

Improving safety in regional anaesthesia

A new NHS invention is giving anaesthetists greater control and reduces the risk of nerve damage, when performing regional anaesthesia.



Over 20 million regional anaesthetic nerve blocks are performed each year throughout the EU and US.¹ Current procedures require two operators, an anaesthetist to position the needle using an ultrasound probe for guidance and an assistant to operate the syringe to inject the anaesthetic solution. The current process relies heavily on the assistant's interpretation of the pressure prior to injection.

This is highly subjective and 'syringe feel' varies between individuals, thus creating the risk for anaesthetic solutions to be injected at high pressure. Safira (SAFer Injection for Regional Anaesthesia), initially devised by a group of clinicians from the NHS, addresses this problem. It brings a new technology to regional anaesthesia and is the first device to both turn the regional block process into a one-person procedure and introduce a built-in safety element to help prevent injection at high pressures.

The challenges of current regional anaesthesia practice

A regional block procedure involves using injections of local anaesthetic to anaesthetise a specific area of the body (such as the leg

or arm) by blocking the nerve to provide pain relief during surgery. It means patients can stay awake but remain pain-free during invasive surgery without requiring a general anaesthetic. Peripheral nerve blocks are one of the most common types of regional anaesthesia (RA).

During this procedure, the anaesthetic is injected near a specific nerve or bundle of nerves to block sensations of pain from a specific area of the body, more commonly for surgery on the arms and hands, the legs and feet, or the face. For patients, regional anaesthesia offers a number of advantages over general anaesthesia, including faster recovery time and fewer side effects, and eliminates the need for an airway device during surgery.

Current regional anaesthesia practice requires two operators: an anaesthetist who holds an ultrasound probe in one hand and uses this to guide the needle tip placement

with the other hand. The assistant is then required to inject the anaesthetic solution, applying their judgement to decide if the pressure in the syringe is at a safe level before the injection is made.

Studies have shown, however, that the assistant can find it difficult to judge the pressure correctly and less than 4% of anaesthetists are confident their assistants are applying the correct pressure.² High pressures have been shown to damage the nerve fascicles and can cause serious nerve damage.³

Dr. John Gibson, one of the pioneers behind Safira, explains: "Ultrasound guided regional anaesthesia is a three-handed technique. The first hand is used to hold the ultrasound probe.

"The second hand, usually the dominant hand, is used to guide the block needle. A third hand is required to inject the local anaesthetic, hence a second person – an assistant – is needed to give the injection.

"However, a potential complication of regional anaesthesia is nerve injury, which can be potentially life changing. One way that the risks of this can be significantly reduced is if the injection is only given when the pressure required to inject is below a certain level, or the force on the syringe plunger required to inject is small."

So, how can an NHS inspired technology change working practices and help reduce the risks of nerve injury in patients?

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Advancing regional anaesthesia

Cambridge-based medical device development company, Medovate, was founded in 2017 to support the development and commercialisation of pioneering medical technologies created within the NHS.

Spun out of the NHS three years ago, the company collaborates with innovators working on the frontline of healthcare delivery who have spotted a gap in their specific area of care. These clinicians are kept involved throughout the whole development process of the device right through to its commercialisation.

Medovate's current pipeline of novel medical technologies is focused on anaesthesia, airway management, critical care and surgery. During the development of Safira, the company worked closely with consultant anaesthetists Dr. Peter Young, Dr. Emad Fawzy, Dr. Joseph Carter, and Dr. John Gibson from the Queen Elizabeth Hospital King's Lynn NHS Foundation Trust.

As an NHS innovation envisioned by a frontline clinical team, the device was developed to be intuitive to use, be easily integrated into current practice and promote improved safety during injection of regional anaesthesia. The key driving force was to reduce the potential for nerve injury by using built-in safety mechanisms to mitigate this risk.

Safira also has the potential to realise additional time and cost saving benefits as revealed by health economic modelling. As Dr. Young explains:

"Any new innovation should be convenient for normal workflow while improving care for patients at an acceptable cost. Safira has been designed to put control in the hands of the operator, while improving workflow and offering patients the protection against this mechanism of nerve injury."

There are two main advantages for the use of Safira for anaesthetists, Dr. Joseph Carter explains – and two areas where it addresses current unmet clinical needs:

"The current system of trying to make sure that nerve injections are not occurring at high pressures is flawed for two reasons: firstly, by asking an operator what the feel of the injection is and asking if it is difficult to inject – at this point that pressure has already been applied to the system and therefore to the distal end and the needle tip, which may be in a nervous structure. Secondly, we know from clinical studies that humans are not good at sensing when pressures are too high, or when pressures change through injections.

"There are key advantages for the use of Safira. First, by giving control of the injection back to the anaesthetist this allows for improved precision of the injection of small doses of anaesthetic, and will facilitate hydro-dissection; second, the pressure limiting feature in the system means that the

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individual anaesthetist can be certain that they are doing all that they can to try and reduce the risk of a permanent nerve injury."

