

Surgery for constipation: systematic review and practice recommendations

Results IV: Recto-vaginal reinforcement procedures

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Abstract

Aim To assess the outcomes of recto-vaginal reinforcement procedures in adults with chronic constipation.

Method Standardised methods and reporting of benefits and harms were used for all CapaCiTY reviews that closely adhered to PRISMA 2016 guidance. Main conclusions were presented as summary evidence statements with a summative Oxford Centre for Evidence-Based Medicine (2009) level.

Results Forty-three articles were identified, providing data on outcomes in 3346 patients. Average length of procedures ranged between 20 and 169 min, and length of stay between 1 and 15 days. Complications typically occurred after 7–17% of procedures (range 0–61%). Post-operative bleeding was uncommon (0–4%) as well as haematoma or sepsis (0–2%). Fistulation did not occur in most studies. Two procedure-related deaths were observed for 3209 patients. Although

inconsistent, 78% of patients reported a satisfactory or good outcome, with 30–50% experiencing reduced symptoms of straining, incomplete emptying or reduced vaginal digitation. About 17% of patients developed anatomical recurrence. Considering measures of harm and global satisfaction rating scales, there was insufficient evidence to prefer one type of procedure over another. There was no evidence to support better outcomes based on selection of patients with a particular size or grade of rectocele.

Conclusion Evidence supporting recto-vaginal reinforcement procedures is currently derived from observational studies and comparisons, with only one high quality study. Large trials are needed to inform future clinical decision making.

Keywords Recto-vaginal reinforcement, constipation, rectocele, STARR, transvaginal repair, transanal repair

Introduction

Background and procedural variations

Chronic constipation is related to an inability to evacuate the rectum in over half of all adults presenting for specialist advice. This phenomenon, which may be variably described as obstructed defaecation or rectal evacuation disorder (and many other terms), is characterised by excessive straining, the feeling of incomplete evacuation, post-defaecatory seepage and often mucous discharge, and pelvic pain [1]. In some of these patients there is clinical and radiological (usually proctographic)

evidence of a dynamic structural abnormality leading to physical impediment to emptying during defaecation. By far away, the way most common abnormalities are rectocele and/or intussusception.

Traditionally a rectocele may be considered either a bulge into the vagina, giving vaginal prolapse symptoms, or the sensation of a lump or mass. Also, a herniation of the rectum into the vagina preventing complete evacuation may lead to 'trapping' of faeces in the 'pocket' and subsequent incomplete evacuation (ballooning may also lead to loss of vector forces along the anorectal axis). This process can lead to dissatisfaction with emptying and repeated visits to the toilet, post-defaecatory soiling and the need to apply pressure to the posterior vaginal wall or perineum to splint the rectocele and maximise emptying. Many women will also 'digitate' or manually assist emptying using a finger

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either in the rectocele via the anus to aid with complete emptying or in the vagina to splint against the posterior vagina to prevent trapping and direct evacuatory forces down along the axis of the anus.

It follows that strategies have been employed to anatomically correct a rectocele by reinforcing the barrier between the rectum and vagina (rectovaginal septum). Access for rectovaginal reinforcement varies with three main approaches described: the posterior vagina (posterior repair [2]), the perineum (transperineal repair [3]), or via the anus (transanal repair [4,5]). Vaginal repairs all involve an incision in the posterior wall either longitudinally to open the entire length of the rectocele or transversely to produce a broad based flap and expose the entirety of the rectocele, or a combination of the two incisions in the shape of an inverted 'T'. In most repairs the redundant rectal wall is plicated outside the bowel wall. The vaginal wall is then reconstructed with resection of any excess vaginal mucosa. Many repairs include some degree of approximation of the *levator ani* and pelvic side wall muscles to formally reinforce the reconstruction of the rectovaginal septum, although with the reputed higher risk of dyspareunia. More recently attempts have been made to localise specific defects in the rectovaginal septum. This has led to 'site specific' repairs [6,7], where the individual defects are repaired before the vaginal wall is closed. All of these types of repairs may be augmented by mesh reinforcement, usually using one of a variety of collagen meshes.

The rectovaginal septum may be entered through a transperineal route. A transverse or curved incision is made in the perineal body towards the vagina and the dissection extended anterior to the sphincter complex to gain access to the rectovaginal septum. Having gained exposure, a repair is made in the same way as in a transvaginal approach. The potential advantage to this route is that it may be combined with a sphincteroplasty in those women with a deficient sphincter and a concurrent rectocele.

Finally, a rectocele can be considered as a redundant pocket of rectum, rather than a weakness in the rectovaginal septum leading to herniation of the rectum. A transanal repair addresses the rectal redundancy with either an anterior Delorme's style repair (Sarle's repair [5]) or with a sutured pexy of the anterior rectal wall (Block repair [4]). In the former repair, the mucosa is dissected free from the rectal muscle and excised. Following this, the rectal muscle coat is plicated longitudinally to obliterate the rectocele pocket and the mucosa is re-approximated to close the defect. In the Block repair, full thickness longitudinal sutures are placed anteriorly to draw together the redundant anterior rectal pocket and close the rectocele. It is evident that these procedures necessitate a degree of rectal wall excision or suspension respectively.

Scope

The overall purpose of the CapaCiTY review series is to assess the efficacy and harms of procedures for chronic constipation in adults. The focus is therefore directed to a population presenting with symptoms of obstructed defecation, rather than women with only prolapse, urinary symptoms or both (see overview and methods paper). One group of procedures considered beyond the scope of this systematic review included those where excision is effected without reinforcement, e.g. rectal excision only, such as stapled transanal resection of the rectum (STARR). As is noted above, anterior Delorme's or Sarle's procedures are included, which include a degree of resection, but also have a significant element of reinforcement with muscle wall plication (targeted at the rectovaginal plane), which is not present in pure resection. This noted, a small number of studies have specifically focused stapled resection to the obliteration of a rectocele by anterior deployment of a stapler to exact mucosal excision (much like stapled haemorrhoidopexy). In a sense, these reinforce the RV septum by tightening tissue and have been included for completion in this review. Further, most compare this approach with one of the other approaches also covered in this review. The separate review covering rectal excision includes numerous studies of STARR in which the device is used to excise circumferential full-thickness excision and the reviews overlap in only one study [8]. Circumferential Delorme's procedures are excluded from this review as their focus is not on reinforcement of the rectovaginal septum but rather on general resection for prolapse (covered in rectal suspension review). Studies where outcomes could not be segregated by eligible procedure were also excluded, due to a mixed patient population with internal and external rectal prolapse, mixed indications including numerous pelvic floor abnormalities or limited postoperative outcomes.

Previous reviews

There have been no systematic reviews of the results of rectocele repair for the treatment of obstructed defaecation or constipation. There has been a systematic Cochrane review (with updates) on the surgical management of pelvic organ prolapse in women [9–13], which includes review of posterior vaginal repair for rectocele. This review included seven randomised trials on women with posterior vaginal wall prolapse [3,14–19], three trials comparing vaginal and transanal approaches [3,14,18]. In addition, another trial provided data for women with rectocele undergoing posterior repair with and without absorbable mesh [16].

There has been one systematic review of the use of biologics in urogynaecological repairs [20]. In addition, the International Continence Society, 5th International Consultation on Incontinence, Paris, February 2012, pages 1411–1414 [21], covers posterior repair. Neither this, nor the Cochrane process focussed on the specific management of patients with constipation.

