

Eyes of the needle

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Chapter

Valorization

8

Valorization: “Het proces van waarde-creatie uit kennis, door kennis geschikt en/of beschikbaar te maken voor maatschappelijke (en/ of economische) benutting en geschikt te maken voor vertaling in concurrerende pro-ducten, diensten, processen en nieuwe bedrijvigheid”
aangepaste definitie op basis van Landelijke Commissie Valorisatie 2011

8.1 Valorization

Valorization: based on pragmatic analysis of the relevance, risks, and benefits of the use of spectral tissue sensing in percutaneous needle-based procedures in the anesthesiology.

8.2 Relevance

In health care, patient safety, quality of life, and costs are important issues. Therefore, it is no surprise that much research is focused on these items.

In this thesis, we analyzed and evaluated the value of spectral tissue sensing in percutaneous needle-based procedures.

Safety aspects of interventional needle-based procedures in regional anesthesia and pain medicine were discussed and placed into historical perspective. The shortcomings, sensitivity, and specificity of the currently used techniques were described.

As already said, despite the use of ultrasound, radiography, nerve stimulation, and other precautions during injections, cases of nerve damage are still reported.¹⁻³ Patients and clinicians fear neurological complications of nerve blocks, such as muscle weakness, neuropathic pain, or seizures, due to accidental intravascular injection of local anesthetics or nerve damage.^{4, 5} Even transient neurological complications may have an impact on the quality of life of the involved patients. More serious neurological complications may occur after interventional pain therapy at the spinal level. Reports of spinal cord damage, brain infarctions, and death have been published.⁵⁻¹¹

In this thesis, the hypothesized value of STS during interventional locoregional and interventional pain procedures was evaluated. It was supposed that the information provided by STS about the tissue in front of the needle tip could improve the correct needle tip position and improve the performance and safety of interventional needle-based procedures performed in regional anesthesia and pain therapy.

The optical characteristics of different tissues were studied, and with these results, the STS system was developed. The information obtained at the needle tip was compared with the standard or good clinical practice at this moment (aspiration, ultrasound-guided, live fluoroscopy, and DSA). We developed an optical tissue database to render STS as a valuable tool for percutaneous needle-based procedures in (locoregional) anesthesia and pain practice. This thesis focused on the optical identification of adipose tissue, muscle, blood, and nerve fascicles. We proved that STS can reliably identify blood and has the potential to detect tissue transition of the needle tip during the procedure, and the optical characteristics of fascicular nerve tissue are described.

All these potentials of STS suggest a theoretical potential to lower the complication rate during these procedures. Generally, it is nearly impossible to clearly prove a significantly lower incidence of complications of a new technology in the field of locoregional

anesthesia and pain medicine. This is due to the low reported incidence of the complications and the very high inclusion number for such a study.

We conclude that the STS system has the potential to be clinically relevant and could improve the safety of regional anesthesia and pain medicine.

8.3 Patient and professional safety

Complications in health care are multifactorial and, for all involved parties, upsetting. In the field of anesthesia, nerve damage is a known complication. In a closed claims analysis, nerve damage has accounted for 22% of claims since 1990.

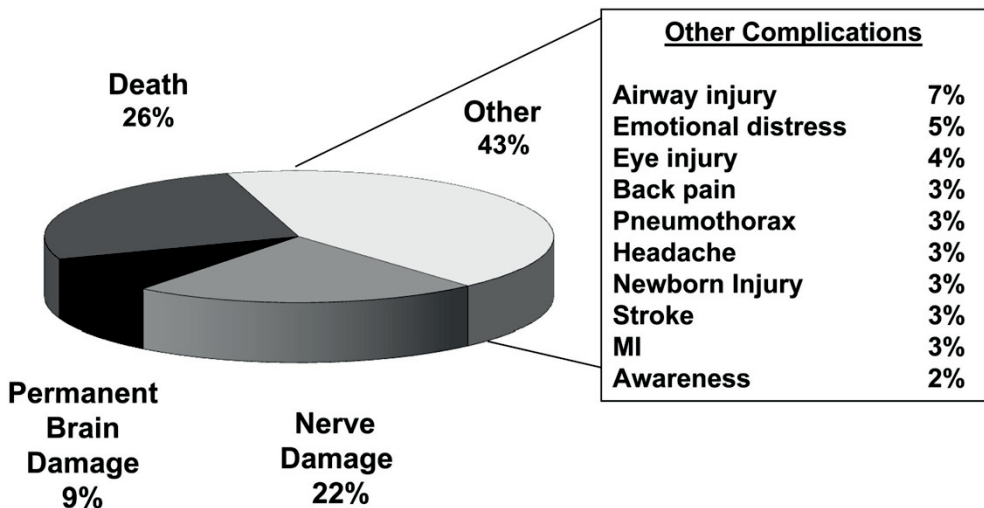


Figure 8.1: Most common complications- 1990 or later (n = 5230). Data from the closed claims project [12].

