별첨 1 비뚤림위험 평가

1. 비뚤림위험 평가

1) 무작위배정 비교임상시험

RoB

연번(Ref ID)		1
1저자(출판연도)		Shao (2019)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	☐ 낮음 ☐ 높음 ■ 불확실	From January 2014 to January 2017, 93 patients were recruited into our randomized clinical trial and divided into two different groups in a randomized manner. ➜ 세부 내용 언급 없음
Allocation concealment (배정순서 은폐)	☐ 낮음 ☐ 높음 ■ 불확실	
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	☐ 낮음 ☐ 높음 ■ 불확실	언급 없음
Blinding of outcome assessment (결과평가에 대한 눈가림)	☐ 낮음 ☐ 높음 ■ 불확실	언급 없음
Incomplete outcome data addressed (불충분한 결과자료)	☐ 낮음 ☐ 높음 ■ 불확실	After 12 mo of follow-up, 30 patients' (30/34, 88.2%) final outcomes were judged as effective and 4(4/34, 11.8%) as moderate in group A, whereas in group B, 30 (30/37, 81.1%) patients' outcomes were judged as effective, 5 (5/37, 13.5%) as moderate, and 2 (2/37, 5.4%) as poor. ➜ 추적관찰에 따라 결측치가 발생하였고, 발생 원인은 언급 없음
Free of selective reporting (선택적 보고)	■ 낮음 ☐ 높음 ☐ 불확실	The complications of the operation (e.g., postoperative bleeding, anal fissure, rectal stricture, incontinence to flatus, persistent pain, etc.), the depth of the rectocele, and the ODS scores were recorded before and after operation. ➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음

ROB

연번(Ref ID)		2
1저자(출판연도)		Shi (2017)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	☐ 낮음 ☐ 높음 ■ 불확실	This study was a prospective, randomized, controlled clinical trial and the total number of patients enrolled in this study was 39. ➜ 세부 내용 언급 없음
Allocation concealment (배정순서 은폐)	☐ 낮음 ☐ 높음 ■ 불확실	The 39 patients were divided into 2 groups (TVMR group with 19 patients and STARR group with 20 patients). ➜ 세부 내용 언급 없음
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	☐ 낮음 ☐ 높음 ■ 불확실	언급 없음
Blinding of outcome assessment (결과평가에 대한 눈가림)	☐ 낮음 ☐ 높음 ■ 불확실	언급 없음
Incomplete outcome data addressed (불충분한 결과자료)	■ 낮음 ☐ 높음 ☐ 불확실	Long-term curative effect was assessed at 1 year after the surgery, at which time the TVMR group had 1 case of recurrent defecation dysfunction and a recurrence rate of 5.26%, whereas the STARR group had 6 cases and a recurrence rate of 30.00% (P<0.05). ➜ 결측치 없음
Free of selective reporting (선택적 보고)	■ 낮음 ☐ 높음 ☐ 불확실	(Statistical analysis) The pain at the 1st week and 3rd month after surgery was evaluated with numerical rating scale (NRS) (중략) ODS, effective rate ➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음

ROB

연번(Ref ID)		3
1저자(출판연도)		Gentile (2014)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	■ 낮음 □ 높음 □ 불확실	Patients enrolled for the study were divided into two groups by using a computer-generated list for randomization: the code enclosed in a numbered envelope corresponding to one of the two techniques was shown at the beginning of the operation to the surgeon.
Allocation concealment (배정순서 은폐)	■ 낮음 □ 높음 □ 불확실	
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	■ 낮음 □ 높음 □ 불확실	All data were recorded and collected by an independent observer not from the surgical team and the assessed outcome was not blinded.
Blinding of outcome assessment (결과평가에 대한 눈가림)	□ 낮음 ■ 높음 □ 불확실	
Incomplete outcome data addressed (불충분한 결과자료)	■ 낮음 □ 높음 □ 불확실	Tabel Ⅱ~Ⅳ ➜ 결측치 없음
Free of selective reporting (선택적 보고)	■ 낮음 □ 높음 □ 불확실	(Methods) Postoperative complication, Anything concerning operative time, postoperative pain, day of discharge and late complications was recorded. The time of recovery of work was also assessed. ➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음