Summary of search results and study quality

The search yielded a total of 72 citations for full text review (Fig. 1). From these, 44 articles published between 1990 and 2016 contributed 43 studies to the systematic review (one cohort was spread across two publications with a focus on perioperative morbidity [22] and clinical outcomes [23], respectively). Data on outcomes were provided for a total of 3346 patients (study mean: 78, range 13–307) (Table 1). Specific exclusions after full-text review (and after exclusion of five non-English language publications) included: four studies where the population sample was confirmed to be <20 patients; eight studies where follow up was less than 12 months; two studies of out of scope procedures; four studies where data were considered as duplicate; three studies where outcomes could not be segregated by eligible procedure; and two studies with no relevant outcome data.

The quality of studies varied. The 43 included studies included three randomised controlled trials (RCTs) and 40 observational studies. The former included one good quality RCT (level IB) with a low level of susceptibility to bias and two with less well described methodology (level IIB). The 40 observational studies included eight good quality cohort studies with low susceptibility

to bias (level IIB). Other studies were a mix of prospective and retrospective case series. Mean study follow-up was 2.1 years (range 0.7–6.2 years); 19 studies originated from European centres, 12 from the USA and 12 from other countries. The studies covered the full spectrum of types of repair and are shown in Fig. 2.

Results

Perioperative data

The 43 studies included 62 patient cohorts receiving one of eight procedures (Table 2). Perioperative data were reported inconsistently by studies, with 24 (39%) cohorts reporting average procedural duration and 29 (47%) reporting average length of stay (Tables 2 and 3). There was considerable variation in these measures when comparing procedures: design heterogeneity, small numbers of studies and large range of values precludes any clear pattern. The overall average duration of procedures was 67 (range 20–169) minutes, and the overall average length of stay was 3.9 (range 1–15) days.

Summary evidence statements: perioperative data

- The average duration of procedures was about one hour, although this is inconsistently reported and ranged widely between studies from 20 to 169 min (level IV).
- The average length of stay was about 4 days although this is inconsistently reported and ranged widely between studies from 1 to 15 days (level IV).
- There was inadequate evidence to determine variations in procedural duration or length of stay by type of procedure (level IV).

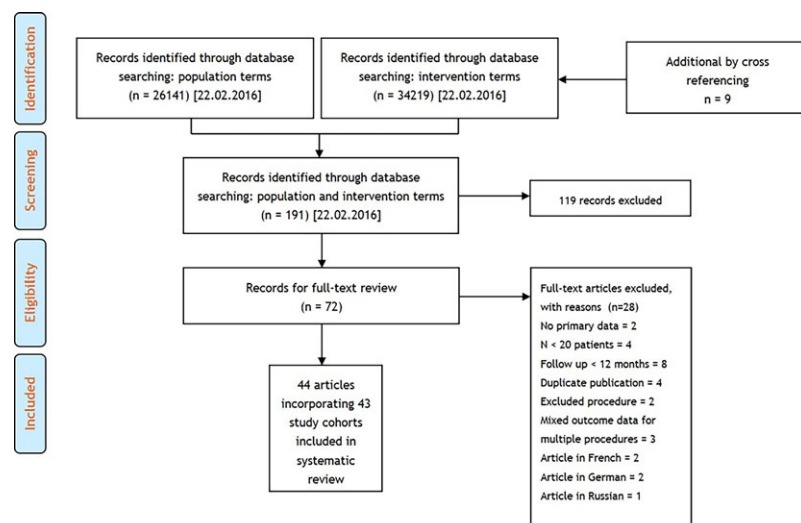


Figure 1 PRISMA diagram of search results.

Table 1 All studies included in systematic review.

Authors	Year	Centre	Country	N	FU (months)	Design	Grade*
Arnold [24]	1990	Columbus, OH	USA	64	24	RCS	IV
Janssen [25]	1994	Utrecht	Netherlands	76	12	PCS	IV
Infantino [26]	1995	Padova	Italy	21	24	RCS	IV
Murthy [27]	1996	Washington DC	USA	33	31	RCS	IV
van Dam [22,23]†	1996/2000	Rotterdam	Netherlands	75 and 89	14 and 52	PCH	IIB
Kahn [18]	1997	London	UK	231	72	RCS	IV
Khubchandani [28]	1997	Allentown, PA	USA	123	38	RCS	IV
Cundiff [29]	1998	Durham, NC	USA	69	12	RCS	IV
Tjandra [30]	1999	Melbourne	Australia	59	19	RCH	IV
Van Laarhoven [31]	1999	London, St Marks	UK	22	27	RCS	IV
Boccasanta [32]	2001	Milan‡	Italy	267	24	RCS	IV
Lopez [33]	2001	Stockholm	Sweden	25	61	PCH	IV
Ayabaca [34]	2002	Rome	Italy	60	48	RCS	IV
Ayav [35]	2004	Nancy	France	21	58	RCS	IV
Heriot [36]	2004	London	UK	45	24	RCS	IV
Maher [37]	2004	Brisbane	Australia	38	12.5	PCS	IV
Mercer-Jones [38]	2004	Newcastle	UK	22§	12.5	PCS	IV
Nieminen [14]	2004	Tampere	Finland	30	12	RCT	IIB
Abramov [7]	2005	Evanston, IL	USA	307	12	PCH	IIB
Dippolito [39]	2005	Bethlehem, PA	USA	13	16	RCS	IV
Milani [40]	2005	Milan	Italy	63	17	PCS	IV
Roman [41]	2005	Rouen	France	71	74	RCS	IV
Thornton [42]	2005	Sydney	Australia	82	44	RCH	IIB
Altman [43]	2006	Stockholm	Sweden	23	36	PCS	IV
Paraiso [15]	2006	Cleveland, OH	USA	105	24	RCT	IB
Yamana [44]	2006	Tokyo	Japan	30	38	PCS	IV
Gustilo-Ashby [45]	2007	Cleveland, OH	USA	99	12	RCT	IIB
Lim [46]	2007	Melbourne	Australia	53	36	RCS	IV
Puigdollers [47]	2007	Barcelona	Spain	35	12	PCS	IV
Sardeli [48]	2007	Aarhus	Denmark	51	27	RCS	IV
Tsujinaka [49]	2007	Chiba	Japan	111	12	PCH	IIB
Biehl [50]	2008	Atlanta, GA	USA	195	13.8	RCS	IV
Harris [8]	2009	Orlando, FL	USA	73	14	RCH	IV
Schwandner [51]	2009	Giessen	Germany	102	18	RCS	IV
Leal [52]	2010	Teresina	Brazil	35	12	PCS	IV
Cruz [53]	2011	Brazil	Brazil	75	21	PCS	IV
Chung [54]	2012	Seoul	S Korea	50	12	RCH	IIB
Mahmoud [55]	2012	Mansoura	Egypt	45	12	PCH	IIB
Sung [17]	2012	Providence, RI	USA	160	12	PCH	IIB
van der Hagen [56]	2012	Stadskanaal	Netherlands	27	12	RCS	IV
Guzman Rojas [57]	2015	‡	Australia/Chile	137	16	PCH	IIB
Shafik [58]	2015	Cairo	Egypt	84	12	PCS	IV
Melich [59]	2016	Chicago, IL	USA	23	12	PCS	IV

N, Number of patients; PCS, Prospective Case Series; PCH, Prospective Cohort Study; RCS, Retrospective Case Series; RCH, Retrospective Cohort Study; RCT, Randomised Controlled Trial.

