Trials

STUDY PROTOCOL

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A comparison of efficacy of erector spinae plane block versus serratus anterior plane block plus subcostal transversus abdominus plane block for bariatric laparoscopic sleeve gastrectomy surgery: study protocol for a randomised clinical trial

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Abstract

Background Obesity is a rapidly growing global health concern. Limited long-term success of diet, behavioural modification and medical therapy have led to the increased performance of bariatric surgery. Laparoscopic sleeve gastrectomy, which permanently reduces the size of the stomach, has been shown to cause considerable weight loss, as well as improving or even eliminating obesity related medical comorbidities such as diabetes, obstructive sleep apnoea and hypertension. Unfortunately, this surgery can also result in significant postoperative pain which, when combined with the dangers of perioperative opioid administration for bariatric patients, can lead to a significantly reduced quality of recovery. Opioid-sparing analgesia has been widely recommended for perioperative bariatric patients, but research into the optimum regional analgesia approach for this surgery is lacking, with no trials to date comparing different regional analgesic techniques. This study protocol describes a randomised clinical trial aimed at answering this question, comparing the quality of recovery after laparoscopic sleeve gastrectomy for patients who receive erector spinae plane block, versus those who receive serratus anterior plane block plus subcostal TAP block.

Methods We propose a prospective, randomised, blinded (investigator) clinical trial in a tertiary hospital in Ireland. Seventy patients presenting for laparoscopic sleeve gastrectomy will be randomised to two study groups—group A will receive bilateral erector spinae blockade; group B will receive left sided serratus anterior plane block plus subcostal TAP blocks. Both groups will receive the same dose of the same local anaesthetic and the different regional technique performed will be the only difference in their care. The primary outcome will be QoR-15 scores at 24 h postoperatively, a validated international tool for assessing a patient's overall postoperative recovery.

Discussion Regional analgesia should be a mainstay of perioperative opioid-sparing analgesia where possible. This is especially important in the bariatric cohort who are particularly susceptible to the complications of perioperative

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opioid administration. To the best of our knowledge, this trial will be the first to compare efficacy of two different regional analgesia techniques for bariatric patients undergoing laparoscopic sleeve gastrectomy surgery.

Trial registration This trial was pre-registered on clinicaltrials.gov, registration number NCT05839704, on March 5, 2023. All items from the World Health Organisation Trial Registration Data Set have been included.

Keywords Bariatric surgery, Laparoscopic sleeve gastrectomy, Opioid-sparing analgesia, Erector spinae plane block, Serratus anterior plane block, Subcostal TAP block, Quality of recovery

Background

The World Health Organisation describes obesity as an excessive accumulation of fat that presents a risk to health [1]. Obesity, commonly defined as a BMI of greater than 30, is a serious international public health concern, with recent statistics showing that more than one billion people worldwide are now living with obesity [2]. It is also a rapidly growing global health issue—the prevalence of obesity among adults has more than doubled since 1990 and these figures are predicted to rise annually [2]. Obesity is an independent risk factor for a myriad of medical conditions, including type 2 diabetes mellitus, obstructive sleep apnoea, hypertension, hyperlipidaemia and ischaemic heart disease [3].

Obesity is also a difficult condition to treat, with options including involving lifestyle modifications, psychological therapies, medical management and surgery. Limited long-term success of behavioural and pharmacological therapies in serious obesity have led to increasing interest in bariatric surgery. Surgery is currently recommended for severely obese patients (BMI > 40, or BMI > 35 in the presence of significant medical comorbidities) who are suffering from complications of obesity, are at high risk of morbidity and mortality and who have not achieved adequate weight loss with lifestyle modification and medical management [4]. Bariatric surgery can result in very substantial weight loss, resolution of obesity-related comorbidities and greatly improved quality of life for patients. Successful treatment of obesity via bariatric surgery has been shown to eliminate type two diabetes mellitus in up to 80% of patients [5], while bariatric surgery has been similarly shown to improve or eliminate obstructive sleep apnoea, hypertension, dyslipidaemia and metabolic syndrome [4].

