NEEDLEYE

FIELD OF THE INVENTION

[0001] The present invention relates to anesthesia, more specifically to local anesthesia using a needle with a needleye for identifying the location of the needle as it is inserted into the patient's body. More specifically, the present invention provides a double lumen needle combined with an ultrasound or a fiber-optic probe for regional-peripheral anesthesia blocks.

SUMMARY OF THE INVENTION

[0002] The present invention provides a device for regional anesthesia, comprising: (i) a straight needle having a distal end which is a pointed, bent free tip, and a hub fixedly connected to the proximal end of the needle; (ii) a tubular needle guide for slidably receiving said straight needle, said needle guide having two inclined tips and being fixedly attached along at least part of its length to at least a portion of the straight section of said needle on the outside thereof, said needle guide being substantially shorter than said needle and extending between a point located behind said bent free end portion of said needle and a point located ahead of the hub thereof; and (iii) a tissue visualization unit.

BRIEF DESCRIPTION OF THE DRAWINGS

[0003] **Fig. 1** illustrates a NeedlEye according to the invention composed of a Tuohy epidural needle part with a catheter inside and the needle guide with the ultrasound transducer or the fiberoptic probe inside.

[0004] **Fig. 2** illustrates a Tuohy epidural needle (B) and a NeedlEye (A) during an epidural procedure. The needle guide of the NeedlEye protects the NeedlEye from an inadvertent puncture of the dura like it is seen at the Tuohy needle.

[0005] **Fig. 3** illustrates a spinal procedure using a Tuohy needle (A) and a NeedlEye (B). It is shown that the use of the spinal needle in the NeedlEye is going in a straight line unlike the case of the Tuohy needle above.

[0006] **Fig. 4** is a picture of a NeedlEye composed of a Tuohy needle part and a needle guide.

DETAILED DESCRIPTION OF THE INVENTION

[0007] A device for regional-peripheral anesthesia with ultrasound mini transducer or fiber-optic mini probe, including an epidural needle having a bent free end portion with an inclined, pointed tip, and a hub fixedly connected to its other end and a tubular guide needle for an ultrasound mini transducer or fiber-optic mini probe. The guide needle has two inclined tips and is fixedly attached along at least part of its length to at least a portion of the straight section of the epidural needle. The guide needle is substantially shorter than the epidural needle and extends between a point located behind the bent free end portion of the epidural needle and a point located ahead of the hub thereof.

[0008] US 5,163,901 describes a device for combined spinal-epidural anesthesia, including an epidural needle having a bent-free end portion with an inclined, pointed tip, and a hub fixedly connected to its other end and a tubular guide needle for a spinal needle. The guide needle has two inclined tips and is fixedly attached along at least part of its length to at least a portion of the straight section of the epidural needle. The guide needle is substantially shorter than the epidural needle and extends between a point located behind the bent free end portion of the epidural needle.

[0009] Chiang *et al*., "Eyes in the Needle: Novel Epidural Needle with Embedded High-frequency Ultrasound Transducer-Epidural Access in Porcine Model", *Anesthesiology*, 2011, Vol. 114, pp. 1320-1324, used a custom-designed ultrasound transducer and a conventional epidural needle. The outside diameter of the ultrasound transducer was 0.7 mm; the transducer fit into the hollow chamber of an 18-gauge epidural needle (inside diameter, 0.84 mm and outside diameter, 1.27 mm). The transducer was made from a single lead magnesium niobate-lead titanate (PMN-PT) crystal. The crystal was polished to a thickness of 50 μm, with a width of 0.5 mm. The transducer was non-focused with a central frequency of 40 MHz and a ~6 dB fractional bandwidth of 50%. The transducer could distinguish two interfaces separated by a distance of 0.15 mm (axial resolution) and penetrate the tissue to a depth of 10 mm. The gain was set to 40 dB and 54 dB for the study. A pulser/receiver (Panametrics 5900, Panametrics, Inc., Waltham, MA) was used to emit and receive the echo signal. The reflected echo signal was displayed on an oscilloscope (LeCroy LT342, LeCroy

Corporation, Chestnut Ridge, NY) and digitized at 500 MS/s with 8-bit signal resolution. The dura mater could be observed approximately 3.5 mm away from the ultrasound transducer when the gain was set at 40 dB and as far as 7.5 mm when the gain was set at 54 dB. The gain did not affect the depth of tissue penetration (10 mm). At a frequency of 40 MHz and a gain of 40 dB the dura was seen 4.1 ± 0.95 mm in front of the needle tip. The area between the ultrasound spikes obtained from the LF and dura mater measured approximately 2-4 mm wide and was identified as the epidural space. It was able to distinguish the epidural space from the fluid-filled subarachnoid space based on the axial order of the tissue planes.

