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Randomized Clinical Trial

A comparison between thoracic epidural analgesia and rectus sheath catheter analgesia after open midline major abdominal surgery: randomized clinical trial

Anton Krige[1,*], Sarah G. Brearley[2], Céu Mateus[2], Gordon L. Carlson[3] and Steven Lane[4]

[1]Department of Anaesthesia and Critical Care, Royal Blackburn Teaching Hospital, Blackburn, UK
[2]Division of Health Research, Lancaster University, Faculty of Health and Medicine, Lancaster, UK
[3]Department of Surgery, Salford Royal NHS Foundation Trust, Stott Lane, Salford, UK
[4]Department of Biostatistics, University of Liverpool, Liverpool, UK

Correspondence to: Anton Krige, Department of Anaesthesia and Critical Care, Royal Blackburn Teaching Hospital, Haslingden Road, Blackburn, BB2 3HH, UK (e-mail: Anton.Krige@elht.nhs.uk)

Abstract

Background: Rectus sheath catheter analgesia (RSCA) and thoracic epidural analgesia (TEA) are both used for analgesia following laparotomy. The aim was to compare the analgesic effectiveness of RSCA with TEA after laparotomy for elective colorectal and urological surgery.

Methods: Patients undergoing elective midline laparotomy were randomized in a non-blinded fashion to receive RSCA or TEA for postoperative analgesia at a single UK teaching hospital. The primary quantitative outcome measure was dynamic pain score at 24 h after surgery. A nested qualitative study (reported elsewhere) explored the dual primary outcome of patient experience and acceptability. Secondary outcome measures included rest and movement pain scores over 72 h, functional analgesia, analgesia satisfaction, opiate consumption, functional recovery, morbidity, safety, and cost-effectiveness.

Results: A total of 131 patients were randomized: 66 in the RSCA group and 65 in the TEA group. The median (interquartile range; i.q.r.) dynamic pain score at 24 h was significantly lower after TEA than RSCA (33 (11–60) *versus* 50.5 (24.50–77.25); $P = 0.018$). Resting pain score at 72 h was significantly lower after RSCA (4.5 (0.25–13.75) *versus* 12.5 (2–13); $P = 0.019$). Opiate consumption on postoperative day 3 (median (i.q.r.) morphine equivalent 17 (10–30) mg *versus* 40 (13.25–88.50) mg; $P = 0.038$), hypotension, or vasopressor dependency (29.7 *versus* 49.2 per cent; $P = 0.023$) and weight gain to day 3 (median (i.q.r.) 0 (−1–2) kg *versus* 1 (0–3) kg; $P = 0.046$) were all significantly greater after TEA, compared with RSCA. There were no significant differences between groups in other secondary outcomes, although more participants experienced serious adverse events after TEA compared with RSCA, which was also the more cost-effective.

Conclusions: TEA provided superior initial postoperative analgesia but only for the first 24 h. By 72 hours RSCA provides superior analgesia, is associated with a lower incidence of unwanted effects, and may be more cost-effective.

Introduction

Enhanced recovery protocols aim to speed recovery after major surgery by reducing morbidity and accelerating functional recovery, with a focus on early mobilization and early oral nutrition[1,2]. Effective analgesia is crucial to achieving these goals by attenuating the stress response and providing adequate pain relief to allow mobilization, optimize respiratory function and sleep, and minimize factors that delay the return of normal gastrointestinal function[2–4].

Provision of effective analgesia is particularly challenging following open midline abdominal surgery where significant wound pain persists for at least 72 h, as opposed to minimally invasive approaches where the majority of the pain is visceral and subsides within 24 h[5,6]. To date, the most common analgesic approach has relied on thoracic epidural infusions to provide the bulk of the pain relief and is currently recommended within enhanced recovery after surgery guidelines[2,7–11]. Although the superior efficacy of thoracic epidural analgesia (TEA) is well established in comparison with high-dose systemic opiates[8], TEA is not without limitations. These include hypotension (approximately 20 per cent incidence), motor blockade, tethering to infusion pumps, need for urinary catheterization, and high failure rates[7,12,13].

Rectus sheath blocks, maintained via rectus sheath catheters (RSCs), are an alternative for delivering analgesia following midline open abdominal surgery[14,15]. In non-randomized studies, RSC analgesia (RSCA) was well tolerated and effective in patients undergoing major open urological pelvic surgery[16], and provided equivalent analgesic effect to TEA in patients undergoing open midline colorectal surgery, or radical cystectomy[17,18]. However, findings from randomized clinical trials (RCTs) have been less consistent[19,20].