During the past two decades, an increasing number of bariatric surgical procedures have been performed worldwide. The most prevalent procedures from 2000 to 2010 were gastric bypass or gastric banding surgeries. In the past decade, however, laparoscopic sleeve gastrectomy (LSG), a permanent method of reducing the size of the stomach, has become increasingly popular. The SLEEVEPASS and SM-BOSS trials, both published in 2018, conferred similar weight loss and improvement in comorbidities such as type 2 diabetes after LSG when compared with gastric bypass, but with lower morbidity and mortality rates [6, 7]. LSG has also been shown to decrease concentrations of ghrelin, the human 'hunger hormone', which may also contribute to the reduction in hunger and rapid weight loss in many patients postoperatively [8].

Unfortunately, bariatric surgery is frequently complicated by considerable postoperative pain, which can be difficult to manage [9]. The analgesic options for LSG patients provided by PROSPECT (PROcedure-SPECific postoperative pain managemenT) guidelines, designed to provide practical recommendations for pain management in potentially painful operations, are limited to paracetamol, NSAID/COX 2 inhibition, low dose dexamethasone, port site infiltration and rescue opioids postoperatively. The guidelines cite limited literature as a barrier to definitively recommending an optimal analgesic regimen for the surgery and call for more randomised trials to investigate further [10]. Guidance on regional analgesia techniques is notably absent from these recommendations, and there is a scarcity of research investigating the efficacy of different regional analgesic approaches in bariatric surgery across the literature as a whole.

In the absence of regional analgesia, the primary rescue treatment for patients suffering from pain after LSG is opiate therapy. The adverse effects of postoperative opiate administration have been extensively described, including respiratory depression, sedation, nausea, vomiting, constipation and urinary retention. These adverse outcomes are particularly important in the bariatric population, who are at increased risk of developing dangerous complications such as atelectasis, respiratory dysfunction and obstructive sleep apnoea postoperatively [9]. As such, alternative analgesic methods to opiate therapy have been preferred in bariatric patients. The Guidelines for Perioperative Care in Bariatric Surgery: Enhanced Recovery after Surgery Society Recommendations, first published in 2016 and updated in 2021, recommend that opioid-sparing analgesia using a multimodal approach should be employed to improve postoperative recovery. The guidelines recommend that regional anaesthetic techniques should be performed where possible but state that the current evidence does not allow the recommendation of one specific technique. They do

however cite ultrasound guided transversus abdominis plane (TAP) block and erector spinae plane block (ESB) as potential promising options [11].

Several regional analgesic options exist for LSG surgery, including serratus anterior plane block (SAPB), TAP block, quadratus lumborum block and ESB. Abdominal wall blocks such as the TAP block have been investigated with equivocal results [12, 13], likely in part because they provide only somatic analgesia [14]. The ESB is a relatively novel regional anaesthesia technique first described in 2016. A very limited number of studies to date have been performed regarding ESB in bariatric surgery, with early indications suggesting that it may provide an opportunity for increased postoperative analgesia in this cohort of patients [15].

At present in our institution, the methods utilised for regional analgesia for the majority of LSG surgery include either bilateral ESB blockade or a combination of both left sided SAPB and bilateral subcostal TAP block. To date, there is a lack of clarity regarding which block is the optimum technique for LSG patients and there have been no clinical trials published comparing two different regional analgesic approaches. This study aims to contribute to filling this gap in the literature by examining quality of recovery postoperatively after ESB versus that provided by SAPB plus subcostal TAP block.