*Oxford CEBM [60].

†Same cohort of patients, study from 1996 used for peri-operative data and study from 2000 long term outcome data.

‡Multicentre study.

§Twenty-four patients entered study: two were excluded due to rectal injury and so no mesh implanted.

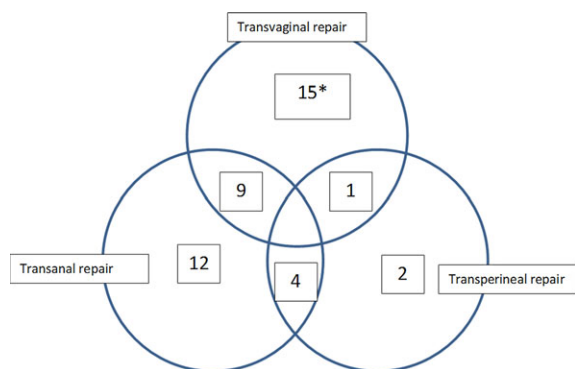


Figure 2 Venn diagram showing the distribution of studies between different types of repair. KEY: Box denotes number of studies in each category. *includes only one Level IB RCT [15].

Harms

Perioperative complications

Four measures of harm were reported by a majority of studies within the review: overall complications, bleeding, fistulation and haematoma/sepsis. There was considerable heterogeneity in surgical morbidity, reported as overall procedural complication rates; with individual study rates varying from 0% to 61% (see Table 2). This heterogeneity may have reflected (for example) differing inclusion, procedural content, context of care, or thresholds or conventions for recording complications. Random effects meta-analysis found the overall complication rate to be 11.5% (95% CI: 7.2–16.6%), $I^2 = 87%$ (Fig. 3). Overall complication rates varied within and between procedures without evidence to favour one or more procedures. Although variable, the bleeding complication rate was generally low being reported as zero in 50% of cohorts of procedures. Random effects meta-analysis found the pooled bleed rate to be 2.0% (95% CI: 0.7–3.6%), $I^2 = 68%$. The reported fistulation rate was consistently low (0% in 80% of cohorts). Random effects meta-analysis found the fistulation rate to be 0.0% (95% CI: 0.0–0.1%), $I^2 = 0%$. The rate of haematoma or sepsis varied between studies but was generally low (0% in 56% of cohorts). Random effects meta-analysis found the pooled rate of haematoma or sepsis to be 0.9% (95% CI: 0.2–2.0%), $I^2 = 54%$ (Fig. 4). Although there was some evidence of variation by procedure, sub-group findings are based on selective reporting of relatively few and small studies and should be viewed with caution.

Other measures of short term harm were less consistently reported: perioperative pain (37% of cohorts), urine retention (6%) and UTIs (10%).

Long term adverse outcomes

Measures of long term harm were poorly reported: urgency (19%) and anal stenosis (13%). Although 37 cohorts (60%) made some assessment of dyspareunia, these assessments were not made in an adequately comparable fashion. Wide variations between studies may reflect inconsistency in the studies when reporting improvement, deterioration or *de novo* dyspareunia. Rates of mesh erosion were as high as 30% but were only reported in two studies [40,46]. This adverse outcome is devastating for the female sufferer and is rightly receiving extensive media coverage, focus by some regulatory bodies (e.g. Scottish Government) and much interest by surgeons themselves. It is thus unfortunate that in the narrowly defined context of this systematic review, evidence regarding this outcome was of poor quality.

Summary evidence statements: harms

- Evidence is drawn from observational studies and comparisons. Most comparisons featured considerable heterogeneity, which may have multiple causes (level IV).
- Overall procedural complication rates ranged from 0% to 61%. However, these complications typically occurred in about 7–17% of procedures (level IV).
- Post-operative bleeding rates were low, typically ranging from 0% to 4% (level IV).
- Fistulation was a very rare complication, not occurring at all in most studies (level IV).
- Mesh erosion was a common complication, but only reported in two studies (level IV).
- The occurrence of haematoma or sepsis was typically low at around 0–2% (level IV).
- Considering measures of harm, there was insufficient evidence to prefer one type of procedure over another (level IV).
- Long term adverse outcomes were poorly reported (level IV).
- Dyspareunia was reported too inconsistently to make meaningful comparisons between procedures, although it may be central to patient decision making (level IV).
- Only two procedure-related deaths were reported for 3209 patients included in studies (level IV).

Efficacy

Most studies used *ad hoc* questionnaire assessment of symptoms ($n = 27$) to assess efficacy; other tools used included Cleveland Clinic Constipation score ($n = 2$), Wexner constipation score ($n = 3$), obstructed defaecation score ($n = 4$) with single studies using the following: PAC QOL; Short Form-36 (SF-36); St Mark's

Table 2 Perioperative data by procedure.

Author	Year	N	Length of procedure*	Length of stay [†]	Total Cx rate	Bleeding	Fistulation	Pain	Haematoma/Sepsis	Urgency	Anal stenosis	Urine retention	UTI	Dyspareunia (new)	Other
<i>(a) Transvaginal repair: standard</i>															
Arnold [24]	1990	29	NR	5.6 (3–14)	34	0	0	17	3	NR	NR	NR	NR	23	NR
Infantino [26]	1995	8	NR	NR	12.5	0	0	0	12.5	NR	NR	NR	NR	NR	NR
Kahn [18]	1997	231	NR	NR	NR	NR	NR	22	NR	13	NR	NR	NR	9	NR
Cundiff [29]	1998	69	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	-10	NR
Lopez [33]	2001	25	NR	6.3 (3–16)	28	0	0	0	20	0	NR	4%	4%	13 [§]	NR
Maher [37]	2004	38	52 (10–125)	4.3 (3–10)	7.9	0	0	0	2.6	0	NR	NR	2.6%	-32	2.6% inadvertent proctotomy
Nieminen [14]	2004	15	35 (20–50)	NR	0	0	0	0	0	0	NR	NR	NR	0	NR
Abramov [7]	2005	183	NR	NR	5.4	3	0	NR	0	NR	NR	NR	NR	33	NR
Paraiso [15]	2006	37	150 (SD68)	2 (1–19)	43.2	5	0	NR	14	NR	NR	NR	11%	0	1 ileus
Yamana [44]	2006	30	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	7	NR
Gustilo-Ashby [45]	2007	33	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Tsujinaka [49]	2007	40	63.5 (19–123)	15 (10–22)	NR	5	0	17.5	0	NR	NR	NR	NR	NR	NR
Harris [8]	2009	37	85.5	3	18.9	2.7	0	0	5.4	NR	NR	NR	NR	12	NR
Schwandner [51]	2009	102	36.5 (29–67)	4.1 (2–7)	11	2	0	NR	2	NR	NR	NR	2%	NR	NR
Chung [54]	2012	24	74	2	12.5	0	0	0	0	0	NR	NR	NR	8	NR
Sung [17]	2012	81	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Shafik [58]	2015	84	45 (35–55)	4.2 (3.1–5.6)	NR	0	1.2	0	0	8.3	NR	NR	NR	2.4	6% constipation
<i>(b) Transvaginal repair: site-specific</i>															
Abramov [7]	2005	124	NR	NR	6.4	3	0	NR	0	NR	NR	NR	NR	33	0%
Paraiso [15]	2006	37	151 (69)	2 (1–7)	30	0	0	NR	0	NR	NR	NR	NR	0	NR
Gustilo-Ashby [45]	2007	37	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Sardeli [48]	2007	51	32.5 (15–90)	2.1 (1–14)	24	12	2	NR	4	NR	NR	NR	NR	4	Urinary incontinence 2%
Guzman Rojas [57]	2015	137	NR	NR	0	0	0	NR	0	NR	NR	NR	NR	15	NR
<i>(c) Transanal repair: block sutured repair</i>															
Arnold [24]	1990	35	NR	5.6 (3–14)	34	0	0	17	3	NR	NR	NR	NR	21	NR
Infantino [26]	1995	13	NR	NR	0	0	0	0	0	NR	NR	NR	NR	NR	0
Van Laarhoven [31]	1999	7	NR	NR	14	4.5	NR	NR	NR	NR	NR	NR	NR	NR	NR
Boccasanta [32]	2001	44	79.6	4.5	1.5	25	5	NR	0	NR	NR	NR	NR	0	0
Tsujinaka [49]	2007	71	30.5 (16–97)	9 (6–17)	NR	5.6	0	11	0	NR	NR	NR	NR	0	NR
<i>(d) Transanal repair: stapled transanal resection</i>															
Boccasanta [32]	2001	15	79.6	4.5	1.5	0	0	0	0	NR	7	NR	NR	0	NR
Ayav [35]	2004	21	NA	3.3 (2–5)	0	0	0	0	0	0	0	NR	NR	-4.7	NR

