Systematic review

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Surgery for constipation: systematic review and practice recommendations

Results III: Rectal wall excisional procedures (Rectal Excision)

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Abstract

Aim To assess the outcomes of rectal excisional 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-seven studies were identified, providing data on outcomes in 8340 patients. Average length of procedures was 44 min and length of stay (LOS) was 3 days. There was inadequate evidence to determine variations in procedural duration or LOS by type of procedure. Overall morbidity rate was 16.9% (0–61%), with lower rates observed after Contour Transtar procedure (8.9%). No mortality was reported after any procedures in a total of 5896 patients. Although inconsistently reported, good or satisfactory outcome occurred in 73–80% of patients; a reduction of 53–91% in Longo scoring system for obstructive defecation syndrome (ODS) occurred in about 68–76% of patients. The most common long-term adverse outcome is faecal urgency, typically occurring in up to 10% of patients. Recurrent prolapse occurred in 4.3% of patients. Patients with at least 3 ODS symptoms together with a rectocoele with or without an intussusception, who have failed conservative management, may benefit from a rectal excisional procedure.

Conclusion Rectal excisional procedures are safe with little major morbidity. It is not possible to advise which excisional technique is superior from the point of view of efficacy, peri-operative variables, or harms. Future study is required.

Keywords surgery, constipation, rectal excision, STARR, TRANSTAR

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 characterized 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. The most common abnormalities are rectocoele and/or intussusception. Theoretically, these anatomical variants could lead to the features of obstructed defaecation by a process of loss of force vector (ballooning of the rectum into a rectocoele or invagination of the rectum into an intussusception, rather than evacuation of stool on straining) or mucosal obstruction (in the case of an intussusception) [1]. Correction of these variants can be carried out by surgically excising the redundant rectal wall, i.e. that ballooning out or prolapsing in, thus restoring 'normal' anatomy.

Techniques

The stapled transanal rectal resection (STARR) procedure uses two circular procedure for prolapsing

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haemorrhoids (PPH)01 stapling devices (Ethicon Endosurgery, INC., Cincinnati, Ohio, USA), or at times, two circular PPH03 devices. They are used sequentially to remove the anterior rectal wall prolapse and then the posterior rectal wall prolapse. These full thickness rectal wall excisions result in defects that are anastomosed with staples contained within the device. The STARR procedure was derived from the technique of stapled haemorrhoidopexy and was introduced into clinical practice by Antonio Longo using the PPH01 device [2]. Initially, most STARR procedures were performed with PPH01; however, subsequently the PPH03 device was developed, essentially for haemorrhoidopexies, to reduce intra-operative staple line bleeding. The two devices, PPH01 and PPH03, differ only with respect to the closed staple height, which varies between 1–2.5 mm and 0.75–1.5 mm, respectively. The PPH03 device is no longer licensed for use for STARR because of concerns that the staple line height was insufficient for the thickness of tissue that was resected and anastomosed. As with all new techniques, in order to ensure that safety and efficacy concerns were addressed, a number of initiatives were put in place by the manufacturer. The procedure could only be performed by trained surgeons who then mentored other surgeons. In the UK, the PPH01 device is no longer used for haemorrhoidopexies, and consequently Ethicon will only permit the sale of this device to institutions with surgeons trained in the STARR technique. The European STARR registry was established through collaboration between Ethicon Endosurgery and the colorectal societies in the UK, France, Germany and Italy. Outcomes from this registry have been published and, in response, the National Institute for Health and Care Excellence (NICE) issued interventional procedure guidance in 2010. The NICE guidance concluded that 'the current evidence on safety and efficacy of stapled transanal rectal resection (STARR) for obstructed defaecation syndrome (ODS) is adequate ..... the procedure may therefore be used with normal arrangements for clinical governance, consent and audit.' [www.nice.org.uk/ipg351].

Despite its proven safety and efficacy, the STARR procedure still had limitations. These were primarily related to the stapling device itself. The two biggest concerns were that the rectal resection was performed 'blind' within the low rectum and that the volume of the resected tissue was entirely dependent upon the capacity of the stapling device housing, rather than the extent of the prolapse. As such, the surgeon was unable to modify the extent of resection in relation to the size of the prolapse. Consequently, a new stapling device, the Contour Transtar curved cutter stapler (Ethicon Endosurgery, INC.), was introduced [3] in order to allow a tailored correction of the prolapse by removing more tissue. It would also allow this resection to be performed under direct vision. The Contour Transtar stapler utilises replaceable staple cartridges allowing multiple firings with a single device.

Although STARR has been heavily popularized, it is not the first procedure to use of rectal excision as a means of treating prolapse. Edward Delorme originally described his procedure for full-thickness external rectal prolapse in 1900 [4]. There have been several modifications, one being an intra-anal Delorme's procedure for the treatment of recto-anal intussusception [5]. Unlike STARR and Contour Transtar, there is no full-thickness rectal wall excision and only the redundant mucosa is excised. The mucosa is stripped cephalad, and the underlying muscle is plicated together with sutures to concertina the prolapse.

Scope

The purpose of this review was to assess the efficacy and harms of rectal excisional procedures for internal prolapse and/or rectocoele in adults. Procedures considered beyond the scope of systematic review included: (i) those where 'tightening' is effected without excision (covered in rectovaginal reinforcement systematic review); (ii) those where only mucosa is excised (mucosectomy) and there is no plication of the muscular wall; (iii) those where a mucosectomy and plication are limited to the anterior wall (covered in rectovaginal reinforcement systematic review); (iv) those where the whole rectum is resected rather than a component of the wall, i.e. as occasionally performed for megarectum [6]. 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, transanal endocopic microsurgery procedures, technical reports, or cost analyses only.

Previous reviews

One previous meta-analysis including 26 studies [7] addressed the outcome of rectal excisional procedures for constipation.

Summary of search results and study quality

The search yielded a total of 84 articles for full text review (Fig. 1). From these, 47 published between

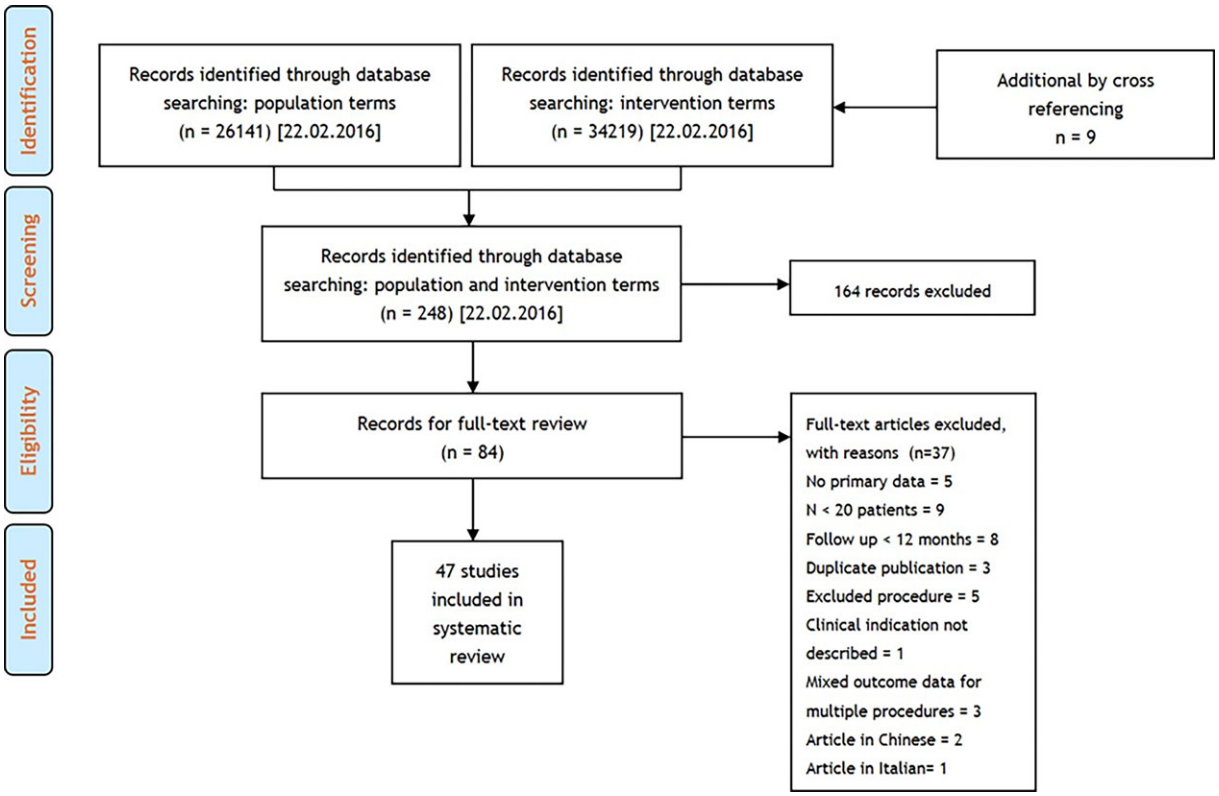

Figure 1 PRISMA diagram of search results.

2000 and 2014 contributed to the systematic review, providing data on outcomes in a total of 8340 patients (range 20–2224 patients per study) (Table 1). Specific exclusions after full-text review (and after exclusion of non-English language publications) included nine studies where the population sample was confirmed to be < 20 patients, eight where follow-up was < 12 months; five studies with out of scope procedures [8–11], three studies where data were considered duplicate [12,13], and three where outcomes could not be segregated by eligible procedure. Other exclusion criteria were: indication not constipation ($n = 1$) and lack of extractable outcome data ($n = 5$).

The quality of studies varied. The 47 included studies (Table 1) included 42 observational studies and five randomised controlled trials (RCTs). The latter included three good quality RCTs (level IB) with low levels of predicted bias, and two with less well described methodology (level IIB). The remaining 42 observational studies encompassed several good quality prospective cohort studies with low levels of bias including four prospectively maintained funded registries (level IIB). Other studies were a mix of prospective and retrospective case series. Mean study follow-up was 1.9 years (range 1.0–5.5 years); 36 studies originated from European centres, three from the USA and eight from other countries.