We propose a prospective, randomised clinical trial of 70 patients scheduled for elective LSG surgery, with 35 patients receiving ESB and 35 receiving SAPB and subcostal TAP blockade. The primary outcome will be quality of recovery 15 (QoR-15) scores at 24 h postoperatively. Secondary outcomes will include postoperative complications (measured using the Comprehensive Complication Index), time to first analgesia in the recovery room, total 24-h opioid consumption, incidence of postoperative nausea and vomiting, need for rescue antiemesis therapy and length of hospital stay.

Aims and objectives

We aim to complete a randomised clinical trial to assess whether one of two regional analgesic techniques, bilateral ESB vs the combination of left sided SAPB plus bilateral subcostal TAP block, provides a superior quality of recovery following laparoscopic sleeve gastrectomy surgery than the other, as measured by the QoR-15 score.

Methods and trial design

This trial protocol is reported in accordance with the SPIRIT reporting guidelines. A completed SPIRIT checklist is included as an additional file [16]. The study timeline detailing the schedule of enrolments, interventions and assessments is outlined in Fig. 1.

Study design

This a prospective, blinded (investigator) randomised clinical trial. Recruitment commenced on 06 March 2023 and is expected to take 24 months.

Study setting

The study will take place in Galway University Hospital, a tertiary referral centre in Ireland.

Eligibility criteria

Inclusion criteria:

- Male and female patients aged over 18
- BMI > 35
- Undergoing LSG surgery
- Ability to provide written informed consent
- ASA grades I–III

Exclusion criteria:

- Inability to provide informed consent
- Pre-existing infection at block site
- Severe coagulopathy
- Allergy to local anaesthesia
- Pre-existing chronic pain condition necessitating attendance at pain clinic
- Baseline use of opioid analgesics
- Previous history of opioid dependence/abuse
- Predicted inability to cooperate with completion of QoR-15 score on postoperative day 1 (due to dementia or any other comorbidity)
- Predicted admission to ICU for prolonged ventilation postoperatively
- Patients with body weight < 100 kg (excluded as the dose of ropivacaine utilised in this protocol would exceed the maximum allowable limit of 3 mg/kg, thus posing an unacceptable risk of local anaesthetic systemic toxicity)

Participant selection, recruitment and consent process

Potential participants will include all patients presenting to hospital to undergo elective LSG surgery. A member of the research team will obtain the surgical list for LSG in advance, as is normal for the anaesthetic preoperative assessment of patients. The research team member will screen the patient for the above inclusion/exclusion criteria using their patient record and preoperative anaesthetic assessment prior to approaching the patient to discuss the study.

If a patient is eligibility for participation in the study, they will be approached by a member of the research

STUDY PERIOD				
TIMEPOINT	***Day of surgery***	***Postop day 1***	***Postop day 30***	***Length of hospital stay***
ENROLMENT:				
Eligibility screen	X			
Informed consent	X			
Allocation	X			
INTERVENTIONS:				
ESB + standard care	●	●		
SAPB + ESB + standard care	●	●		
ASSESSMENTS:				
QoR-15 score	**X**			
Pain score at 24h		X		
Time to first analgesia		X		
Total 24h opioid consumption		X		
Incidence of PONV		X		
Postoperative complications		X	X	X
Length of hospital stay				X

Fig. 1 SPIRIT figure. Overview of particpation timeline showing schedule of enrolments, interventions and assessments

team on admission, which will occur either the evening before or the morning of surgery. Each potential participant will be provided with both a verbal explanation of the study and, if they are amenable to consider participation, an information leaflet outlining the study design. They will be provided with adequate time (a minimum of ten minutes) to read and consider the information provided. The research team member will then return and time will be allowed for the participant to ask questions regarding the study. Participants will be informed that participation is entirely voluntary, and their treatment will not be affected by a choice not to participate. They will also be informed that they can withdraw from the study at any time, again with no effect on their treatment. If the patient agrees to participate, they will be given a consent form to provide written consent.