ROB

연번(Ref ID)		4
1저자(출판연도)		Boccasanta (2007)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	■ 낮음 □ 높음 □ 불확실	Patients were randomly assigned to undergo SA or STARR using random permuted blocks with sizes varying from four to six and sequentially numbered. Sealed envelopes with a random number table were prepared.
Allocation concealment (배정순서 은폐)	■ 낮음 □ 높음 □ 불확실	
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	■ 낮음 □ 높음 □ 불확실	The assignment of the treatment was made by a nurse in the ward before the operation.
Blinding of outcome assessment (결과평가에 대한 눈가림)	□ 낮음 □ 높음 ■ 불확실	언급 없음
Incomplete outcome data addressed (불충분한 결과자료)	■ 낮음 □ 높음 □ 불확실	Table 1, 3(6개월) ➜ 결측치 없음
Free of selective reporting (선택적 보고)	■ 낮음 □ 높음 □ 불확실	Primary outcome measure was the incidence of failure, (중략); incidence of residual skin tags was also evaluated, even if it was not considered as a failure. Secondary outcome measures were: operative time, blood loss, hospital stay, postoperative pain by the Visual Analog Scale (VAS), time to return to normal activity, continence and constipation scores, overall patient satisfaction index, and defecographic data. ➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음

ROB

연번(Ref ID)		5
1저자(출판연도)		Boccasanta (2004)
영역	비뚤림위험	사유
Adequate sequence generation (무작위 배정순서 생성)	■ 낮음 □ 높음 □ 불확실	The patients were randomly assigned to undergo surgery with STAPL or STARR, using random permuted blocks with sizes varying from four to six; sealed envelopes sequentially numbered were produced.
Allocation concealment (배정순서 은폐)	■ 낮음 □ 높음 □ 불확실	
Blinding of participants and personnel (연구 참여자, 연구자에 대한 눈가림)	■ 낮음 □ 높음 □ 불확실	(Blinding procedures) The assignment of the treatment was made by a nurse in the ward before the operation. Another nurse in the operating theatre measured the duration of the operation. All patients were operated on by the same surgical team, using the following techniques without modifications
Blinding of outcome assessment (결과평가에 대한 눈가림)	□ 낮음 □ 높음 ■ 불확실	언급 없음
Incomplete outcome data addressed (불충분한 결과자료)	■ 낮음 □ 높음 □ 불확실	Fig 6: withdrawn, lost to FU 없음 ➜ 결측치 없음
Free of selective reporting (선택적 보고)	■ 낮음 □ 높음 □ 불확실	Primary study endpoints were to compare the two treatment groups relative to postoperative pain behavior (VAS score), anorectal manometry changes and symptoms resolution rate, according to the used Constipation Scoring and Continence Grading Systems. Secondary outcome measurements were operative time, intraoperative and postoperative complications, hospital stay, and time to return to work. ➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음

