STUDY PROTOCOL

Long-term outcomes of ultrasound-guided percutaneous bilateral cardiac sympathetic denervation in patients with refractory arrhythmic storm: a single-center case series.

code CEImPA 2023.139

Oviedo, April 11, 2023

PROJECT TITLE

Long-term outcomes of ultrasound-guided percutaneous bilateral cardiac sympathetic denervation in patients with refractory arrhythmic storm: a single-center case series.

BACKGROUND AND CURRENT STATE OF THE ARTS

Electrical storm (TS) or constant ventricular tachycardia is a life-threatening condition associated with high morbidity and mortality. It is defined as three or more sustained events of ventricular tachycardia (VT) or ventricular fibrillation within a 24-hour period, with or without implantable cardioversion-defibrillation (ICD) therapy [1-2], with a prevalence of 10%–25% in patients with ICDs.

If left untreated, TS can lead to left ventricular systolic dysfunction, which can progress to heart failure [3]. Treatment includes the use of antiarrhythmic drugs to suppress ventricular arrhythmias (VAs), ICD reprogramming, and antitachycardia pacing techniques. In some complex cases, urgent catheter ablation may be necessary to treat VAs and TS. However, these conditions are sometimes refractory to standard medical therapies. In these cases, neuromodulation, which reduces sympathetic efferent tone to the myocardium, can help suppress refractory arrhythmias and can be achieved with a stellate ganglion block (SGB) [4-7], sometimes representing the patient's last option, either as definitive therapy or as a bridge to transplantation.

Although SGB has been shown to be effective in terminating the electrical storm, there is a lack of robust clinical evidence supporting its use, as it is not possible to conduct double-blind randomized trials in this clinical setting. Current evidence comes from small case series reports in the literature [8-13].

At our hospital, a multidisciplinary team of cardiologists, intensivists, and anesthesiologists manages these patients. To date, we have performed numerous SGB with good results. This experience has led to the need for this project, to publish our experience on this topic and contribute to the widespread use of this treatment in the management of these patients

STUDY HYPOTHESIS

SGB and bilateral cardiac sympathetic denervation (BCSD) produce a sustained cessation of refractory electrical storms.

OBJECTIVES

Primary

- To describe the effectiveness of SGB and BCSD bilateral in patients with advanced heart failure and electrical storm refractory to conventional treatment.

Secondary

- To study the long-term (12 months) temporary effectiveness after performing the technique.
- To describe the characteristics and comorbidities of these patients.
- To describe the complications arising from the techniques.

STUDY METHODOLOGY

DESIGN: A prospective, single-center observational study.

STUDY POPULATION: Patients with advanced heart failure and arrhythmic storm refractory to conservative and ablative medical treatment in the arrhythmia unit of the Central University Hospital of Asturias.

ETHICAL CONSIDERATIONS: The study has been has been authorized by the Ethics Committee for Research with Medicinal Products of the Principality of Asturias, with code CEImPA 2023.139.

INCLUSION CRITERIA: All patients over 18 years of age diagnosed with arrhythmic storm refractory to conservative medical treatment.

EXCLUSION CRITERIA: Patients with contraindications to perform the interventional technique (active infection at the puncture site and refusal by the patient).

ANALYZED VARIABLES

The primary study outcome was arrhythmic burden, assessed both in the early period (first 24 hours) and in the long term (during the 12 months following BCSD).

Secondary variables included baseline clinical characteristics and comorbidities of the enrolled patients. Procedure-related complications were also recorded, including local hematoma, hoarseness, brachial plexus involvement, respiratory compromise and adverse reactions to the injected substances. In addition, variables related to long-term prognosis were recorded (heart transplantation, and all-cause mortality).

SAMPLE SIZE ESTIMATION: All consecutive cases eligible for this therapy were collected between April 2023 and March 2025.

DATA COLLECTION: A data collection form will be used for the study. The researcher will include the patient sample in it, without any identifying information.

STATISTICAL ANALYSIS

Statistical analyses were performed using the R statistical software package. Continuous variables are expressed as mean ± standard deviation, and categorical variables as absolute numbers and percentages. Comparisons between groups were performed using Student's t-test for continuous variables (after confirmation of normality) and the chi-square test for categorical variables, with Fisher's exact test applied when chi-square assumptions were not met.