Standard care

Standard care for all patients in the study will involve opioid-sparing analgesia, including a regional analgesia technique. Patients enrolled in the study will be randomised

to receive one of the two described regional analgesia techniques, with the same dose of local anaesthetic administered to all patients. Group A will receive standard care plus preoperative bilateral ESB under ultrasound guidance at the level of the T7 transverse process. Group B will receive a left sided SAPB plus bilateral subcostal TAP block at the end of surgery, prior to emergence from general anaesthesia. The different block provided will be the only difference in patient care.

Standard care will include initial intravenous access while awake, after the patient has walked to theatre and positioned themselves on the operating table. Anaesthesia will be induced using 100 mcg fentanyl, propofol titrated to induction of general anaesthesia and rocuronium 1 mg/kg body weight. Airway management technique will be at the discretion of the presiding anaesthetist, but all patients will be intubated. Anaesthesia will be maintained using titrated doses of sevoflurane in oxygen/air. Further IV access and arterial line insertion for haemodynamic monitoring will follow post induction of general anaesthesia. Surgery will be performed by the same consultant surgeon and their team for each case.

Standard medication regime

An opioid-sparing analgesic approach will be employed throughout the patient's perioperative course. Intraoperative analgesics administered will be as follows:

- Ketamine, administered as a 0.1 mg/kg IV bolus followed by 0.1 mg/kg/h IV infusion stopped at commencement of surgical skin closure
- Dexmedetomidine, administered as a 0.1mcg/kg IV bolus followed by 0.1 mcg/kg/h IV infusion, again stopped at commencement of surgical skin closure
- Magnesium sulphate IV infusion will be titrated to offset any sympathetic response to surgical insult (up to 50 mg/kg)
- Paracetamol 2 g IV
- Diclofenac 75 mg IV

Other medications administered intraoperatively include antiemetics (dexamethasone 0.1 mg/kg IV to a maximum of 8 mg, ondansetron 4 mg IV and droperidol 625 mcg IV) and muscle relaxant reversal (sugammadex titrated to train of four monitoring). IV fluids will be given in the form of 1000 ml compound sodium lactate administered intraoperatively via fluid warmer, with supplemental IV fluids administered depending on surgical blood loss and patient haemodynamics.

Postoperatively, patients will be transferred to the recovery room and then to the ward when recovery room discharge criteria are met. Patients will be prescribed oxycodone 1–2 mg IV as required in the recovery room, which will be administered by recovery nursing staff when pain is greater than 2/10 on the verbal rating scale (VRS) pain score in line with hospital policy. On discharge to the ward, all patients will be prescribed paracetamol 1 g IV 6 hourly and diclofenac 50 mg PO 8 hourly. Rescue analgesia will be prescribed in the form of oxycodone immediate release 5–10 mg PO 4 hourly PRN, which will be administered by ward nursing staff for breakthrough pain as required. Ondansetron (4 mg PO/IV 8 hourly as required) will be prescribed for treatment of postoperative nausea or vomiting.

Intervention

Patients randomised to the ESB group will receive bilateral ultrasound guided ESB. The blocks will be performed with the patient awake and in the sitting position, prior to induction of general anaesthesia. Forty milliliters of 0.75% ropivacaine, diluted to 60 ml with 20 ml 1% lignocaine with adrenaline, will be injected (30 ml each side) at the level of the T7 transverse process bilaterally.

Patients randomised to the SAPB plus subcostal TAP block group will receive ultrasound guided left sided SAPB and bilateral subcostal TAP block under general anaesthetic after their surgery has concluded. Again, 40 ml of 0.75% ropivacaine, diluted to 60 ml with 20 ml 1% lignocaine with adrenaline, will be injected (20 ml per injection).

All blocks will be performed, under full aseptic conditions, either by or under the direct supervision of the same consultant anaesthesiologist throughout the duration of the study. This consultant anaesthesiologist will have had no role in patient recruitment, the randomisation process or data collection postoperatively.

