



Percutaneous **Left stellate ganglion block **I**n out-of-hospital cardiac arrest due to refractory **V**entricular arrhythmias (LIVE study II).**

Blocco percutaneo del ganglio stellato di sinistra nell'arresto cardiaco extra-ospedaliero causato da aritmia ventricolare refrattaria.

Observational and prospective study.

Purpose: Evaluation of ventricular fibrillation termination following Percutaneous Left Stellate Ganglion Block (PLSGB) performed during Out-of-Hospital Cardiac Arrest (OHCA) subtended by ventricular arrhythmias refractory to standard treatment.

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1. Background

The influence of the Autonomic Nervous System (ANS) on heart rhythm is known since decades and the effectiveness of its modulation with beta-blockers to reduce arrhythmias and mortality is widely demonstrated [1-3]. In the last twenty years, it has also been shown that it is possible to modulate the ANS also with non-pharmacological interventions: left cardiac sympathetic denervation (LCSD), i.e. the surgical resection of the lower half of the stellate (cervico-thoracic) ganglion and T2 to T4 sympathetic ganglia, has been shown to be effective in reducing ventricular arrhythmias, both in inherited arrhythmogenic cardiopathies and in structural heart disease (both ischemic and non-ischemic) [3-8]. Many elements play a role in LCSD effectiveness in arrhythmias reduction: the most important being an increase in ventricular fibrillation (VF) threshold, a reduction in transmural repolarization heterogeneity and an increase in the effective refractory period [9-11]. Since 2000 onwards, there is also increasing evidence about the percutaneous stellate ganglion block (PSGB) as an effective weapon for the treatment of ventricular arrhythmias refractory to traditional interventions in an emergency setting; the most recent evidence supports the use of PSGB on top of contemporary therapies in the management of refractory ventricular arrhythmias [12-18]. This technique, which consists in the injection of 5-10 mL of local anaesthetic at the C6 level, is known since the first half of the twentieth century and is widely used for the treatment of sympathetic-related pain syndromes. At the level of C6 the site of puncture is far away from the lung with a resulting lower rate of pneumothorax compared with insertion at level of C7. The needle is advanced onto Chassaignac's tubercle, and it is then withdrawn to inject the local anaesthetic. The operator can use ultrasounds as a guide for needle insertion or use a technique based on anatomic landmarks and no superiority of one technique over the other has been demonstrated [19-24]. A possible marker of the block's efficacy is the occurrence of miosis ipsilateral to the side of the block, as not only the sympathetic efferent fibers to the heart, but also sympathetic efferent fibers to the eye are blocked [17]. Many reports also from our centre [25-28] have demonstrated the potential therapeutic effect of PSGB in dramatically reducing arrhythmic recurrences in patients with different heart conditions (either ischaemic, non-ischaemic, and genetically determined cardiopathies). Considering its efficacy and that the reported rate of complications is very low, this technique has become part of clinical practice [29-33] for the management of refractory ventricular arrhythmias and is encouraged also by the European Heart Rhythm Association (EHRA)[34]. In line with this evidence, the Fondazione IRCCS Policlinico San Matteo has promoted, and is currently leading, a multicenter observational study on in-hospital stellate ganglion block for arrhythmic storm ("*STAR study*") and a specific training course endorsed by the School of Anesthesia and Intensive Care of the University of Pavia and with the use of a 3D model of the neck, printed ad-hoc, is offered by Fondazione IRCCS Policlinico San Matteo to all the medical doctors (anaesthesiologists, cardiologists and emergency physicians) of the Fondazione itself and of all other Italian and non-Italian hospitals, who are interested.

Regarding the specific setting of refractory cardiac arrest, some of the previous cited papers included patients in cardiac arrest in their population and a case report has been published even



regarding the execution of PSGB in patients during extracorporeal cardiopulmonary resuscitation [35]. Moreover, a specific paper including patients suffering out-of-hospital cardiac arrest (OHCA) have been published and the results are promising [12]: in all patients in whom miosis was observed after PSGB, the subsequent shock was effective in terminating the ventricular arrhythmia, at variance with the cases in which miosis was not observed and the shock continued to be ineffective in terminating the arrhythmia. However, more data are needed to better quantify the efficacy of PSGB in OHCA patients with refractory ventricular arrhythmias.