Event-free survival (arrhythmic recurrence, heart transplantation, or mortality) was evaluated using Kaplan–Meier survival analysis.

LIMITATIONS OF THE STUDY: those due to the prospective design of the study and those arising from the impossibility of reviewing the patients included in the study database.

CREDIT AUTHORSHIP CONTRIBUTION STATEMENT:

JML: Project administration as doctoral thesis, writing – review & editing. BMJ: writing – review & editing. LBA: writing – review & editing. DGI: data curation. JMR: data curation. BDM: data curation. VAF: data curation. FEF: review & editing. All authors have read and agreed to the published version of the manuscript.

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INFORMED CONSENT FOR

STELLATE GANGLION BLOCK – CERVICOTHORACIC SYMPATHETIC BLOCK

NAME AND SURNAME .....
DATE OF BIRTH .....
REGIONAL HEALTH CARD NUMBER .....
MEDICAL RECORD No. .....
ID CARD, NIE OR PASSPORT No. .....

HEALTH AREA
Department of Anesthesiology

UDO-013-01 STELLATE GANGLION BLOCK – CERVICOTHORACIC SYMPATHETIC

DESCRIPTION OF THE PROCEDURE AND ITS PURPOSE

The procedure consists of inserting a needle to administer medication (local anesthetic and/or corticosteroids) to the so-called **stellate ganglion**, which is a nervous structure of the sympathetic nervous system located anterior to the vertebral bodies of the lower cervical vertebrae and the first thoracic vertebra at their lateral borders. This structure conducts sympathetic innervation to the upper limbs, upper thorax, and areas of the neck and head.

It is mainly indicated for the treatment of Complex Regional Pain Syndrome of the upper limbs, as well as atypical pain involving the head, neck, and chest. It is also used for the control of **refractory arrhythmic storms.**

It may be necessary to insert an intravenous line (IV fluids), and local anesthesia with mild sedation is used to increase patient comfort. Ultrasound and/or fluoroscopic guidance with radiological contrast is required to determine the final position of the needle. The procedure usually lasts between **20 and 25 minutes**.

This treatment is intended to relieve pain and improve functionality and may also be useful for diagnostic purposes in conditions that may require other techniques; however, it is **not curative**. The degree and duration of pain relief vary considerably from one patient to another.

RELEVANT OR IMPORTANT CONSEQUENCES

The use of this technique does not entail significant permanent sequelae with certainty.

RISKS OF THE PROCEDURE

Most frequent complications:

- Local discomfort at the puncture site, which may be mild or intense and usually resolves within a few hours with standard analgesics.
- Vasovagal syncope: dizziness that may occur in certain individuals in response to specific situations (sight of blood, needles, etc.), accompanied by sweating, sensations of heat or cold, and fainting. Notify the physician immediately if these symptoms occur.
- Temporary worsening of pain in the days immediately following the procedure.

Other less frequent but important complications:

- Allergic or intolerance reactions to medications, contrast agents, or instruments used.
- Complete block (very rare): usually occurs when a large amount of local anesthetic is absorbed into the epidural space or is accidentally injected intrathecally. It causes symptoms similar to vasovagal syncope but may temporarily require respiratory support. In expert hands, it is usually not severe.
- Cervical hematoma due to puncture of neck veins or arteries. This is usually transient and resolves with compression, but may be potentially serious if it compresses the trachea or arteries supplying the brain.

- Hoarseness due to vocal cord paralysis: may occur transiently if the recurrent laryngeal nerve is affected by the anesthetic. Usually temporary, but may become permanent if nerve injury occurs.
- Accidental intravascular injection of anesthetic: at neck level, this may cause loss of consciousness, seizures, coma, or even death.
- Injury to nearby cervical or thoracic nerves, resulting in loss of function (paralysis), varying degrees of pain (from mild discomfort to severe pain), or local/regional symptoms that may be temporary or permanent.
- Accidental puncture of the lung, causing air or blood to enter the pleural space.
- Puncture of the vertebral arteries: a serious complication that may lead to cerebral infarction, stroke, or death.