[0010] The dura mater signal was observed in all insertions, whereas the LF (Ligamentum Flavum) was seen in 25 of 30 (83.3%) insertions. However, both the LF and dura mater were seen in the same sonogram frame in only 11 (36.6%) of the 30 insertions. The angle between the needle and the midline axial plane was 30-45^{o} in this study (Chiang *et al.*). This angle reduced the back-scattered ultrasound signal strength by 30-50% compared with a perpendicular insertion. This attenuation proportionally affected the depth of ultrasound penetration and reduced the differences in the character of the LF and dura mater signals. However, the operator was still able to identify two distinct tissue planes. There was no significant difference in the ultrasound signals obtained from the thoracic compared with the lumbar region in the porcine model. It was identified the LF and dura mater in the same number of insertions in both regions of the spine. Ultrasound and contrast studies confirmed correct placement of all the catheters in the epidural space of the lumbar and thoracic areas of the spine.

[0011] With the 40 MHz frequency, it is possible to see the dura mater at 3.5-7.5 mm from the modified needle. The epidural space in the porcine model is approximately 2-4 mm wide. The human epidural space is 6.9 ± 4 mm. The resolution of the signal should therefore allow inserting an epidural catheter with similar accuracy in humans. The high resolution of the modified needle may reduce the risk of accidental dural puncture compared with other techniques of epidural placement. In addition, using the dura mater as a landmark for epidural catheter insertion may also reduce the rate of failed analgesic blocks by improving the accuracy of catheter placement. This technique may provide a better quality of block because air and saline are not injected (Chiang *et al.*).

[0012] Kuo *et al.*, "Fiber-needle Swept-source Optical Coherence Tomography System for the Identification of the Epidural Space in Piglets", *Anesthesiology*, 2015,

Vol. 122, pp. 585-594, describes a method using a fiber-needle–based swept-source optical coherence tomography (SSOCT) to identify epidural space. An optical fiber probe was placed into a hollow 18-gauge Tuohy needle. It was then inserted by an experienced anesthesiologist to continuously construct a series of two-dimensional SSOCT images by mechanically rotating the optical probe. To quantify this observation, both the average SSOCT signal intensities and their diagnostic potentials were assessed. The insertions were performed three times into both the lumbar and thoracic regions of five pigs using a paramedian approach.

[0013] A side-looking SSOCT was constructed to create a visual image of the underlying structures. The image criteria for the identification of the epidural space from the outside region were generated by the analysis of a training set (n = 100) of *ex vivo* data. The SSOCT image criteria for *in vivo* epidural space identification are high sensitivity (0.867 to 0.965) and high specificity (0.838 to 0.935). The mean value of the average signal intensities exhibits statistically significant differences ($P < 0.01$) and a high discriminatory capacity (area under curve = 0.88) between the epidural space and the outside tissues. Optical coherence tomography (OCT) was originally demonstrated in 1991 as a unique biomedical imaging modality capable of cross-sectional imaging of the human eye at an axial resolution of approximately 10 to 15 μm. OCT is based on low-coherence interferometry. By scanning the mirror in the reference arm of a Michelson interferometer, the reflectivity profile of the sample is obtained, and no light outside the short coherence length will interfere (this is called time-domain OCT). This reflectivity profile is called an axial depth scan (A-scan). Although this is analogs to ultrasound imaging, OCT has a higher resolution than ultrasonography. Moreover, no exogenous contrast agent or contact gels are necessary in the OCT system. Further developments in the OCT include the transformation of the technology from the “time-domain” OCT to the “Fourier-domain” OCT. Fourier-domain OCT allows imaging at higher rates by an order of magnitude. In Fourier-domain OCT, it can be performed using a single detector by sweeping the source spectrum and detecting the intensity due to the component frequencies. Fourier-domain OCT of this type has been called swept-source OCT (SSOCT), which shows improved sensitivity and thus enables the rapid three-dimensional imaging of tissues (Kuo *et al.*).