Perioperative data

Perioperative data were reported by 47 studies reporting 55 procedures (Tables 2 and 3). Measures of variation of continuous measures included ranges or standard deviations but were inconsistently reported. Average procedural duration and length of stay (LOS) varied between procedures but design heterogeneity, small numbers of studies and large range of values precluded any clear conclusions (Table 3). The overall average duration of procedures reported by cohorts was 44 (range 23–95) min, and the overall average LOS was 3.0 (range 1.0–8.0) days (Figs 2 and 3). In one RCT of 100 patients (STARR *vs* Contour Transtar) [37], Contour Transtar took significantly longer to perform (52.2 *vs* 42.4 minutes $P = 0.008$). However this reduction was not apparent more broadly within the pooled findings (Fig. 2). While LOS for intra-anal Delorme's procedure was shorter (2 days) this was based on only one study reporting this outcome in 34 patients.

Table 1 All studies included in systematic review.

Author	Year	Centre	Country	Total *N*	FU*	Design	Level†
Liberman [14]	2000	Omaha	USA	34	43	RCS	IV
Boccasanta [15]	2004	Milan	Italy	50	23	RCT	IB
Boccasanta [16]	2004	Milan	Italy	90	16	PCH	IIB
Pescatori [17]	2006	Rome	Italy	26	36	RCS	IV
Arroyo [18]	2007	Elche	Spain	37	24	PCH	IIB
Gagliardi [19]	2008	Multicentre	Italy	85‡	17	RCS	IV
Dindo [20]	2008	Zurich	Switzerland	24	18	PCH	IIB
Lehur [21]	2008	Multicentre	France, Italy, UK	119	12	RCT	IIB
Arroyo [22]	2008	Multicentre	Spain	104	26	PCH	IIB
Lenisa [3]	2009	Multicentre	Europe	75	12	PCH	IIB
Harris [23]	2009	Orlando	USA	75	12	RCH	IV
Jayne [24]	2009	Multicentre	UK, Germany, Italy	2224§	12	PCH	IIB
Reboa [25]	2009	Genoa	Italy	33	18	PCH	IIB
Boccasanta [26]	2010	Milan	Italy	142	24	PCH	IIB
Isbert [27]	2010	Nuremberg	Germany	150	12	RCH	IIB
Zhang [28]	2010	Beijing	China	50	12	PCH	IIB
Madbouly [29]	2010	Alexandria	Egypt	46	42	PCH	IIB
Schwandner [30]	2010	Regensburg	Germany	379	12	PCH	IIB
Ram [31]	2010	Ramat Aviv	Israel	30	26	PCS	IV
Zehler [32]	2010	Hamburg	Germany	20	66	PCS	IV
Goede [33]	2011	Bristol	UK	344	12	PCS	IV
Meurette [34]	2011	Nantes	France	30	48	PCS	IV
Martellucci [35]	2011	Siena	Italy	133	19	PCS	IV
Patel [36]	2011	Houston	Texas	37	20	PCH	IIB
Boccasanta [37]	2011	Milan	Italy	100	36	RCT	IB
Stuto [38]	2011	Pordenone	Italy	2171	12	PCH	IIB
Song [39]	2011	Seoul	South Korea	58	34	RCH	IV
Ding [40]	2011	Beijing	China	86	12	PCH	IIB
Renzi [41]	2011	Naples	Italy	61	24	RCT	IB
Reibetanz [42]	2011	Wuerzburg	Germany	170	18	RCH	IIB
Naldini [43]	2011	Pisa	Italy	30	24	PCH	IIB
Biviano [8]	2011	Rome	Italy	60	38	PCH	IIB
Savastano [44]	2012	Vicenza	Italy	64	27	PCH	IIB
Jiang [45]	2012	Wuhan	China	43	12	RCS	IV
Boenicke [46]	2012	Wuerzburg	Germany	181	19	PCH	IIB
Kohler [47]	2012	Dresden	Germany	80	39	PCS	IV
Hasan [48]	2012	Cairo	Egypt	40	12	PCH	IIB
Ganio [49]	2013	Vercelli	Italy	167	36	RCS	IV
Adams [50]	2013	London	UK	37	13	RCS	IV
Masoni [51]	2013	Rome	Italy	187	12	RCS	IV
Bock [52]	2013	St Gallen	Switzerland	70	48	RCS	IV
Zhang [53]	2013	Beijing	China	75	30	PCH	IIB
Panicucci [54]	2014	Pisa	Italy	54	12	PCH	IIB
Borie [55]	2014	Nimes	France	52	18	RCH	IV
Ribaric [56]	2014	Multicenter	Europe	100	12	PCH	IIB
Gentile [57]	2014	Naples	Italy	66	12	RCT	IIB
Leardi [58]	2014	L'Aquila	Italy	51	36	PCS	IV

RCS, retrospective cohort study; PCS, prospective case series; RCT, randomised controlled trial; PCH, prospective cohort study.
*Mean follow up in months.
†Oxford CEBM [13].
‡Report on 123 patients, but only 85 operated on.
§Report on 2838 patients for complications, 2224 reached 12 months follow-up.

Table 2 Perioperative data by procedure.

Author	Year	N	Time (minutes)	LOS (days)	Post-op bleed Req. Treatment %	Sepsis %	Post-op anastomotic dehiscence %	Total complications %	Mortality %
(a) PPH-01									
Boccasanta [15]	2004	25	41.8 ± 6	2.1 ± 0.8	4	0	0	40	0
Boccasanta [16]	2004	90	43.3 ± 9	2.1 ± 0.8	4.4	0	0	16.5	0
Arroyo [18]	2007	17	45.9 (9.8)	NR	6	0	0	NR	0
Gagliardi [19]	2008	85 †	NR	NR	2.3	3	0	18	0
Dindo [20]	2008	24	60 (40–110)	3 (1–10)	4.1	0	0	25	0
Lehur [21]	2008	119	40 (15–56)	2.1 (1–6)	1.8	1.8	0	15	0
Arroyo [22]	2008	37‡‡	46.7 (9.3)	2.2 (0.7)	2.8	0	0	NR	0
Boccasanta [26]	2010	74	35.8 ± 6.1	2.6 ± 0.5	4	0	0	28.3	0
Harris [23]	2009	36	52.7	2.6	19.4§§	2.8	0	61.1¶¶	0
Isbert [27]	2010	68	57 ± 15.4	3.4 ± 1.6	3	0	2	7.3	0
Jayne [24]	2009	2224‡	44 (15–210)	3.7 (1–36)	5	4.4	3.5*	36	0
Reboa [25]	2009	33	37 ± 7	1.5 ± 0.6	0	0	0	15.1	0
Zhang [28]	2010	50	28	NR	0	0	0	NR	0
Madbouly [29]	2010	46	48.4 ± 9.6	1	0	0	0	15.2	0
Schwandner [30]	2010	379	40	5.5	2.9	1.6	7.1*	21.2	0
Ram [31]	2010	30	40 (35–80)	2 (1–4)	0	0	NR	36.7	0
Zehler [32]	2010	20	53.5 (45–65)	8 (3–22)	15	0	0	20	0
Goede [33]	2011	344	NR	NR	2.7	NR	NR	16.3	0
Meurette [34]	2011	30	40 ± 8	3 ± 1	NR	NR	NR	27	0
Patel [36]	2011	37	NR	1	0	NR	NR	35.1	0
Boccasanta [37]	2011	50	42.4 (6.9)	3.2 (0.6)	2	0	0	4	0
Stuto [38]	2011	2171¶	95 (15–230)	3.6 (1–21)	NR	NR	NR	NR	NR
Song [39]	2011	58	35.1 ± 11.3	3.91 ± 0.84	4	0	NR	NR	0
Ding [40]	2011	86	30 ± 7	5 ± 1.8	0	0	0	NR	0
Renzi [41]	2011	30	28.1 (11.5)	1.2 (0.5)	6.6	0	NR	NR	0
Reibetanz [42]	2011	170§	NR	NR	0	0	0.6	7	0
Naldini [43]	2011	15	NR	3.4 (3–6)	0	NR	NR	0	0
Biviano [8]	2011	30	NR	NR	0	0	0	6	0
Savastano [44]	2012	32	28 (20–45)	2 (1–3)	13	0	0	NR	0
Boenicke [46]	2012	181**	NR	NR	1	0	0.5	8.2	0
Kohler [47]	2012	80	67 (34–182)	NR	6	1	1	22.5	0
Hasan [48]	2012	40	35 ± 10	1.7 ± 2.3	0	0	0	NR	0
Adams [50]	2013	37	NR	1 (0–8)	5.4	2.7	0	32	0
Zhang [53]	2013	75	NR	NR	0	0	0	NR	0
Panicucci [54]	2014	54 ††	NR	NR	NR	NR	NR	NR	NR
Borie [55]	2014	25	NR	5.6 ± 2.1	0	0	0	24	0
Leardi [58]	2014	51	NR	3	2	0	0	2	0
(b) PPH03									
Arroyo [18]	2007	20	40.1 (10.4)	NR	0	0	0	NR	0
Arroyo [22]	2008	67***	46.7 (9.3)	2.2 (0.7)	2.8	0	0	NR	0
Jiang [45]	2012	43	23 ± 4	5 (4–6)	0	0	0	NR	0
Gentile [57]	2014	30	40	NR	NR	NR	NR	20	NR
(c) Contour Transtar									
Lenisa [3]	2009	75	45 (24–90)	4 (1–16)	2.6	0	0	7	0
Isbert [27]	2010	82	51 ± 18.2	3.6 ± 2.3	3	0	0	7.5	0
Martellucci [35]	2011	133	42 (26–71)	NR	1.5	NR	1.5	15.7	0
Boccasanta [37]	2011	50	52.2 (8.7)	3.5 (1.0)	2	0	0	2	0
Renzi [41]	2011	31	33.1 (15.7)	1.25 (0.5)	3.2	0	NR	NR	0

Table 2 (Continued).