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Reported here are the results of an RCT, undertaken to assess the efficacy, safety, and acceptability to patients of RSCA compared with TEA. Secondary aims were to explore the effect of the analgesic technique on postoperative morbidity, in particular gut function, and haemodynamic stability[21].

Methods

Study design

This non-blinded RCT was performed at a single teaching hospital (Royal Blackburn Teaching Hospital) in the UK between February 2014 and February 2017. The study was conducted according to the principles of the Declaration of Helsinki and the protocol was approved by the appropriate ethics authority (Greater Manchester East Research Ethics Committee, REC reference 13/NW/0782 61767) and registered with Controlled Trials (ISRCTN 81223298). Written informed consent was obtained from all participants. The protocol was published (providing full methodological details) before recruitment started[21]. Additionally, a full qualitative study was nested within the RCT to explore the dual primary outcome of patients' experiences, expectations, and acceptability of receiving either RSCA or TEA, and will be reported separately.

Participants

Eligible patients were aged 18 years and above, with an American Society of Anesthesiologists (ASA) score of 1 to 3[22], and were scheduled to undergo elective major abdominal surgery via open midline incision (laparotomy). Patients in whom TEA was contraindicated (such as those with coagulopathy, sepsis, or severe aortic stenosis), who required simultaneous perineal surgery (such as abdominoperineal resection), who underwent planned surgery other than with a midline incision, who had a history of a chronic abdominal pain syndrome, opiate tolerance or an allergy to local anaesthetic drugs, or who were unable to give informed consent were excluded (*Appendix S1*).

Intervention and comparator

Patients were randomized in a 1:1 ratio to receive either the RSCA or TEA packages for 72 h after surgery; patients were stratified by age, sex, and type of surgery. Random sequence generation was performed, and allocation concealment was maintained, with a computerized system (InForm, version 4.6; Oracle Corporation, Redwood City, California, USA).

All participants were included in the Enhanced Recovery Program (ERP) perioperatively, ensuring a standardized care pathway, apart from the assigned study interventions. Full details of the ERP, general anaesthetic regimen, RSCA, and thoracic epidural placement and analgesia, management of breakthrough pain, and postoperative management, are included in *Appendix S1* and the previously published protocol[21].

Briefly, RSCs were inserted bilaterally under ultrasound guidance after induction of general anaesthesia; the catheters were tunnelled subcutaneously to a level above the costal margin. Initial boluses to establish the block were 20 ml of 0.25 per cent bupivacaine injected via each catheter into the potential space between the rectus muscle and the posterior rectus sheath[23]. A 10-mg bolus of intravenous (i.v.) morphine was administered approximately 45 min before the end of surgery to provide visceral analgesia and a transdermal fentanyl patch was applied (12 µg if 70 years or above and/or 65 kg or under, and 25 µg if under 70 years and more than 65 kg; 72-h duration of action). The alternative would be the provision of a morphine patient-controlled analgesia (PCA) for visceral pain control; however this leads to less-consistent analgesia, reducing sleep quality and further hampering mobility with tethering to an additional infusion pump. If more than 3 h had passed since the initial bolus, an additional RSCA bolus (40 ml of 0.2 per cent ropivacaine) was administered via an AmbIT Preset PCA pump (Summit Medical Products Inc, South Sandy, Utah, USA). Thereafter, boluses were delivered at 4-h intervals via the pumps.

RSCA was discontinued on postoperative day 3 for colorectal surgery and day 4 for radical cystectomy cases, which reflects local TEA duration for such surgery as specified below.

Thoracic epidurals were sited under aseptic conditions before the induction of general anaesthesia at T7 to T9 for right-sided colonic resections and T9 to T11 for left-sided colonic/rectal resections and radical cystectomies. Following a suitable test dose, a bolus of 10 ml 0.25 per cent bupivacaine with 100 µg fentanyl was administered to establish a block. An epidural infusion of 0.125 per cent bupivacaine and 2 µg/ml fentanyl was commenced at 10 ml/h and then titrated to effect.

On the second postoperative night for colorectal surgery and the third postoperative night for radical cystectomy cases, a fentanyl patch (dosing as per the RSCA regimen) was applied, after which the epidural was weaned overnight and removed the following morning as per local practice.

The use of low-dose fentanyl patches is a standard approach in this hospital, with more than 15 years of experience with more than 10 000 cases before the study and no adverse events. This ensured that both groups were receiving approximately the same dose of systemic fentanyl via different administration routes.