Reducing the risk of nerve injury

While complications such as transient or serious nerve damage resulting from regional anaesthesia procedures are relatively rare, when they do occur, they can have significant implications for patients, leading to severe pain or permanent paralysis of the area involved, research shows.⁴ Meanwhile, transient nerve damage, though less severe, can involve additional costs from requiring follow-up appointments and potentially further tests. There is also the potential for negligence cases to be raised in more extreme cases. Studies have shown that injection of regional anaesthesia at pressures above 20psi can result in transient or serious nerve damage (transient nerve damage in up to 8% of cases⁵ and serious nerve damage in up to 1% of cases³). Moreover, injection 'feel' is highly subjective and varies between individuals. Studies consistently show 40%-70% injections occur above 20psi, with a significant portion above 30psi.⁶

Safira is built to help reduce these risks. Designed using a clinician-led approach, it incorporates a built-in safety feature to promote safer injection during regional anaesthesia procedures by automatically stopping injection above 20psi, thereby helping to reduce the risk of nerve damage.

The device will also have a positive impact on the confidence of anaesthetists. Safira uses a foot pedal operator which allows the anaesthetist to control the syringe to either aspirate or inject the local anaesthesia, thus eliminating the need for an assistant. By turning the regional anaesthesia process into a one-person process, the anaesthetist can be confident that they have full control of the procedure and the built-in safety mechanism reassures them that they are not injecting at too high a pressure.

"The main reasons to consider for switching to use Safira for regional anaesthetics are control and safety," Dr. Carter adds. "In terms of control, the ability to precisely deliver small doses of local anaesthetic is very desirable in the process of a regional block.

"From a safety perspective the fact that the injection pressure is limited to a

level below which the risk of permanent nerve injury is reduced is a very desirable feature for both patients and anaesthetists performing the block. The use of Safira will change the process of a block for most clinicians in so far as it will allow them to perform the block process themselves."

Further, with its integrated safety solution to help limit the injection pressure threshold, Safira can effectively help to reduce the chance of accidental nerve damage in patients, omitting follow-up procedures and additionally potentially reducing the risk of litigation.

Perhaps as importantly, the device also brings economic savings. Research shows that Safira could save up to five minutes per procedure and limits the costs associated with extra operators.¹ This means that procedures can be performed faster, saving valuable theatre time. At a time when health systems across the world are experiencing huge strains and critical care remains under pressure, every inch of efficiency that can be procured is welcome news. Eliminating the need for an assistant, Safira also creates an additional safety net to address the challenges of COVID-19.

"In the current COVID environment the fact that there is a reduction in exposure between the operator and their assistants, and also between the patient and clinical staff, means that from a social distancing perspective, this is a step forward in clinical practice," Dr. Carter explains.

Latest guidance

COVID-19 has brought additional challenges to health systems globally, posing new threats to both patients and healthcare workers. In March of last year – as the UK went into its first lockdown – the European and American Societies of Regional Anaesthesia produced joint recommendations stating that regional anaesthesia should be preferred over general anaesthesia whenever possible, and practice recommendations for regional anaesthesia during the pandemic have since been published.⁷

This guidance was issued on the basis that general anaesthesia (GA) with airway intervention leads to aerosol generation, thus exposing healthcare teams to the risks ►

of transmission both during intubation and extubation. Growing evidence shows that COVID-19 infection can occur from airborne exposure to the virus.⁸

Regional anaesthesia, which is not aerosol-generating, thus mitigates the risks associated with Aerosol Generating Procedures (AGP's), which result in the release of airborne particles (aerosols) from the respiratory tract and could therefore pose a threat if the patient is suffering from the disease.

The Royal College of Anaesthetists and Association of Anaesthetists further advised the use of local or regional anaesthesia where practicable and safe to help reduce the demand for key drugs required during the critical care of COVID-19 patients.⁹

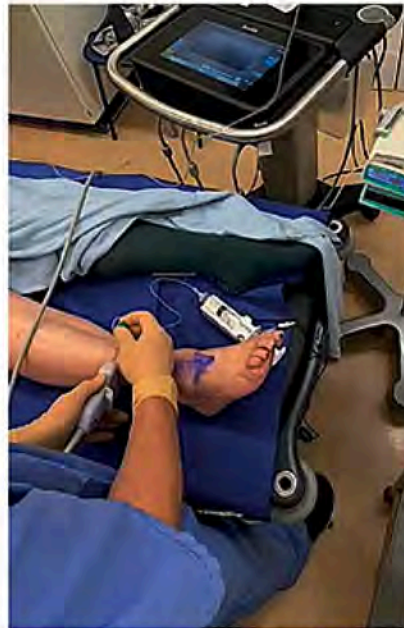
Earlier last year there were reports of anaesthetic medicines being in short supply, with a bid for clinicians to use alternatives.¹⁰ As regional anaesthesia numbs only a small part of the body, sedation requires only small amounts of anaesthetic drugs.¹¹

Safira is intended to enhance current regional anaesthesia practice thus mitigating many of these risks. The device is just as relevant in a COVID environment as it is in a non-COVID environment, Dr. Carter concludes:

"The technology allows a single operator, to conduct the whole regional block. In a world where social distancing has fast become the norm, this has huge safety implications, minimising the potential points of contact and thus helping to reduce the risks of transmission of COVID-19."