The most common events leading to injury in anesthesia were regional block-related; 20% of claims in 1990–2007 were related to these injuries. In perspective, claims related to the respiratory system or cardiovascular system accounted for 17% and 13%, respectively.¹²

Market reports estimate that worldwide, 12 million nerve blocks are performed per year. The growth per year is estimated at 3-4% for regional anesthesia and 10% for nerve blocks for chronic pain treatment.

A growing body of evidence indicates that the use of regional anesthesia offers many advantages over general anesthesia, not only in terms of reducing perioperative complications but also regarding resource utilization and patient satisfaction.¹³ Besides the growing popularity of regional anesthesia, the patient population is changing, and the indications for regional anesthesia may grow.

The average age of the world's population is increasing. According to the US Census, the age group ≥ 65 -years is expected to more than double between 2014 and 2060, increasing to 98.1 million (23.6% of the total population of the US).¹⁴ This also has an impact on the amount of surgery performed in older patients.^{15, 16} As such, the care of older surgical patients is of increasing importance. For instance, in this population, it is of great importance to achieve adequate pain control. Untreated pain or oligoanalgesia may cause delirium and cognitive dysfunction.¹⁷ Recent evidence from the SAGES (Successful Aging after Elective Surgery) trial has demonstrated that postoperative delirium is a distinct predictor of other adverse events after surgery. A combination of delirium with other postoperative complications leads to the poorest long-term outcomes and adversely affects hospital length of stay, rates of institutionalized discharge, and 30-day readmission rates.^{18, 19}

The American Geriatrics Society recommends the use of postoperative regional analgesia when possible to minimize the administration of opioids in order to avoid opioid-related side effects, such as nausea, vomiting, disturbed sleep, and respiratory depression.²⁰⁻²²

In experienced hands, it seems likely that peripheral nerve block would be safer than general anesthesia. However, evidence to prove this assumption will never be available due to the low numbers of severe anesthesia-related complications.²³

Also, in the field of chronic pain treatment, an increase in patient numbers is anticipated. Invasive analgesic therapies provide an alternative to the medical management of chronic pain. With the increasing incidence of chronic pain worldwide, more therapies have evolved to address the growing need for pain relief options. These therapies include spinal injections, nerve blocks, radiofrequency ablation, neurostimulation, and intrathecal drug delivery.²⁴

Altogether, the amount of needle-based percutaneous procedures is expected to grow in the next decade, and the need to improve the safety of these procedures will grow due to the more vulnerable population. There is a clear need to improve needle-based procedures and to ease the needle tip identification during the procedure to reduce the number of complications.

8.4 Improved technical accuracy

The STS system provides information about the final needle position and offers the possibility to document this in the patient files. This information may prove beneficial in legal procedures in case neurological damage occurs after an interventional procedure. But, the STS system has more to offer.

Table 7.1 shows the additive value of STS and the shortcomings of commonly used techniques of nerve localization. As can be seen from Table 7.1, STS scored best com-

pared with the other tools. The combination of ultrasound and STS fulfils 12 of the 14 criteria. For instance, aspiration can be fully replaced by STS. For x-ray-based procedures, the injection of contrast fluid and DSA could be replaced by STS. The reduction of x-ray and contrast fluid administration is beneficial for the patient and the clinician: less exposure to x-rays and no administration of contrast fluids. Contrast fluids have well-known complications, like allergy and impairment of kidney function.²⁵

More information on the tissue characteristics in front of the needle tip could also improve the training of residents. Ultrasound images and anatomical knowledge could be confirmed in real time with the use of optical tissue information.

8.5 Summary

STS is positioned as an innovative technology that could improve the technical accuracy and safety in a growing, more complicated, and vulnerable patient population.

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