[0014] An optical method using a forward-looking needle-fiber time-domain OCT system was proposed by Li *et al.*, "Range technique in scattering medium using a needle-

fiber optical coherence tomography system", *Opt Rev*., 2006, Vol. 4, pp. 201-6, for guiding epidural anesthesia. Their report presented an OCT system based on a slow mechanical scanning time-domain setup that monitors the axial information in front of the needle by providing A-mode signals. However, the forward-looking probe is limited by the shallow OCT imaging penetration depth of several millimeters; it is not very useful for guidance purposes. Moreover, the ranging performance in their report was only investigated using a phantom.

[0015] The NeedlEye has a side lumen for the ultrasound mini transducer or the fiberoptic mini probe while the Epidural needle lumen is for the anesthetic solution injection and the catheter insertion while the ultrasound or the Fiber-optic devices are creating the eye at the end of the double lumen needle.

[0016] Bromage P.R., "Rotation of the Epidural Needle: A Caution", *Anesthesia & Analgesia*, 1995, Vol. 81(1), p. 209, wrote that *"Moore (Anesth. Analg., 1994, Vol. 79, p. 810) is correct in stating that 'none of us have an eye on the end of a needle' to see whether a rotating tip can cut the dura"*.

[0017] It seems that in 2017 Bromage and Moore are not correct.

[0018] This is the first double lumen needle invented for the purpose of regional anesthesia (Spinal, Epidural, Peripheral blocks) using ultrasound mini transducer or fiber-optic mini probe inside one of its lumens. The Spinal block can also be done through the epidural needle before inserting the epidural catheter as a needle-through-needle technique.

[0019] **Fig. 1** illustrates an exemplary NeedlEye of the invention composed of a Tuohy needle part with a catheter inside and a needle guide with an ultrasound transducer or a fiber-optic probe inside.

[0020] **Fig. 2** illustrates how a Tuohy needle (B) and a NeedlEye (A) are used during an epidural procedure. The needle guide of the NeedlEye protects the NeedlEye from an inadvertent puncture of the dura as seen for the Tuohy needle.

[0021] **Fig. 3** illustrates a spinal procedure while using a Tuohy needle (A) and a NeedlEye (B). As shown, the use of a spinal needle with the NeedlEye is going in a straight line, contrary to when used with the Tuohy needle.

[0022] **Fig. 4** is a picture of a NeedlEye composed of a Tuohy needle part and a needle guide.

[0023] All these procedures can be done while there is an "eye at the end of the needle" during all the time of the procedure. Non-limiting examples of such procedures include: Epidural anesthesia, Spinal anesthesia, Combined spinal-epidural anesthesia, Transversus abdominis plane (TAP) block, Infraclavicular block, etc.

[0024] For example, a physician may insert the double lumen needle of the invention while monitoring its progress within the patient's body via a monitor which receives real-time data from the tissue visualization unit located within the needle. This enables the physician to verify that he/she does not miss the desired analgesia point, which is critical, e.g. in epidural and spinal anesthesia as well as in peripheral blocks. This further enables to prevent unintentional damage to the patient due to, e.g. damage to the spinal cord, dura, or peripheral neurons.

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CLAIMS

1. A device for regional anesthesia, comprising:
   - a straight needle having a distal end which is a pointed, bent free tip, and a hub fixedly connected to the proximal end of the needle;
   - a tubular needle guide for slidably receiving said straight needle, said needle guide having two inclined tips and being fixedly attached along at least part of its length to at least a portion of the straight section of said needle on the outside thereof, said needle guide being substantially shorter than said needle and extending between a point located behind said bent free end portion of said needle and a point located ahead of the hub thereof; and
   - a tissue visualization unit.

2. The device of claim 1, wherein said tissue visualization unit is an ultrasound mini transducer or a fiber-optic mini probe

3. The device of claim 1, wherein said tissue visualization unit is located within the needle or within the needle guide.

4. The device of claim 1, wherein said straight needle is a double lumen needle and said visualization unit is located within one of said lumens.

5. The device of claim 1, wherein said needle guide is located in a plane substantially normal to the plane defined by said needle and its bent free end portion.

6. The device of claim 1, wherein said straight needle is an epidural needle.

7. The device of claim 6 further comprising a spinal needle slidingly fitting said needle guide and being of sufficient length to linearly project from the front tip of said needle guide for a distance far enough to penetrate the dura mater and enter the subarachnoid space, while the tip of said epidural needle remains in the epidural space.