Study outcomes and assessments

The primary outcome measure was the difference between groups in median pain score on movement from supine to sitting position at 24 h after extubation, measured with a visual analogue scale (VAS) of 0–100 mm[24,25]. Secondary outcomes comprised measures of analgesic effectiveness, functional recovery[26–29], morbidity (postoperative morbidity score (POMS) on day 5 and Dindo–Clavien grading complications)[30], and safety[31]. Prolonged postoperative ileus was defined as failure of return of bowel function by postoperative day 4[32].

Full details of outcomes and assessments are provided in *Appendix S1*.

Adverse events and serious adverse events (SAEs) were defined according to Directive 2001/20/EC, 4 April 2001, of the European Parliament (Clinical Trials Directive) and International Conference on Harmonisation GCP E6 guidelines.

All patient and outcome measure data were captured and recorded in the InForm electronic case report form using patient diaries, case notes, the hospital patient administration system, and the hospital electronic blood results system.

Statistical analysis

The Kelly study showed that the minimum clinically significant VAS pain score when managing severe pain was 10 mm[33]. Varying s.d. values from 14 mm to 18 mm have been reported[10], thus a s.d. of 18 mm was estimated for this study. To achieve 85 per cent power to detect a 10 mm difference in the primary endpoint, from a VAS pain score on movement at 24 h of 40 mm (s.d.18 mm) in the TEA group, to 30 mm (s.d. 18 mm) in the RSC group, at the 5 per cent level (two-sided t test), required 60 patients in each arm of the study. Losses to follow were