2) 비무작위 비교연구

RoBANS ver 2.0

연번(Ref ID)		6
1저자(출판연도)		Chen (2020)
영역	비뚤림위험	사유
대상군 비교 가능성	■ 낮음 □ 높음 □ 불확실	➜ Table 1 기초특성, 두 군간 유의한 차이 없음
대상군 선정	□ 낮음 □ 높음 ■ 불확실	Patients with limited FTRP (full-thickness rectal prolapse) were identified and were given a physical examination, full colonoscopy, and conventional defecography. Cases with a prior or current history or evidence of active perirectal sepsis, anorectal fistula, anal or colorectal malignancy, inflammatory bowel disease, or prior anorectal surgery were excluded from analysis. (중략) The recruitment for analysis and the separation into particular groups are shown in Figure 1. ➜ 두 군의 선택배제 기준이 동일한지 확인하기 어려움
교란변수	■ 낮음 □ 높음 □ 불확실	➜ Table 1 기초특성, 두 군간 유의한 차이 없음
노출 측정	■ 낮음 □ 높음 □ 불확실	➜ 해당 중재는 수술적 치료법으로 적절하게 노출되었을 것으로 봄
평가자의 눈가림	□ 낮음 ■ 높음 □ 불확실	There are several limitations of our study. The numbers are small with a considerable number lost to follow-up, and the retrospective design of the study leaves the potential for bias in the outcome assessment.
결과 평가	■ 낮음 □ 높음 □ 불확실	Table 2: CCCS, WIS, recurrence rate ➜ 검증된 평가도구를 이용하여 결과를 측정함
불완전한 결과자료	□ 낮음 ■ 높음 □ 불확실	Figure 1: Lost to follow up (17명, 5명) ➜ 결측치가 있고, 두 군간 차이가 있음
선택적 결과 보고	■ 낮음 □ 높음 □ 불확실	➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음

RoBANS ver 2.0

연번(Ref ID)		7
1저자(출판연도)		Altomare (2018)
영역	비뚤림위험	사유
대상군 비교 가능성	■ 낮음 □ 높음 □ 불확실	The patients were well matched according to age, severity of pelvic floor dysfunction (ODS score, Vaizey score and TAPE score) and quality of life related to constipation (PAC-QoL) (Table 1). ➜ Table 1 기초특성, 두 군간 유의한 차이 없음
대상군 선정	■ 낮음 □ 높음 □ 불확실	A retrospective study was performed using a prospectively maintained database of patients complaining of obstructed defecation who attended our colorectal unit between 2006 and 2016. Only patients fulfilling the following selection criteria were included in the study: female gender, the presence of rectorectal or rectoanal intussusception (grades Ⅲ and Ⅳ of the Oxford classification) as main cause of ODS, type of operation performed (STARR or ventral rectopexy), and an ODS score > 10. Exclusion criteria were male gender, the presence of very large (> 4 cm), non-emptying rectocele as main cause of constipation without intussusception, significant fecal incontinence (Vaizey score > 5), previous surgery on rectum or anus, inflammatory bowel disease, pregnancy, other type of surgery to relieve ODS, slow transit constipation defined as ≤ 2 bowel movements per week and/or colonic transit time > 70 h, any psychiatric diseases. The occurrence of large rectocele as the main cause of ODS without intussusception was considered an exclusion criterion for both STARR and VRP because these cases are managed by the perineal/transvaginal route in our Institution. ➜ 두 군의 선택배제 기준이 동일함
교란변수	■ 낮음 □ 높음 □ 불확실	➜ Table 1 기초특성, 두 군간 유의한 차이 없음
노출 측정	■ 낮음 □ 높음 □ 불확실	➜ 해당 중재는 수술적 치료법으로 적절하게 노출되었을 것으로 봄
평가자의 눈가림	□ 낮음 □ 높음 ■ 불확실	언급 없음
결과 평가	■ 낮음 □ 높음 □ 불확실	ODS, TAPE score, PAC-Qol ➜ 검증된 평가도구를 이용하여 결과를 측정함
불완전한 결과자료	■ 낮음 □ 높음 □ 불확실	➜ 결측치 없음
선택적 결과 보고	■ 낮음 □ 높음 □ 불확실	➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음

