Single-shot liposomal bupivacaine in place of rectus sheath catheters to provide non-opioid analgesia after laparotomy: a quality improvement project to reduce the need for ongoing nursing input

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ABSTRACT
Opioid-sparing pain management is an integral component of enhanced recovery after colonic and rectal surgery. In our hospital, rectus sheath catheters (RSCs) are routinely placed during emergency laparotomy for colorectal procedures to allow a postoperative compartmental block of the surgical site with repeated doses of bupivacaine. However, RSCs require a significant amount of clinical nursing time to maintain and ‘top-up’. We present a quality improvement project in which we administered single-shot liposomal bupivacaine (LB) intraoperatively as an alternative to bolus doses of conventional bupivacaine delivered through RSCs. Having thereby reduced the demands placed on nursing time through a reduction in the use of RSCs, we sought to establish whether there was any associated change in analgesic efficacy. Patient pain scores, use of patient-controlled analgesia (PCA) and length of stay following surgery were analysed before and after the introduction of LB. No disruption in these outcomes was identified using statistical process control analysis. A direct comparison of results for patients who received LB versus those who received bolus dosing of bupivacaine via RSCs found no significant differences, with a median total PCA dose of 270 mg oral morphine equivalents (OME) for patients who received LB versus 396 mg OME for patients who had RSCs (p=0.54). The median length of stay for patients who received LB was 15.5 days versus 16 days for those who had RSCs (p=0.87). We conclude that LB represents a viable alternative to boluses of conventional bupivacaine via RSCs in promoting enhanced recovery after emergency laparotomy and look to extend its use locally.

INTRODUCTION
Over the past 15 years, rectus sheath catheters (RSCs) have emerged as an analgesic modality to provide non-opioid analgesia following major abdominal surgery, offering advantages over thoracic epidural in terms of their side effect profile. They have been used in our own institution throughout this period to good effect. A disadvantage to the use of RSCs is that their maintenance is a drain on nursing resources. A significant amount of clinical nursing time is required by the drawing up and repeated injection of bupivacaine once a patient is recovering on the ward. While pumps exist that provide continuous infusion of bupivacaine through an RSC and avoid the need for bolus dosing, these are not available in our hospital and are more expensive than simple catheters. Internal data collected through observation and interviews with 14 clinicians found that patients recover more quickly after emergency laparotomy in the presence of a single-shot liposomal bupivacaine (LB) infusion. LB can be adopted in place of rectus sheath catheters, relieving the demands placed on nurses without compromising patients’ pain management.

WHAT IS ALREADY KNOWN ON THIS TOPIC
⇒ Opioid-sparing pain management is an integral component of enhanced recovery after colonic and rectal surgery.
⇒ Following laparotomy, repeated injections of bupivacaine through rectus sheath catheters are an effective means of providing non-opioid analgesia.
⇒ Rectus sheath catheters, although effective, demand a large amount of clinical nursing time.

WHAT THIS STUDY ADDS
⇒ Single-shot liposomal bupivacaine offers an alternative to regular doses of conventional bupivacaine given through a rectus sheath catheter.
⇒ The introduction of liposomal bupivacaine in place of rectus sheath catheters does not compromise the pain management of patients who have undergone emergency laparotomies.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY
⇒ Liposomal bupivacaine can be adopted in place of rectus sheath catheters, relieving the demands placed on nurses without compromising patients’ pain management.
⇒ The analgesic efficacy of liposomal bupivacaine should be compared with that of rectus sheath catheters in prospective, controlled, randomised trials.
nursing colleagues found that administering every bolus dose through an RSC in accordance with the protocol developed by our local pain team takes, on average, 30 min (with a range between 20 and 40 min). This does not include the time taken to indirectly monitor patients for symptoms or signs of local anaesthetic toxicity. With top-ups repeated 4–5 times daily, a single patient’s RSCs can occupy 11%–15% of a nurse’s working week. Within England, there was an estimated 10% vacancy rate within the Registered Nursing staff group at the end of March 2022. This is in the context of a largely unchanged number of registered nurses per 1000 population over the previous decade, despite the increasing demand for care. As a result, there is a clear necessity within the UK to drive initiatives that reduce the total number of nursing hours required to provide good patient care.