Table 2 (Continued).

Author	Year	N	Length of procedure*	Length of stay†	Total Cx rate	Bleeding	Fistulation	Pain	Haematoma/Sepsis	Urgency	Anal stenosis	Urine retention	UTI	Dyspareunia (new)	Other
Harris [8]	2009	36	52.7	2.6	61	19	0	2.7	0	NR	NR	NR	NR	10.5	NR
Leal [52]	2010	35	45 (33–70)	1	14	23	0	0	0	8.5	8.5	NR	NR	NR	NR
Cruz [53]	2011	75	42	1	13	17	0	4	0	NR	9.3	NR	NR	NR	NR
Mahmoud [55]	2012	22	20 (sd45)	2.0 (0.8)	NR	NR	NR	NR	NR	NR	NR	NR	NR	-58	4.4% overall <i>de novo</i> FI
<i>(c) Transanal repair: Delorme's or Sarrle's Style</i>															
Janssen [25]	1994	76	NR	NR	2.6	1.3	0	1.3	0	NR	0	NR	NR	NR	NR
Murthy [27]	1996	33	NR	3.7 (1–8)	21	NR	3	NR	NR	NR	NR	18	NR	NR	NR
Khubchandani [28]	1997	123	NR	NR	NR	NR	1	NR	NR	NR	NR	NR	NR	NR	2.8% flap retraction
Tjandra [30]	1999	59	NA	NR	3.4	1.7	0	NR	0	NR	NR	2	NR	NR	NR
Bocassanta [32]	2001	82	79.6	4.5	1.5	8	1	NR	NR	NR	2.1	3.5	NR	0	NR
Ayabaca [34]	2002	13	NR	NR	30	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Niemenen [14]	2004	15	35 (6)	NR	13	0	0	0	0	0	NR	NR	NR	7	0
Dippolito [39]	2005	13	NR	1.9	30	NR	NR	NR	NR	0	NR	NR	NR	NR	Minor complication
Roman [41]	2005	71	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Thornton [42]	2005	40	NA	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Puiggollers [47]	2007	11	NA	NR	NR	0	0	NR	NR	NR	NR	NR	NR	NR	NR
Chung [54]	2012	26	61.5	2	0	0	0	0	0	0	NR	NR	NR	0	0
Mahmoud [55]	2012	23	45 (6)	4.0 (1.6)	NR	NR	NR	NR	NR	NR	NR	NR	NR	-58	4.4% <i>de novo</i> FI
<i>(f) Combined transvaginal and transanal Delorme/Sarrle style</i>															
van Dam [22]	1996	75	NR	NR	NR	NR	4	NR	5.30	NR	NR	NR	20	NR	NR
<i>(g) Transperineal repair</i>															
Bocassanta [32]	2001	126	73.4	5.2	0	0	0	NR	NR	NR	NR	NR	NR	17	1 Death
Ayabaca [34]	2002	11	NR	NR	30	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Puiggollers [47]	2007	24	NR	NR	8.3	0	0	NR	8.3	NR	NR	NR	NR	NR	NR

Table 2 (Continued).

Author	Year	N	Length of procedure*	Length of stay†	Total Cx rate	Bleeding	Fistulation	Pain	Haematoma/Sepsis	Urgency	Anal stenosis	Urine retention	UTI	Dyspareunia (new)	Other	Repair type	Mesh type
(h) Mesh repairs																	
Van Laarhoven [31]	1999	15	NR	NR	14	4.5	NR	NR	9.1	NR	NR	NR	NR	NR	NR	TP	Synthetic marlex
Mercer-Jones [38]	2004	24	NR	2 (1-6)	14	0	0	0	14	0	NR	NR	NR	4.5		TP	Synthetic prolene/Vipro II
Milani [40]	2005	63	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	18%	19.5% mesh erosion	TV	Synthetic prolene PX
Altman [43]	2006	23	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	VAS‡ 2 post	NR	TV	Synthetic prolene PX
Paraiso [15]	2006	31	1.69 (62)	2 (1-6)	42	3	0	NR	6	NR	NR	NR	19	0	NR	TV	PX
Gustilo-Ashby [45]	2007	29	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	TV	PX
Lim [46]	2007	53	39	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	26%	19% vaginal discharge; 30% mesh erosion; 63% atrophic vaginitis	TV	Synthetic vipro II
Biehl [50]	2008	95	NR	NR	NR	1	1	NR	1	NR	3‡	NR	NR	25	11% incision dehiscence	TV	PDX
Biehl [50]	2008	100	NR	NR	NR	1	0	NR	NR	NR	7.4‡	NR	NR	36	5.3 incision dehiscence	TV	HDA
Sung [17]	201	79	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NA	NA	TV	PSS
van der Hagen [56]	2012	27	56 (50-68)	3 (2-6)	7.4	NR	NR	NR	NR	NR	NR	NR	NR	3.70%	7.4% port site infection	TV	Synthetic prolene
Melich [59]	2016	23	NR	NR	4	0	0	0	4	NR	NR	NR	NR	11%	NR	TV	PDX strattice

All rates are percentages where negative values indicate reduction from preoperative state; Cx, complication; NR, Not recorded; TV, transvaginal repair; TP, transperineal repair; PX, porcine xenograft; PDX, porcine dermal xenograft; HAD, human dermal allograft; PSS, porcine sub-intestinal submucosa.

* Mean minutes (range).

† Mean (range) days.

‡ Visual analogue score 2 pre, 1.6 post.

§ Twenty-seven percentage at 5 years follow up.

¶ Vaginal stenosis.

Table 3 Summary of selected data from Table 2.