8. The device of claim 7, further comprising obturators for said epidural needle and said spinal needle.

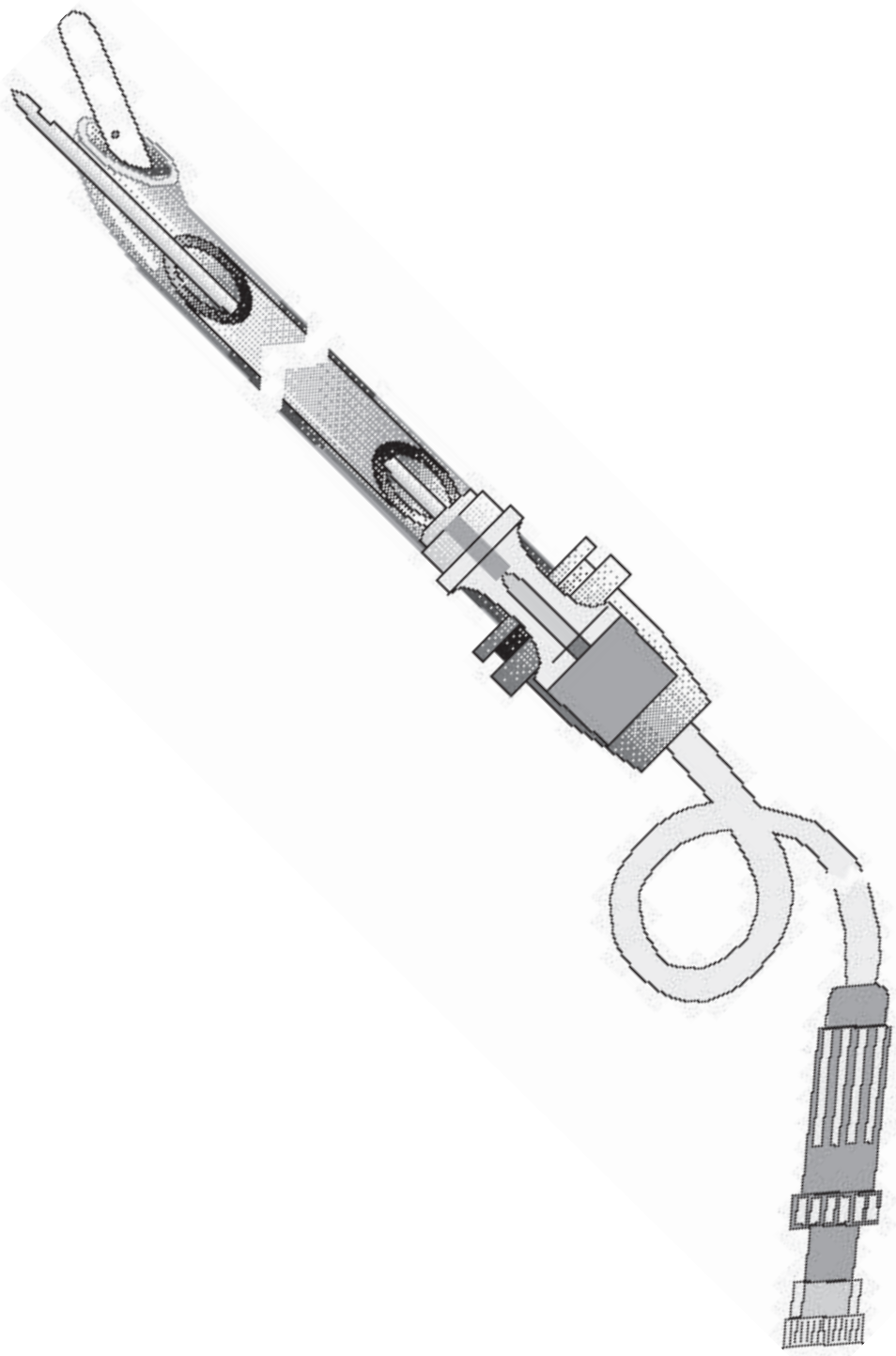

Fig. 1