Liposomal bupivacaine (LB) is a formulation of bupivacaine with a greater duration of action than its conventional counterpart. This is achieved through extended release of the active drug from biodegradable multivesicular liposomes over a period of up to 72–96 hours. The only LB product with marketing authorisation in the UK is EXPAREL (Pacira). It has been used in the USA since its approval by the US Food and Drug Administration in 2011, and a strong evidence base has emerged for its role within orthopaedic surgery. Additionally, there is evidence to support the use of LB in abdominal surgery when given as a transversus abdominis plane block. Specific to colorectal resections, but not discriminatory in the mode of its delivery, two systematic reviews with meta-analysis associate the use of LB with reduced postoperative morphine requirements and shorter lengths of stay. To our knowledge, there are no studies that directly compare the efficacy of LB to bupivacaine delivered via RSCs.

Through the introduction of LB in place of conventional bupivacaine, we can capitalise on the longer duration of action provided by LB, obviating the necessity for repeated doses of local anaesthetics and therefore the requirement for RSCs. As an alternative to boluses of conventional bupivacaine delivered through RSCs, LB offers the opportunity to reduce the nursing hours involved in the care of patients.

**DESIGN**

**Context**

This project was conducted in an English University Teaching Hospital with approximately 800 inpatient beds. The hospital employs a software application called EPIC to record electronic patient notes, medications, observations and investigation results, which can be interrogated to report data for audit purposes.

It is routine practice for our patients who undergo emergency laparotomies to receive multimodal analgesia that includes patient-controlled analgesia (PCA) and RSCs. The role of PCA is to provide patient-initiated, opiate-based relief of breakthrough pain. Bupivacaine delivered by RSCs is used to minimise the requirement for such opiate-based analgesia and promote an enhanced recovery after surgery (ERAS). A typical bolus dose of 20 mL of 0.125% bupivacaine is delivered through each RSC four times per day.

Patients or the public were not involved in the design, conduct, or reporting, or dissemination of plans of our study. It is reported with reference to the Standards for Quality Improvement Reporting Excellence guidelines.  

**Objective**

The overall intention of our quality improvement initiative is to reduce the nursing hours required for the postoperative care of patients who undergo emergency laparotomies. Our a priori understanding was that this could be achieved with a reduction in the use of RSCs. The purpose of this particular project was to study whether there was any change in the efficacy of pain management provided to patients following the introduction of LB and thus the reduction in the use of RSCs.

**Population**

We studied adult patients admitted consecutively under the colorectal service over the course of 12 months, from 1 September 2021 to 31 August 2022. We included those who underwent emergency laparotomies and received RSCs or LB (n=90). We then excluded those patients who were sedated postoperatively (n=11), died within 5 days of surgery (n=1) or did not receive PCA (n=13). The total number of patients was 65. There were 47 patients who received conventional bupivacaine bolus dosed through RSCs and 18 who received LB.

**Intervention**

We secured LB (EXPAREL) for our hospital pharmacy and facilitated its use by four early-adopter colorectal consultant surgeons. EXPAREL was introduced at the beginning of March 2022, between two 6-month periods of continuous audit. In the second 6 months of the audit, eligible patients operated on by early-adopter surgeons received single-shot, intraoperative LB in place of repeated doses of conventional bupivacaine delivered via RSCs. Following the two periods of audit, data were presented to the colorectal and upper gastrointestinal consultant surgeons at a departmental meeting and the next steps were agreed upon. The structure of our project therefore follows that of a single ‘plan-do-study-act’ (PDSA) cycle, involving a period of planning and audit prior to an intervention, a reaudit and finally a meeting in which results were discussed and further service modifications planned.

The introduction of LB required close liaison with the hospital pharmacy, the involvement of the hospital’s pain team, the anaesthetic lead, the surgical divisional managers and colorectal consultant surgeons. This liaison took the form of email communication and informal meetings. Theatre staff were trained locally in the preparation and administration of LB by drug
representatives. No in-person training was provided to surgeons, as the method of administration of LB is very similar to the administration of conventional bupivacaine through an RSC (see below), but they were provided with written education on the drug prior to its introduction. No formal training was provided to ward-based nursing staff.

The LB was administered using a technique similar to that used for the placement of RSCs. Prior to the fascial closure of the midline wound, a Tuohy needle was used to access the potential space between the rectus muscle and its posterior sheath. At this point, instead of introducing an RSC, LB was injected through the needle prior to its removal. EXPAREL (20 mL) was mixed with 40 mL of 0.25% bupivacaine hydrochloride and 40 mL of 0.9% saline, giving a total volume of 100 mL, with 50 mL injected into each side of the wound. As EXPAREL is stored at a low temperature, it is possible to feel the cold liquid dissipating through the rectus sheath, and this can be aided through massage.