Procedure	Procedure duration (min)			Length of stay (days)			Follow-up (months)		
	N	Mean	Range	N	Mean	Range	N	Mean	Range
Standard TVR	8	67.6	(35.0–150.0)	9	5.2	(2.0–15.0)	17	22.9	(8.0–72.0)
Site-specific TVR	2	91.8	(32.5–151.0)	2	2.1	(2.0–2.1)	5	18.2	(12.0–27.0)
Block sutured TAR	2	55.1	(30.5–79.6)	3	6.4	(4.5–9.0)	5	22.2	(12.0–27.0)
Delormes/Sarles TAR	3	62.0	(45.0–79.6)	5	3.2	(1.9–4.5)	13	27.2	(12.0–74.0)
Delormes/Sarles TAR + TVR	0	–	–	–	–	(0.0–0.0)	1	52.0	–
Stapled transanal resection	5	47.9	(20.0–79.6)	6	2.4	(1.0–4.5)	6	20.4	(8.0–58.0)
Transperineal repair	1	73.4	–	1	5.2	–	3	28.0	(12.0–48.0)
Mesh repair	3	88.0	(39.0–169.0)	3	2.3	(2.0–3.0)	12	19.0	(12.0–36.0)
All procedures	24	66.6	(20.0–169.0)	29	3.9	(1.0–15.0)	62	23.1	(8.0–74.0)

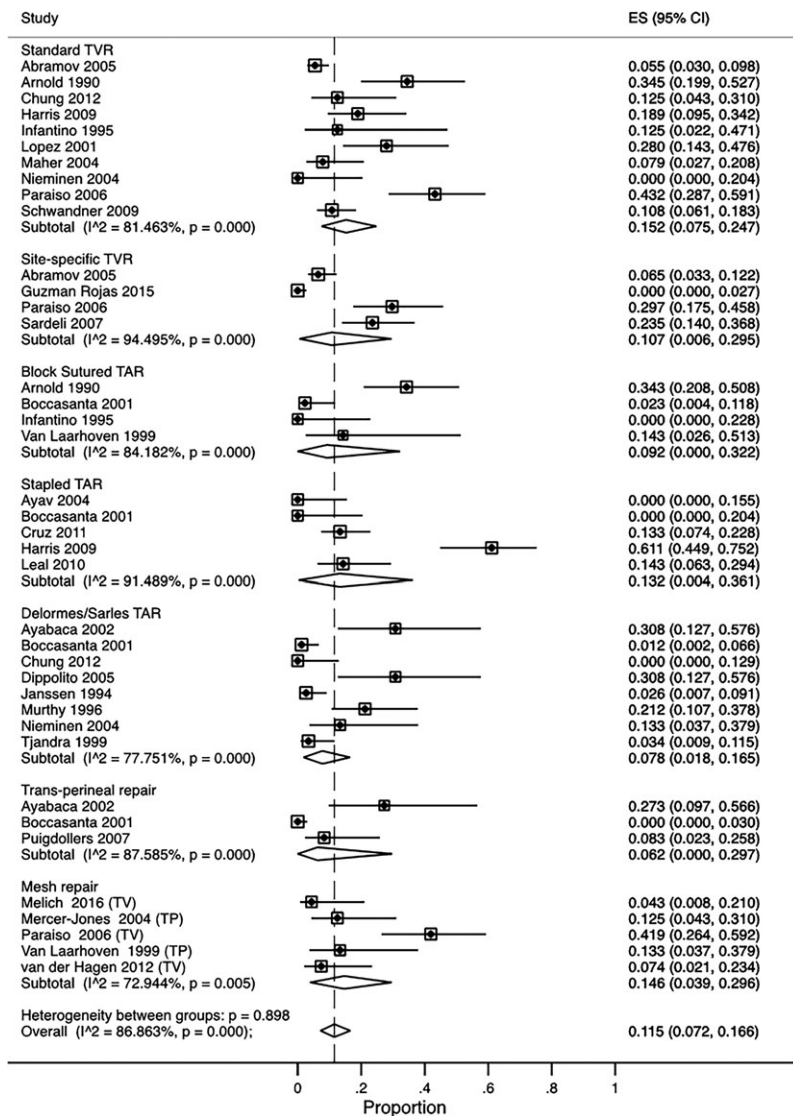


Figure 3 Forest plot showing rates of total procedural complications (percentage of patients) by procedure type. KEY: TVR, transvaginal repair; TAR, transanal repair; TV, transvaginal; TP, transperineal.

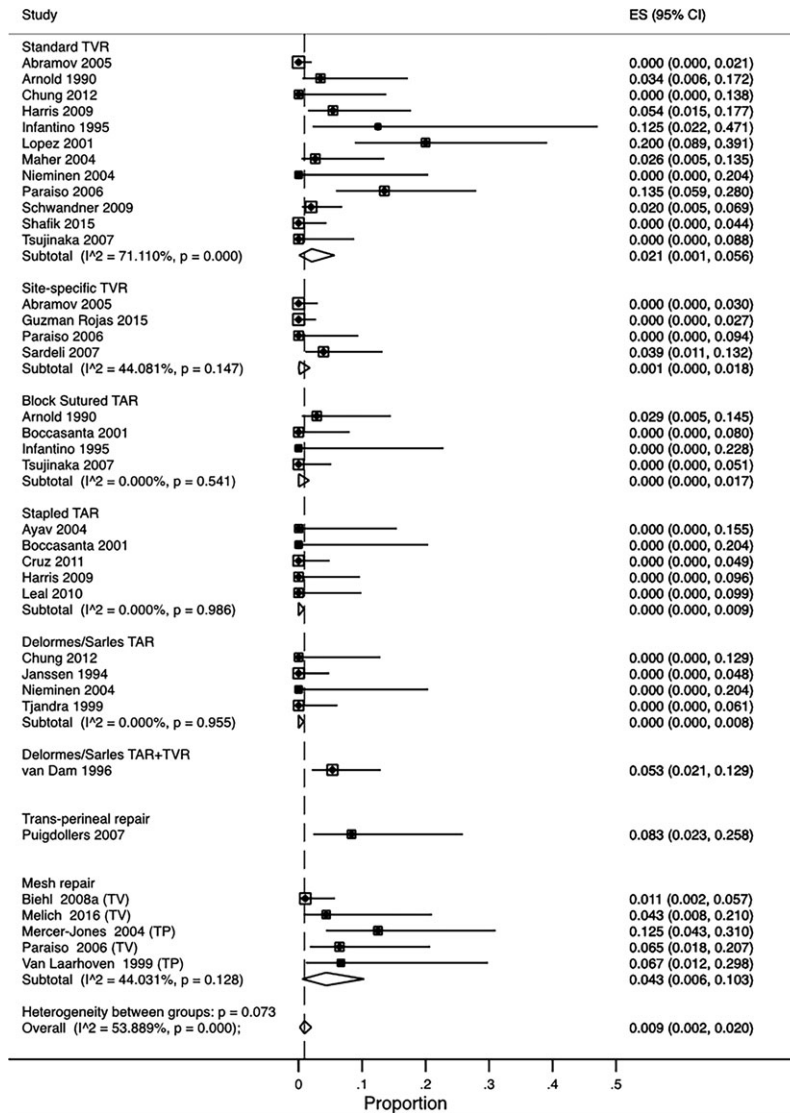


Figure 4 Forest plot showing rates of haematoma or sepsis (percentage of patients) by procedure type. KEY: TVR, transvaginal repair; TAR, transanal repair; TV, transvaginal; TP, transperineal.

incontinence score; Pelvic Floor Distress Inventory-20 (PFDI-20) questionnaire; Pelvic Floor Impact-7 (PFI-7) questionnaire; Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Global 'success' or 'satisfaction' ratings (GSR) were obtained via a variety of methods for 47 of the 62 cohorts (where 'satisfied' or 'very satisfied', 'good', 'very good' and 'excellent' were interpreted as positive outcomes) (Table 4). Further, some studies also reported individual symptoms. No study reported acquiring data objectively using personnel not involved in the surgical care of the patient or data collection blind to intervention status (RCTs were not observer-blinded).

