BOWEL PREPARATION

BEFORE VAGINAL PROLAPSE SURGERY

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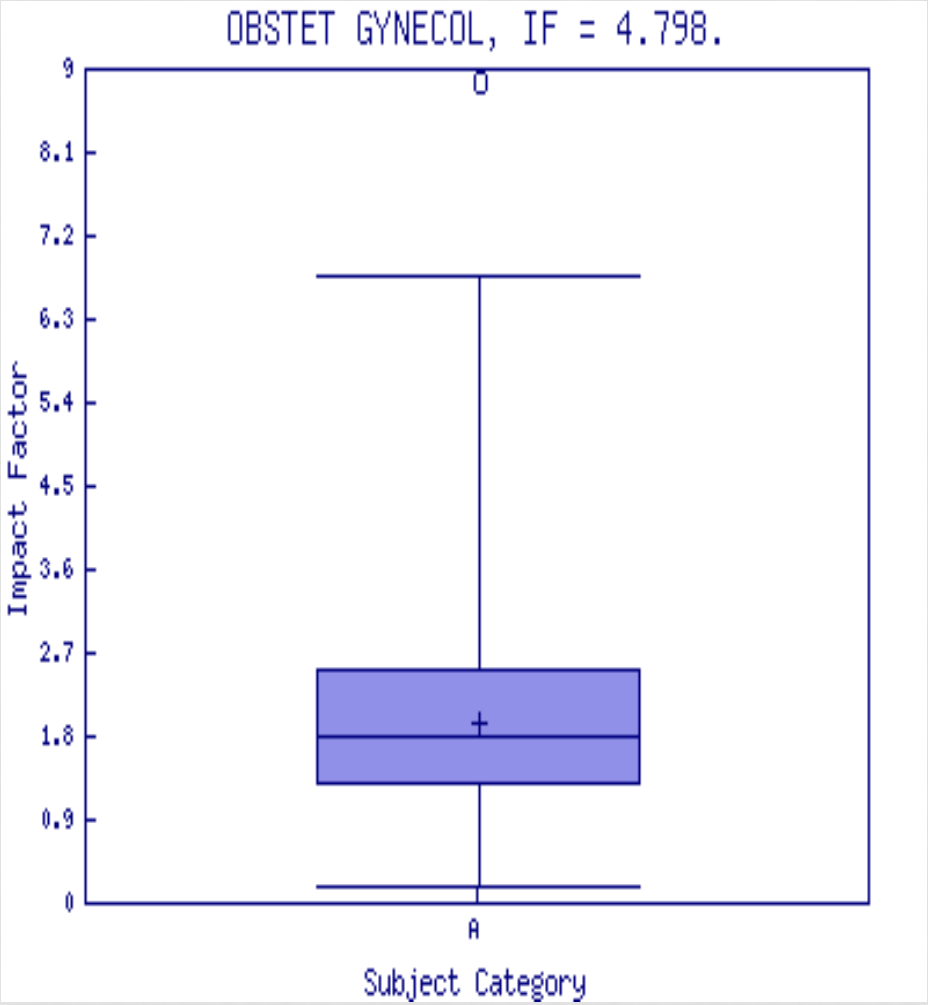
GYNECOLOGY & OBSTETRICS



Category Name	Total Journals in Category	Journal Rank in Category	Quartile in Category
OBSTETRICS & GYNECOLOGY	78	2	Q1

VAGINAL PROLAPSE

- **陰道脫垂**是指陰道壁的組織或骨盆腔的支持性韌帶及膈膜，因為鬆弛而無法維持本來緊密的結構。
- 骨盆腔支持陰道壁的主要組織有骨盆腔膈膜、泌尿生殖膈膜、以及其他支持性的韌帶。陰道壁的頂端由於緊連著子宮頸部位，**因此陰道脫垂往往同時伴有子宮下垂或子宮脫垂**。
- 造成陰道壁脫垂的原因大致有**先天性構造鬆弛**、**經陰道生產**或因**手術或外力等造成的傷害**、及**長期慢性腹部高壓**造成的脫垂，如長期提重物或慢性咳嗽等。
- 症狀包括：下墜感、長期便秘、裏急後重、下腹及骨盆腔疼痛、尿失禁或頻尿、陰道壁突出陰道口外等。
- 大部分的陰道壁脫垂多不是單一發生，有時合併好幾種脫垂一起存在。

