A randomized trial of internal jugular vein cannulation: the ultrasound guided technique versus the landmark technique.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36116

Source
ToetsingOnline

Brief title
Right internal jugular vein cannulation

Condition

- Other condition

Synonym
-

Health condition

bij dit onderzoek is geen sprake van een aandoening

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Central venous access, jugular vein, ultrasound

Outcome measures

Primary outcome

Primairy endpoints are succesful cannulation, the number of attempts (where one attempt is defined as a pass of the needle through the skin and than pulling back the needle. Puncturing again on the same puncture place but in the same or another direction or another skin puncture is defined as next attempt) and the rate of complications (pneumothorax, major bleeding, local hematoma, carotis artery puncture and nerve puncture).

Secondary outcome

-

Study description

Background summary

Placement of a central venous catheter (CVC) for surgery is used for hemodynamic monitoring and venous access. Most often the right internal jugular vein (RIJV) is used. The RIJV is preferred over the left-sided internal jugular vein because cannulation of the left jugular vein is more difficult and associated with a higher complication rate. The most common mechanical complications during central venous cannulation are arterial puncture, hematoma formation, hemothorax and pneumothorax. Since the late 60s many different anatomic landsmark-guided techniques for internal jugular vein puncture have been described but in spite of improvement of the landmark technique the

complication rate is still as high as 19%. The ultrasound-guided technique has significantly decrease this complication rate. The reason why this technique isn*t the *golden standard* for internal jugular vein cannulation is because of the impracticality. The correct equipment is needed (eg ultrasound device, sterile sheath for the transducer) and a well trained operator to perform the procedure. Besides these features, scepticism say that there are studies which prove that there isn*t any difference between ultrasound-guidance and the landmark technique with respect to complications or success rate. Nevertheless, the majority of the studies, whether it*s in a critical care setting or elective surgery, say that ultrasound guidance is the safest way to perform right internal jugular vein cannulation.
Studies suggest that one of the problems of the ultrasound technique is a lack of experience. In this study we attempted to determine if there was any difference between cannulation of the RIJV using the blind landmark technique or the ultrasound technique performed by a trainee in (his/her second year of education) with supervision of an anaesthesiologist.

Study objective

In this study we attempt to determine if there is any difference between cannulation of the RIJV using the blind landmark technique or the ultrasound technique performed by a trainee in anesthesia (in his/her second year of education) with supervision of an anaesthesiologist.

Study design

For this study we are randomly assign 216 patients to cannulation of the right jugular vein by ultrasound guidance or by using the anatomic landmark method followed by an ultrasound check after placement of the cannule. Only patients who will undergo elective surgery are included. Exclusion criteria are <18 years of age, coagulopathy (with INR > 1.5, activated partial thromboplastine time >1.5 and platelets < 50.000mm3), neck or head surgery in the past, radiation therapy of the neck, local infection of the skin, known thyroid pathology and skeletal deformities. All punctures are performed by a trainee in anesthesia in his second year of training.

The blind technique
All procedures are performed using an aseptic technique: cleaning the skin with chlorohexidine 0.5% in alcohol 70% and sterile drapes around around the puncture place. The operator wear a sterile gown, cap, mask and sterile handgloves. Patients are placed in a 15º-30º Trendelenburg position with the head rotated to the left at a 30º angle. After correct positioning of the head, the triangle which is formed by the sternocleidomastoid muscle, and the clavicular and the sternal head are identified. The operator places the index and middle finger of his left hand on the carotid artery and 1 centimeter lateral to the carotis artery the needle will be advanced through the skin to

the ipsilateral nipple. An 18G-gauge needle is used connected to a 10 mL syringe.(Arrow-Howes; Arrow international, Reading, USA). After the RIJV is punctured a guidewire is placed into the RIJV. A triple lumen (8,5 Fr.) indwelling catheter is placed using the Seldinger technique. After placing of the cannule the correct positioning of the cannule is checked by ultrasound.

The ultrasound technique
All procedures are performed under the same conditions as described with the blind technique. The ultrasound examinations are performed with a 12-3 mHz broadband linear transducer (L12-3, Philips Ultrasound, Bothell, USA).With the two dimensional ultrasound imaging we measure the depth of the jugular vein to the skin, the diameter of the jugular vein and the carotid artery and the distance between the puncture place of the needle to the jugular vein. According to Cavanna et al. we will use *the three-handed method*. The jugular vein is visualized using the *out of plane technique*. When the jugular vein is in the middle of the monitor the operator starts the puncture while the assistant facilitate the procedure by holding the probe to the skin. The needle is passed through the skin perpendicular to the probe in a 30º angle in relation to the skin. The procedure is performed under continuous vision until the needle punctures the jugular vein and the syringe is filled with blood. Then a guidewire is placed into the vein and confirmation of the correct place of the guidewire is obtained by checking whether the guidewire is in the correct lumen of the jugular vein by using the *in plane technique* in which the probe was rotated in a parallel position with the jugular vein. The needle is removed and the triple lumen catheter is placed over the guidewire into the jugular vein.

A final verification of the correct CVC positioning is obtained after the connection to a pressure transducer. In both groups following surgery, a x-thorax is made to exclude a pneumo- or hematothorax and to confirm the correct positioning of the CVC.

In both groups demographic characteristics are recorded including gender, height, weight, BMI and type of surgery. We collect data about neck movement and sternomental and thyromental distances. From the ultrasound images we collect the measurements of the diameter of both carotid artery and the RIJV, the surface area of both the carotid artery and the RIJV, the depth of the anterior border of the jugular vein to the skin, the place where the needle punctures the jugular vein (measured from the left side of the jugular vein)and the position of the jugular vein in relation to the carotid artery. At the end of the procedure the distance between the puncture and the clavicula is measured.

Study burden and risks

None

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

All patients who will undergo elective surgery and who need a central venous catheter or patients who need a central venous catheter for antibiotics or parenteral nutrition.

Exclusion criteria

Exclusion criteria were <18 years of age, coagulopathy (with INR > 1.5, activated partial thromboplastine time >1.5 and platelets < 50.000mm3), neck or head surgery in the past, radiation therapy of the neck, local infection of the skin, known thyroid pathology and skeletal deformities

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2011
Enrollment:	216
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL36338.060.11