SAFIRA™ CASE STUDY

Evaluation of SAFIRA™ device conducted by:

Dr Evan Chen, Anesthesiologist
Dr Jeff Klein, Anesthesiologist

BASED AT:

SPECIALTY SURGICAL CENTER
380 LAFAYETTE ROAD
SPARTA, NEW JERSEY 07871
USA

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EVALUATION OF SAFIRA AN FDA CLEARED DEVICE FOR THE ADMINISTRATION OF REGIONAL ANESTHESIA

BACKGROUND

Regional Anesthesia particularly peripheral nerve blocks (PMBs) are commonly performed in an outpatient surgery setting in the United States and are considered to offer both improvements in analgesia and patient recovery.

Whilst the incidence of nerve injury is low it is a well-known complication of regional anesthesia, whilst any complication is considered multifactorial, the administration of LA at high pressures > 20 PSI into a nerve fascicle is documented as a major contributor.

The device used for this evaluation SAFIRA™ consists of an electronic pump driver unit with a 20 PSI cut off, a single use 20ml Luer proprietary syringe and a foot-pedal operating system.

This evaluation summarises the experience of two anesthesiologists performing a total of 20 PNB's using the SAFIRA™ system over a four-week period in the ambulatory surgery setting between February and March 2021.

The purpose of this evaluation was to establish the ease of use, and acceptability of SAFIRA™ compared to standard PNB practice.

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MATERIALS & METHODS

A total of 20 PNB's were performed over a period of four weeks in the ambulatory surgery center setting using SAFIRA™.

For each block, the SAFIRA™ driver, foot-pedal, and SAFIRA syringe with 20ml of either 0.25% to 0.5% marcaine were assembled.

The syringe was then connected to either a 3- or 4-inch 21-gauge Medline stimulation needle depending on the depth of the nerve to be blocked.

Finally, a Stimuplex HNS 12 nerve stimulator was attached to the needle to complete the setup.

A SonoSite M-Turbo equipped with a HFL50 ultrasound probe was used to visualize the sonoanatomy.

While performing each nerve block, the skin was first swabbed with 2% chlorhexidine gluconate with 70% isopropyl alcohol. Second, 0.5ml of 1% lidocaine was injected to form a skin wheal.

Third, the 21-gauge stimulation needle was inserted under ultra-sound guidance.

Once the needle approached the nerve of interest, a nerve stimulator was used for nerve blocks where a motor response could be elicited.

The nerve stimulator was used to confirm the nerve of interest and to assure that the needle was at a safe distance from the nerve before injection of local anesthetic. Finally, the SAFIRA™ pedal was pressed to aspirate the syringe to check for an absence of blood return before local anesthetic was injected for every 5ml.

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RESULTS

Types of blocks performed in order of frequency were interscalene, adductor canal, popliteal, and one TAP, supraclavicular, IPack, and infraclavicular block. Visualization of local anesthetic spread under ultrasound was the same between using SAFIRA and when an assistant aided in pushing the local anesthetic. Patients were comfortable in the immediate postoperative period regardless of technique.

When EXPAREL was admixed with MARCAINE creating a more viscous solution for the IPack block, the SAFIRA driver was not able to push the syringe. The syringe was then detached from the driver and was pushed manually by an assistant.

"In summary, the SAFIRA system has the potential to improve the regional anesthesia experience through self-automation, more control and ease of use..."

CONCLUSION

In summary, the SAFIRA™ system has the potential to improve the regional anesthesia experience through self-automation, more control and ease of use whenever a nerve stimulator is not required.

When only one operator is needed to perform the nerve block, the assistant then becomes available to perform other tasks which may improve operating room efficiency.

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BENEFITS OBSERVED

(Listed in order of importance)

1. Opening injection pressure limit of 20 PSI ensuring a safer nerve block.

2. Intuitive use; easy to understand how to aspirate and inject with the foot-pedal.

3. Easy setup and disassembly of syringe, driver, and foot pedal.

4. Lightweight, small, and portable.

5. The foot pedal can be placed to suit whether the operator wishes to use the left or right foot to operate the foot-pedal.

IMPROVEMENTS OBSERVED

1. The rate of injection could be improved up to 2x faster without compromising the safety.
2. When using a nerve stimulator an assistant is still required.
3. An attachment could be made to position SAFIRA closer to the ultrasound machine so the operator can be more focused on the screen.
4. As the current driver is battery operated and allows 200 blocks to be completed a rechargeable battery could be considered in the future.
5. Consider the ability to inject more viscous solutions such as EXPAREL since this local anesthetic is also indicated for long acting interscalene blocks.
6. Suggest that the foot pedal be made of non-porous material for easier cleaning.