Author	Year	*N*	Time (minutes)	LOS (days)	Post-op bleed Req. Treatment %	Sepsis %	Post-op anastomotic dehiscence %	Total complications %	Mortality %
Naldini [43]	2011	15	NR	3.1 (2–5)	3.3	NR	NR	3.3	0
Savastano [44]	2012	32	43 (32–65)	4 (3–7)	6	0	9.3	NR	0
Masoni [51]	2013	187	48 (32–78)	< 3	0	0	0	7.4	0
Bock [52]	2013	70	NR	NR	0	0	0	23	0
Ribaric [56]	2014	100	43.8 ± 13.9	4.36 ± 2.75	1	0	0	11	0
(d) Intra-anal Delorme's procedure									
Liberman [14]	2000	34	NR	1.8 (2.4)	3	8.8	0	35.3	0
Pescatori [17]	2006	26	NR	NR	15.4	16†††	12.5†††	45†††	0
Ganio [49]	2013	167‡‡‡	NR	NR	0	1.2	1.8	10.2	0
Gentile [57]	2014	36	65	NR	NR	NR	NR	19.4	0

NR, not recorded.
All PPH03, except Jiang [45] translinear stapler.
*Reported as staple line complications, including dehiscence.
†Report on 123 patients, but only 85 operated on.
‡Report on 2838 patients for complications, 2224 reached 12 months follow-up.
§101 patients had Countour Transtar.
¶208 patients had Contour Transtar.
**Some patients had Contour Transtar.
††18 patients had Contour Transtar.
‡‡Complications are reported for 104 patients (67 had PPH03).
§§It is uncertain if this required intervention as recorded as 'rectal bleeding'.
¶¶Total complications included tenesmus, diarrhoea, faecal incontinence, and pruritis ani.
***Complications are reported for 104 patients (37 had PPH01); NR: not recorded.
†††These percentages are based upon analysis of 40 patients (14 patients having had PPH01 or PPH01 with manual mucosectomy).
‡‡‡91 patients also had levatoroplasty.

Summary evidence statements: perioperative data

1 The average duration of procedures was 44 min, although this ranged widely between studies from 23 to 95 min (level II).
2 The average length of stay was 3 days although this ranged widely between studies from 1 to 8 days (level II).
3 There was inadequate evidence to determine variations in procedural duration or length of stay by type of procedure (level IV).

Harms

Perioperative complications

Five measures of perioperative harm were reported by a majority of studies within the review. In general, there was considerable heterogeneity between cohort findings. This heterogeneity may have reflected (for example) differing inclusion, procedural content, context of care, or thresholds or conventions for recording complications.

Overall procedural complication rates varied between cohorts from 0% to 61% Fig. 4. Random effects meta-analysis found the overall complication rate to be 16.9% (95% CI: 12.7–21.5%), I^2 = 93%. The Contour Transtar procedure reported a lower overall complication rate of 8.9% (95% CI: 5.1–13.5%), I^2 = 70%, although cohort findings within this category were heterogeneous and non-comparative. The two RCTs (IB) comparing STARR to Contour Transtar reported no difference in perioperative complication rates [37,41], although these included only 161 patients in total and six events. A more generalisable estimate of the overall complication rate may come from the European STARR registry which reported an overall morbidity rate of 36% from 2838 patients [24]. The inclusion criteria for morbidity in this registry incorporated urgency (20%), but this was not universally applied in most other studies, explaining its discrepancy from the pooled findings.

Rates of post-operative bleeding requiring treatment varied between cohorts from 0% to 19% (Fig. 5). Random effects meta-analysis found the pooled bleed rate to be 1.6% (95% CI: 0.9–2.5%), I^2 = 63%. Regarding

Table 3 Procedural data.

	Procedure duration (mins)			Length of stay (days)			Follow-up (months)		
Procedure	*N*	Mean	Range	*N*	Mean	Range	*N*	Mean	Range
PPH-01	25	44.6	(28.0–95.0)	25	2.9	(1.0–8.0)	37	23.0	(12.0–66.0)
PPH-03	4	37.5	(23.0–46.7)	2	3.6	(2.2–5.0)	4	18.5	(12.0–26.0)
Contour Transtar	8	44.8	(33.1–52.2)	7	3.4	(1.3–4.4)	10	22.6	(12.0–48.0)
Delorme's	1	65.0	–	1	1.8	–	3	38.3	(36.0–43.0)
Total	37	43.8	(23.0–95.0)	35	3.0	(1.0–8.0)	54	23.5	(12.0–66.0)

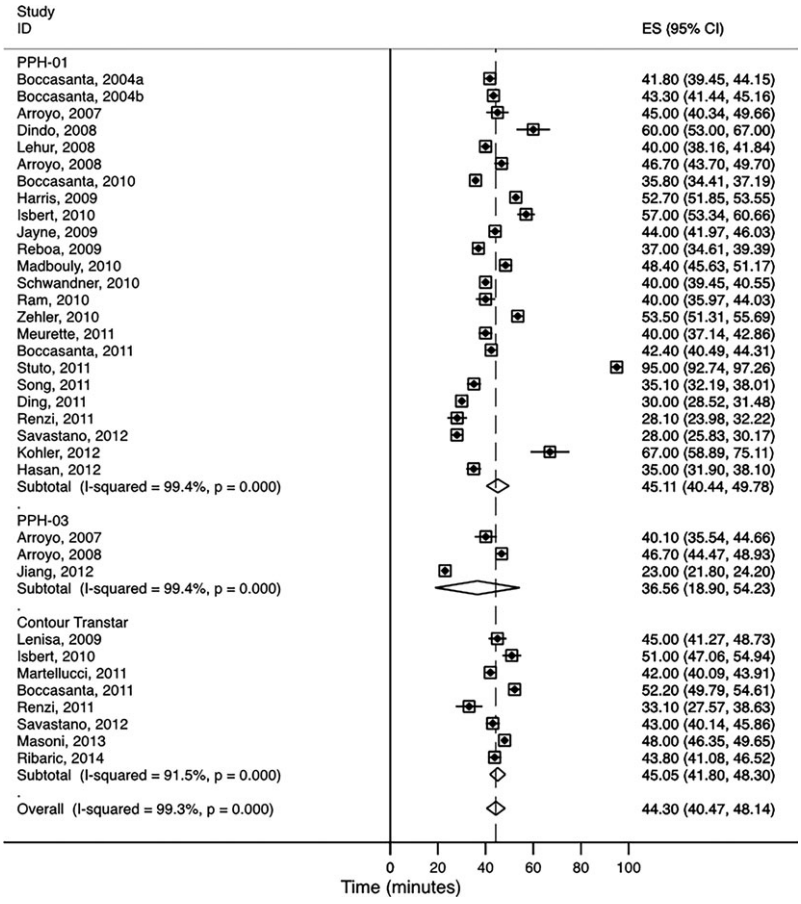

Figure 2 Forest plot showing procedure duration by operation type.

intra-operative bleeding from staple lines, results from one prospective cohort study (IIB) showed that less intraoperative staple line sutures were required with PPH03 compared with PPH01 [18]. Details of treatments provided (e.g. transfusion or re-operation) were unclear in many instances.

Sepsis rates varied from 0% to 16%, but were consistently low, occurring in no patients in 78% of cohorts reported. Random effects meta-analysis found the sepsis rate to be 0.2% (95% CI: 0.0–0.7%), $I^2 = 63\%$. Septic complications were mostly related to urinary tract infections, *C. difficile* infection, or more rarely, pneumonia. Sepsis rates for Delorme's procedure appeared high at 6.2% (95% CI: 0.0–19.4%), $I^2 = 82\%$, but findings from the three studies were highly heterogeneous and the only moderately large study [49] reported a 1.2% sepsis rate. The rate of post-operative anastomotic dehiscence (wound rupture) varied between cohorts from 0% to 13% but was consistently low, occurring in no patients in 76% of cohorts reported. Random effects meta-analysis found the pooled rate of anastomotic dehiscence to be 0.3% (95% CI: 0.0–0.8%), $I^2 = 62\%$.

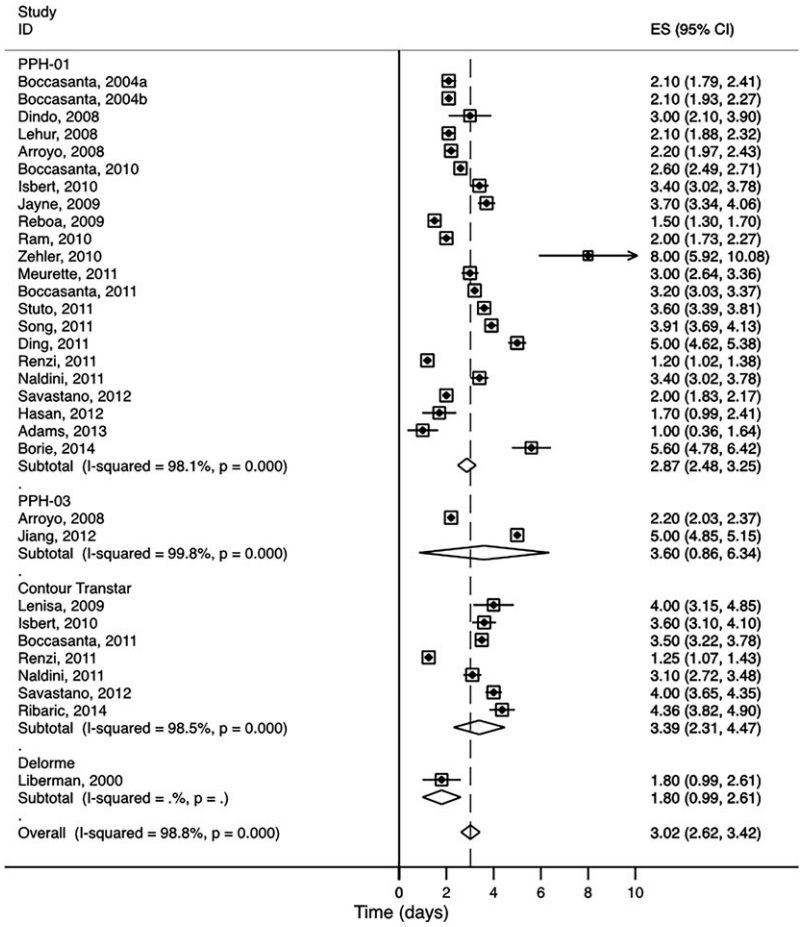

Figure 3 Forest plot showing length of stay by operation type.

