The relation between electrical current and efficacy of stimulating catheters for brachial plexus block

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The purpose of the present study is to investigate whether there is a relation between the minimal current at the tip of the stimulating catheter necessary to elicit an appropriate motor response, and the efficacy of the PNB catheter.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON33387

Source
ToetsingOnline

Brief title
StimCath

Condition

- Bone and joint therapeutic procedures

Synonym
cuff- or stability repair of the shoulder; shoulder surgery

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Sint Maartenskliniek interne financiering

Intervention

Keyword: brachial plexus block, stimulating catheters

Outcome measures

Primary outcome

1. The minimal current necessary to evoke an appropriate motor response.

2. PCA morphine consumption in terms of administered boluses.

Secondary outcome

Age, length, weight and gender.

Study description

Background summary

Peripheral nerve block (PNB) as an anesthetic technique is rapidly gaining popularity among anesthesiologists and patients. Compared to general anesthesia or central neuraxis blockade, interference of PNB with vital functions is minimal and postoperative analgesia is excellent.
PNB can be administered as a single shot or continuously. When postoperative pain is mild to absent or expected to be short-lived, the single shot approach is sufficient. However, when pain is expected to be moderate to severe for several days, a continuous technique using a PNB catheter is more appropriate.

Nerve stimulation (NS), alone or in combination with Ultrasound, is at present the most widely used method in PNB to ensure close proximity of the needle tip to the nerve before injecting the local anesthetic. Using a current of 100-150 nC at the tip of the advancing needle, an appropriate motor response is sought to find the approximate location of the target nerve. By gradually reducing the current while advancing the needle and maintaining the appropriate motor response, the needle tip is positioned close enough to the nerve to ensure adequate blockade when injecting the local anesthetic dose through the needle. There is general consensus that the minimal current eliciting the appropriate motor response for an adequate nerve block has to be between 20 - 50 nC.

There are stimulating and non-stimulating PNB catheters. Non-stimulating catheters are inserted a couple of centimeters blindly through the needle, usually after the loading dose has been administered. Whether the catheter tip is correctly placed, i.e. in close proximity to the nerve, does not become

apparent until after the effect of the loading dose has worn off, usually late at night. If the catheter is not correctly placed, patients will have no, or little benefit of the local anesthetics they receive through the catheter.
The advantage of a stimulating catheter is that it can be inserted while stimulating at the tip of the catheter; this allows monitoring of the path of the advancing catheter, i.e. staying close to the nerve or moving away from it.
From a theoretical perspective, a stimulating catheter offers several advantages: if during advancement an appropriate motor response can be maintained, the success rate of the catheter will be very high, i.e. postoperative analgesia is expected to be adequate. When the motor response is lost, the needle tip can be manipulated in order to change the path of the advancing catheter to one where motor response is maintained. However, sometimes it is not possible to maintain a motor response and in that case there is little difference between a stimulating and a non-stimulating catheter. Another advantage of an appropriately inserted stimulating catheter is that the loading dose can be fractionated, reducing the incidence of systemic toxicity.
The literature is mixed about the advantages of stimulating catheters. Some studies found an advantage compared to non-stimulating catheters (1-8), whereas others did not (9-12).
Obviously the tip of the catheter needs to be in the vicinity of the nerve to be effective. When an appropriate motor response can be elicited with a low current at the tip of the catheter, close proximity is evident. However, when the necessary current is relatively high or an appropriate motor response is absent, the tip of catheter may still be close enough to the nerve to be effective, it may be at an intermediate distance with a partial effect, or it may be too far off and inadequate for postoperative analgesia.

Whether there is a relation between the minimal current necessary to elicit an appropriate motor response and the efficacy of the catheter has not yet been investigated.
Since stimulating catheters are more expensive than non-stimulating catheters, resolving this issue is not only important in terms of patient care, but also from an economical perspective.

Study objective

The purpose of the present study is to investigate whether there is a relation between the minimal current at the tip of the stimulating catheter necessary to elicit an appropriate motor response, and the efficacy of the PNB catheter.

Study design

The design of the study is prospective and single blind. Forty patients scheduled for Cuff- or stability repair of the shoulder will be studied. The study will be conducted at the Sint Maartenskliniek Nijmegen according to the

Declaration of Helsinki and later revisions thereof and in accordance with the ICH guidelines for Good Clinical Practice. No patients will be recruited before written approval has been obtained from the local Medical Ethics Review Committee as well as from the board of Directors of the Sint Maartenskliniek Nijmegen.
Patients will be assessed for eligibility during the preoperative screening visit, at least 48 h before the planned date of surgery. Patients will be informed about the study verbally and in writing. At a later date, at least 24 h before the planned date of surgery, patients will be asked to participate in the study by the investigators and when affirmative will be asked to sign the written informed consent form.

Procedures before and during surgery

Intravenous access and routine monitoring will be established in all patients. Using Ultrasound guidance and NS, a brachial plexus catheter will be inserted five cm past the needle tip using an in-plane technique in the interscalene area by an experienced anesthesiologist (RS, NJ).
Brachial plexus block will be established by injecting a total volume of 20 mL ropivacaine 0.75 % in fractionated doses. Time is designated T = 0 upon conclusion of the loading dose.
Surgery will be performed under general anesthesia with propofol, remifentanil and a laryngeal mask airway.

Treatment schedule

After the brachial plexus catheter has been inserted five cm past the needle tip, the minimal current necessary to evoke an appropriate motor response (deltoid, biceps or triceps muscle) will be determined and registered. The observer of motor response (KS) is blinded for the current.
One hour after administration of the brachial plexus loading dose, a continuous infusion of ropivacaine 0.2 % 8 mL/h will be connected to the brachial plexus catheter and maintained until T = 24 h. Upon arrival in the recovery, a PCA morphine device will be connected to the intravenous cannula. Patients will be instructed in the use of the PCA device preoperatively and to maintain postoperative painscores (NRS 0-10) at or below 3.
At T = 24h, the catheter will be removed and the PCA device will be disconnected by the investigator (KS). The total amount of asked and received boluses of morphine will be registered.

Study burden and risks

Not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients >= 18 years
- ASA classification I - III
- Patients undergoing cuff- or stability repair of the shoulder under continuous brachial plexus block
- Written informed consent

Exclusion criteria

- Known hypersensitivity to amide-type local anesthetics
- Known hypersensitivity to opioids
- Known history of peripheral neuropathy

- Patients receiving chronic analgesic therapy
- Inability to understand numerical pain scores
- Inability to operate a Patient-controlled Analgesia (PCA) device

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	stimulating catheter
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Naropin
Generic name:	Ropivacaine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21800
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-012374-12-NL
CCMO	NL28034.072.09
OMON	NL-OMON21800