Data were too inconsistently reported to usefully analyse efficacy outcomes either in their natural units or after standardisation. Instead a binary response of global improvement (yes/no) was derived for each cohort of

patients. Reported in 76% of procedures, random effects meta-analysis found global improvement to be 72.8% (95% CI: 66.8–78.3%), $I^2 = 86\%$ (Fig. 5); again there was considerable heterogeneity between findings. Given the crudeness and imprecision of estimates, as well as small numbers of studies/patients for some procedures, there is insufficient evidence that particular procedures provide higher levels of improvement.

For individual symptoms, changes in percentage of patients experiencing each symptom were not reported for a majority of studies. Straining was reported for 45% of total procedures; incomplete emptying for 47%; vaginal digitation for 50%. Other symptoms were less frequently reported. All symptom measures featured considerable heterogeneity and selective reporting by (generally) small studies limiting any comparison between procedures. These caveats accepted, the overall

Table 4 Percentage success based on global satisfaction ratings and individual recorded symptoms.

Authors	Year	N	FU	Global % improved	% Reduction in symptom				
					Straining	Incomplete empty	Vaginal digitation	Anal digitation	Perineal digitation
(a) Transvaginal repairs (including site specific repair)									
Transvaginal									
Arnold [24]	1990	29	24	77	NR	NR	NR	NR	NR
Infantino [26]	1995	8	36	75	88	75	75	NR	NR
Kahn [18]	1997	231	72	NR	-11	-11	67	77	77
Cundiff [29]	1998	69	12	*	30	NR	NR	NR	NR
Lopez [33]	2001	25	61	NR	NR	91	48	NR	NR
Maher [37]	2004	38	12.5	97	60	NR	84	NR	84
Nieminen [14]	2004	15	12	93	NR	NR	66	66	66
Abramov [7]	2005	183	12	NR	18	NR	NR	NR	NR
Paraiso [15]	2006	37	24	74	32	17	24	NR	24
Yamana [44]	2006	30	38	90	90	60	42	NR	NR
Gustilo-Ashby [45]	2007	33	12	48	31	28	34	NR	34
Tsujinaka [49]	2007	40	12	80	NR	NR	35	NR	35
Harris [8]	2009	37	8	78	†	NR	NR	NR	NR
Schwandner [51]	2009	102	18	70	NR	83	67	NR	67
Chung [54]	2012	24	12	75	NR	NR	NR	NR	NR
Sung [17]	2012	81	12	NR	9	30	18	NR	18
Shafik [58]	2015	84	12	94	NR	NR	NR	NR	NR
Site specific									
Abramov [7]	2005	124	12	NR	20	NR	NR	NR	NR
Paraiso [15]	2006	37	24	88	35	18	37	NR	37
Gustilo-Ashby [45]	2007	37	12	50	31	28	34	NR	34
Sardeli [48]	2007	51	27	NR	NR	14	NR	NR	NR
Guzman Rojas [57]	2015	137	16	85	36	NR	NR	NR	NR
(b) Transanal repairs									
Block sutured									
Arnold [24]	1990	35	NR	83	80	NR	NR	NR	NR
Infantino [26]	1995	13	24	85	92	77	86	NR	NR
Van Laarhoven [31]	1999	7	27	43	NR	0	17	NR	NR
Boccasanta [32]	2001	44	24	42	NR	NR	NR	NR	NR
Tsujinaka [49]	2007	71	12	83	NR	NR	34	NR	34
Stapled									
Boccasanta [32]	2001	15	11.3	42	NR	NR	NR	NR	NR
Ayav [35]	2004	21	58	76	NR	76	67	NR	NR
Harris [8]	2009	36	8	83	†	NR	NR	NR	NR
Leal [52]	2010	35	12	88	‡	NR	NR	NR	NR
Cruz [53]	2011	75	21	NR	NR	NR	NR	NR	NR
Mahmoud [55]	2012	22	12	78	51	45	45	NR	NR
Delorme's style									
Janssen [25]	1994	76	12	84	56	41	21	NA	NA
Murthy [27]	1996	33	31	62	19	19	NR	NR	NR
Khubchandani [28]	1997	123	38	82	NR	NR	NR	NR	NR
Tjandra [30]	1999	59	19	NR	NR	78	39	39	NR
Boccasanta [32]	2001	82	24	42	NR	NR	NR	NR	NR
Ayabaca [34]	2002	13	48	69	68	NR	NR	NR	NR
Nieminen [14]	2004	15	12	73	NR	NR	39	39	39
Dippolito [39]	2005	13	16	92	NR	86	NR	NR	NR

Table 4 (Continued).

Authors	Year	N	FU	Global % improved	% Reduction in symptom				
					Straining	Incomplete empty	Vaginal digitation	Anal digitation	Perineal digitation
Roman [41]	2005	71	74	29.6	NA	50.7	42.30	42.3	NA
Thornton [42]	2005	40	44	28	NR	NR	NR	NR	NR
Puigdollers [47]	2007	11	12	66	52	74	52	NR	52
Chung [54]	2012	26	12	77	NR	NR	NR	NR	NR
Mahmoud [55]	2012	23	12	78	51	45	45	NR	NR
Combined TV and TA									
van Dam [22]	2000	89	52	69	NR	NR	NR	NR	NR
(c) Transperineal repairs									
Boccasanta [32]	2001	50	24	41	NR	NR	NR	NR	NR
Ayabaca [34]	2002	11	48	73	NR	NR	NR	NR	NR
Puigdollers [47]	2007	24	12	66	52	74	52	NR	52
(d) Mesh repairs									
Mesh									
Van Laarhoven [31]	1999	15	27	87	NA	67	47	NA	NA
Mercer-Jones [38]	2004	22	12.5	55	30	50	23	NA	NA
Milani [40]	2005	63	17	NA	NA	NA	NA	NA	NA
Altman [43]	2006	23	36	NA	16	6	15	-6	NA
Paraiso [15]	2006	31	24	90	27	65	44	NA	44
Gustilo-Ashby [45]	2007	29	12	76	31	28	34	NA	34
Lim [46]	2007	53	36	47	31	NA	NA	NA	NA
Biehl [50]	2008	95	13.8	NA	NA	NA	NA	NA	NA
Biehl [50]	2008	100	13.8	NA	NA	NA	NA	NA	NA
Sung [17]	2012	79	12	NA	9.2	30	18	NA	18
van der Hagen [56]	2012	27	12	NA	NA	NA	NA	NA	NA
Melich [59]	2016	23	12	NA	NA	NA	NA	NA	NA

Negative values indicate increase in symptoms.

*Global improvement over all studied = 8.6 (scale from 0 to 10).

†ODS score Post 1.86 (no data pre).

‡Cleveland Clinic Constipation score Pre 15.2 vs Post 4.4 ($P = 0.001$).

pooled finding for reduction in strain was 38.0% (95% CI: 27.1–49.6%), $I^2 = 94%$; reduction in incomplete emptying was 44.4% (95% CI: 30.2–58.9%), $I^2 = 96%$; and reduction in vaginal digitation was 42.7% (95% CI: 34.9–50.6%), $I^2 = 86%$.