There was inadequate evidence to select between procedures on the basis of individual complications.

No deaths were reported in any cohort of patients reporting mortality, which included a total of 5896 patients (Table 3). Incidences of serious complications were reported but these were rare. These included: one case of sepsis with retropneumoperitoneum [19], two cases of intra-operatively recognized rectal perforation requiring diverting colostomy [32,35], one case of rectovaginal abscess requiring diversion [50], one case of suture line disruption requiring diversion [30], and one case of rectal necrosis requiring a colostomy [24]. There were no cases of inadvertent small bowel injury as a result of peritoneal inclusion with anterior rectal wall excision and enterocoele excision. This is despite the fact that in one study [42], 84 of 101 patients who had Contour Transtar, and 14 of 69 patients who had PPH01, had peritoneum present in the resected tissue.

Long-term adverse outcomes

Although obstructed defecation is a benign condition, it may have a significant impact on a patient's quality of life. Studies have consistently reported a number of long-term conditions and symptoms occurring after stapled rectal excision procedures that may have a further negative impact upon quality of life. Measures reported by more than half of cohorts include: rectal stenosis (83% of cohorts), recto-vaginal fistula (76%), pain/proctalgia (70%), and urgency after defaecation (72%); those less consistently reported include recurrent prolapse (46%) and dyspareunia (33%) (Table 4).

Random effects meta-analysis found that reported rectal stenosis rates were 0.2% (95% CI: 0.0–0.6%), I^2 = 30%, although individual cohorts varied from 0.0% to 7.4%, with no stenosis reported in 67% of cohorts. Recto-vaginal fistula was a very rare outcome, occurring in just 3 of 4851 patients (0.062%) studied. Rectal pain or proctalgia lasting > 6 months post-procedure was reported by 0.7% of patients (95% CI: 0.1–1.6%), I^2 = 79%, although individual cohorts varied from 0% to 17%, with no proctalgia reported in 53% of cohorts. Similarly to pooled findings, there was no difference in pain comparing STARR and Contour Transtar in the two level 1B RCTs [37,41]; at 36 months, the incidence of pain was significantly less compared with pre-

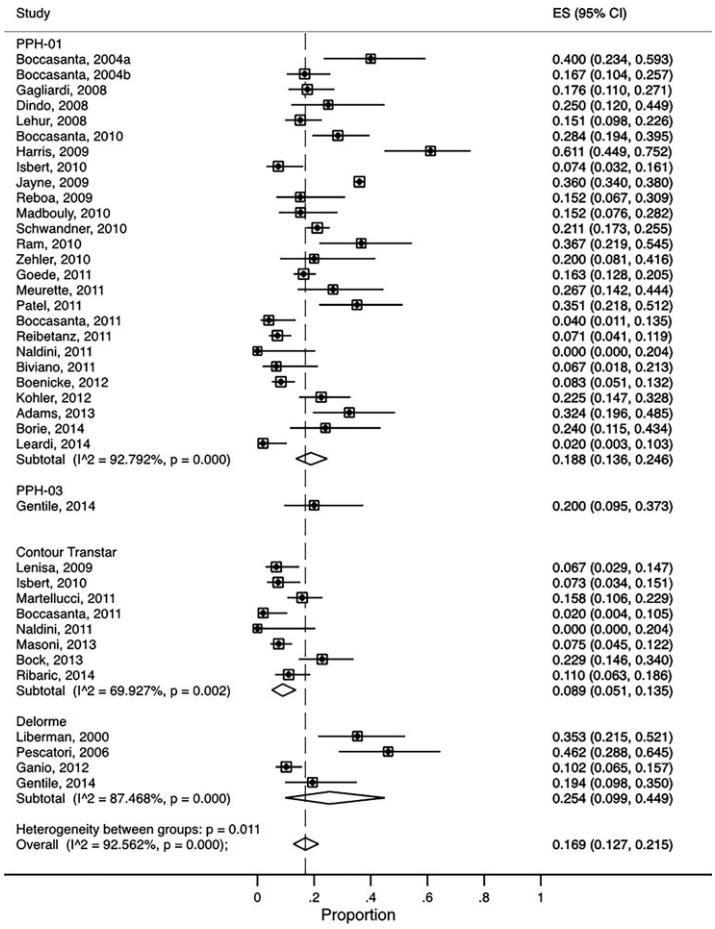

Figure 4 Forest plot showing rates of complications by operation type.

operative values in both groups [37]. The two studies with the highest reported incidence of proctalgia were both PCHs (IIB). At 38 ± 18 months post-STARR (n = 30), 17% complained of intermittent anal pain, however despite the fact that pre-operative Cleveland Clinic Constipation scores were recorded, there was no analysis about *de novo* pain [8]. At 12 months post-STARR (n = 2838), 7.1% complained of persistent pain [24]. Again there was no analysis regarding the *de novo* nature of this pain.

Urgency of defecation, at least one year post-procedure, was reported by 5.2% of patients (95% CI: 2.7–8.2%), I^2 = 92%, although findings were heterogeneous and individual cohorts varied from 0% to 34% (Fig. 6). The European STARR registry reported higher urgency rates of 20% at 12 months [24] and the German STARR registry reported rates of 25% at 12 months [30]. Both groups of authors pointed to poor recording of pre-operative urgency symptoms, relying on the subset scores from patients' Symptom Severity Score (SSS). Schwander *et al.*[30] suggest that this high incidence reflected numbers with new onset urgency with a score of > 1 in SSS, 5.5% had score > 3, and 8% of patients observed a reduction in urgency compared with pre-op. Jayne *et al.* [24] acknowledged in a subsequent reply to an invited expert's analysis of their paper, that *de novo* urgency was not recorded in their registry but 20% of patients reported this as a complication. Analysis of the subset question in their SSS suggested that 39.9% of patients experienced urgency pre-operatively and this fell to 26.8% at 12 months post-STARR. The highest reported incidence of urgency came from an RCT (IB) comparing STARR/PPH01 (34% at 3 years) with Contour Transtar (14% at 3 years) (P = 0.035) [37]. Urgency was reported as being *de novo* in both groups. However, the text in the results reports that the symptoms resolved in all but one patient (it is probable that this refers to tenesmus which is reported for one patient post-op). The other RCT (level IB) comparing STARR/PPH01 with Contour Transtar showed no difference in urgency rates after 24 months [41].

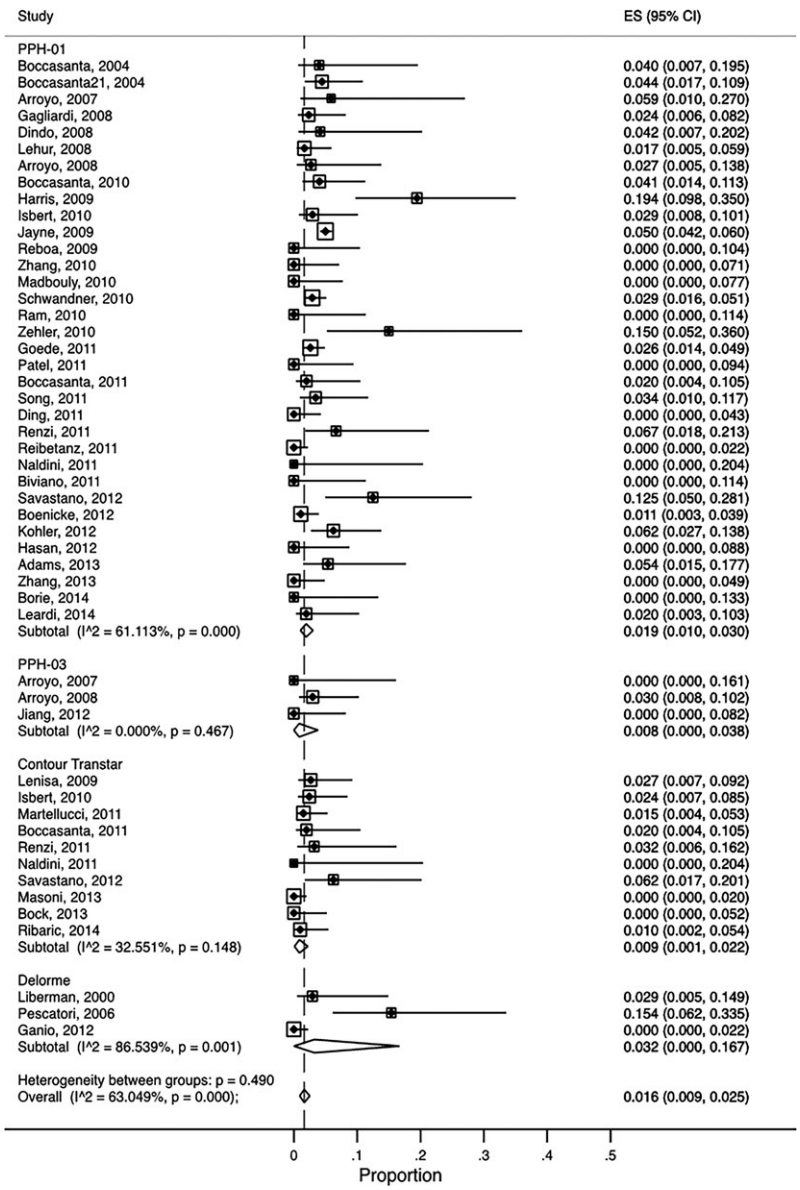

Figure 5 Forest plot showing rates of bleeding by operation type.

Summary evidence statements: harms

1 Evidence is largely drawn from observational studies and comparisons. Findings were heterogeneous, making estimates tentative and imprecise (level IV).

2 Overall procedural complication rates ranged from 0% to 61%. However, these complications may typically occur in about 13–22% of procedures (level II).

3 The Contour Transtar procedure may feature a lower overall complication rate although this needs to be confirmed with better research (level IV).

4 Post-operative bleeding requiring treatment may typically occur in 1–3% of patients (level II).

5 Post-operative sepsis and anastomotic dehiscence are rare complications rare typically occurring in less than 1% of patients (level II).

