

Studie naar de relatie tussen elektrische drempel en efficiëntie van stimulatie katheters bij brachiaal plexus blok voor operaties van de schouder.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21800

Bron

Nationaal Trial Register

Verkorte titel

StimCath

Aandoening

Orthopedic surgery, cuff- and stability repair of the shoulder
Orthopedische operatie, cuff en stabiliteitsherstel van de schouder

Ondersteuning

Primaire sponsor: Sint Maartenskliniek Nijmegen

Overige ondersteuning: Sint Maartenskliniek Nijmegen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

2. PCA morphine consumption in terms of administered boluses.

Toelichting onderzoek

Achtergrond van het onderzoek

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, whereas others did not.

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.

Doel van het onderzoek

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.

Onderzoeksopzet

T=0 upon conclusion of the brachial plexus block loading dose;

T=1h; start continuous infusion ropivacaine 0.2% 8mL/h through brachial plexus catheter;

At arrival in recovery; start iv PCA morphine device

T=24h; disconnection of continuous infusion to brachial plexus and iv. PCA morphine device.

Onderzoeksproduct en/of interventie

Using Ultrasound guidance and nerve stimulation, 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. 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, remifentanyl and a laryngeal mask airway.

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients over 18 years;
2. ASA classification I – III;
3. Patients undergoing cuff- or stability repair of the shoulder under continuous brachial plexus block;
4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known hypersensitivity to amide-type local anesthetics;
2. Known hypersensitivity to opioids;
3. Known history of peripheral neuropathy;
4. Patients receiving chronic analgesic therapy;
5. Inability to understand numerical pain scores;
6. Inability to operate a Patient-controlled Analgesia (PCA) device.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	17-05-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33387
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2204
NTR-old	NTR2328

Register

CCMO

ISRCTN

OMON

ID

NL28034.072.09

ISRCTN wordt niet meer aangevraagd.

NL-OMON33387

Resultaten

Samenvatting resultaten

N/A