The aim of reinforcing the rectovaginal septum is to restore normal anatomy which theoretically will enable normal evacuation. Given the underlying aim of surgery is to correct anatomy, an assessment of anatomical recurrence is also important (although this is necessarily only a surrogate of clinical outcome). Studies variously and inconsistently reported clinical, radiological and symptom recurrence (Table 5). Clinical recurrence was reported for 44% of cohorts (Fig. 6). The overall clinical recurrence rate was 17.1% (95% CI: 11.7–23.3%), $I^2 = 89%$, with individual

findings for procedures varying from 0% to 55%. There is a suggestion that site specific TVR features a higher clinical recurrence rate than other procedures, based on four studies and 349 patients, although this may be a chance finding given the selective reporting by studies (Fig. 6). One study showed that the results of a site specific repair are further compromised by the concurrent use of collagen mesh [15].

Summary evidence statements: efficacy

- Data on efficacy were inconsistently measured and findings heterogeneous, making estimates tentative and imprecise (level IV).
- Although inconsistent, assessments of patient global improvement typically suggest a good outcome in about 67–78% of patients (level IV).

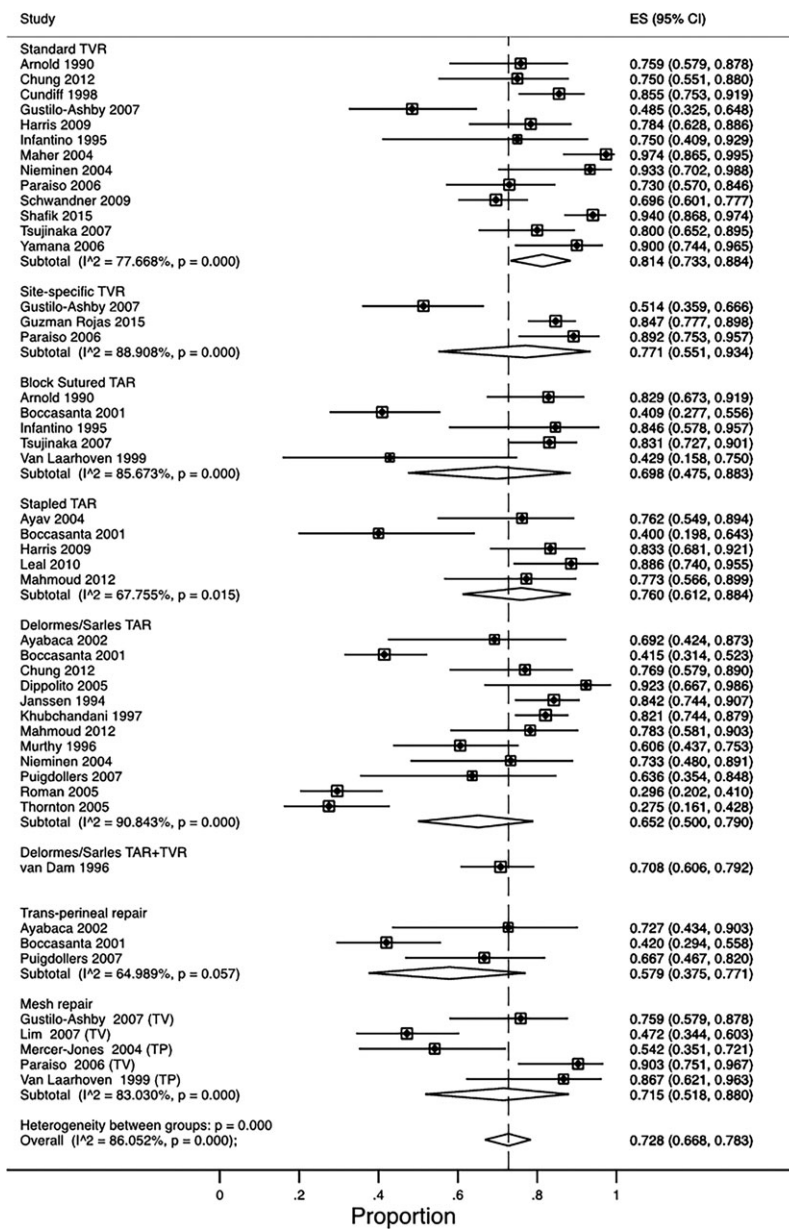


Figure 5 Forest plot showing rates of global rating of satisfaction (percentage of patients) by procedure type. KEY: TVR, transvaginal repair; TAR, transanal repair; TV, transvaginal; TP, transperineal.

- Findings for global improvement, derived from global satisfaction rating scales, provide insufficient evidence to prefer one type of procedure over another (level IV).
- Other patient symptom scores were inconsistently reported (level IV).
- Approximately 30–50% of patients may experience reduced symptoms of straining, incomplete emptying or reduced vaginal digitation (level IV).
- Anatomical recurrence (as judged by a variety of measures) occurred in approximately 17% patients at mean follow up of 23.4 months (range 12–74) (level IV).

Patient selection

Patient selection is generally perceived by experts as important when choosing a surgical approach. There was a vast variation in the preoperative investigation of patients in the studies. Most studies included evacuation imaging (33 out of the total 43) where defaecation proctography was used in all but one (which used isotope imaging) [36]. There was selective use of anal ultrasound, anorectal physiological assessment, with colonic transit studies being recorded in 12 studies. There was however little correlation between the results of surgery and preoperative investigation results. Key features include the presence of a symptomatic

Table 5 Recurrence rates by type of operation

Authors	Year	N	FU	Recurrence rate %		
				Clinical	Radiological	Symptoms
(a) Vaginal repairs						
Transvaginal						
Arnold [24]	1990	29	NR	NR	NR	NR
Infantino [26]	1995	8	36	13	NR	NR
Kahn [18]	1997	231	72	11	NR	NR
Cundiff [29]	1998	69	12	NR	NR	NR
Lopez [33]	2001	25	61	NR	NR	NR
Maher [37]	2004	38	12.5	NR	NR	NR
Nieminen [14]	2004	15	12	7	7	7
Abramov [7]	2005	183	12	18	NR	4
Paraiso [15]	2006	37	24	25	NR	NR
Yamana [44]	2006	30	38	0	3.3	0
Gustilo-Ashby [45]	2007	33	12	NR	NR	NR
Tsujinaka [49]	2007	40	12	NR	NR	NR
Harris [8]	2009	37	8	11	NR	NR
Schwandner [51]	2009	102	18	NR	NR	53
Chung [54]	2012	24	12	NR	NR	NR
Sung [17]	2012	81	12	39	NR	35
Shafik [58]	2015	84	12	NR	NR	6
Site specific						
Abramov [7]	2005	124	12	44	NR	11
Paraiso [15]	2006	37	24	40	NR	NR
Gustilo-Ashby [45]	2007	37	12	NR	NR	NR
Sardeli [48]	2007	51	27	41	NR	NR
Guzman Rojas [57]	2015	137	16	25	20	34
(b) Transanal repairs						
Block suture						
Arnold [24]	1990	35	NR	NR	NR	NR
Infantino [26]	1995	13	24	7.6	NR	NR
Van Laarhoven [31]	1999	7	27	NR	NR	NR
Boccasanta [32]	2001	44	24	13	NR	5.9
Tsujinaka [49]	2007	71	12	NR	NR	NR
Stapled						
Boccasanta [32]	2001	15	11.3	13	NR	5.9
Ayav [35]	2004	21	58	NR	57	NR
Harris [8]	2009	36	8	2.7	NR	NR
Leal [52]	2010	35	12	NR	NR	NR
Cruz [53]	2011	75	21	NR	11	NR
Mahmoud [55]	2012	22	12	NR	NR	NR
Delorme's style						
Janssen [25]	1994	76	12	84	56	41
Murthy [27]	1996	33	31	NR	NR	NR
Khubchandani [28]	1997	123	38	8.9	NR	8.9
Tjandra [30]	1999	59	19	NR	NR	1.7
Boccasanta [32]	2001	82	24	13	NR	5.9
Ayabaca [34]	2002	13	48	NR	NR	NR
Nieminen [14]	2004	15	12	40	40	33
Dippolito [39]	2005	13	16	92	NR	86
Roman [41]	2005	71	74	29.6	NA	50.7

Table 5 (Continued).