步驟 1：研究探討的問題為何？

研究族群/問題 (Population/ Problem)	The women older to undergo reconstructive vaginal prolapse surgery
介入措施(Intervention)	• intake of a clear liquid diet; • self-administration of two separate saline enemas at 4:00 PM and at 6:00 PM, • nothing by mouth after midnight on the day of surgery.
比較(Comparison)	/
結果(Outcome)	**Primary outcomes** • intraoperative stooling, • adequacy of visualization, • difficulty with bowel handling were also evaluated. • Perioperative parameters collected included : operative time, estimated blood loss, use of preoperative antibiotics, surgical complications. type(s) of surgical procedures performed. **Secondary outcomes** • patient's overall satisfaction

步驟 2：研究的品質有多好？(內在效度)

招募(Recruitment) - 受試者是否具有代表性？(p.233)

最好的狀況是？
我們是否知道病人族群為何(收案場所、納入 / 排除 條件)？在理想情況下，納入本研究之受試者應具有連續性(有時為隨機取樣)，了解符合收案條件的對象且簽署同意書。

- This was a single-blind, randomized trial conducted in women presenting to the Urogynecology Care Clinic at the University of Alabama at Birmingham between January 2011 and August 2012.
- Eligible participants were women older than 19 years of age scheduled to undergo reconstructive vaginal prolapse surgery to include an apical suspension with posterior compartment repair.
- Women were excluded if they had a history of a total colectomy, a diagnosis of inflammatory bowel disease, colorectal cancer receiving treatment, or chronic constipation.
- Written informed consent was obtained from all participants in accordance with a research protocol approved by the University of Alabama at Birmingham Institutional Review Board for Human Use.

評讀結果：■是　□否　□不清楚

步驟 2：研究的品質有多好？(內在效度)

分派(Allocation) - 分派方式是否隨機且具隱匿性…？ (p.234)

最好的狀況是？
最理想的方式是以中央電腦進行隨機分配，此方式常用於多中心試驗，而較小型的試驗可由獨立人員(如：醫院藥師)「監督」隨機分配的過程。
在

- Block randomization was applied using blocks of 10. The allocation sequence was computer-generated and concealed in sequentially numbered, opaque, sealed, and stapled envelopes.
  *Participants assigned to the intervention were no blinded.
  *Surgeons assessing the primary outcome and data analyst were blinded to the allocation.
- Each participant was provided with the assigned preparation regimen by research staff.

評讀結果：■是　□否　□不清楚

步驟 2：研究的品質有多好？(內在效度)

...每個組別，在研究開始時的情況是否相同？ (p.234-235)

最好的狀況是？
若隨機分配順利，各組研究對象的條件應是相近、可互相比較的。每組研究對象的基本條件越相近越好。應有指標可確認各組研究對象之間的差異是否達到統計上顯著的差異(如 p 值)。

- Demographic, clinical, and intraoperative characteristics were similar between the two groups (Table 1).
- Ninety-nine percent of the intervention group and 100% of the participants in the control group received concomitant vaginal apical suspension (P>.05).
- Concurrent posterior colporrhaphy was performed in 96% and 97% of intervention and control groups, respectively (P=.68).
- There were no significant differences among concomitant hysterectomy, conversion to laparotomy, estimated blood loss, or operative time between groups (P>.05).