6 Serious acute post-operative complications are very rare occurring in about one in a thousand patients (level II).

7 In the longer term (12 months or more), rectal stenosis is a rare complication typically occurring in less than 1% of patients (level II).

8 The most common longer term adverse outcome is urgency of defaecation, typically occurring in up to 10% of patients (level II).

9 Longer term pain is experienced typically by less than 2% of patients (level II).

Table 4 Long-term adverse outcomes after rectal excisional procedures.

Author	Year	*N*	Stenosis	Recto vaginal fistula	Recurrent Prolapse	Pain/ proctalgia > 6 months	Dyspareunia	Urgency after 12 months
(a) PPH01								
Boccasanta [15]	2004	25	4	0	0	0	0	0
Boccasanta [16]	2004	90	3.3	0	0	0	0	1.1
Arroyo [18]	2007	17	6	0	6	0	NR	0
Gagliardi [19]	2008	85*	0	0	9.4	1.1	1.1	8.2
Dindo [20]	2008	24	0	0	NR	4.1	0	NR
Lehur [21]	2008	119	0	0	NR	1.8	0	NR
Arroyo [22]	2008	37††	0	0	5.7	0.9	NR	5.8
Harris [23]	2009	36	0	0	2.7	2.7	10.5	16.7[E]
Jayne [24]	2009	2224†	0.6	0.04	NR	7.1	0.1	20
Reboa [25]	2009	33	0	0	NR	0	NR	6
Boccasanta [26]	2010	74	1.3	0	0	0	0	2.7
Isbert [27]	2010	68	0	0	2.9	3	NR	4.4
Zhang [28]	2010	50	0	0	2	2	0	2
Madbouly [29]	2010	46	6.5	0	NR	0	NR	0
Schwandner [30]	2010	379	2.1	NR	NR	0.5	NR	25.3§§
Ram [31]	2010	30	NR	NR	NR	0	NR	NR
Zehler [32]	2010	20	0	0	NR	NR	NR	NR
Goede [33]	2011	344	2.9	NR	NR	NR	NR	11.5***
Meurette [34]	2011	30	NS	NR	NR	0	NR	6.8
Patel [36]	2011	37	2.7	NR	NR	NR	5.4	NR
Boccasanta [37]	2011	50	0	0	12	0	NR	34¶¶
Stuto [38]	2011	2171§	NR	NR	NR	NR	NR	NR
Song [39]	2011	58	1.7	NR	NR	0	NR	0
Ding [40]	2011	86	0	0	NR	0	NR	0
Renzi [41]	2011	30	NR	0	NR	NR	3.3	10
Reibetanz [42]	2011	170‡	0	0	NR	0	NR	NR
Naldini [43]	2011	15	NR	NR	NR	NR	NR	20
Biviano [8]	2011	30	0	0	3	17	0	6
Savastano [44]	2012	32	6.25	0	NR	0	0	0
Boenicke [46]	2012	181¶	0	0	NR	0	NR	NR
Kohler [47]	2012	80	0	0	5	0	NR	12.5
Hasan [48]	2012	40	0	0	0	2.5	NR	2.5
Adams [50]	2013	37	2.7	0	5.4	NR	NR	NR
Zhang [53]	2013	75	0	0	4	NR	NR	1.3†††
Panicucci [54]	2014	54**	NR	NR	NR	NR	NR	7.4
Borie [55]	2014	25	0	0	NR	NR	12‡‡	NR
Leardi [58]	2014	51	0	0	2	NR	NR	0
(b) PPH03								
Arroyo [18]	2007	20	0	0	5	0	NR	0
Arroyo [22]	2008	67‡‡‡	0	0	5.7	0.9	NR	5.8
Jiang [45]	2012	43	0	0	NR	2	NR	NR
Gentile [57]	2014	30	NR	NR	NR	NR	16.6	NR
(c) Contour Transtar								
Lenisa [3]	2009	75	0	0	NR	0	NR	13
Isbert [27]	2010	82	0	0	0	3	NR	4.8
Martellucci [35]	2011	133	0	0.8	NR	1.5	NR	6.8
Boccasanta [37]	2011	50	0	0	0	0	0	14
Renzi [41]	2011	31	NR	NR	NR	NR	0	9.6
Naldini [43]	2011	15	NR	NR	NR	NR	NR	13

Table 4 (Continued).

Author	Year	*N*	Stenosis	Recto vaginal fistula	Recurrent Prolapse	Pain/ proctalgia > 6 months	Dyspareunia	Urgency after 12 months
Savastano [44]	2012	32	0	0	NR	0	0	3.2
Masoni [51]	2013	187	0	0.5	NR	NR	NR	0
Bock [52]	2013	70	0	NR	8.6	NR	NR	0
Ribaric [56]	2014	100	0	0	NR	1	NR	3
(d) Intra-anal Delorme's procedure								
Liberman [14]	2000	34	3	0	3	0	NR	NR
Pescatori §§§ [17]	2006	26	7.5	0	35	2.5	NR	NR
Ganio [49]	2013	167 ¶¶¶	1.8	0	5.4	2.4	NR	NR
Gentile [57]	2014	36	NR	NR	NR	NR	11.1	NR

NR, not recorded.
All PPH03, except Jiang [45] translinear stapler.
*Report on 123 patients, but only 85 operated on.
†Report on 2838 patients for complications, 2224 reached 12 months follow-up.
‡101 patients had Countour Transtar.
§208 patients had Contour Transtar
¶Some patients had Contour Transtar
**18 patients had Contour Transtar.
††Complications are reported for 104 patients (67 had PPH03).
‡‡Not stated if de novo.
§§This reflects numbers with score of > 1 in Symptom Severity score, 5.5% had score > 3, and 8% of patients observed a reduction in urgency compared with pre-op.
¶¶Table refers to this incidence at 3 years, however text reports that all urgency resolved in all but one patient.
***Authors report that 74% of patients had pre-op urgency.
†††Uncertain if this is de novo.
‡‡‡Complications are reported for 104 patients (37 had PPH01).
§§§These percentages are based upon analysis of 40 patients (14 patients having had PPH01 or PPH01 with manual mucosectomy).
¶¶¶91 patients also had levatoroplasty.

10 Rectovaginal fistula is a very rare longer term complication, occurring in about one in about one in every one thousand six hundred patients (level II).

11 There was insufficient evidence to establish whether specific post-operative or longer term complications varied between procedures (level IV).

12 In all studies where mortality was recorded, there were no deaths in a total of 5896 patients studied (level II).

Efficacy

Measurement of clinical outcome was consistently recorded in many studies using a variety of the available subjective summative scoring instruments for constipation symptoms (Table 6). These included the Cleveland Clinic Constipation Score (21 studies), obstructed defecation syndrome (ODS) score (30 studies), Symptom Severity Score (SSS) (eight studies).

The Longo scoring system for ODS was reported for 56% of cohorts. Reduction in ODS occurred in 72.2% of patients (95% CI: 68.5–75.8%), $I^2 = 83\%$ (Fig. 7). There was considerable heterogeneity between findings, which varied from 53–91% and may reflect multiple causes. Although findings are imprecise, there was no robust evidence that one procedure produced greater score reductions than another. Improvement in constipation was reported in all studies where it was recorded. In many publications regarding surgical treatment of constipation, success has been defined as > 50% improvement in objective scores. A total of 18/21 studies reported > 50% improvement in CCS; all studies (30/30) reported > 50% improvement in ODS; 5/8 studies reported > 50% improvement in SSS. Significant improvement in ODS was seen in both arms of the two RCTs (IB) comparing STARR (PPH01) and Contour Transtar [37,41] and in the other level IB RCT comparing STARR with PPH01 and mucosectomy (with PPH01) together with levatoroplasty [15]. Whilst this

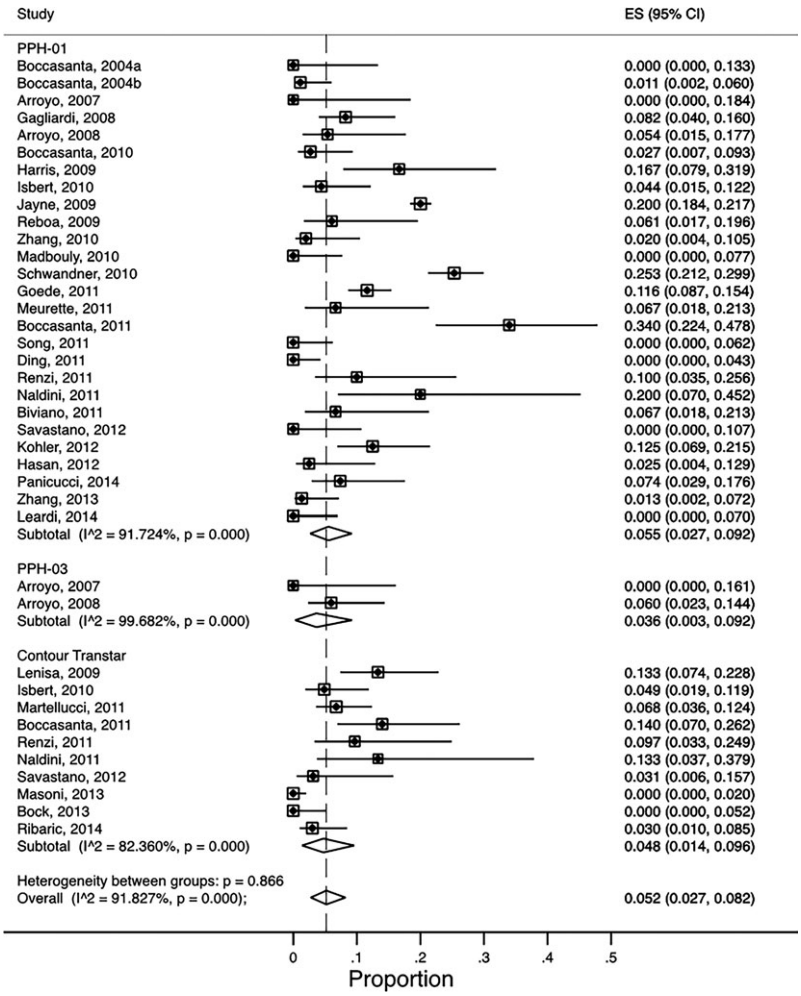

Figure 6 Forest plot showing rates of rectal urgency after 12 months by operation type.

improvement was maintained at three years, without difference between procedures in one trial [37], in the other at 24 months the improvement was maintained in the Contour Transtar group but not in the STARR group and there was a significant difference in scores between the two groups [41]. In the other two RCTs of lesser quality (IIB), STARR (PPH01) was shown to be significantly better for functional outcome compared with biofeedback (although there was > 50% attrition rate in the biofeedback group) [21], and STARR (PPH01) was shown to give similar functional results compared with Intra-anal Delorme's with levatoroplasty [57]. In other non-randomised (level IIB) comparisons of STARR (PPH01) *vs* Contour Transtar [8,27,43] there was no difference in functional outcome. One prospective cohort study (level IIB) compared PPH01 with PPH03 [18] and showed no difference in functional outcome, and a further compared STARR with macrogol therapy [8]. There was no difference in outcome when looking at response rates, however it was unclear if groups were matched and no report on different laxative use was included in inclusion criteria. One would normally assume that macrogol or other medical management would have been tried before selecting a patient for a rectal excisional procedure.