Authors	Year	N	FU	Recurrence rate %		
				Clinical	Radiological	Symptoms
Thornton [42]	2005	40	44	NR	NR	56
Puigdollers [47]	2007	11	12	NR	NR	NR
Chung [54]	2012	26	12	NR	NR	NR
Mahmoud [55]	2012	23	12	NR	NR	NR
Combined TV and TA						
van Dam [22]	2000	89	52	NR	NR	29
(c) Transperineal repairs						
Boccasanta [32]	2001	50	24	13	11	6.40
Ayabaca [34]	2002	11	48	NR	NR	NR
Puigdollers [47]	2007	24	12	NR	NR	NR

Authors	Year	N	FU	Recurrence rate %			Repair type	Mesh type
				Clinical	Radiological	Symptoms		
(d) Mesh repair								
Van Laarhoven [31]	1999	15	27	NA	NA	NA	TP/TA	Synthetic marlex
Mercer-Jones [38]	2004	24	12.5	4.50	NA	NA	TP	Synthetic prolene/Vipro II
Milani [40]	2005	63	17	NA	NA	NA	TV	Synthetic prolene
Altman [43]	2006	23	36	NA	NA	NA	TV	Porcine xenograft
Paraiso [15]	2006	31	24	55	NA	NA	Site specific	Porcine xenograft
Gustilo-Ashby [45]	2007	29	12	NA	NA	NA	TV	Porcine xenograft
Lim [46]	2007	53	36	22	NA	NA	TV	Synthetic vipro II
Biehl [50]	2008	95	13.8	1	NA	NA	Site specific	Porcine dermal xenograft
Biehl [50]	2008	100	13.8	7	NA	3	Site specific	Human dermal allograft
Sung [17]	2012	79	12	38.9	NA	34.8	TV	Porcine subintestinal submucosa
van der Hagen [56]	2012	27	12	NA	NA	NA	TV	Synthetic prolene
Melich [59]	2016	23	12	4	4	4	TV	Porcine dermal xenograft strattice

rectocele greater than 2 cm on proctography with evidence of contrast trapping at the end of maximal evacuation. Where graded, generally rectoceles operated upon were grade 2 or 3. Only one study measured the rectocele clinically with POPQ assessment [37]. Other than medical co-morbidity precluding surgery there were very few consistent exclusion criteria in any of the studies, although several excluded those women with slow transit constipation. Furthermore, in the few studies that related preoperative assessment to outcome, none could show an association between baseline symptoms or size of rectocele and functional outcome. The need to digitate to assist evacuation did not appear to predict outcome following surgery, but may predict the need to digitate postoperatively.

Summary evidence statements: patient selection

- Although patient selection is perceived as vital in predicting outcome it was inconsistently documented (level IV).

- There was no evidence to support better outcomes based on selection of patients with a particular size or grade of rectocele (level IV).

Conclusions

A systematic review of evidence for the perioperative and long terms benefits and harms of recto-vaginal reinforcement procedures to treat symptoms of constipation identified only one high quality study. Two further randomized controlled trials were identified although these were small and had methodological limitations. The evidence base was therefore characterised almost exclusively by observational studies of variable and often uncertain methodological quality. Future studies should provide robust and comparative evidence for clinicians to support patient decision making, both in terms of the incremental benefits and harms of procedures.

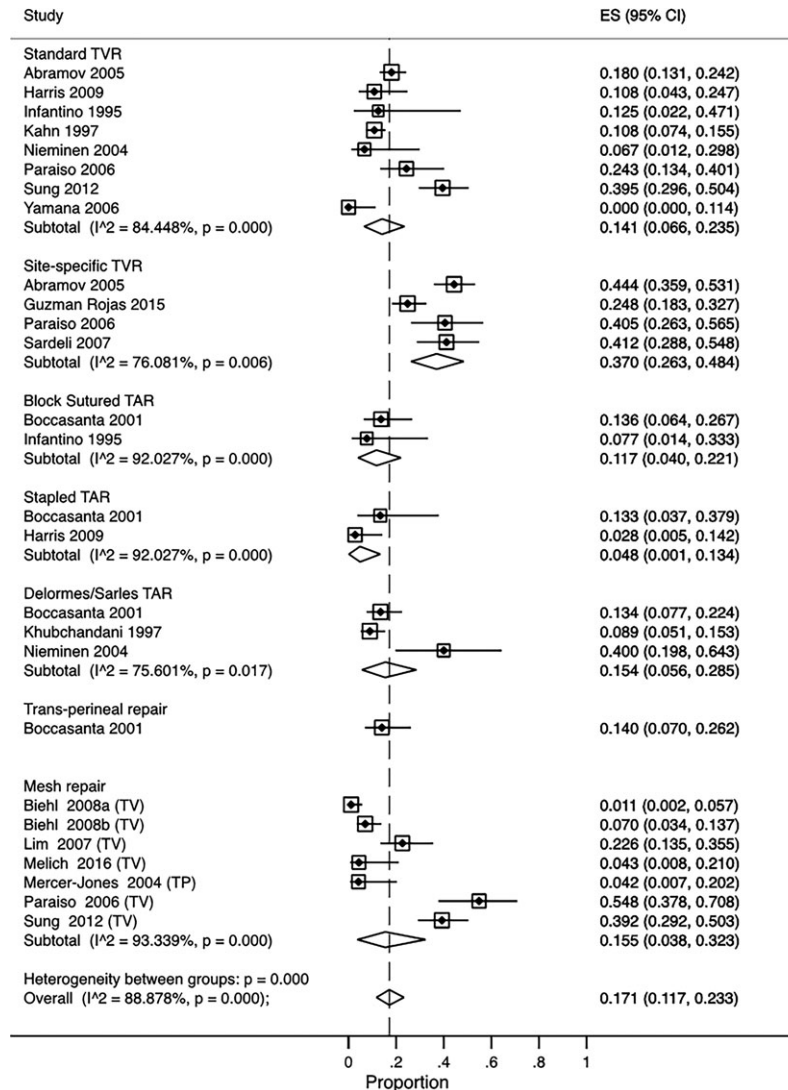


Figure 6 Forest plot showing rates of clinical recurrence (percentage of patients) by procedure type. KEY: TVR, transvaginal repair; TAR, transanal repair; TV, transvaginal; TP, transperineal.

Greater understanding is required of the mediating effects of prognostic factors particularly preoperative definition of both functional and radiological parameters that impact upon treatment success.

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Conflicts of interest

The authors declare no conflict of interest.

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