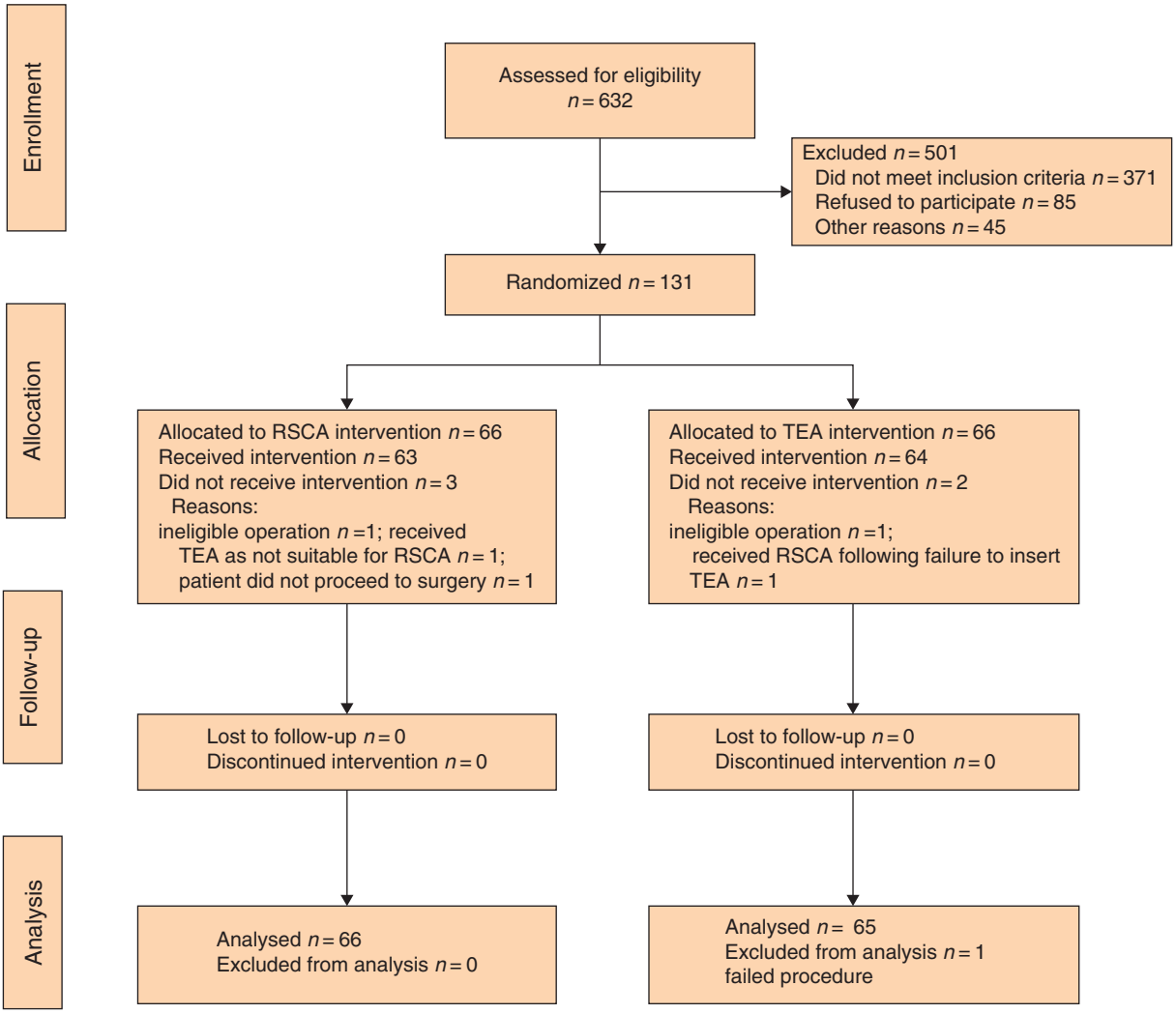

Fig. 1 CONSORT[34] diagram.
RSCA, rectus sheath catheter analgesia; TEA, thoracic epidural analgesia.

estimated at 10 per cent (the MASTERS study had only 3.5 per cent losses)[10], bringing the total sample size to 132 participants[21].

All analyses were performed according to the intention-to-treat principle and conducted with SPSS® Statistics for Windows, version 25 (IBM, Armonk, New York, USA).

The primary analysis tested the null hypothesis that there was no difference in mean VAS pain scores on movement at 24 h after surgery between those receiving TEA and RSCA analgesia.

The independent sample *t* test and Mann–Whitney *U* test were used to assess between-group differences depending on the distribution of the data when the data was measured on a continuous scale. Categorical variables were assessed for between-group differences with the chi-squared test, unless the data had an expected cell frequently less than 5. If this occurred, then a Fisher's exact test was used. Differences across time points were investigated with the repeated measures ANOVA.

A limited cost-effectiveness analysis comparing in-hospital costs in each treatment arm was performed (*Appendix S1*).

Results

Patient disposition and baseline characteristics

A total of 132 individuals were enrolled between February 2014 and February 2017. A total of 131 patients completed the study (*Fig. 1*) with 66 receiving RSCA and 65 receiving TEA. Only one patient in each arm crossed over to the other arm of the study and all other protocol deviations were minor involving non-compliance with the standardized non-opioid adjuvant analgesia. The two groups were well matched for baseline characteristics and the categories of surgery (*Table 1*).

Pain outcomes

Generally, there was high variability in pain intensity in both groups at all time points, both at rest and on movement (*Fig. 2*). Pain on movement 24 h after extubation was significantly lower in the TEA group (median (i.q.r.) VAS 33 (11–60) compared with the RSCA group (median (i.q.r.) VAS 50.5 (24.5–77.25); $P = 0.019$; *Fig. 2a*). The pain at rest was also significantly lower at 6 h in the TEA group (median (i.q.r.) VAS 6 (0–23)) compared with the RSCA group (median (i.q.r.) VAS 20 (4–43); $P = 0.034$; *Fig. 2b*); however, by 72 h, pain at rest was significantly lower in the RSCA group (median (i.q.r.) VAS 4.5 (0.25–13.75)) *versus* TEA group (median (i.q.r.) VAS 12.5 (2–31); $P = 0.019$; *Fig. 2b*).

Time to the first dose of opiate was significantly shorter in the RSCA group compared with the TEA group (148 min *versus* 1231 min; $P = 0.005$). The daily opiate consumption was, however, modest in both groups and similar on postoperative days 1 and 2. On postoperative day 3, daily opiate consumption

Table 1 Patient characteristics and demographics at baseline

Characteristic	RSCA ($n = 66$)	TEA ($n = 65$)	P
Age, years			
Median (i.q.r.)	67 (54—64)	67 (59—72)	>0.999*
Range	44–84	40–84	
Female, *n* (%)	23 (34.4)	20 (30.8)	0.588†
Mean(s.d.) BMI, kg/m^2	27.9 (4.92)	27.3 (5.38)	0.859‡
ASA classification, *n* (%)			
I	10 (15.4)	16 (24.6)	0.428‡
II	41 (61.3)	37 (56.9)	
III	14 (21.5)	12 (18.5)	
Median (i.q.r.) P-POSSUM morbidity	35 (19.86–61.36)	32.7 (21.59–47.29)	0.459*
Median (i.q.r.) P-POSSUM mortality	1.8 (0.79–4.79)	1.1 (1.0–5.1)	0.495*
Procedure, *n* (%)			
Major rectal resection	25 (37.9)	22 (33.8)	
Major colonic resection	25 (37.9)	27 (41.5)	0.810†
Radical cystectomy	16 (24.2)	16 (24.6)	
Mean(s.d.) incision length, mm	219.6 (68.5)	220 (95.6)	0.980‡