**Measurement**

The audit was conducted through a remote review of the patients’ electronic medical records. Institutional approval was obtained prior to any data collection. We measured patient-reported pain scores (0–10), duration of use of PCA, cumulative dose of PCA required by postoperative day (POD) 5, total dose of PCA required and length of stay. Additionally, we observed and informally interviewed nursing staff, as discussed above, to determine the typical demands placed on them through the care of RSCs.

**RESULTS**

Much of our measurement concerned the use of PCA as a surrogate marker for the adequacy of pain management. Patients receiving poorer pain relief through the effects of their local anaesthetic (whether delivered through an RSC or single-shot LB) are expected to use their PCA more. Opioid use as a surrogate marker for the efficacy of non-opioid analgesia has already been established through a number of relevant studies.20–26 A reduction in opioid consumption is also an end in itself for colorectal ERAS pathways, while length of stay is a function of ERAS.27 28 The data on PCA use as statistical process control charts, along with the data on length of stay, are presented in figure 1. We demonstrate that there was no loss of ‘control’ in the use of PCA or length of stay following the introduction of LB.

![Figure 1](http://bmjopenquality.bmj.com)  
**Figure 1** Introduction of LB does not cause loss of ‘control’ in PCA use and length of stay.
We also measured patients’ pain directly through subjective pain scores. We found that pain scores were recorded with variable regularity in the clinical record, resulting in an inconsistent number of data points between patients. Averages of the pain scores that were recorded show that the introduction of LB was not associated with any worsening in patient-reported pain (figure 2). Median pain scores for patients receiving bolus doses of conventional bupivacaine via RSCs were 4, 3.15 and 4 on POD 1, 2 and 3, respectively. Median pain scores for those patients receiving single-shot LB were 3.3, 3.6 and 2 on POD 1, 2 and 3, respectively.

In addition to the use of statistical process control charts, we made a direct comparison of our measurements between patients who received repeated doses of conventional bupivacaine delivered via RSCs and those who received single-shot LB. Using heteroscedastic two-tail T-testing, we found that there was no statistically significant difference in any of the measurements between the two cohorts of patients (figure 3). There was a non-significantly lower PCA use in the patients who received LB, with a median PCA dose at POD 5 of 254 mg oral morphine equivalents (OME) given to patients receiving LB versus 366 mg OME for those receiving single-shot LB. Using conventional bupivacaine delivered via RSCs (p=0.32). The median total PCA dose was 270 mg OME for patients receiving LB versus 396 mg for patients who had RSCs (p=0.54). The length of stay was also non-significantly lower for patients who received LB (median 15.5 days) versus those who had RSCs (median 16 days) (p=0.89). The median day at which PCA was taken down was POD 3 for the LB group and POD 5 for the RSC group (p=0.57).

**DISCUSSION**

**Summary**

We believe that we have demonstrated the feasibility of using LB in the context of laparotomy, alongside evidence that it did not disrupt the efficacy of postoperative analgesia. Through this work, we also highlight the potential that LB affords to reduce the demands placed on nurses. This is because LB is a single-shot drug that does not require nurses to administer bolus doses in the way of conventional bupivacaine delivered through RSCs.

**Interpretation**

From our data, the introduction of LB did not disrupt the efficacy of postoperative analgesia. Establishing accurately the analgesic benefit afforded by LB was outside the scope of this quality improvement project and would require an experiment with randomisation and control. Rather, our aim was to establish that there was no reduction in the efficacy of pain management correlative to a reduction in the number of RSCs in use. There is a paucity of evidence in the literature that evaluates LB against bupivacaine given by RSCs with which we might compare our results.

At its close, the data from this project were presented to the colorectal and upper gastrointestinal consultant surgeons in our hospital at a departmental meeting. Together, these surgeons comprise the senior clinicians responsible for managing general surgical emergencies and undertake the vast majority of emergency laparotomies. As a result of the information provided and the resulting discussion, there was an agreement to continue and expand the use of LB. Our results may be of similar use to other centres that are considering the introduction of LB.
LIMITATIONS

The fact that the design of this project was oriented towards service evaluation during a process of quality improvement rather than experimentation, and the small number of patients involved, prevents us from drawing strong conclusions as to the relationship between the introduction of LB and the overall adequacy of post-laparotomy pain management. The number of patients receiving LB was limited by the total number of patients undergoing emergency laparotomies as well as the number of early-adopter surgeons deploying LB in place of repeated doses of bupivacaine through RSCs.

