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Administration Case Report With iovera°

This case report represents the individual experience of Dr Pieter Vreede and is intended to demonstrate his methodology for using iovera° to treat rib fracture pain.

Pacira BioSciences, Inc. recognizes that there are alternative methodologies for administering iovera^o treatment, as well as individual patient considerations.

| CASE INFORMATION | | |
|---------------------|--|--|
| Physician Name | Pieter Vreede, MD, Anesthesiologist | |
| Affiliation | Riverview Health Noblesville, IN iovera° user since 2016 | |
| Treatment Performed | iovera° treatment (with Smart Tip 190) for right-side rib fracture (T2-T7) | |

| PATIENT CHARACTERISTICS | | |
|--|---|--|
| Gender | Female | |
| Age | 70 years | |
| Patient History and Characteristics | Patient with multiple broken ribs, with a flail segment involving 4 of these ribs that resulted from a fall off a bicycle. Rib plating surgery was presented as an option due to return of severe pain following other unsuccessful long-term treatment options, including an ESP catheter block with On-Q infusion ball that worked but didn't last long enough. | |
| Pretreatment Medications | Acetaminophen, NSAIDs Opioids ESP nerve block | |

| DAY OF iovera [°] TREATMENT | | |
|---|--|--|
| Patient Pain Assessment and Medications | Pretreatment pain: 10/10 at worst Pain on arrival: 7/10 with pain medication | |
| Patient Positioning | Used lateral decubitus position with affected side up for iovera [°] treatment and right arm on top of left arm to help move medial edge of scapula away from spine | |
| Pain Location | Unilateral right side of chest cavity | |
| Nerves Marked for Treatment | Intercostal nerves (T2-T7) | |

TREATMENT NOTES

Treatment Site Preparation



Rib fracture location was confirmed using fluoroscopy. The site of each block was marked medial to the location of the fracture at each interspace.

Pretreatment Anesthetic



Patient was given a single-shot ESP block to anesthetize the intercostal nerves to prevent any pain associated with the iovera° procedure on those nerves. Patient's right posterior chest wall was coated with ChloraPrep[™] and draped while using a sterile ultrasound probe cover, gloves, and gel for the procedure. Fentanyl and midazolam were given IV, as needed, for patient comfort. Patient was placed in the Trendelenburg position to aid in optimizing the iovera° Handpiece positioning at a 45° angle above horizontal during each iovera° treatment cycle.

Treatment Details



The iovera° Smart Tip 190 needle was selected using an in-plane ultrasound approach from a caudad to cephalad direction. The needle was then advanced to the inferior border of the rib of interest at the level of the body of the EICM, which typically attaches to the inferiormost border of the rib.

Initial contact with the inferior border of the rib is made to avoid risks of foreshortening or not being able to visualize the tip of the needle well under ultrasound in larger patients, thus maintaining a safe distance from the lung.

Once the rib was felt, the Smart Tip 190 needle was walked off the rib by adjusting the needle trajectory slightly deeper and advancing it underneath the rib approximately 2 to 5 mm. The approach angle of the Smart Tip 190 is more acute for T2-T6, resulting in less advancement of the needle off the inferior border of the rib to avoid causing a pneumothorax. The Smart Tip 190 creates a much longer (16 mm) than wider (7.1 mm) ice ball; therefore, a caudad to cephalad in-plane ultrasound-guided approach is preferred to the traditional perpendicular approach. This preferred approach optimizes success in freezing the nerve because of the variable location of the nerve relative to the inferior border of the rib.

EICM=external intercostal muscle; IICM=internal intercostal muscle; IMICM=innermost intercostal muscle; IV=intravenously. ChloraPrep[™] is a trademark of Becton, Dickinson and Company.