*Mann–Whitney *U* test. †Chi-square test. ‡Independent sample *t* test.
RSCA, rectus sheath catheter analgesia; TEA, thoracic epidural analgesia; i.q.r., interquartile range; P-POSSUM, Portsmouth physiological and operative severity score for the enumeration of mortality and morbidity.

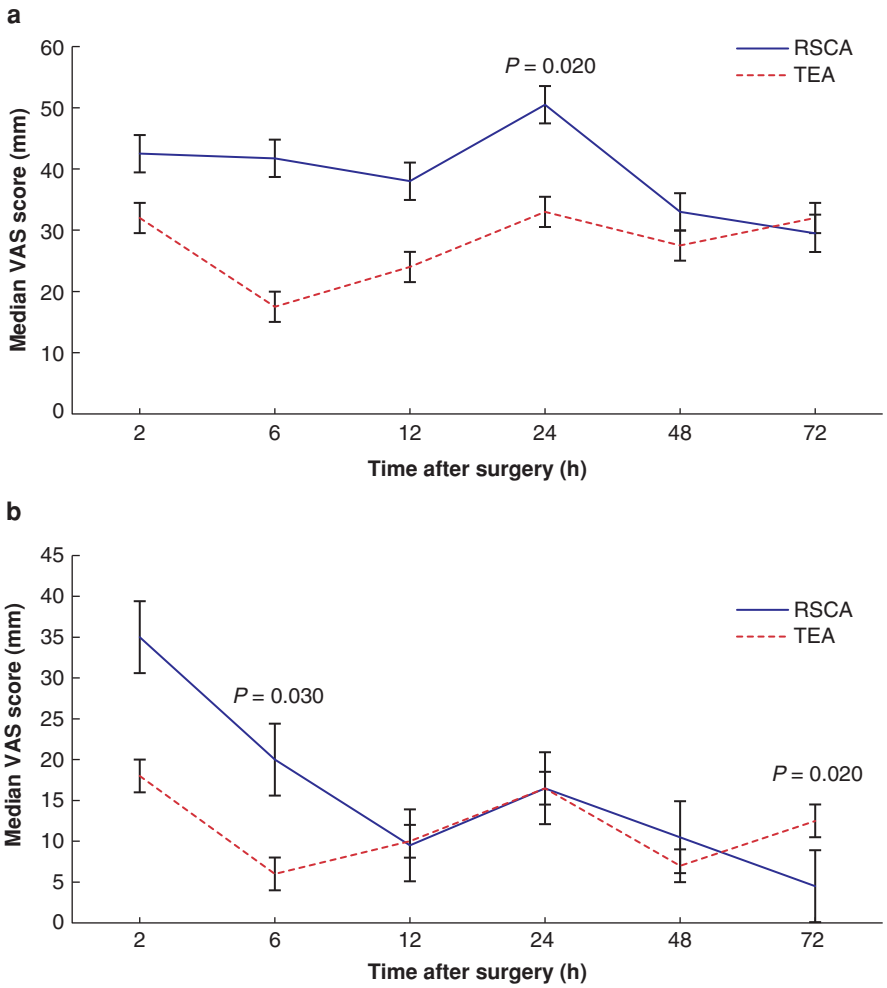

Fig. 2 Median (interquartile range) visual analogue scale (VAS) pain scores
a Scores on movement and **b** Scores at rest. RSCA, rectus sheath catheter analgesia; TEA, thoracic epidural analgesia.

was significantly lower in the RSCA group than in the TEA group (median (i.q.r.) morphine equivalent 17 (10–30) mg *versus* 40 (13.25–88.50) mg; $P = 0.038$); a similar non-significant trend was also seen on postoperative day 4 (median (i.q.r.) morphine equivalent 16.5 (9.5–32.5) mg *versus* 30 (10–69.5) mg; $P = 0.068$) (*Table 2*).