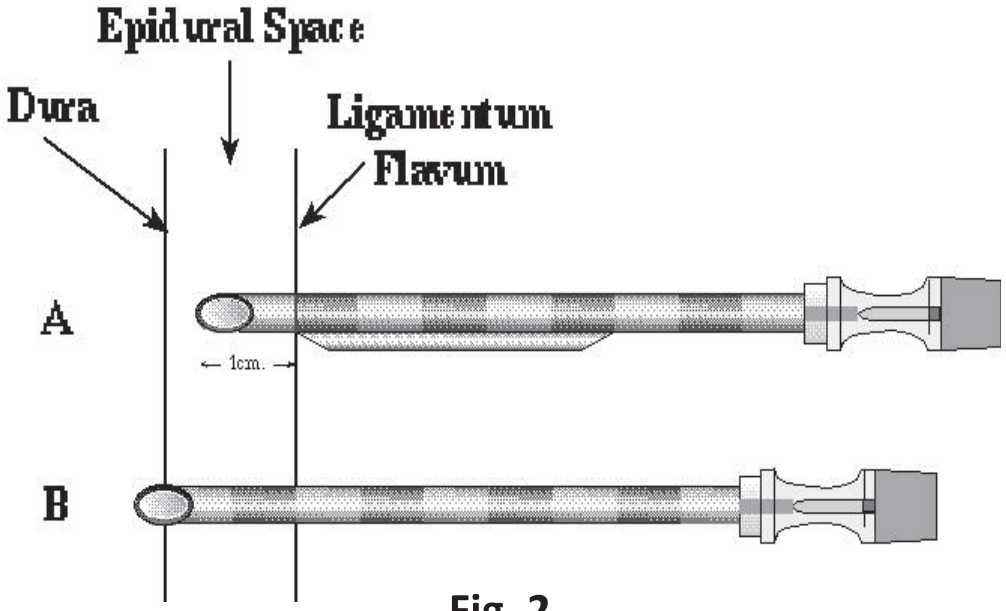
Epidural Space
Dura
Ligamentum
Flavum
A
1cm.
B

Fig. 2

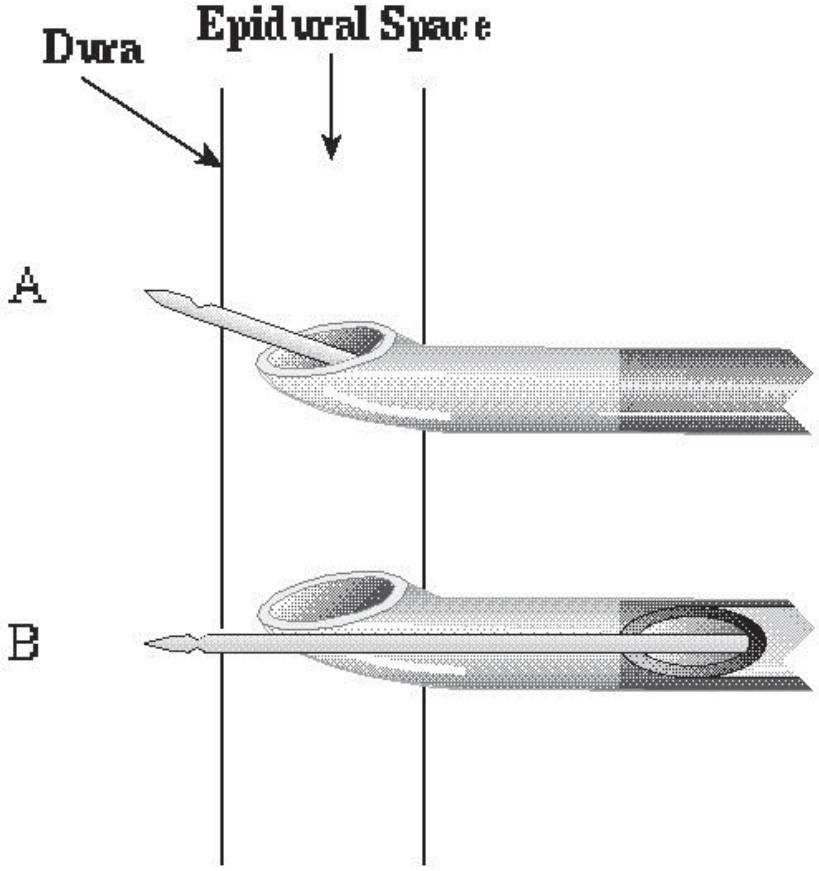
Dura
Epidural Space
A
B

Fig. 3

Fig. 4