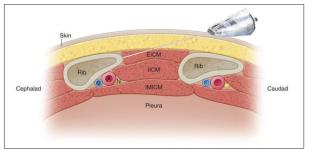


FIGURE 1: Contact of the iovera[°] Smart Tip 190 with the inferior border of the rib

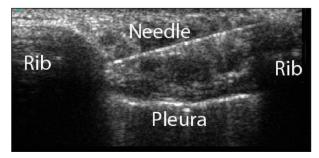


FIGURE 2: Ultrasound image illustrating needle placement

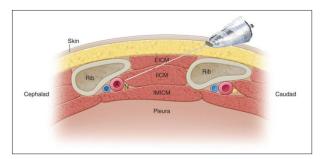


FIGURE 3: Freezing of the nerve after walking off the rib

TREATMENT NOTES

Treatment Details (continued)

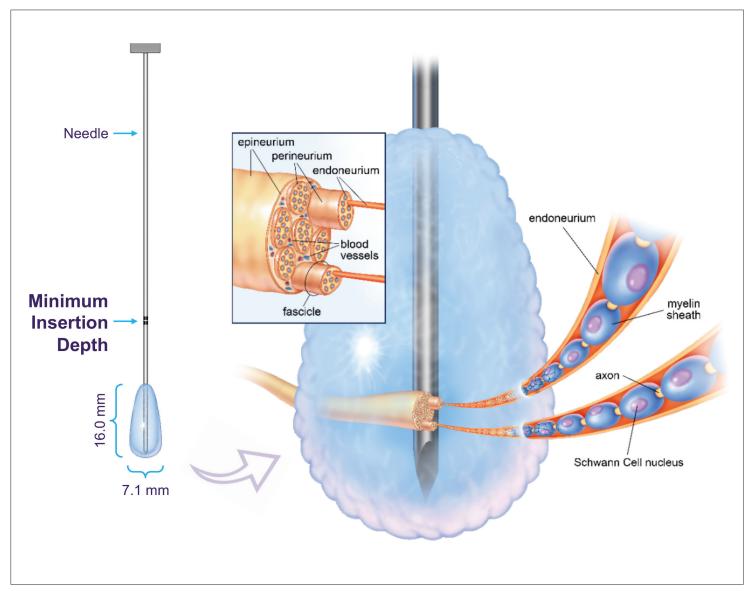


FIGURE 4: Depiction of ice ball created by the Smart Tip 190 needle during a treatment cycle



With the Smart Tip 190 needle in place, the iovera° Handpiece was gently lifted to a 45° angle from the horizontal position (for proper Handpiece function during the treatment cycle) without moving or bending the needle. Next, the treatment cycle to the intercostal nerve was initiated. The treatment was repeated at each remaining marked rib site to achieve the desired effect. Ideally, up to 2 ribs cephalad and caudad to the affected ribs are treated as well to optimize pain control due to sensory fiber overlap.

After all treatments were completed, bandages were applied at each site. A chest x-ray was performed to rule out pneumothorax.

FIGURE 5: Representation of iovera[°] Handpiece lifted to a 45[°] angle from the horizontal position without bending the needle in a thoracotomy case

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| TREATMENT SITE AND EFFECT | | | | |
|--|----------------------------|---|--|--|
| Treatment Site | | Provided Effect | | |
| T2-T7 Intercostal Nerves Cryoneurolysis of up to 2 dermatomes cephalad and caudad to the rib fractures is preferable to optimize long-term analgesic outcomes with iovera° treatment | | Blockade of ipsilateral sensory and motor fibers of the ICNs: anterior, lateral, and posterior chest wall | | |
| POSTTREATMENT ASSESSMENT | | | | |
| Posttreatment Day 0 | Substantial improvement du | e to residual ESP block | | |

| Posttreatment Day 1 | Pain improvements from iovera° treatment persisted after the ESP block wore off. All opioids were stopped, and patient was able to sleep on affected side without discomfort. She resumed walking a few miles each day. Potential rib plating was cancelled. |
|-----------------------|---|
| Posttreatment Month 3 | Through 3 months, the patient felt that the treatment was very helpful in alleviating pain and subsequently never needed plating of the displaced rib fractures. Once the nerves regenerated completely, she experienced only mild ongoing pain that did not limit her function to any significant degree. |

PHYSICIAN'S EXPERIENCE WITH iovera°

Scan here to learn more about Dr Vreede's experience with iovera° or go to **iovera.com/testimonials**



Scan here to contact us if you have any questions or go to iovera.com/contact-us



For full safety information, please visit www.iovera.com/safety.

Disclosure: Dr Vreede is a paid consultant for Pacira BioSciences, Inc.