There were no significant differences between the groups regarding functional analgesia (comprising measures of

Table 2 Postoperative opiate consumption

Total morphine equivalent (mg)	RSCA	TEA	P
Day 1; median (i.q.r.)	30 (10–48)	28 (12–68)	0.650*
Day 2; median (i.q.r.)	30 (12–40)	30 (20–90)	0.342*
Day 3; median (i.q.r.)	17 (10–30)	40 (20–95)	0.038*
Day 4; median (i.q.r.)	16.5 (10–33)	30 (10–70)	0.068*
Total; median (i.q.r.)	50 (16–81)	47 (23–203)	0.365*

*Mann–Whitney *U* test.
i.q.r., interquartile range; RSCA, rectus sheath catheter analgesia; TEA, thoracic epidural analgesia.

respiratory function, mobility, and sleep quality) over the first 3 postoperative days and no difference in nausea and vomiting during the same interval (*Table S1*). More patients receiving RSCA reported overall excellent satisfaction with their entire analgesia experience to the end of the first 3 postoperative days, but this did not reach statistical significance (46.6 *versus* 36.2 per cent; $P = 0.509$) (*Table S2*).

Functional recovery

Functional recovery scores as assessed by the postoperative quality of recovery scale (PQRS) were generally similar between groups (*Table 3*). Only the activities of daily living domain of the day 7 PQRS score reached statistical significance in favour of the TEA group in terms of the proportion of participants recovering to baseline scores (53.4 *versus* 71.4 per cent; $P = 0.053$). Notably, large proportions of participants in both groups had not recovered to baseline for the emotive and cognitive domains at 30 days after surgery.

In terms of markers of return of gut function, there was no statistically significant difference between groups for time to first food intake ($P = 0.087$) or first bowel opening ($P = 0.148$). Time to first flatus was statistically significantly shorter in the TEA group compared with the RSCA group (median (i.q.r.) 50.1 (26.53–72.48) h *versus* 30.3 (14.56–54.10) h; $P = 0.002$) (*Table S3*).

Neither the duration of stay in the postoperative care unit or critical care unit (median (i.q.r.) 32 (28.25–53) *versus* 34 (30–56.1) h), the time to reach fitness for discharge from hospital (214 (164–281) *versus* 198 (166–373) h), nor the actual hospital length of stay (220 (171–299.25) *versus* 201 (173.25–339.50) h), was significantly different between groups (*Table S4*).

Morbidity

There was no statistically significant difference in postoperative morbidity between treatment groups, as measured by the POMS score on postoperative day 5 (*Table 4*).

There was no between-group difference in the charted fluid balance over the first 48 h after surgery, but the median weight gain from baseline to postoperative day 3 was greater in the TEA *versus* RSCA group (median (i.q.r.) 0 (−1–2) kg *versus* 1 (0–3) kg; $P = 0.046$).

The rate of prolonged ileus was higher in the RSCA group *versus* TEA group but did not reach statistical significance (25 *versus* 20 per cent; $P = 0.496$).

The proportion of participants with the composite of either postoperative hypotension or vasopressor dependency was significantly lower in the RSCA group than in the TEA group (29.7 *versus* 49.2 per cent, $P = 0.027$), and the median duration of norepinephrine dependency (14.5 h *versus* 31 h) was shorter in the RSCA group (*Table S5*), although the difference was not statistically significant ($P = 0.483$).

Table 3 Functional recovery scores as assessed by postoperative quality recovery score

Day/PQRS domain	Participants recovered, *n* (%)		P
	RSCA	TEA	
Day 4*			
Physiological	41 (71.9)	45 (80.4)	0.294
Nociceptive	53 (93.0)	51 (91.1)	0.489
Emotive	22 (38.6)	30 (53.3)	0.110
ADL	16 (28.1)	18 (22.1)	0.637
Cognitive	29 (51.8)	30 (53.6)	0.850
TOTAL	19 (33.3)	20 (35.7)	0.790
Day 7†			
Physiological	3 (6.0)	3 (6.1)	0.980
Nociceptive	49 (84.5)	49 (87.5)	0.643
Emotive	16 (27.6)	20 (35.7)	0.351
ADL	31 (53.4)	40 (71.4)	0.048
Cognitive	34 (59.6)	28 (50.0)	0.303
Day 30*			
Nociceptive	46 (76.6)	47 (79.7)	0.643
Emotive	22 (36.1)	25 (42.4)	0.479
ADL	49 (80.3)	45 (76.3)	0.590
Cognitive	33 (55.0)	40 (67.8)	0.152

*Chi-squared test. †Fisher's exact test.
ADL, activities of daily living; PQRS, postoperative recovery score; RSCA, rectus sheath catheter analgesia; TEA, thoracic epidural analgesia.

