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The comparison of pain relieving efficay of subcostal transversus abdominis plane (TAP) catheters with epidural infusion in patients undergoing surgery on their upper abdomen

Submission date
05/11/2009

Recruitment status
No longer recruiting

Registration date
23/11/2009

Overall study status
Completed

Last Edited
19/09/2013

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UHL 10780

Study information

Scientific Title
Comparison of analgesic efficacy of oblique subcostal transversus abdominis plane (TAP) catheters with epidural analgesia in patients undergoing upper abdominal surgery.

Study objectives
The benefits of adequate postoperative analgesia are clear, and include a reduction in the postoperative stress response, reduction in postoperative morbidity and in certain types of surgery, improved surgical outcome. Effective pain control also accelerates recovery from surgery. The benefits of utilising regional analgesic techniques include reduction in pain intensity, decreased incidence of side effects from systemic analgesics and improved patient comfort. A substantial component of the pain experienced by patients after abdominal surgery is derived from the abdominal wall incision.
The Transversus Abdominis Plane (TAP) Block was first described by McDonnell et al as a landmark technique. TAP Block involves blocking the sensory afferents that supply the anterior abdominal wall including the skin, muscles and the parietal peritoneum. Hebbard et al subsequently described an ultrasound guided technique for the TAP block which they named the Posterior TAP block. Hebbard also described another ultrasound-guided technique called the Oblique Subcostal TAP block which provides analgesia for surgery on the upper abdominal wall. There has been a report from Leicester General Hospital of the effectiveness of the oblique subcostal TAP block in providing analgesia in patients who have had surgery on the upper abdominal wall and as effective rescue analgesia in patients in whom the epidural is ineffective. There has also been a recent report of inserting catheters into the oblique subcostal plane and providing analgesia for over 72 hours in patients who have had hepatobiliary surgery.
The initial pilot data collected in Leicester General Hospital reveals that oblique subcostal TAP catheters could be used as a viable alternative to thoracic epidurals in patients undergoing upper abdominal surgery. There have been no clinical trials on the analgesic efficacy of either single shot oblique subcostal TAP blocks or oblique subcostal TAP catheters for surgery on the upper abdominal wall.
Thoracic epidural analgesia has been considered as the gold standard in providing pain relief after surgery on the abdominal wall. Although epidural infusions when effective provide excellent analgesia, there is potential for significant side effects like epidural haematoma, epidural abscess, meningitis etc. In patients where the epidural analgesia is ineffective or is contraindicated, the only other effective option for postoperative analgesia is patient controlled analgesia (PCA) with morphine. Large doses of morphine can cause side effects like nausea, vomiting, respiratory depression, sedation etc. Although patients on PCA morphine are comfortable at rest, they have significant pain on movement (poor dynamic analgesia).
Oblique subcostal TAP catheters could be a viable alternative to epidural infusions for providing analgesia during the postoperative period. The block can be performed easily using ultrasound guidance, has an excellent safety profile to date, provides effective dynamic analgesia and has a significant opioid sparing effect. Before the oblique subcostal TAP catheters gain widespread acceptance, they have to be compared against epidural analgesia which is the gold standard in providing postoperative pain relief.
The proposed study involves the utilisation of ultrasound to locate the oblique subcostal transversus abdominis (TAP) plane, insertion of catheters into the TAP plane on each side and comparison of the analgesic efficacy of the TAP catheters with thoracic epidural catheters during the first 72 postoperative hours in patients who have had upper abdominal surgery.

See publications below for more information:
1. Hebbard P. Subcostal Transversus Abdominis Plane block under ultrasound guidance. Anesth Analg 2008; 106: 674-75
2. Niraj G, Kelkar A, Fox A. Oblique subcostal TAP catheters: An alternative to epidural analgesia after upper abdominal surgery? Anaesthesia 2009; 64(10): 1137-1140

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leicestershire, Northamptonshire & Rutland Research Ethics Committee (LNR 1) approved on the 21st of Dec 2009 (ref: LNR 09/H406/80)

Study design
Single centre interventional randomised active controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Upper Abdominal Surgery

Interventions
Please note that as of 05/07/10 this trial has been completed. The original anticipated end date was 30/12/10.

1. Ultrasound guided insertion of oblique subcostal transversus abdominis plane (TAP) catheters
2. Thoracic epidural

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
The Visual Analogue Scale (VAS) scores at rest and on coughing before surgery and at the 9 time periods after surgery.

Secondary outcome measures
1. Post operative categorical nausea scores before surgery and at the 9 time periods after surgery (none = 0; mild = 1; moderate = 2; severe = 3).
2. Patient satisfaction with postoperative analgesia at 24 h, 48 h and 72 h
3. Any complications with either epidural catheters or TAP catheters during first 72 hours after surgery

Overall study start date
01/07/2009

Completion date
05/07/2010

Eligibility

Key inclusion criteria
All patients aged over 18 years who are scheduled for elective upper abdominal surgery involving incisions with the lower end of the incision at or above thoracic T 10 dermatome
1. Bisubcostal incision
2. Unisubcostal incision
3. Upper midline incision
4. Nephrectomy incision

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
66

Key exclusion criteria
1. Lack of consent including from those patients who lack mental capacity to give informed consent
2. Patients with history of drug allergy to bupivacaine
3. Patients with history of chronic pain conditions: defined as patients with history of pain for above 3 months and who consume regular analgesics for their chronic pain
4. American Society of Anesthesiologists (ASA) Class 4 and 5
5. Upper abdominal surgery where the lower end of the incision extends below T 10 dermatome

Date of first enrolment
01/07/2009

Date of final enrolment
05/07/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Specialist Registrar
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Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

University Hospitals of Leicester NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2011		Yes	No