Explanation of choice of comparators

LSG surgery involves the insertion of a number of trocars into the anterior abdominal wall [17]. The number and positioning of trocars can vary depending on the individual patient and surgical preference. A larger number of ports will have a direct effect on the postoperative pain of these patients while widely positioned ports can make effective coverage with regional analgesia techniques more difficult. Any regional approach should be focused on the individual surgery being performed, and the choice of technique in laparoscopic surgery should be tailored to the specific incision sites used. In our institution, a variable number of trocars are used in this surgery, with the largest incision site located in the left upper quadrant, where the dissected part of the stomach is withdrawn.

As mentioned, providing regional analgesia for these multiple incision sites can be challenging. In this study, we compare two regional analgesia approaches which are aimed at meeting this challenge. The first arm of the

study employs bilateral ESB to cover all incision sites, while the second arm employs the tailored approach of left sided SAPB to cover the high left upper quadrant trocar site, in combination with bilateral subcostal TAP blockade to cover all other trocar sites.

Study outcomes

Primary outcome

The primary outcome measured in this study will be quality of recovery at 24 h, as measured by the QoR-15 score. This score is calculated from a questionnaire, in which patients use a grading system from 0 to 10 to answer fifteen questions regarding their postoperative recovery [18]. The score, designed to provide a multifaceted assessment of a patients' postoperative recovery, is a validated means of assessing quality of patient recovery after surgery and is now recommended as an endpoint in clinical trials focused on the assessment of postoperative pain [19].

Secondary outcomes

Secondary outcomes assessed will be as follows:

- Pain scores at rest and on movement at 24 h using a verbal response scale
- Time to first analgesia postoperatively
- Total opioid consumption in the first 24 h postoperatively
- Incidence of nausea and vomiting and use of antiemetic rescue
- Incidence and severity of postoperative complications using the Comprehensive Complication Index (CCI) score
- Length of hospital stay

Participant timeline

Patient participation in this study will commence upon their preoperative admission to hospital, either the evening before or the morning of surgery. Enrolment and consent will take place at this time. The interventions will take place as described above in the perioperative period. Postoperative data collection will occur initially during a patient visit at 24 h postoperatively when patients will be asked to complete the QoR-15 score. Time to first postoperative analgesia, total 24-h opioid consumption, incidence of postoperative nausea and vomiting and need for rescue antiemetic therapy will also be recorded at this time.

Participation will run until at least thirty days postoperatively. Postoperative complications will be assessed via chart review at either 30 days after surgery or upon hospital discharge if their length of stay is longer than 30 days. Complications will be graded using the Comprehensive Complication Index (CCI) score. This is the final data collection in the study, patient participation ceases either at 30 days after surgery or when they are discharged from hospital.

Sample size

The primary outcome in this study will be the QoR-15 score at 24 h postoperatively. The established minimum clinically important difference in QoR-15 across a range of minor, intermediate and major surgeries is 6.0 [19, 20] and the mean SD of QoR-15 scores is in the order of 8–16 [21]. Taking an SD of 8, assuming type 1 error = 0.05 and type 2 error = 0.2, the power calculation requires 29 patients in each group. To accommodate for patients who may withdraw from the study or be lost to follow-up, our aim is to recruit 35 patients to each study arm, giving a total study sample size of 70.

Intervention group allocation

Patients will be randomised to one of the two trial groups using computer generated random numbers by a member of the research team. Sealed opaque envelopes numbered sequentially with study numbers from 1 to 70 will be used to conceal a folded page containing the group allocation for each study number. As patients present for their surgery, they will be assigned the next study number and corresponding envelope. Block randomisation will occur in group of six to ensure an even number of patients in each group as the study progresses. The two trial groups will be named 'ESB' and 'SAPB + TAP'. A randomisation key containing the enrolment log will be held by the principal investigator who will play no role in data collection. The research team will have no access to this key until all data collection is complete.