Table 1. Participant Demographic, Procedural, and Intraoperative Data

Characteristic	Mechanical Bowel Preparation (n=75)	Control (n=75)	Missing	*P*
Age (y)			10	
Mean±SD	62±10	60±10		.24
Range	25–78	39–78		
Parity	2 (2–3)	2 (2–3)	15	.71
Previous hysterectomy, yes ❸	47 (63)	50 (67)		.61
Prior prolapse surgery, yes	24 (32)	18 (24)		.28
Prior placement of transvaginal mesh, yes	4 (5)	1 (1)		.37
Vaginal surgery, yes	71 (99) ❶	73 (100)	5	.50
Conversion to laparotomy, yes ❸	1 (1)	4 (5)	6	.37
Concurrent hysterectomy, yes	24 (33)	24 (33)	5	.95
Classify hysterectomy subtypes				
Vaginal	24 (100)	22 (92)		.49
Laparoscopic-assisted	0 (0.0)	2 (8)		
Other	0 (0)	0 (0)		
Concurrent apical suspension			5*	
Uterosacral suspension	53 (76)	50 (68)		.61
Sacrospinous suspension	15 (21)	20 (27)		
Sacrocolpopexy	2 (3)	3 (4)		
Concurrent posterior repair, yes	69 (96) ❷	71 (97)	5	.68
Concurrent anterior repair, yes	55 (76)	54 (74)	5	.74
Concurrent enterocele repair, yes	25 (35)	25 (34)	6	.90
Concurrent placement of transvaginal mesh, yes	3 (4)	5 (7)	5	.72
Proctotomy or enterotomy	0 (0)	0 (0)	6	—
Surgical site infections, yes	0 (0)	0 (0)	5	—
Estimated blood loss (mL) ❸	100 (75–150)	100 (75–150)	12	.42
Operative time (min) ❸	110 (90–130)	115.5 (99–133)	9	.12

SD, standard deviation.
Data are median (interquartile range), n, or n (%) unless otherwise specified.
* Two did not receive apical.

評讀結果：■是　□否　□不清楚

步驟 2：研究的品質有多好？(內在效度)

維持(Maintenance) - 各組是否給予相同的治療？(P.233)

