical performance, delivery of structured competency-based feedback, and establishment of formal qualification certification pathways.

In terms of procedural efficiency, the 28.6% relative reduction in median time (30 vs. 42 minutes) has direct implications for improving resource utilization and patient flow in emergency and inpatient settings. Even more profound is the paradigm shift represented by DDAD—its fixed geometric design, clear insertion technique, and repeatable procedural steps provide this procedure with the institutional conditions for standardized training and quality monitoring for the first time, whereas manual disimpaction relies entirely on the operator's subjective tactile feedback, with massive variability between operators and no possibility for objective review. Therefore, the introduction of DDAD is not merely a tool upgrade, but a systematic reconstruction of training systems, quality assurance, and accountability mechanisms. Compared with traditional enemas and manual disimpaction, DDAD fills a clear clinical gap between conservative treatment and emergency surgery—it provides a minimally invasive, bedside-available, sedation-free, single-use intervention that circumvents the ineffectiveness of enemas for hard fecalomas while avoiding the high trauma associated with manual disimpaction.

Our findings should be interpreted cautiously within the framework of the following limitations. First, the single-center design limits external validity and requires multicenter validation. Second, the open-label

design carries an inherent risk of bias, but this was minimized through blinded adjudication and independent monitoring. Third, the study population was limited to OOC-related etiologies, and its applicability to other etiologies (neurogenic bowel, opioid-induced constipation, postoperative ileus) remains unknown. Fourth, the 1-month follow-up is insufficient to assess long-term outcomes such as anorectal function or stricture formation. Fifth, the sample size is insufficient for meaningful between-group comparisons of rare events. Sixth, although based on our training experience, the learning curve for DDAD appears to be much shorter than that for manual disimpaction, this was not formally evaluated; future implementation studies should incorporate structured training and competency assessments. Seventh, although DDAD was designed with anatomical adaptability in mind (e.g., standardized insertion depth referenced to the sacrococcygeal curvature), its performance in patients with extreme pelvic anatomical variations (such as severe spinal kyphosis or a history of prior pelvic surgery) still requires further investigation.

Declarations

Conflict of Interest Statement: Jianhua Zhang is the inventor and patent holder of the Digital Assisted Defecation Device (DDAD). He was only involved in study design and device development, and did not participate in patient enrollment, outcome assessment, data analysis, or manuscript writing. All other authors declare no competing interests.

Funding Sources: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Author Contributions: Study concept and design: Jianhua Zhang, Mingzheng Zhang. Data acquisition: Qiang Guo, Lei Tang, Zhaojing Yuan, Jianguo Hao, Guofu Zuo, Peng Li, Ping Yan, Jing Cai. Data analysis and interpretation: Qiang Guo, Mingzheng Zhang. Drafting of the manuscript: Mingzheng Zhang. Critical revision: Jianhua Zhang. Statistical analysis: Qiang Guo. Study supervision: Jianhua Zhang.

Data Sharing Statement: De-identified individual participant data and analysis code can be obtained from the corresponding author upon reasonable request, subject to approval by the Institutional Review Board and the signing of a data sharing agreement.

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Figures



Figure 1
Schematic Diagram of the DDAD

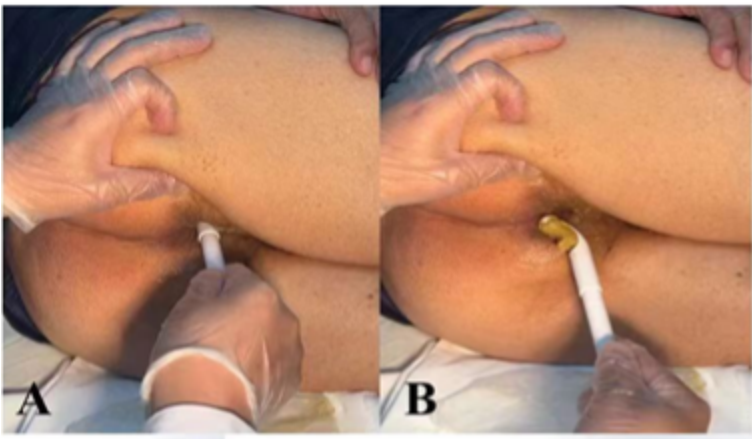


Figure 2
Efficacy of Disposable Defecation Aid for Fecal Impaction Secondary to Outlet Obstructive Constipation