The effect of time post-procedure and efficacy was examined in the four level I/IIB studies with a follow-up of > 30 months [8,37,53,57]. Three studies showed greater than 75% reduction in subjective scores [8,37,57] and the other greater than 50% reduction, regardless of the procedure provided.

Global 'success' or 'satisfaction' ratings (GSR) were obtained via a variety of methods in 28 of 55 cohorts (Table 5), where 'satisfied' or 'very satisfied', 'good', 'very good' and 'excellent' were interpreted as positive outcomes. Further 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. Most reports assert that the majority of patients

Table 5 Percentage success based on global satisfaction ratings (GSR).

Author	Year	*N*	FU mean	GSR %*
(a) PPH01				
Boccasanta [15]	2004	25	23	88
Boccasanta [16]	2004	90	16	90
Dindo [20]	2008	24	18	83
Isbert [27]	2010	68	12	80
Reboa [25]	2009	33	18	75.7
Zehler [32]	2010	20	66	80
Goede [33]	2011	344	12	81
Patel [36]	2011	37	20	71.9
Boccasanta [37]	2011	50	36	66
Song [39]	2011	58	34	63.4
Renzi [41]	2011	30	36	60
Biviano [8]	2011	30	38	60
Kohler [47]	2012	80	39	77.5
Hasan [48]	2012	40	12	75
Adams [50]	2013	37	13	50
Zhang [53]	2013	75	30	64
Panicucci [54]	2014	54 †	12	87
Borie [55]	2014	25	18	84
Leardi [58]	2014	51	36	81
(b) PPH03				
Jiang [45]	2012	43‡	12	72
Gentile [57]	2014	30	12	73§
(c) Contour Transtar				
Lenisa [3]	2009	75	12	77.3
Isbert [27]	2010	82	12	81.5
Martellucci [35]	2011	133	19	69.8
Bock [52]	2013	70	48	87
(d) Intra-anal Delorme's procedure				
Liberman [14]	2000	34	43	76.4
Ganio [49]	2013	167	36	78.2¶
Gentile [57]	2014	36	12	73**

*Proportion good or excellent.
†18 patients had Contour Transtar.
‡linear stapler.
§GSR is based on 66 patients (36 had intra-anal Delorme's).
¶91 patients also had levatoroplasty.
**GSR is based on 66 patients (30 had PPH03).

undergoing PPH01, PPH03, Contour Transtar, and intra-anal Delorme's procedure were satisfied. Random effects meta-analysis found the global satisfaction rating to be 76.3% (95% CI: 72.8–79.5%), I^2 = 59% (Fig. 8). There was considerable heterogeneity between findings, which varied from 51% to 90% and may reflect multiple causes. Although findings are imprecise there was no evidence that one procedure produced higher levels of satisfaction than another.

Disease-specific and generic QoL scoring instruments were used less often including PAC QoL (11 studies, data not shown), EQ-VAS (six studies, data not shown), EQ-5D (two studies, data not shown), FIQL (one study, data not shown). Using such instruments, improvements in QoL were associated with symptom improvements in most studies except for Ribaric *et al.* [56] who showed non-significant improvements in EQ-5D and EQ VAS in 100 patients 12 months after Contour Transtar and Madbouly *et al.* [29] who, reporting on 46 patients after PPH01, showed significant improvements in PAC QoL at 18 months but not at 42 months.

The aim of rectal excision procedures is to enable normal evacuation and assessment of constipation symptoms is therefore the most important outcome. However, many patients also suffer from incontinence, either as a result of neurogenic/traumatic sphincter pathologies or from the effects of a high grade recto-anal intussusception. Instrumented excisional procedures are postulated to increase the risk of faecal incontinence by their very nature. Indeed one of the exclusion criteria in many studies was greater than minor faecal incontinence (Table S1). Objective scores (Wexner or St Marks incontinence score, FISI) when reported (Table 6) showed either no change or reduction in scores other than in one study where an increase was reported [47]. In this study after PPH01, the median Wexner incontinence score rose from 3.3 to 5.5 after 2–3 years. It was reported that a third of patients developed incontinence symptoms 1–4 years after the procedure.

While anatomical outcome is necessarily only a surrogate of clinical outcomes, recurrent prolapse was reported for less than half of cohorts and occurred in 4.3% of patients (95% CI: 2.0–7.3%), I^2 = 78%. Again findings were heterogeneous and there was no robust evidence that one procedure was associated with higher long term adverse outcomes than another. One RCT comparing STARR with Contour Transtar reported that at three years post-procedure 12% of STARR patients had a clinical recurrence compared with none of the Contour Transtar patients (P = 0.035) [37]. The weight of resected tissue was significantly greater in the Transtar group.

Summary evidence statements: efficacy

1 Data on efficacy were inconsistently measured and findings heterogeneous, making estimates tentative and imprecise (level IV).
2 Although inconsistent, patient global satisfaction ratings typically suggest (at least) satisfactory outcome in about 73–80% of patients (level II).
3 Although inconsistent, a reduction of 53–91% in Longo scoring system for obstructive defecation syndrome occurred in about 68–76% of patients (level II).

Table 6 Functional outcomes by procedure.

Author	Year	*N*	FU[‡‡]	% reduction in CCS	% reduction in Longo/ ODS score	% reduction in SSS score	Any significant increase or decrease in FI scores
(a) PPH01							
Boccasanta [15]	2004	25	23	68.6	\	\	N
Boccasanta [16]	2004	90	16	65.3	\	\	N
Arroyo [18]	2007	17	24	\	\	68	\
Gagliardi [19]	2008	85 *	17	\	\	\	\
Dindo [20]	2008	24	18	54.5	\	\	\
Lehur [21]	2008	119	12	\	71	\	\
Arroyo [22]	2008	37[††]	26	62.3	\	\	\
Boccasanta [26]	2010	74	24	\	88.4	\	\
Harris [23]	2009	36	12	\	88	\	\
Isbert [27]	2010	68	12	46.8	65.5	\	N
Jayne [24]	2009	2224[†]	12	\	67.3	76.1	Decrease
Reboa [25]	2009	33	18	72.4	\	\	\
Zhang [28]	2010	50	12	63.5	66.3	70.3	\
Madbouly [29]	2010	46	42	\	75.3	\	\
Schwandner [30]	2010	379	12	\	\	49.4	N
Ram [31]	2010	30	26	\	\	\	\
Zehler [32]	2010	20	66	\	65	40	Decrease
Goede [33]	2011	344	12	\	89	\	Decrease
Meurette [34]	2011	30	48	\	58.6	\	N
Patel [36]	2011	37	20	\	58.6	\	\
Boccasanta [37]	2011	50	20	\	83	\	N
Stuto [38]	2011	2171[§]	12	\	70	\	Decrease
Song [39]	2011	58	34	58.5	\	\	\
Ding [40]	2011	86	12	\	60.5	\	N
Renzi [41]	2011	30	36	\	59.6	\	\
Reibetanz [42]	2011	170[‡]	18	47	\	\	\
Naldini [43]	2011	15	24	\	73.4	\	\
Biviano [8]	2011	30	38	76.1	\	\	\
Savastano [44]	2012	32	27	\	87	\	\
Boenicke [46]	2012	181[¶]	19	58.9	\	\	N
Kohler [47]	2012	80	39	54.8	\	\	Increase
Hasan [48]	2012	40	12	83.8	\	\	\
Adams [50]	2013	37	13	\	\	\	\
Zhang [53]	2013	75	30	54.6	53.5	\	N
Panicucci [54]	2014	54 **	12	68.5	74.4	\	\
Borie [55]	2014	25	18	\	59	\	\
Leardi [58]	2014	51	36	\	76	\	Decrease
(b) PPH03							
Arroyo [18]	2007	20	24	\	\	68	\
Arroyo [22]	2008	67R	26	62.3	\	\	\
Jiang [45]	2012	43	12	62.9	\	\	\
Gentile [57]	2014	30	12	\	\	\	\
(c) Contour Transtar							
Lenisa [3]	2009	75	12	\	83	50.2	N
Isbert [27]	2010	82	12	50	68	\	N
Martellucci [35]	2011	133	19	48	\	\	\
Boccasanta [37]	2011	50	36	\	85	\	N
Renzi [41]	2011	31	24	\	64.5	\	\

Table 6 (Continued).