Table 4 Postoperative morbidity on day 5 as assessed by postoperative morbidity score

POMS domain	Participants with morbidity, *n* (%)		P
	RSCA	TEA	
Pulmonary	7 (11.1)	6 (9.4)	0.747
Infectious	6 (9.5)	11 (17.2)	0.205
Renal	0	1 (1.6)	0.504
Gastrointestinal	12 (19.0)	11 (17.2)	0.785
Cardiovascular	1 (1.6)	3 (4.7)	0.317
Neurological	0	2 (3.1)	0.257
Wound infection	0	2 (3.1)	
Haematology	0	1 (1.6)	0.144
Pain	1 (1.6)	4 (6.3)	0.197
Total POMS score			
0	48 (76.2)	45 (70.3)	
1	6 (9.5)	7 (10.9)	
2	6 (9.5)	8 (12.5)	
3	3 (4.8)	3 (4.7)	
7	0	1 (1.6)	

P values obtained with Fisher's exact test.
RSCA, rectus sheath catheter analgesia; POMS, postoperative morbidity score; TEA, thoracic epidural analgesia.

Safety and procedural failure rates

There was no difference in the number or severity of postoperative complications as measured by the Dindo–Clavien classification (*Table S6*).

SAEs were reported for five participants in the TEA group (delirium, $n = 1$; sedation, $n = 1$; excessive sedation, $n = 1$; and respiratory depression, $n = 2$) and one participant in the RSCA group (excessive sedation, $n = 1$) (*Table S7*).

There were fewer intervention failures in the RSCA group (21 *versus* 29 per cent; $P = 0.135$) but this difference did not reach statistical significance. The most common reason for the early failure of the intervention in both groups was catheter disconnection followed by catheter dislodgement (detailed categorization shown in *Table S8*).

The duration of the interventions was similar with a median (i.q.r.) of 81 (73–95.5) and 74 (56.5–79.0) h respectively for RSCA and TEA.

Cost-effectiveness analyses

Based on observed costs, RSCA was on average 457.60 Euro cheaper than the TEA (2888.79 Euro for RSCA and 3346.39 Euro for TEA). Full details, including sensitivity analyses, are reported in *Appendix S2*.

Discussion

This study showed significantly lower early pain intensity on movement in the TEA group, but significantly lower late pain intensity at rest in the RSCA group. The latter finding corresponded to a significantly greater opiate consumption in the TEA group on the third postoperative day. As RSCA provides only somatic analgesia, time to first opiate was significantly shorter with RSCA than with TEA because of the additional intravenous morphine that was required in the theatre recovery area to manage the initial visceral pain component in some patients receiving RSCA (in addition to the standardized dose of intraoperative morphine administered in that group). None of the other measurements of analgesic effectiveness (mobility, respiratory function, sleep quality, nausea and vomiting, and overall experience of their analgesia) reached statistical significance between groups, although more patients in the RSCA group reported excellent satisfaction with their overall analgesia during the first 3 postoperative days. Additionally, while patients in the RSCA group incurred lower treatment costs, primarily due to a shorter mean duration of stay in hospital than patients in the TEA group this difference requires confirmation in a larger and adequately powered study.

Turky *et al.* also compared RSCA and TEA in 100 patients following abdominal cancer surgery (a mixture of colorectal surgery, cystectomy, and hysterectomy) requiring open midline incisions[20]. The pain scores in both groups were lower than in the present study, particularly the dynamic pain scores. However, the dynamic pain scoring followed coughing in their study, whereas in the present study it followed moving from a supine position to sitting unaided, with the latter likely to induce far greater abdominal muscle engagement and therefore a stronger pain stimulus. In contrast with the present study, all pain scores were similar between interventions, whereas the TEA group had significantly lower opiate consumption (intra- and postoperative intravenous fentanyl consumption) leading to significantly greater early sedation in the RSCA group. They found no difference in any other postoperative complications. A longer critical care and duration of hospital stay in the RSCA group was also in contrast with the findings of the present study. A key difference in methodology was the use of a fentanyl/levobupivacaine mixture in the Turky *et al.* study and plain ropivacaine in the present study for the RSC boluses, and this addition of opiate to the infusion may account for the difference in findings. Indeed the 2013 study by Shabana *et al.* showed superior analgesia when the local anaesthetic was combined with morphine for RSCA[35]. In addition Turky *et al.* employed a more aggressive opiate rescue analgesia strategy, which may also explain the lower pain scores than in the present study[20].