The analysis of data collected in our Cardiac Arrest Registry of Lombardia region (“*Lombardia CARE*”) concerns the patients who suffered from an Out-of-Hospital Cardiac Arrest (OHCA) with medical aetiology (Utstein style 2014 based) and a first shockable rhythm in the Province of Pavia from 1 July 2020 to 30 June 2022. The patients who needed 5 shocks or more to terminate the arrhythmia (n=10) showed a significantly lower rate of sustained return to spontaneous circulation (ROSC) until admission and transfer of care to the receiving hospital (defined as “survived event” following Utstein-style) as compared to those who needed less than 5 shocks (n=43) to restore a perfusing rhythm until admission (22.2% Vs 44.3%, p=0.01).

2. Methods

2.1 Inclusion criteria

- All patients with an OHCA with a shockable rhythm and in which the cause of the cardiac arrest is medical (following Utstein-style 2014).
- Patients who received LPSGB after at least 4 unsuccessful shocks during ACLS algorithm;

2.2 Exclusion criteria

- Patients in which the cause of the cardiac arrest is non-medical following Utstein-style 2014 (trauma, overdose, drowning, electrocution, asphyxia, etc.).
- Patients who has an anisocoria at the arrival of a medical doctor on the scene.

2.3 Study flow

This is an observational and prospective study. All patients meeting the inclusion criteria will be consecutively enrolled in the study. The decision to perform PSGB or not and the type of technique (anatomic or echo-guided) is left to the EMS rescue team medical doctor (MD) according to clinical practice (standard of care). Considering the available literature, it is expected that the PSGB will be performed after all the actions provided in the ACLS algorithm and which are considered useful in the clinical situation (intubation and ventilation, administration of iv/io adrenaline, amiodarone or lidocaine, use of mechanical chest compression, etc.). Moreover, considering that the PGSB is useful for the treatment of refractory ventricular arrhythmias, it is expected it will be performed after the



administration of the 4th shock if the 3rd shock was unsuccessful in restoring a stable perfusing rhythm, considering all the shocks administered both by an AED or by manual defibrillator. As recommended by the guidelines, it is expected that the evaluation of the effectiveness of the 3rd shock will be carried out at the end of the two-minute cycle after shock delivery. Those patients with refractory OHCA transported with ongoing ACLS who receive the fourth shock once in the Emergency Department will be also considered. On the contrary, the patients with prehospital ROSC who suffer a new cardiac arrest once in the Emergency Department won't be considered in the present study. The presence of anisocoria immediately before the PSGB and 1-2 minutes after the PSGB will be evaluated. Considering the setting and the need of a rapid effect of the anaesthetic, it is expected that the anaesthetic used will be lidocaine 2%, which is also already available among EMS drugs. After the end of the event, the MD will be asked to fill in a questionnaire (Questionario Medico LIVE study II v 1.0 del 30/Sep/2022) regarding the feasibility of the technique in the pre-hospital setting, the practicability of its implementation compared to the usual procedures performed in the pre-hospital setting and any problems encountered. The responses will be scored from 1 to 10 (1=perfect feasibility; 10=no feasibility). All eventual complications associated with PSGB procedure will be carefully recorded.

The effectiveness of the PSGB will be evaluated if at least one shock will be delivered after the execution of PSGB.

The data will be compared to our historical cohort of patients with the same OHCA characteristics (who received more than 4 shocks) enrolled in the Cardiac Arrest Registry of Lombardia region: "*Lombardia CARE*".

2.4 Involved Units

- AAT di Pavia 118 Unit – Fondazione IRCCS Policlinico San Matteo – Pavia.
- Cardiac Intensive Care Unit (UTIC) – Fondazione IRCCS Policlinico San Matteo – Pavia.
- Intensive Care Unit – Fondazione IRCCS Policlinico San Matteo – Pavia.
- Azienda Regionale Emergenza Urgenza (AREU) – Milano.