After patient recruitment, the sealed envelope labelled with the patients' study number and containing their group allocation will be placed in their physical patient record. They will then be met preoperatively by the attending consultant anaesthesiologist who will open the envelope to reveal their group allocation, before conducting their anaesthetic management, including their regional analgesia technique.

Blinding

In performing the blocks, the attending anaesthesiologist will not be blinded to group allocation but will play no role in data collection. All other members of the research team, who are those who will be involved in data collection, will be blinded to group allocation. The details of each block will be recorded in full in the patient's anaesthetic record, and as such, group allocation can and will

be revealed immediately if a clinical concern arises, such as a suspicion of local anaesthetic toxicity.

Data collection

The following data will be collected in the perioperative period:

Preoperative:

- Age
- Sex
- BMI
- Date of surgery

Intraoperative:

- Time of regional analgesia block
- Duration of general anaesthesia
- Duration of surgery
- Any intraoperative rescue analgesia required (other than that outlined in standard care above)

Postoperative (at 24 h):

- QoR-15 score
- Pain scores at rest and on movement, using numeric pain rating scale from 0 to 10
- Time to first analgesia in the recovery room or on the ward
- Total opiate use in the first 24 h postoperatively
- Incidence of nausea or vomiting in the first 24 h postoperatively
- Antiemetic use in the first 24 h postoperatively

Follow-up (at 30 days or at hospital discharge if greater than 30 days postop):

- Length of hospital stay
- Comprehensive Complication Index (CCI) score

Data management and confidentiality

The data listed above will be collected by the blinded research team with the aid of a paper proforma. These paper forms will contain only study number and will not contain any patient identifiers or group allocation details. These forms will then be stored in a locked filing cabinet in the hospital's department of anaesthesiology, in a locked office requiring key card access. Prior to data analysis, the data from these proformas will be uploaded onto a password protected study spreadsheet on the hospital computer system. Once uploaded onto this spreadsheet, all paper proformas will be destroyed using the hospital's confidential waste disposal bins. Once the study has been completed, and following a period of 10 years to ensure data integrity, all electronic data will also be permanently destroyed.

Patient consent forms will be stored in a separate locked filing cabinet in the department of anaesthesiology. These consent forms will not contain study numbers or any other information which would allow the data collected during the study to be linked back to the individual patients.

The only identifiable data will be stored on the enrolment log, which will be saved to a USB key and stored in a locked filing cabinet in the locked office of the principal investigator, who has no role in data collection, for the duration of the study.

Only members of the trial research team will have access to the data during the trial and after the final dataset is completed.

Statistical methods

Data will be divided into normally distributed and non-normally distributed date using the Kolmogorov–Smirnov test. Normally distributed data will be compared using the unpaired t test. Non-normally distributed data will be compared using the Mann–Whitney U test. All data will be summarised as mean + SD or median (25–75% range) as appropriate.

Oversight and monitoring

The trial will be overseen and monitored by the Galway University Hospital Clinical Research Ethics Committee, who will be in contact with the principal investigator regularly during the study. An annual progress update will be provided to the hospital's Clinical Research Ethics Committee until the trial is completed. The committee is fully independent from the research team and there are no competing interests.

Harms/adverse event reporting

Group allocation can and will be revealed immediately if a clinical concern arises, such as a suspicion of local anaesthetic toxicity. This can be done without delay as all details of the patients' intervention will be recorded in the patient's anaesthetic record. Any complications arising from the study interventions will be managed as per best medical practice. Adverse events will be reported to the hospital's Clinical Research Ethics Committee.

Protocol amendments

We do not anticipate any amendments to be made to this study protocol and there have been no amendments to date. Any potential amendments will be immediately communicated to the Clinical Research Ethics Committee.

Discussion

As yet, despite significant postoperative pain and well documented issues surrounding opiate analgesia in bariatric patients, the evidence supporting the use of regional analgesia techniques in LSG surgery is sparse, and there are no trials comparing different regional approaches for these patients. Our aim in conducting this prospective randomised clinical trial is to compare patient recovery after bilateral ESB versus after left sided SAPB plus bilateral subcostal TAP blockade.