最好的狀況是？
各研究組別之間，除了對病人的介入之外，其餘的治療應完全相同(即為了執行本研究所增加的治療、檢驗或評估應相同)。

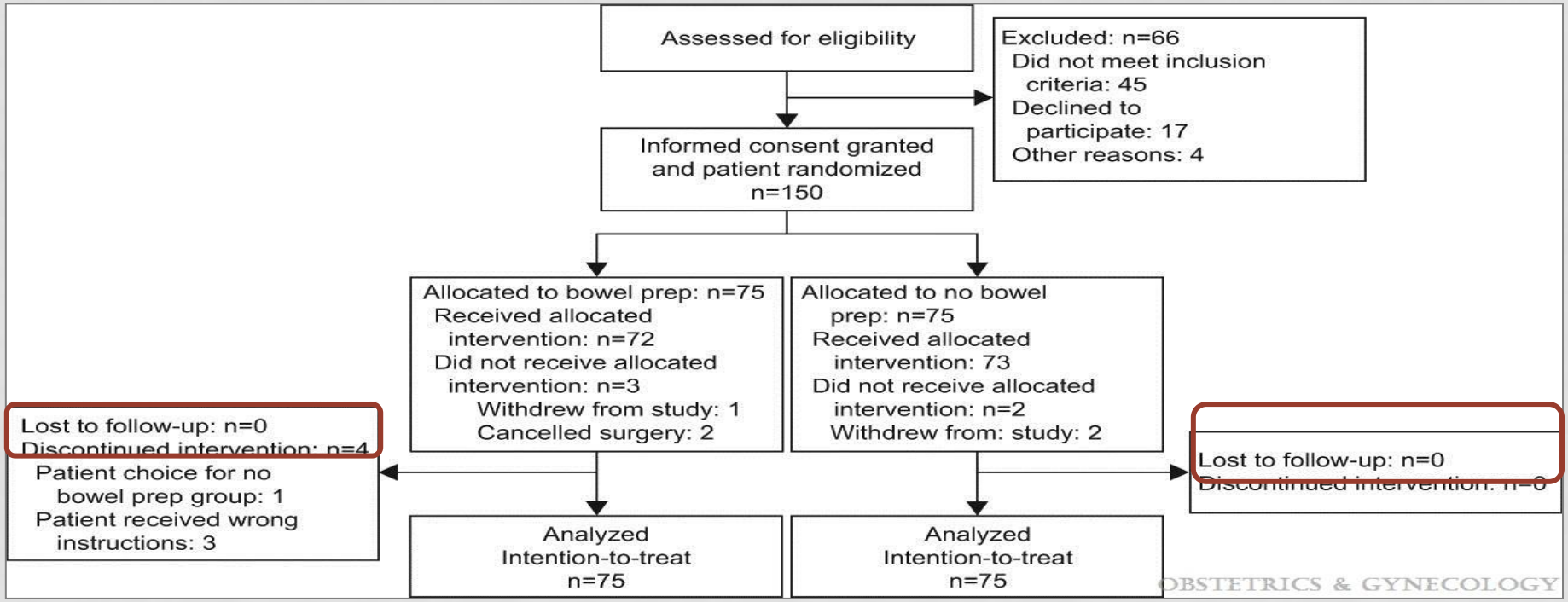
- Participants received preoperative counseling and were randomly assigned with a 1:1 ratio to receive mechanical bowel preparation (intervention group) or not (control group). On the day before surgery, verbal and written instructions to the intervention group included 1) intake of a clear liquid diet; 2) self-administration of two separate saline enemas at 4:00 PM and at 6:00 PM, along with 3) nothing by mouth after midnight on the day of surgery.
- Saline enemas were chosen as the intervention because they are the institutional standard for those surgeons who use a mechanical bowel preparation.

評讀結果：■是　□否　□不清楚

步驟 2：研究的品質有多好？(內在效度)

…是否有足夠的追蹤(Follow up)？ (P.234)

最好的狀況是？
研究中流失(無法繼續追蹤)的病人，最好少於 20%。 病人應依照隨機分配的組別進行統計分析(即「治療意向分析法」Intention – to-treat , ITT analysis)



評讀結果：■是　□否　□不清楚

步驟 2：研究的品質有多好？(內在效度)

評估(Measurement) - 受試者與評估者是否對治療方式及(或)評估目的維持盲法(blind)？ (p.234)

最好的狀況是？
在客觀結果(如：死亡)方面，盲法的重要性較低，但在主觀結果(如：症狀或功能)方面，評估者維持盲法非常重要。

- Participants assigned to the intervention were no blinded.
- Surgeons assessing the primary outcome and data analyst were blinded to the allocation.

評讀結果：□是　■否　□不清楚

步驟 3：研究結果的意義為何？

使用何種評估方式，療效有多大？ NNT (=1/ARR)

這個研究結果是否可能隨機(巧合)發生？
p值/ 信賴區間 (Confident Interval, CI)

Table 2. Surgeon Assessment of Surgical Field

Variable	Mechanical Bowel Preparation (n=75)	Control (n=75)	Missing	P
Overall assessment of surgical field			5	
❶ Excellent or good	61 (85)	66 (90)		.30
Fair or poor	11 (15)	7 (10)		
Set all missing to successes				
Excellent or good	64 (85)	68 (91)		.31
Fair or poor	11 (15)	7 (9)		
Set all missing to failures				
Excellent or good	61 (81)	66 (88)		.26
Fair or poor	14 (19)	9 (12)		
Evaluation of preparation			5	
Rectum empty	58 (81)	51 (70)		.14
❷-1 Gas	1 (1)	0 (0)		.50
Fluid	3 (4)	2 (3)		.68
❷-2 Particulate formed stool	9 (13)	17 (23)		.09
Large solid stool	1 (1)	3 (4)		.62
Adequate visualization			5	
Yes	71 (99)	73 (100)		.50
No	1 (1)	0 (0)		
Stooling on the field			5	
Yes	10 (14)	5 (7)		.16
No	62 (86)	68 (93)		
Difficulty handling bowel ❸			6	
Yes	2 (3)	0 (0)		.50
No	70 (97)	72 (100)		

Data are n (%) or n unless otherwise specified.