3. Study endpoints

3.1 Primary Outcome:

- Primary electrocardiographic endpoint: to assess whether the rate of VF termination is higher after the LPSGB as compared to the historical cohort.

3.2 Secondary Outcomes:

1. To assess whether the rate of ROSC until admission and transfer of care to the receiving hospital is higher in the patients treated with PSGB as compared to historical controls.
 2. To assess whether the rate of ROSC until admission and transfer of care to the receiving hospital is higher in the patients treated with PSGB and in which anisocoria is present after the PSGB, but not before PSGB.
 3. To assess whether the survival rate at hospital discharge is higher in the patients treated with PSGB.
 4. To assess whether the survival rate with good neurological outcome (CPC 1 ore 2) at 1 month after the event is higher in the patients treated with PSGB.
 5. To assess whether the survival rate at hospital discharge is higher in the patients treated with PSGB and in which anisocoria is present after the PSGB, but not before PSGB.
 6. To assess whether the survival rate with good neurological outcome (CPC 1 ore 2) at 1 month after the event is higher in the patients treated with PSGB and in which anisocoria is present after the PSGB, but not before PSGB.
 7. To assess the occurrence of complications associated with PSGB in the pre-hospital setting.
 8. To assess the perceived feasibility and practicability of PSGB (measured by questionnaire: Questionario Medico LIVE study II v 1.0 del 30/Sep/2022) in the pre-hospital setting by the operators.
- ### 4. Sample Size and study duration
- The sample size calculation is based on the primary clinical endpoint (VF termination). Basing on our previous data showing a shock success rate of about 46% [36] and on a previous paper in which 11 patients with OHCA treated with PLSGB, performed once arrived at the hospital with ongoing CPR, the shock success rate was 63% [12]. Considering also that in the present study the procedure will be performed directly in the out-of-hospital setting and consequently in an earlier phase of cardiac arrest, we aim to observe an increase of shock success to 80%. So, considering a power of 80% and a two tailed α -error of 0.05 the number of patients needed per group is of 31. The study duration is 5 years.



5. Statistical analysis

The main descriptive statistics as mean and standard deviation or median and interquartile range will be used to describe all the numeric variables collected during the study.

Categorical variables will be described using the appropriate frequency tables (showing absolute number and percentage frequency).

P-value lower than 0.05 will be considered significant.

All the statistical analyses will be performed using a statistical software (MedCalc software version 12.5.0.0 by MedCalc software bvba).

Following is a more detailed analysis plan for primary and secondary end-points.

Primary end-point:

The chi-square test, or the Fisher's exact test, will be used to evaluate differences between the rate of VF termination in patient treated with LPSGB and the historical cohort.

Secondary end-points:

The chi-square test, or the Fisher's exact test, will be used to evaluate:

1. differences in the rate of ROSC until admission to the hospital in patients treated with PSGB and the historical cohort.
2. differences in the rate of ROSC until admission to the hospital in patients treated with PSGB and in which anisocoria is present after the PSGB, but not before PSGB and patients treated with PSGB and in which anisocoria is not present either before or after the PSGB
3. differences in the survival rate at hospital discharge is patients treated with PSGB and the historical cohort.
4. differences the survival rate with good neurological outcome (CPC 1 ore 2) at 1 month after the event in patients treated with PSGB and the historical cohort.
5. differences in the survival rate at hospital discharge is patients treated with PSGB and in which anisocoria is present after the PSGB, but not before PSGB and patients treated with PSGB and in which anisocoria is not present either before or after the PSGB.
6. differences the survival rate with good neurological outcome (CPC 1 ore 2) at 1 month after the event in patients treated with PSGB and in which anisocoria is present after the PSGB, but not before PSGB and patients treated with PSGB and in which anisocoria is not present either before or after the PSGB.
7. The occurrence of complications associated with PSGB in the pre-hospital setting will be shown as a percentage frequency, together with the binomial 95% confidence interval.
8. The perceived feasibility and practicability of PSGB in the pre-hospital setting by the operators will be assessed by calculating mean and standard deviation\ median and interquartile range of the scores at the questionnaire: Questionario Medico LIVE study II v 1.0 del 30/Sep/2022.