Erector spinae plane blockade

The erector spinae muscle group is formed by the spinalis, longissimus and iliocostalis muscles, which run vertically on either side of the vertebral column from the sacrum to the base of the skull. The ESB, first described by Forero et al. in 2016, is performed by depositing local anaesthetic in the fascial plane between the erector spinae muscle group and the tip of the vertebral transverse process [22]. Local anaesthetic spreads in this fascial plane with reliable coverage of three dermatomes above and below the injection site. Cadaveric studies have shown that ESB affects both the dorsal and ventral rami of the spinal nerve. The ventral ramus divides into anterior and lateral branches, with its terminal branches providing sensory innervation of the entire anterolateral thoracoabdominal wall. It has also been shown that the local anaesthetic diffuses to the adjacent paravertebral space, thereby providing both somatic and visceral sensory block of the abdomen, making it an ideal regional analgesic approach for abdominal surgery [23].

Serratus anterior plane blockade

SAPB was first described by Blanco in 2013 as a novel ultrasound-guided method of providing analgesia of the thoracic wall [24]. It blocks the lateral branches of the intercostal nerves of T2–T9 spinal nerves by injecting local anaesthetic into the plane either superficial or deep to the serratus anterior muscle. As the innervation of the upper abdominal wall is derived from T6 to T10, blockade of these sensory nerves in the thoracic region has also been shown to offer excellent analgesia for upper abdominal incisions [25–28].

Subcostal transversus abdominus plane blockade

The analgesic benefits of the TAP block, first described in 2007 by McDonnell et al., have been well described for patients undergoing abdominal surgery [29]. The subcostal approach variation to the TAP block was first introduced by Hebbard et al. in 2008 with the aim of providing more reliable coverage of the supra-umbilical abdominal wall from T6–T9. The subcostal TAP block has since been shown to provide postoperative analgesia and reduce open consumption for patients undergoing both open and laparoscopic upper abdominal surgery [30–32].

Strengths and limitations

An undoubted strength of our study is that the regional analgesia technique will be performed by, or under the direct supervision of, the same consultant anaesthesiologist, while the surgery will be performed by the same consultant surgeon, for the duration of the study. Any difference in outcome which may have been contributable to variations in either anaesthetic or surgical approach of different consultants will as such be eliminated.

We have chosen to exclude patients who are already suffering from chronic pain conditions requiring pain clinic attendance or the need for baseline opioid therapy. There is a considerable crossover between bariatric surgery patients and chronic pain patients, with rates of significant chronic lower back pain, chronic headaches and fibromyalgia all higher in this cohort [33]. We feel, however, that assessing the pain relief provided for this specific surgery by the regional analgesic techniques chosen will be more reliable if this cohort are excluded.

There are some limitations of our study which we feel it is necessary to address. Ideally, we would favour a fully double-blinded study design. In this instance, however, the attending anaesthesiologist will perform all blocks, and as such, it is unavoidable that they will not be blinded to the group allocation. We have mitigated this by ensuring that this anaesthesiologist will have no role in postoperative data collection nor will they have access to the data after it is collected. All members of the research team involved in data collection will be blinded to group allocation until the study is complete.

The performance of preoperative ESB awake in one arm of our protocol and postoperative TAP + SAPB under general anaesthesia in the other arm is a discussion point of our study. There would be advantages to performing all blocks under general anaesthesia, including an elimination of a placebo effect a patient may experience from witnessing their regional procedure. However, due to the significant difficulties in positioning patients and performing ESB under general anaesthesia in the bariatric cohort, asleep ESB is not feasible for these patients. As such, the bilateral ESB will be administered immediately preoperatively, with the patient awake and in the sitting position. In our experience, SAPB and subcostal TAP blocks are usually performed under general anaesthesia where possible, so these will be performed supine under general anaesthesia immediately after the completion of surgery. This difference is mitigated by the fact that LSG is a procedure with relatively short operating time, cited previously as an average duration of 106 min [34],

minimising the time difference between the two blocks. All postoperative data, including QoR-15 and 24-h opioid consumption, will be collected at 24 h from the end of procedure, when all patients will have a block on board, rather than from block performance.