- No differences existed in the surgeon's intraoperative acceptability of the bowel preparation regarding bowel contents as it related to the surgical field, rated as "excellent or good," in 85% (61/72) of the intervention group compared with 90% (66/73) in the control group (OR 0.59, 95% CI 0.21–1.61; P=.30).
- Surgeons' intraoperative assessment of the rectal vault revealed that there were no differences in the presence of gas or stool between the intervention and the control groups.
- Adequate visualization was similar between groups and there were no differences in intraoperative stooling or difficulty of bowel handling between groups, all P>.05.

步驟 3：研究結果的意義為何？

Table 3. Patient Experience Outcomes

	Mechanical Bowel Preparation (n=75)	Control (n=75)	Missing	*P*
Patient satisfaction (Patient Satisfaction Questionnaire)			9	
Completely	46 (66)	67 (94)		<.001
Somewhat	20 (29)	3 (4)		
Not at all	4 (6)	1 (1)		
Willing to have the same preparation in future			7	
Yes	63 (90)	71 (97)		.09
No	7 (10)	2 (3)		
Willing to try another one			7	
Yes	59 (84)	47 (64)		.007
No	11 (16)	26 (36)		
Patient symptoms, self-reported, 5-point visual analog scale (0–4)				
❸ Trouble taking enema	0.84±1.11	0.10±0.41	7	<.001
Abdominal fullness or bloating	0.81±1.08	0.31±0.77	9	.004
Sleep loss	0.81±1.28	0.32±0.68	8	.023
Fatigue	0.73±1.18	0.29±0.74	7	.007
❷ Abdominal cramps or pain	0.99±1.35	0.35±0.91	8	<.001
Nausea	0.19±0.60	0.06±0.23	8	.09
Vomiting	0.10±0.51	0.04±0.26	7	.39
❹ Anal irritation	0.74±1.02	0.25±0.76	8	<.001
Weakness or faint feeling	0.30±0.75	0.11±0.46	7	.07
Chest pains	0.10±0.52	0.01±0.12	10	.17
❶ Hunger pains	1.09±1.13	0.27±0.73	8	<.001
Chills	0.18±0.49	0.03±0.16	9	.02
Ease of completion	1.10±1.18	0.12±0.55	7	<.001

(OR 0.11, 95% CI 0.04–0.35; P<.001)

Data are n, n (%), or mean±standard deviation unless otherwise specified.

評讀結果：■是 □否 □不清楚

結論

- 使用清水或生理食鹽水灌腸做腸道準備，並沒有顯著改善腸內容物的存在
- 根據Wiebracht等(2011)研究顯示，接受陰道手術的婦女，是否接受腸道準備(Enema)沒有差異
- 陰道脫垂手術前的腸道準備，會降低滿意度和增加不適的腸道症狀
- 強烈建議在婦女進行陰道脫垂重建手術前，不需常規進行腸道準備

臨床現況

	TVT/TVT-O	骨盆重建術
手術前 腸道準備方式	• 午夜禁食 • S-S enema 手術當天早上	• 刻見清 2包+2000ml水 (手術前一天晚上) • 午夜禁食 • S-S enema手術當天 早上

討論

- 接受陰道脫垂手術的婦女，手術前是否不需常規執行腸道準備？

■同意：4人

■懷疑：18人

■不同意：0人


謝謝您的聆聽