RoBANS ver 2.0

연번(Ref ID)		8
1저자(출판연도)		Borie (2014)
영역	**비뚤림위험**	**사유**
대상군 비교 가능성	☐ 낮음 ■ 높음 ☐ 불확실	➜ Table 1 Manometry (Moderate sphincter insufficiency), Endorectal ultrasonography에서 두 군간 유의한 차이를 나타남
대상군 선정	■ 낮음 ☐ 높음 ☐ 불확실	This is a retrospective study including 52 patients (females) who have been operated on between 2002 and 2011. The patients had dyschesia with the presence of a rectocele, associated or not with an intra-rectal prolapse and with-out symptoms of anal incontinence. Patients with an anal continence disorder (n = 1), a full exteriorized prolapse of the rectum (n = 2), a chronic inflammatory bowel disease(n = 1), familial adenomatous polyposis (n = 1), intestinal cancer (n = 1), a history of pelvic radiotherapy (n = 1), transit constipation (n = 3), chronic pelvic pain (n = 4), and non-controlled psychological illness (n = 3) were systematically excluded. A previous abdominal surgery was not consideredas an exclusion criterion for laparoscopic rectopexy. Thepatients have been treated with biofeedback (patients withanismus), simple lifestyle modifications, osmotic laxativesor bulking agents with a switch of laxatives or a combina-tion and irrigation. The medical treatments did not improvethe dyschesia symptoms. ➜ 두 군의 선택배제 기준이 동일함
교란변수	☐ 낮음 ■ 높음 ☐ 불확실	➜ Table 1 Manometry (Moderate sphincter insufficiency), Endorectal ultrasonography에서 두 군간 유의한 차이를 나타남. 이를 적절히 보정하지 않았음
노출 측정	■ 낮음 ☐ 높음 ☐ 불확실	➜ 해당 중재는 수술적 치료법으로 적절하게 노출되었을 것으로 봄
평가자의 눈가림	☐ 낮음 ☐ 높음 ■ 불확실	언급 없음
결과 평가	☐ 낮음 ☐ 높음 ■ 불확실	ODS score, Patient satisfaction, complications, symptoms ➜ 검증된 평가도구 및 주관적 평가도구를 이용하여 결과를 측정함
불완전한 결과자료	■ 낮음 ☐ 높음 ☐ 불확실	Table 6 ➜ 결측치 없음
선택적 결과 보고	■ 낮음 ☐ 높음 ☐ 불확실	➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음

RoBANS ver 2.0

연번(Ref ID)		9
1저자(출판연도)		Ohazuruike (2014)
영역	비뚤림위험	사유
대상군 비교 가능성	■ 낮음 □ 높음 □ 불확실	Although the ID procedure was considered for patients with a supposed higher risk of postoperative incontinence related to clinical evaluation and manometrical and ultrasonographical results, the two groups were considered homogeneous in terms of age, gender, duration of symptoms, preoperative ODS scores and preoperative incontinence score.
대상군 선정	■ 낮음 □ 높음 □ 불확실	Thirty-five consecutive patients were enrolled in the present study. Twenty-three patients underwent STARR procedure using double PPH-01 stapler and 12 patients underwent internal Delorme's procedure.
교란변수	■ 낮음 □ 높음 □ 불확실	Although the ID procedure was considered for patients with a supposed higher risk of postoperative incontinence related to clinical evaluation and manometrical and ultrasonographical results, the two groups were considered homogeneous in terms of age, gender, duration of symptoms, preoperative ODS scores and preoperative incontinence score.
노출 측정	■ 낮음 □ 높음 □ 불확실	➜ 해당 중재는 수술적 치료법으로 적절하게 노출되었을 것으로 봄
평가자의 눈가림	□ 낮음 □ 높음 ■ 불확실	언급 없음
결과 평가	□ 낮음 □ 높음 ■ 불확실	ODS score, Subjective satisfaction ➜ 검증된 평가도구 및 주관적 평가도구를 이용하여 결과를 측정함
불완전한 결과자료	■ 낮음 □ 높음 □ 불확실	Table 4; 6개월 시점 ➜ 결측치 없음
선택적 결과 보고	■ 낮음 □ 높음 □ 불확실	➜ 프로토콜은 없지만 연구방법에 언급된 결과지표가 연구결과로 보고되고 있음