In this protocol, we are using the same total dose of local anaesthetics in each arm. This has been divided into two 30-ml doses each for the bilateral ESB arm and three 20 ml doses for the SAPB + bilateral TAP arm. While there is a discrepancy in volume for each individual injection, we feel that using the exact same total volume of local anaesthetic in both arms of the study is paramount. Research has shown that systemic uptake of local anaesthetic may play a role in the analgesic benefit of fascial plane blocks, including ESB, SAPB and TAP blocks [35–38]. By prioritising using the same total volume of local anaesthetic, we maximise the likelihood that analgesic benefit derived from systemic uptake of local anaesthetic is equivalent in both arms of the study.

We have also chosen to use both ropivacaine and lidocaine with adrenaline in our local anaesthetic injectate. The mixing of local anaesthetics is a controversial topic. Ropivacaine and lidocaine are often used concurrently, in theory, to benefit from both the rapid onset of lidocaine and the long duration of action of ropivacaine. These theoretical benefits have not been proven to occur in reality, however, and studies have shown that mixing local anaesthetics in this manner has very little impact on speed of block onset and duration of action [39]. In our protocol, we have added lidocaine with adrenaline in order to avail of the benefits of adrenaline in minimising the risk of local anaesthetic systemic toxicity. Adrenaline both acts as a marker for intravascular injection and also causes local vasoconstriction, decreasing systemic local anaesthetic uptake. We feel this benefit is particularly valuable in this protocol, where a large dose of ropivacaine (300 mg in total) will be used in each patient.

In summary, bariatric patients are particularly vulnerable to complications in the postoperative period. The pain caused by LSG surgery, combined with the increased dangers of opioid therapy in this cohort, increases this vulnerability. Regional analgesia techniques have been recommended as a mainstay of opioid-sparing therapy in these patients. In this study, we attempt to investigate which the optimum regional analgesic approach may be, by comparing the quality of overall postoperative patient recovery following two different techniques.

Trial status

As of May 1, 2023, 33 patients have been enrolled in this trial. Patient recruitment began on March 6, 2023, and is expected to be completed by March 2, 2025. This is protocol version 1, dated April 2, 2023.

Abbreviations

ASA	American Society of Anaesthesiologists
BMI	Body mass index
CCI	Comprehensive Complication Index
ESB	Erector spinae plane block
LSG	Laparoscopic sleeve gastrectomy
PROSPECT	Procedure specific postoperative pain management
QoR-15	Quality of Recovery 15 assessment
SAPB	Serratus anterior plane block
TAP	Transversus abdominis plane block

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08472-4.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Supplementary Material 4.

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Dissemination plans

Upon completion of this trial, it is the authors' intention to present the data at local, national and international level conferences. The research will also be submitted for publication in peer-reviewed medical journals.

Authors' contributions

PW and DC contributed equally to the study design and the development of this protocol. PW drafted the protocol manuscript. MVDW, MOR, MS and KB, along with PW and DC, contributed to the ethics application. All authors read and approved the final manuscript.

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Availability of data and materials

Datasets will be available from the corresponding author upon reasonable request.

Declarations

Ethical approval and consent to participate

The trial has received ethical approval from the Galway University Hospital Clinical Research Ethics Committee on 25 January 2023. Reference number: 131/23. We will submit an annual progress report, including any adverse events which occur to the Ethics Committee, and inform the Ethics Committee of any changes that are subsequently made to the protocol. All participants in this trial will be required to provide informed written consent to participate. Participants will also be notified of any changes which are made to the study protocol.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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