6. e-CRF e data management

Data will be collected in paper (by filling out a physician questionnaire: Questionario Medico LIVE study II v 1.0 del 30/Sep/2022) and digital form (on REDCap 12.0.27© 2022 Vanderbilt University). All procedures concerning data management and security will adhere to the EU Data Protection Directive 95/46/EC.

None of the recorded and collected data can be linked to the individual they belong to. Each patient will be assigned a unique identification number that will be used to identify the data. The patient's identity is stored in a separate database under the responsibility of the principal investigator along with an identification number and a copy of the data to answer the questions during the "cleaning database" process.

All standard procedures regarding collection, registration, and data security will be observed. In particular, appropriate measures will be taken to protect the data from their accidental or unlawful destruction, accidental loss or alteration, unauthorized access, abuse, and any other misuse.

Data processing cannot take place in "ad hoc" locations (home workstations).

If processing a sensitive data, as a rare exception, should take place in "ad hoc" workstations (home workstations), the computer must comply with the control requirements regarding the protection of personal data, ensuring that personal data protection is sufficient.

7. Informed consent for the use of personal data

Based on the observational design of the present study, and consistently with the STAR study covering the in-hospital setting, the decision to perform PLSGB is left to the physician and the procedure will be performed if deemed useful according with modern evidence in such an emergency condition as a cardiac arrest. Depending on their clinical conditions the patients will be asked to provide the consent for the use of personal data as soon as clinically possible.

The consent to the anonymous use of personal data will be required to the survived patient or, if appointed, to the legal guardian. Patients will then receive the information form and informed consent form to the processing of sensitive data.

The investigator will observe the applicable regulations for the research and documentation of informed consent, adhere to the rules of Good Clinical Practice and the ethical principles derived from the Helsinki Declaration. If an informed consensus module update is required during the study, approval by the Ethics Committee will be required before submitting patient updates.



In accordance with the recommendations of the Helsinki Declaration and local regulations, each patient will be adequately informed of the aims, methods, expected benefits, potential risks and disadvantages associated with the study; the patient will be informed of his right to refuse consent to the use of his or her sensitive data, or to withdraw it at any time, without affecting his or her medical care.

The patient will have all the time needed to evaluate the information received before providing his/her informed consent to the use of sensitive data.

The investigator must receive informed written consent from the survived patients before using them in any way for the purpose of the study. The written consent to the processing of sensitive data must be documented by the date and signature of the patient's and by the date and signature of the investigator or whoever is the author.

The investigator will provide the patient with a signed copy of informed consent and will retain the original together with the other protocol documents; such consent will be obtained after telephone interview or by personal meeting or, if not possible, by postal mail. All possible and reasonable attempts will be made to trace patients.

For deceased patients, data processing will be processed by anonymizing the data through decoding files that will be destroyed at the end of the data collection.

Survived patients will have the possibility to withdraw the consent. In that circumstance data will be considered anonymously or completely erased if clearly requested by the patient.

8. Costs

No additional costs are foreseen.

9. Involved Personnel

Principal Investigator: Dr. Simone Savastano (MD)

Co-Principal Investigator: Dr. Enrico Baldi (MD, PhD)

Data Managers: Dr.ssa Alessia Currao (PharmD), Dr. Roberto Primi (M.Sc.), Dr.ssa Sara Bendotti (M.Sc.), Dr.ssa Donata Cappelletti (M.Sc., PhD), Dr.ssa Sara Compagnoni (MD) and Dr.ssa Francesca Romana Gentile (MD).

10. Publications

Data and publications will be managed by the proposing research group.



The protocol of the study will be made available on proper platform/registry of clinical trials useful for appropriate knowledge and discussion.

The results of the study will be published, independently of the positive or negative result of the same, in order to avoid unnecessary duplication.

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