Similarly, this project did not seek to define a patient population most likely to benefit from LB or define one in which LB is relatively contraindicated. While no particular obstacles or complications were associated with the use of LB in our hospital, this is likely to be the result of patient selection on the part of early-adopter surgeons; it is probable that surgeons administered LB only to those patients they deemed most amenable. It is worth noting that, while an RSC can be resited, there is no similar remedy if LB is injected into the wrong plane and its regional block is thereby ineffective; further doses of local anaesthetics are contraindicated due to the risk of systemic toxicity. Rescue analgesia would have to take the form of a neuraxial block or opiate-based drugs. We therefore envisage that obstacles to the use of LB could include aberrancies of the retro-rectus plane, for example, due to previous surgery, or difficulties in administering rescue analgesia, for example, due to large body habits making neuraxial methods challenging or poor renal function limiting the use of opioids.

This project only involved a single intervention, namely the introduction of LB halfway through the period of continuous audit. A more powerful quality improvement would be achieved through repeated cycles following the PDSA framework rather than the single cycle described here. Following a positive reception to the initial data collected in this project, we have secured a departmental agreement to locally expand the use of LB. Such accordance among surgeons suggests that increased LB use will be sustainable, but this will need to be confirmed.
through an ongoing study. We will continue to audit outcomes following the expanded use of LB. This expansion effectively constitutes a second intervention and will contribute to a further PDSA cycle. Additionally, we will collect further information from key stakeholders, including nurses, surgeons, anaesthetists and hospital management, to determine whether there are any barriers to sustained use of LB.

The outcomes measured in this project were chosen as a means of establishing the adequacy of pain management achieved postoperatively. Unfortunately, as discussed, patient-reported pain scores are not well recorded in patients’ notes, making them a potentially unreliable data source from which to draw conclusions. In contrast, PCA use is an objective and precise measure. However, patients occasionally receive oral opiates in addition to PCA, meaning that PCA use is not always an accurate representation of the total opiate analgesia required by a patient. Additionally, while systemic consumption of opiates is an important facet of ERAS, there are other aspects of recovery not measured in this project, such as postoperative mobilisation, diet, ileus prevention (or time to flatus), fluid management and catheter removal, which could theoretically be affected by LB use. We did measure the length of stay as a variable affected by the adequacy of ERAS but acknowledged that it is affected by a significant number of confounding factors.

Data for this project were collected through an audit of electronic patient records. We lacked the resources to measure the nursing time involved in delivering analgesia to postoperative laparotomy patients; however, inevitably, there will be a reduction in nursing time with the use of LB versus repeated bupivacaine doses through RSCs as LB requires no postoperative nursing activity. To empirically demonstrate that nurses were freed from delivering analgesia to patients receiving LB and to confirm that no further, unidentified nursing tasks were derived from the use of LB, the activity of nurses could be studied through direct observation and questionnaires.

No formal training was provided to ward-based nursing staff in the use of LB. The training was not deemed necessary given that LB does not require any additional skills of ward-based nurses, instead reducing the activity required of them through the obviation of repeated boluses of bupivacaine. However, the training of ward-based nurses is likely to have contributed to a multidisciplinary understanding of LB, its advantages and potential disadvantages and could thereby contribute to ensuring maximally effective postoperative care alongside improved maintenance of any positive changes.

A barrier to sustained use of LB could arise from the higher upfront cost of EXPAREL when compared with bupivacaine given via RSCs. EXPAREL costs £241.80 per patient compared with £57–73 per patient for RSCs with bupivacaine. However, there is an unaccounted cost to RSCs that arises from the nursing time required by their maintenance. Considering the hourly wage of a Band 5 nurse within the National Health Service, we estimate that the financial costs of RSCs and EXPAREL may end up roughly equivalent once nursing time is factored in. The extent to which LB is deemed financially viable as an alternative to RSCs needs to be determined through stakeholder analysis. That said, we feel that there is value to nursing time which is non-piecemeal and should be considered in any process of resource allocation.

CONCLUSION
Through this quality improvement project, we have demonstrated the feasibility of introducing LB in place of repeated doses of conventional bupivacaine given via RSCs for patients who have an emergency laparotomy. Our data provide evidence that using LB instead of conventional bupivacaine does not result in worse postoperative pain scores or an increased use of PCA. While LB could be non-inferior to boluses of bupivacaine delivered through RSCs in terms of its analgesic effects, it is superior in the fact that it requires no postoperative nursing time. Therefore, switching from RSCs to LB allows nurses to be freed for other tasks without compromising patient care.

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Patient consent for publication Not applicable.

Ethics approval This study involves human participants but was not approved. This was a service evaluation which, following the HRA decision tool, did not require ethical approval. This was a quality improvement project without experimentation or changes to standard patient care.

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