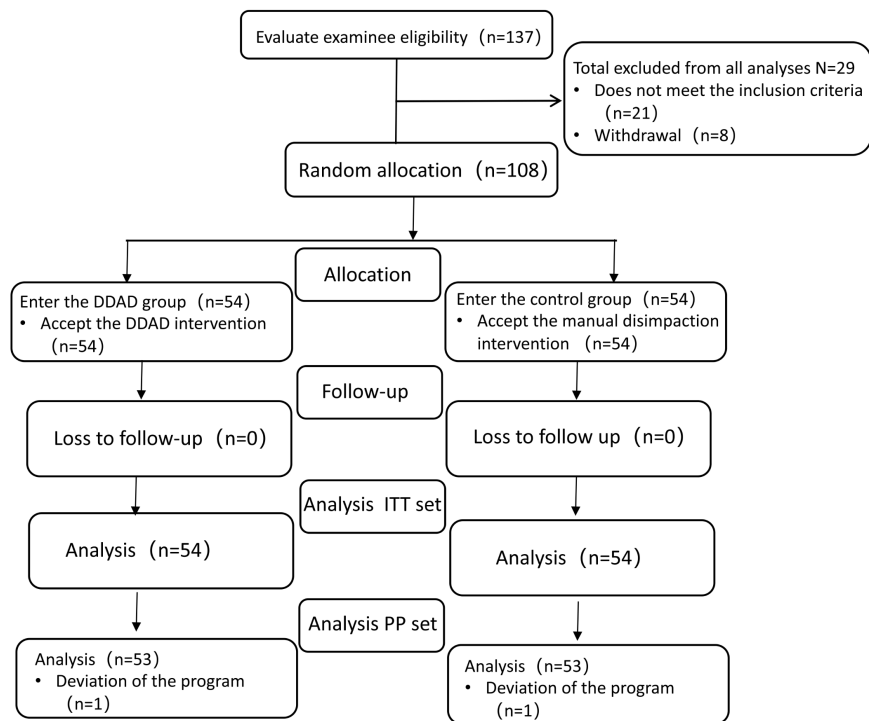


Figure 3
Subject Flow Diagram

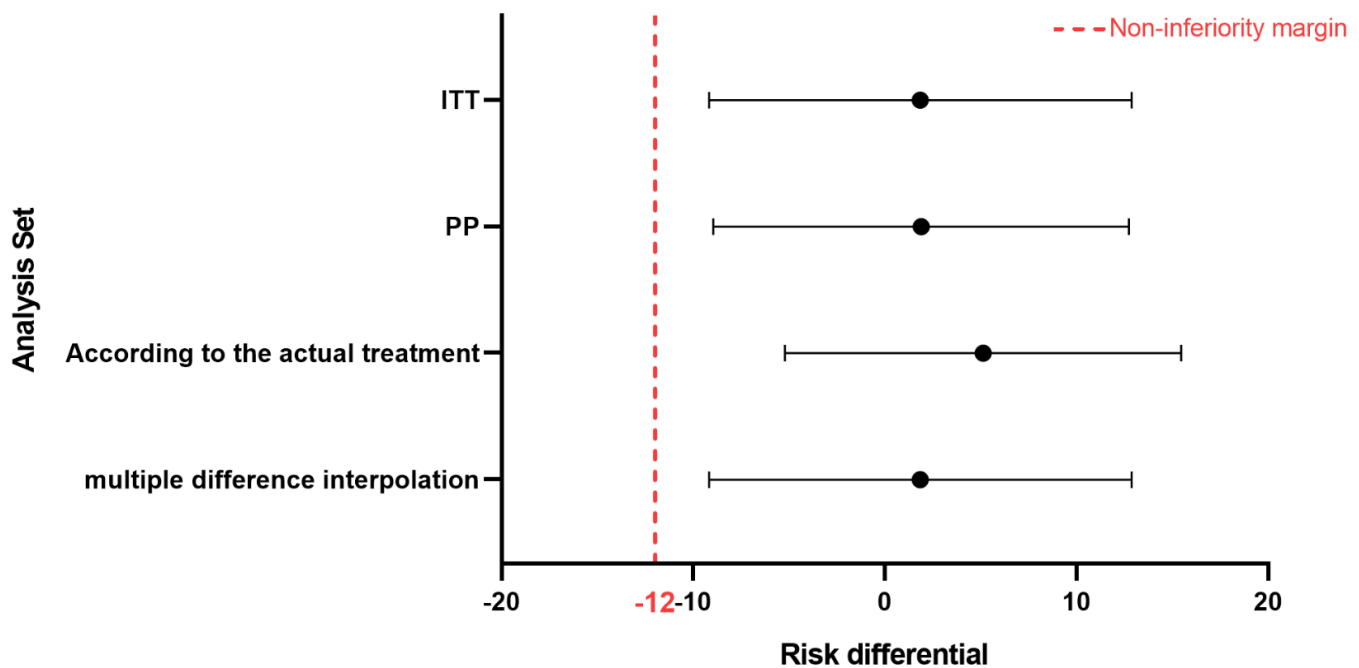


Figure 4

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [trialprotocol.docx](#)