- Exposure to X-rays may produce adverse effects, including a very low risk of cancer. The benefits of the procedure outweigh these risks, and the minimum necessary radiation dose will be used.
- Risk of infection during hospital stay.

ADDITIONAL RISKS IN YOUR CASE

Due to my current condition (mark as appropriate):
☐No risk factors
☐Diabetes
☐Obesity
☐Hypertension
☐Anemia
☐Advanced age
☐Smoking
☐Anticoagulant treatment

..... may increase the frequency or severity of risks or complications.

CONTRAINDICATIONS

- Known allergy to the drugs to be used.
- Infection at the puncture site.
- Systemic infection (sepsis) with high fever and general malaise.
- Blood coagulation disorders.
- Anticoagulant or antiplatelet therapy not appropriately discontinued.

ALTERNATIVES TO THE PROCEDURE

- Modification of current pain management treatment.
- Functional rehabilitation therapy.
- Psychological therapy (psychotherapy).
- Weight loss in cases of overweight.
- Surgery.

AUTHORIZATION FOR "STELLATE GANGLION BLOCK – CERVICOTHORACIC SYMPATHETIC"

I, Mr./Ms. ....., acting as legal representative in the capacity of **guardian, spouse, partner, family member, parent**, of the patient due to **legal incapacity, physical or mental condition preventing decision-making, or being a minor**, whose details are stated above,

DECLARE THAT I HAVE FULLY UNDERSTOOD the information provided and therefore AUTHORIZE the performance of this procedure. All my questions have been clarified during a personal interview with Dr. ....., including the risks and consequences of disease progression should the procedure not be performed.

I am satisfied with the information provided and understand that this document may be REVOKED at any time prior to the procedure. I have received a COPY of this document.

Signed after careful reading.

In ....., on .....

ONLY IN CASE OF REVOCATION OF CONSENT

I, the legal representative of the patient, with ID/NIE/Passport No. ....., do NOT authorize the performance of this procedure or revoke the previously granted consent, having been sufficiently informed of the risks involved.

In ....., on .....

Signature of legal representative:
ID/NIE or Passport:

Signed: Dr. .....
Medical License No.: .....

INFORMATION SHEET FOR INTERVENTIONAL TECHNIQUES

CONSIDERATIONS

- **ALLERGIES**: Inform your physician of any allergies, especially to corticosteroids, morphine derivatives, iodinated contrast, or local anesthetics.
- **ANTICOAGULANTS**: If you take medication affecting blood clotting, it may need adjustment prior to the procedure.
- **DIABETES AND HYPERTENSION**: Inform your physician; medication adjustments may be necessary.
- **PREGNANCY AND/OR BREASTFEEDING**: Inform your physician if you are pregnant or breastfeeding.

SIDE EFFECTS AND/OR COMPLICATIONS ASSOCIATED WITH

Corticosteroids

- Adrenal insufficiency, osteoporosis, hyperglycemia, hypertension, skin changes, hair loss, facial flushing, tendon rupture, muscle atrophy, nerve irritation, bleeding, gastric ulcers, anxiety.
- Local or generalized muscle weakness (steroid-induced myopathy).
- Vascular thrombosis, which may cause tissue death; in the epidural space, this may lead to temporary or permanent paralysis.

Local anesthetics

- Symptoms of systemic toxicity: metallic taste, tinnitus, blurred vision, chills, dizziness, hypotension.
- Massive intravascular injection may cause arrhythmias, seizures, and cardiac arrest; severe but reversible in expert hands.

Iodinated contrast

- Anaphylactic shock.
- Venous or arterial thrombosis.
- Arrhythmias.
- Epilepsy or cerebral infarction.
- Renal failure.

RECOMMENDATIONS AFTER THE PROCEDURE

Do not drive or consume alcohol for **24 hours** after the procedure.

Sedative medications may cause temporary amnesia lasting up to **24–48 hours**. Avoid making important decisions during this period.

For your safety, attend the procedure accompanied. Assistance is recommended after discharge, regardless of how you arrived at the hospital.

Follow the instructions of your physician and nursing staff. Maintain relative rest for at least **24 hours** and seek immediate medical attention if you experience:

- Heat or redness at the injection site
- Fever
- Loss of sensation or movement
- Difficulty controlling bladder or bowel function