Author	Year	*N*	FU‡‡	% reduction in CCS	% reduction in Longo/ ODS score	% reduction in SSS score	Any significant increase or decrease in FI scores
Naldini [43]	2011	15	24	\	69.9	\	\
Savastano [44]	2012	32	27	\	90.3	\	\
Masoni [51]	2013	187	12	67	\	\	\
Bock [52]	2013	70	48	\	56.3	46.7	N
Ribaric [56]	2014	100	12	\	64.7	\	N
(d) Intra-anal Delorme's procedure							
Liberman [14]	2000	34	43	\¶¶	\	\	N
Pescatori [17]	2006	26	36	\	\	\	\
Ganio [49]	2013	167 ***	36	66.7	63.5	\	N
Gentile [57]	2014	36	12	\	\	\	\

N, no change; \, not recorded; FI, faecal incontinence.
All PPH03, except Jiang [45] translinear stapler.
*Report on 123 patients, but only 85 operated on.
†Report on 2838 patients, but 2224 reached 12 months follow-up; complete data for ODS score (41%), complete data for SSS (57%).
‡101 patients had Countour Transtar.
§208 patients had Contour Transtar, 1485 patients completed 12 months follow-up.
¶Some patients had Contour Transtar.
**18 patients had Contour Transtar.
††Complications are reported for 104 patients (67 had PPH03).
‡‡Mean follow-up in months.
§§This study also showed a significant improvement in the Knowles-Eccersley-Scott-Symptom (KESS) score.
¶¶67–93% of patients showed improvement in 4 of CCS domains.
***91 patients also had levatoroplasty.

4 Evidence for longer term benefits persisting from procedures is sparse but suggests improvements may be maintained (level II).
5 Findings from efficacy measures provided insufficient evidence to recommend one type of procedure over another (level IV).
6 The use of Contour Transtar increases the amount of resected tissue and may reduce recurrence rates although this requires further study (level IV).
7 There is no evidence that rectal excisional procedures contribute towards post-operative faecal incontinence (level II).
8 Recurrent prolapse occurred in 4.3% of patients considering all studies (level IV); rates were lower (1.7%) in higher quality studies (level II).

Variation in outcomes by level of evidence

Meta-analytic findings are reported for each of the outcomes reported, subdivided by level of evidence (Table 7). Recurrent prolapse was the only adverse outcome where findings varied by grade of evidence: grade IB/IIB: 1.7% of patients (95% CI: 0.4–3.7%), I^2 = 54%, and grade IV: 9.2% of patients (95% CI: 4.1–15.9%), I^2 = 78%.

Patient selection

Patient selection is generally perceived to be essential when choosing a surgical approach. Whilst rectal excision procedures may be efficient at correcting normal anatomy, there may be many underlying functional and organic pathologies that mean surgery is unsuccessful at 'curing' the patient [59]. It is advised when contemplating a surgical approach to exhaust first all forms of conservative or medical management. Forty-one out of 55 cohorts studied highlight the fact that all patients had undergone a period of conservative management (Table 7).

Many of the current studies reference inclusion and exclusion criteria based upon a previous consensus conference [60], namely that patients should be selected on the basis of recognized symptoms of ODS with evidence of anatomical defects on defaecography (rectocoele and/or internal rectal prolapse) and adequate anal sphincter function (at least assessed by digital rectal

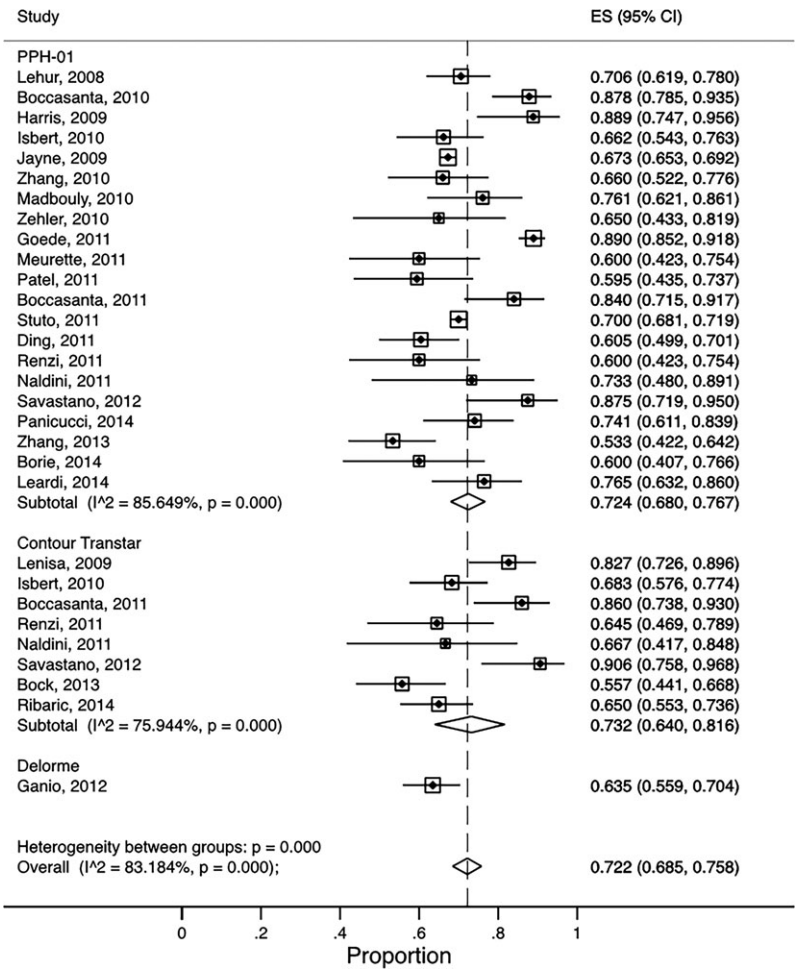

Figure 7 Forest plot showing reduction in Longo's obstructed defacation syndrome (ODS) score by operation type.

examination). In 42 out of the 55 cohorts studied, patients had at least 3 ODS symptoms (Table 8). In general when selecting patients for functional surgery it has also been advised to select patients with a high symptom load [61]. A criticism made to the authors of the European STARR Registry (n = 2224) was that the median ODS score was low (15.7 out of a possible 40) and that the range was high (1–31) [24]. The two level I RCTs reported inclusion criteria of an ODS score > 12 in one [41] and 15 in the other [37]. The majority of studies reported an inclusion criterion of rectal intussusception and/or rectocoele, (38 out of 55 study groups). Thirty-two out of the 55 study groups reported a rectocoele > 2 cm, and in 26 of these, more than 75% of patients had a rectocele > 2 cm. Thirty-seven out of the 55 study groups reported on recto-rectal or recto-anal intussusception, and in 28 of these more than 60% of patients had an intussusception. Multiple classifications were used for diagnosing an intussusception including Pescatori [62], Shorvon [63], and Oxford [64]. Other studies stated that inclusion required a rectal intussusception greater than 10 mm [41] or recto-anal intussusception > 10 mm [31]. One study reported on outcome at five years following PPH01 for patients with a symptomatic rectocoele when the authors specifically excluded intussusception [32]. This study found an 80% satisfaction rate at one year, which remained at five years. It was not possible to draw conclusions regarding efficacy according to either the presence of an intussusception (whichever grade/stage) or rectocoele size.

It is pertinent to discuss exclusion criteria as this may influence the surgeon in their choice of procedure (reinforcement/suspension/excision). Reference was again made in many studies to the consensus statement [60] and a decision making algorithm for STARR [65] when defining exclusion criteria. Specifically, external rectal prolapse, solitary rectal ulcer syndrome (SRUS), anatomical enterocele, and 'significant gynaecological pelvic floor abnormality requiring treatment' were

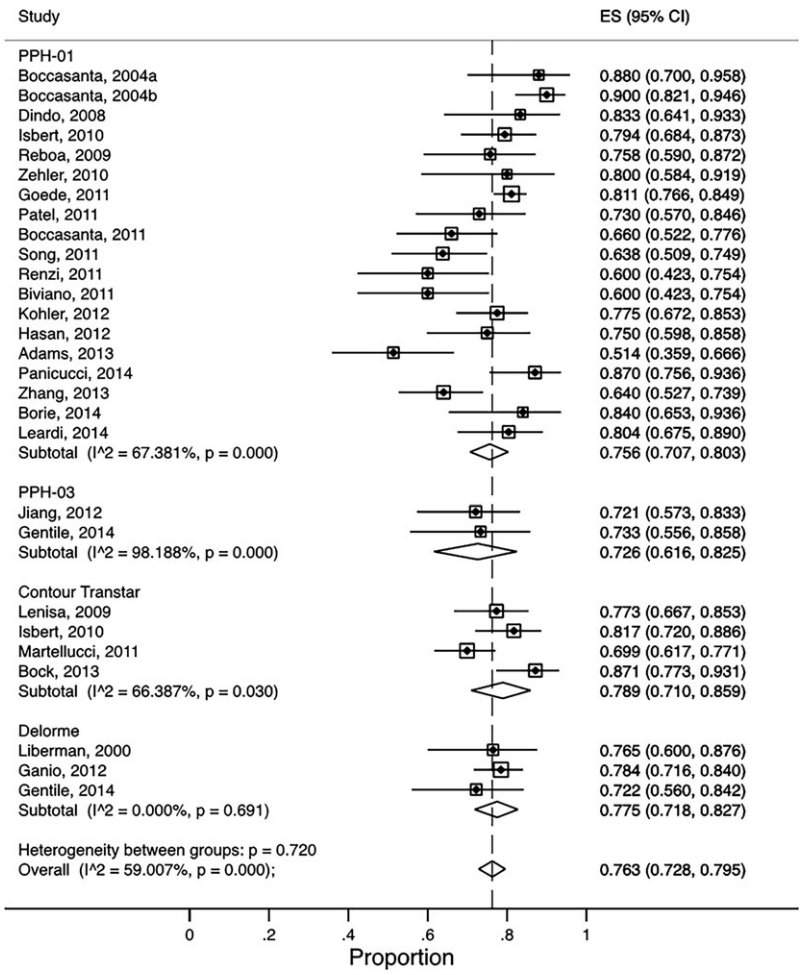

Figure 8 Forest plot showing global satisfaction rating (%) by operation type.

stated as exclusions. Less than 50% of the reviewed studies excluded external rectal prolapse or other pelvic organ prolapse, and no study excluded SRUS (Table S1). Only one study graded pelvic organ prolapse (rectocoele, cystocoele, vault, uterine) with a standardized grading system e.g. POP-Q (data not shown) [26]. Whilst it is sensible to exclude patients with external rectal prolapse, no conclusion can be made regarding excluding patients with SRUS, or concomitant pelvic organ prolapse.