How the device works

The technology consists of three components: a sterile syringe, a driver and a foot pedal. The driver and foot pedal will complete up to 200 blocks before they need replacing, while the syringe is single use sterile. An alternative operating option is in development to cater for



Safira is CE Marked and has FDA approval¹²

clinician preferences. It is easily assembled and allows the anaesthetist to hold the block needle in one hand, the ultrasound probe in the other, while they control the aspiration and injection themselves using the foot pedal operator. The device will not allow the injection to proceed if the pressure within the syringe goes above a certain threshold level and will automatically stop injection. The anaesthetist can then make necessary checks and adjustments as required, such as needle placement, before easily resetting the Safira system and continuing with the block.

Dr. Emad Fawzy adds: "Safira is the first device that makes the procedure suitable for a single operator. It gives the anaesthetist total control over the procedure, avoiding all the communication issues between the anaesthetist and the assistant. For hospitals, it's not just a device that makes the

procedure safer, but it also has a potential economic value, helping to reduce the cost of regional anaesthesia." **CSJ**

References

1. Fong-Soe-Khioe R. Health Economic report Medovate commissioned written by a health economist from the University of East Anglia (UEA)
2. Health Enterprise East (HEE): Research results using a cohort of volunteer anaesthetists
3. Borgeat A, Blumenthal S. Nerve injury and regional anaesthesia [Internet]. Vol. 17, *Current Opinion in Anaesthesiology*. 2004 [cited 2020 Mar 31], p.417–21. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/17023899>
4. Important Complications of Anaesthesia. Information | Patient
5. Jeng CL, Torillo TM, Rosenblatt MA. Complications of peripheral nerve blocks. *Br J Anaesth* [Internet]. 2010 [cited 2020 Mar 31];105(S1):97–107. Available from: https://academic.oup.com/bja/article-abstract/105/suppl_1/97/235950
6. Heij R, Eldin E, Young P, Carter J, Gibson J, Ali A, et al. Regional Anesthesiology Injection Pressures comparing Skilled Assistants with SAFIRA in a Simulated Ultrasound Guided Technique. In: The Anesthesiology annual meeting [Internet]. 2013 [cited 2020 Mar 31]. Available from: <http://www.asaabstracts.com/strands/asaabstracts/abstract.htm?year=2013&index=17&absnum=3085>
7. <https://www.asra.com/page/2905/practice-recommendations-on-neuraxial-anesthesia-and-peripheral-nerve-blocks-dur>
8. [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30514-2/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30514-2/fulltext)
9. <https://icmanaesthesiacovid-19.org/drug-demand-supply-anaesthetic-drug-usage-and-administration>
10. <https://www.bbc.co.uk/news/health-52150861>
11. <https://www.rcoa.ac.uk/documents/anaesthesia-explained/types-anaesthesia>
12. Safira was launched in the US in early 2020, through distribution deals with five US-based companies, including Mercury Medical. It is also available through Vygon in the UK and Europe, as well as other distributors in Australia.

Concerns raised over accidental awareness during C-section

Although accidental awareness during general anaesthesia is rare, and reported experiences have usually only lasted for a few seconds or minutes, the complication remains an important concern for both patients and anaesthetists.

A new study published in *Anaesthesia* shows that 1 in 256 women undergoing pregnancy-related surgery, including Caesarean section, under general anaesthesia experienced awareness – a figure much higher than reported before.

A recent national audit into accidental awareness (NAP5) indicated that approximately 1 in every 19,000

patients undergoing general anaesthesia spontaneously reported accidental awareness to medical staff.

Although this incidence varied for different types of surgery and patient subgroups, the infrequency of reports was reassuring.

Dr. Peter Odor, project lead and consultant anaesthetist at University College Hospital in London, explained: "We identified a complex range of risk factors for awareness, including drug types and variations in practice. Although the incidence of awareness during Caesarean section is much higher than that in the

general surgical population, it is important to emphasise that general anaesthesia remains safe and around half the patients that experienced awareness did not find it distressing."

The researchers found an association with certain anaesthetic drugs (thiopentone) and muscle relaxants. Factors such as emergency operations out-of-hours (late at night) were also associated with awareness.

To access the full paper visit: <https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/10.1111/anae.15385>