Yassin *et al.* also compared RSCA and TEA in 60 patients following upper abdominal surgery requiring midline incisions[19]. Their primary outcome of morphine consumption over the first 72 h was significantly lower in the TEA group, all during the first 24 h. Again, pain intensity at rest and following coughing was similar between groups at all time points and lower than reported in the present study. They did not optimize TEA opting to use fixed infusions, and employed a more aggressive rescue analgesia protocol than in the present study. Their patient population being limited to upper abdominal surgery is a further possible reason for the difference in the results, as it generates less visceral pain—the component not covered by RSCA. Again, dynamic pain was scored following coughing in their study.

Other differences between the present work and previous studies include the use of a pump system to deliver the RSCA boluses, relying on staff to activate it every 4 h. It seems likely that some boluses may have been inadvertently missed in the present study and the study institution has subsequently changed to continuous RSCA infusions. Fentanyl patches were used in this study to maintain a low dose of systemic opiate, similar to the systemic absorption of the epidural opiate, thereby eliminating any need for drug administration compliance. Oral opiate was then used for any further breakthrough pain. Although combining the RSCA with i.v. morphine PCA would likely have reduced the pain intensity scores this would have been at the cost of mobility and morbidity. Finally, a recent cadaveric study has established that Tuohy needle and catheter placement in the medial aspect of posterior rectus sheath space increases the spread of injectate with less risk of arterial injury compared with lateral placement[36]. This placement detail may improve the quality of RSCA.

Effective analgesia is not simply the technique providing the lowest pain intensity scores, which are recognized for their subjectivity and reliance on the individual frame of reference, but should also provide ease of mobility, good respiratory function, the lowest adverse event rates, lowest morbidity, lowest failure rates, cost-effectiveness, staff compliance with administration and management, and most importantly patient acceptability and experience. This study has established that adverse event rates, failure rates, hypotension, and its surrogate vasopressor dependency along with associated weight gain as a proxy for greater i.v. fluid requirements were all more common in the TEA group. In addition, more patients reported excellent early satisfaction in the RSCA group. Furthermore, the health economics analysis measured a cost saving for each RSCA patient, with the difference greatest in the radical cystectomy group.

The present study has the limitations of being single-centre and unblinded. Blinding would have required either a sham epidural or RSCA in each patient in addition to their active intervention, and would have resulted in every patient being tethered to two pumps reducing the mobility of all patients. Such blinding would have been impossible to maintain throughout the intervention for both the patient and staff and potentially would have hampered their recovery. Other similar studies have all been unblinded.

Unanswered questions that warrant further research are comparisons between RSCA bolus or continuous infusion of local anaesthetic, and between surgically placed and ultrasound-guided placement of RSCA.

Two further refinements to the RSCA approach are worthy of consideration. The addition of opiate to the RSCA local anaesthetic infusions seems promising[20,32] and would be easy to implement. The main disadvantage of RSCA is the inability to

provide visceral analgesia, which, although of a shorter duration than the somatic pain, is highly variable in intensity and may generate high systemic opiate requirements in the first 24 h. Spinal opiate analgesia is routinely employed for managing intraoperative as well as early visceral pain following minimally invasive major abdominal surgery and thus combining spinal analgesia with surgically placed RSCA is attractive. This hybrid approach removes the need for intraoperative remifentanil infusions and thus potentially further reduces early postoperative opiate requirements and pain intensity as well as rates of chronic postsurgical pain associated with remifentanil use[37]. Indeed this approach has recently been reported as very successful after transthoracic oesophagectomy surgery[38], which is a notoriously challenging operation for which to provide effective pain relief. Anecdotally similar experiences are being reported for this approach after laparotomy.

Patients requiring planned open midline major abdominal surgery should be offered an informed choice between TEA and RSCA, particularly as there are rarely contraindications to RSCA and this approach entirely avoids the rare but devastating neuraxial injuries which may complicate TEA. Given the increase in open transverse incisions, minimally invasive and robotic surgery, the greatest impact of RSCA will likely be in the emergency laparotomy population (a vulnerable group, typically requiring open midline surgery, who frequently have contraindications to TEA).

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Disclosure. The authors declare no conflict of interest

Supplementary material

Supplementary material is available at *BJS Open* online.

Data availability

The authors are willing to make the data, analytic methods, and study materials used for this study available to other researchers. Such requests should be directed to the corresponding author for consideration and if appropriate subsequent sharing of a secure Dropbox data folder.

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