Anatomical enterocoele is generally regarded as a contraindication to an anterior rectal wall excision [60,65], however many studies did not exclude this (Table S1). Irrespective of this, there were no cases of iatrogenic small bowel injury reported. One study examined the outcome with respect to harms in patients with a functional enterocoele, and those without [42]. All patients had either PPH01 or Contour Transtar and outcomes with respect to harms were similar.

Summary evidence statements: patient selection

1 Patient selection, although perceived as vital in predicting outcome, is inconsistently documented and poorly informed by current evidence (level IV).
2 Patients with at least three ODS symptoms together with a rectocoele with or without an intussusception, who have failed conservative management may benefit from a rectal excisional procedure (level II).
3 It is not possible to advise on excluding patients with concomitant pelvic organ prolapse or SRUS when considering a rectal excisional procedure (level IV).

Conclusions

A systematic review of evidence for the perioperative and long term benefits and harms of rectal excisional procedures identified a modest number of high quality studies together with a larger number of observational lesser quality studies. Whilst the evidence is superior to the level of evidence for other procedures for

Table 7 Outcomes by level of evidence.

	IB/IIB Effect size (95%CI), I^2	IV Effect size (95%CI), I^2	Combined Effect size (95%CI), I^2	IB/IIB *vs* IV *p*
Perioperative data				
Procedure duration (mins)	44.3 (39.9–48.7), 99.2%	44.4 (35.4–53.5), 99.5%	44.3 (40.5–48.1), 99.5%	0.98
Length of stay (days)	2.8 (2.5–3.2), 98.1%	3.6 (2.5–4.7), 98.7%	3.0 (2.6–3.4), 98.8%	0.18
Total complication rate (%)	13.5% (8.3–19.6%), 94.0%	22.0% (15.9–28.7%), 85.5%	16.9% (12.7–21.5%), 92.6%	0.052
Perioperative harm				
Bleeding rate (%)	1.5% (0.7–2.4%), 52.7%	2.2% (0.6–4.3%), 72.4%	1.6% (0.9–2.5%), 63.0%	0.56
Sepsis rate (%)	0.0% (0.0–0.5%), 67.1%	0.8% (0.0–2.2%), 48.8%	0.2% (0.0–0.7%), 62.6%	0.090
Anastomotic dehiscence rate (%)	0.2% (0.0–0.9%), 67.3%	0.2% (0.0–0.9%), 11.2%	0.3% (0.0–0.8%), 61.6%	0.98
Long term adverse outcomes				
Rectal stenosis (%)	0.1% (0.0–0.5%), 24.4%	0.4% (0.0–1.2%), 36.4%	0.2% (0.0–0.6%), 30.3%	0.52
Rectal pain (%)	0.6% (0.0–1.9%), 83.6%	0.8% (0.1–1.8%), 0.0%	0.7% (0.1–1.6%), 78.7%	0.76
Rectal urgency (%)	5.6% (2.7–9.3%), 90.7%	4.2% (0.9–9.2%), 89.1%	5.2% (2.7–8.2%), 91.8%	0.51
Rectal prolapse (%)	1.7% (0.4–3.7%), 53.9%	9.2% (4.1–15.9%), 82.0%	4.3% (2.0–7.3%), 78.7%	0.006
Efficacy				
Global satisfaction rating (%)	76.4% (71.3–81.1%), 59.0%	76.0% (71.1–80.7%), 62.4%	76.3% (72.8–79.5%), 59.0%	0.94
Longo ODS (%)	71.9% (68.5–75.1%), 70.7%	71.3% (58.0–83.0%), 90.9%	72.2% (68.5–75.8%), 83.2%	0.93

constipation it is still rather poor in the field of medicine systematic reviews. Notwithstanding this, certain conclusions can be drawn:

1 In the presence of a rectocoele with or without an intussusception, together with at least three symptoms of ODS, a rectal excisional procedure may benefit the patient after all conservative measures have been exhausted.
2 Reliance on proving efficacy using GSR and unvalidated scoring systems (Longo) is not satisfactory and greater emphasis should be placed in future studies on the use of disease-specific and generic QoL scoring instruments.
3 It is not possible to advise which excisional technique is superior from the point of view of efficacy, perioperative variables, or harms (peri-operative or long term adverse outcomes). Future study is required.
4 Both short- and long-term harms may have been exaggerated in previous reports. Rectal excisional procedures appear to be safe with little major morbidity. Rectal urgency appears to be a problem, but findings are inconsistent because of poor reporting.
5 Despite evidence of mixed grade (IB, IIB and IV) being available for rectal excision procedures, there was little evidence that outcomes varied by grade of evidence. Recurrent prolapse was the only adverse outcome where findings varied by grade of evidence and thus may be a chance finding in the absence of any systematic pattern across outcomes.

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Table 8 Inclusion criteria for procedures.

Author	Year	*N*	Rectocele > 2 cm %	Recto-rectal / Recto-anal Intussusception %	Rectocele + Intussusception %	Failure of conservative RX	At least 3 ODS symptoms
(a) PPH01							
Boccasanta [15]	2004	25	100	100	100	Yes	Yes
Boccasanta [16]	2004	90	97	100	97	Yes	Yes
Arroyo [18]	2007	17	92	27	NR	Yes	Yes
Gagliardi [19]	2008	85*	80	93	73	Yes	Yes
Dindo [20]	2008	24	79	83	NR	Yes	Yes
Lehur [21]	2008	119	92	61	NR	No	Yes
Arroyo [22]	2008	37††	NR	NR	NR	Yes	Yes
Boccasanta [26]	2010	74	100	100	100	Yes	Yes
Harris [23]	2009	36	81	39	39	No	Yes
Isbert [27]	2010	68	100	80	80	Yes	Yes
Jayne [24]	2009	2224†	99	80	NR	Yes	Yes
Reboa [25]	2009	33	67	97	NR	Yes	Yes
Zhang [28]	2010	50	NR	NR	NR	No	No
Madbouly [29]	2010	46	59	41	NR	Yes	Yes
Schwandner [30]	2010	379	NR	NR	NR	No	Yes
Ram [31]	2010	30	67	13	67	No	Yes
Zehler [32]	2010	20	100	0	0	Yes	Yes
Goede [33]	2011	344	NR	100	NR	No	Yes
Meurette [34]	2011	30	100	100	100	Yes	No
Patel [36]	2011	37	100	81	81	Yes	Yes
Boccasanta [37]	2011	50	100	100	100	No	Yes
Stuto [38]	2011	2171§	82	95	NR	No	Yes
Song [39]	2011	58	62	80	NR	Yes	Yes
Ding [40]	2011	86	90	94	77	Yes	Yes
Renzi [41]	2011	30	NR	NR	NR	Yes	Yes
Reibetanz [42]	2011	170‡	NR	NR	NR	No	No
Naldini [43]	2011	15	NR	NR	NR	Yes	Yes
Biviano [8]	2011	30	77	50	NR	Yes	Yes
Savastano [44]	2012	32	NR	NR	NR	No	No
Boenicke [46]	2012	181¶	NR	NR	100	Yes	Yes
Kohler [47]	2012	80	100	100	NR	No	Yes
Hasan [48]	2012	40	90	55	NR	Yes	Yes
Adams [50]	2013	37	NR	NR	NR	Yes	Yes
Zhang [53]	2013	75	NR	87	NR	Yes	No
Panicucci [54]	2014	54 **	NR	NR	NR	Yes	Yes
Borie [55]	2014	25	100	65	65	Yes	Yes
Leardi [58]	2014	51	43	57	0	Yes	No
(b) PPH03							
Arroyo [18]	2007	20	92	27	NR	Yes	Yes
Arroyo [22]	2008	67§§	NR	NR	NR	Yes	Yes
Jiang [45]	2012	43	100	56	56	Yes	Yes
Gentile [57]	2014	30	NR	NR	NR	Yes	No
(c) Contour Transtar							
Lenisa [3]	2009	75	NR	NR	NR	Yes	Yes
Isbert [27]	2010	82	100	65	65	Yes	Yes
Martellucci [35]	2011	133	NR	NR	NR	Yes	Yes
Boccasanta [37]	2011	50	100	100	100	No	Yes
Renzi [41]	2011	31	NR	NR	NR	Yes	Yes

Table 8 (Continued).

Author	Year	*N*	Rectocele > 2 cm %	Recto-rectal / Recto-anal Intussusception %	Rectocele + Intussusception %	Failure of conservative RX	At least 3 ODS symptoms
Naldini [43]	2011	15	NR	NR	NR	Yes	Yes
Savastano [44]	2012	32	NR	NR	NR	No	No
Masoni [51]	2013	187	84	97	NR	Yes	Yes
Bock [52]	2013	70	NR	NR	NR	Yes	No
Ribaric [56]	2014	100	80	73	NR	Yes	No
(d) Intra-anal Delorme's procedure							
Liberman [14]	2000	34	NR	100	70.6	Yes	Yes
Pescatori [17]	2006	26	NR	100	37.5***	No	No
Ganio [49]	2013	167	NR	77.2	66.5	Yes	No
Gentile [57]	2014	36	NR	NR	NR	Yes	No

NR, not recorded.
All PPH03, except Jiang [45] translinear stapler.
*Report on 123 patients, but only 85 operated on.
†Report on 2838 patients for complications, 2224 reached 12 months follow-up.
‡101 patients had Countour Transtar.
§208 patients had Contour Transtar.
¶Some patients had Contour Transtar.
**18 patients had Contour Transtar.
††Inclusions are reported for 104 patients (67 had PPH03).
§§Reported for 104 patients (37 had PPH01).
***Based on total number of 40 cases.

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M Mercer-Jones has no conflict of interest in relation to the content of the manuscript. In the last 2 years he has received fees as a preceptor for Medtronic Inc. C.H.Knowles has no conflict of interest in relation to the content of the manuscript. In the last 2 years he has recieved speaker fees and consultancy payments from Medtronic Inc. remaining authors no conflict.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Forest plot showing rates of sepsis by operation type.
Figure S2. Forest plot showing rates of anastomotic dehiscence by operation type.
Table S1. Exclusion tables. (a) PPH-01; (b) PPH03; (c) Contour Transtar; (d) Intra-anal.

