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Adjunctive hypnotic communication for analgosedation in subcutaneous implantable cardioverter defibrillator implantation. A prospective single center pilot study

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ABSTRACT

Background: Subcutaneous implantable cardioverter defibrillator (S-ICD) is a well-established therapy for sudden death prevention. Considering the painful nature of the procedure anaesthesia may be required for analgo-sedation. Hypnosis is emerging as a promising therapeutic strategy for pain control. Few data are available regarding the use of hypnosis as adjunctive technique for pain control during S-ICD implantation.

Methods: Thirty consecutive patients referred to our centre for S-ICD implantation were prospectively and alternatively allocated with 1:1 ratio in two groups: A) Standard analgo-sedation approach (Hypnosis non responder patients) B) Standard analgo-sedation approach with the addition of hypnotic communication (Hypnosis responder patients). Peri-procedural pain perception and anxiety, perceived procedural length, type and dosage of administered analgesic drugs have been measured using validate scores and compared.

Results: Hypnotic communication was offered to 15 patients of which was successful in 11 patients (73%). There were no statistical differences between the two study groups according to baseline characteristics. Hypnosis communication resulted in significant pain perception reduction (Group A 6,9 ± 1,6 Vs Group B 1,1 ± 0,9, p value < 0,01), *peri*-procedural anxiety (Group A 3,5 ± 1,6 Vs Group B 1,9 ± 0,5, p value < 0,01) and reduced perceived procedural length (Group A 58,7 ± 13,4 min Vs Group B 44,7 ± 5,5 min, p value < 0,01). Fentanyl dosage was significantly lower in Group B patients.

Conclusions: Our results demonstrated a significant reduction of perceived pain, anxiety, procedural time and use of analgesic drugs in hypnosis responder patients. These results reinforce the beneficial effects of the hypnotic technique in patients undergoing S-ICD implantation.

1. Introduction

Implantable Cardioverter Defibrillator (ICD) is a widespread and well-established therapy for sudden death prevention and subcutaneous ICD (S-ICD). The procedure is generally performed under local anaesthesia and sometimes requires anesthesiologic support for analgo-sedation because of the need of a large subcutaneous or intermuscular pocket, and a subcutaneous lead tunnelling. Generally, pain control is managed using local or general anaesthesia. Given the painful nature of this procedure and the frequent shortage of anaesthesiologists, different anaesthesiologic techniques such as serratus plane block [1] or truncated plane block [2] are often considered. On the other side, in the context of implantation procedures, there is an increasing demand for non-pharmacologic therapies that do not carry the same troublesome side effects associated with many medical procedures [3].

Hypnosis has a rich history as a standalone or adjunctive treatment to a variety of medical procedures [4-6], It has been shown that hypnotic analgesia is a benign approach and its application to interventions can result in substantial cost savings [7,8].

Abbreviations: ICD, Implantable Cardioverter Defibrillator; S-ICD, Subcutaneous Implantable Cardioverter Defibrillator; NRS, Numeric Rating Scale.

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Recently, several groups, introduced the hypnotic communication to manage analgo-sedation in electrophysiological procedure, more specifically in transcatheter ablation [9-11].

In addition our group reported the first successful case of hypnotic communication used as adjunctive technique for analgo-sedation during S-ICD insertion in a patient with Brugada syndrome [12].

Based on these considerations a prospective study with an alternated allocation with 1:1 ratio comparing standard analgo-sedation versus analgo-sedation with adjunctive hypnotic communication in consecutive patients undergoing S-ICD implantation was planned.

Aim of the study was to evaluate the feasibility and safety of hypnotic communication in this group of patients and, after being induced, the impact of hypnosis on anxiety and pain reduction and consequently on the tolerance of the procedure.

2. Methods

2.1. Patients

Thirty consecutive patients referring to our centre for S-ICD implantation have been prospectively enrolled. Patients underwent an alternated allocation with 1:1 ratio and on the basis of hypnosis responsiveness they were allocated in two groups: A) Standard analgo-sedation approach (Hypnosis non responder patients) B) Standard analgo-sedation approach with the addition of hypnotic communication (Hypnosis responder patients) in order to evaluate the impact of hypnosis on the S-ICD implant. Considering that to evaluate the analgesic effect of hypnosis we should take into account only responder patients, the analysis have been conducted in an "As Treated" approach. The study protocol was approved by the local Institutional Review Board. All patients provided written informed consent. The study was conducted in compliance with the good clinical practices protocol and Declaration of Helsinki principles.

2.2. Implant procedure

A two-incision implant technique intervention for S-ICD was performed [13,14]. This procedure, as described above, consists of an incision in the left underarm area to create an intermuscular generator pocket (in the virtual space between the latissimus dorsi and the serratus anterior muscles) and a sub-cutaneous tunnelling of the lead in the thoracic and parasternal area.

Once the pocket was created, a small xiphoid incision was performed. A subcutaneous tunnel was created to position the lead from the xyphoid incision towards the pocket through the anterior left hemithorax and a second tunnel along the sternum towards the supra-sternal notch (as per normal standard configuration for S-ICD implantation) [14]. The electrode was connected to the device which was placed in the pocket. Two separate non-absorbable sutures were inserted in the xyphoid incision to fix the lead and a suture knot was tied to support the S-ICD.

At the end of the procedure, according to the internationals guidelines, the defibrillation test was performed in both groups. The test was performed under deep sedation guided by an anaesthesiologist. In group B patients this was accomplished with the same methodology after having re-orientated the patients from hypnosis.

2.3. Pain control protocol.

Local anesthesia with Lidocaine 2% 15 ml was administered at the site of surgical incision in both groups. Fentanyl 0.05 mg bolus and Paracetamol 1 gr was given as a standard protocol in both groups. Further doses of analgesic/sedative drugs were administered in both groups during the procedure depending on the patients' demand. In case of uncontrolled pain, despite the use of the above mentioned drugs, deep sedation/narcosis with Propofol managed by the anesthesiologist was applied.

The goal of the protocol was to obtain a painless (Numeric Rating Scale, NRS $\leq$ 2) procedure.

In order to make evident the real effect of hypnosis, Group A patients were approached with a friendly talk with the aim to reduce anxiety to increase the patients' compliance to the procedure (sham procedure).

In Group B the same analgesic protocol was used with the adjunctive use of hypnotic communication.

However in all cases, an anaesthesiologist was always available as a back-up plan in case of patients' need.

In the post procedural setting analgesic drugs were administered in both groups if required. Anyway in the hypnosis group a post procedural analgesic hypnotic conditioning was induced in order to provide analgesia lasting until the next day.

3. Hypnotic technique

Hypnosis leads to a modified state of mind (*para*-physiologic) with muscle relaxation.

The hypnotic workflow may be divided into the following stages:

A. Checking confirmation of the indication; explanation of the medical care, lowering of inappropriate anxiety and definition of the aim (training).
B. Focusing patient's attention in order to be dissociated from the surroundings.
C. Suggestions.
D. Validation of hypnotic status.
E. Reinforcement and consolidation.
F. Posthypnotic suggestions (self-hypnosis).
G. Discussion (physician-patient comparison).

The patient remains in a status characterized by a change in the external stimuli consciousness and space–time orientation. From the outside the patient seems to be asleep, but from the inside his mind is alert and awake and in control. In such a state the patient can be guided to imagine being in a safe and pleasant place. Throughout the procedure the physician reinforces and consolidates the status interacting verbally with the patient (Workflow E). At the end of the procedure, before the patient is re-orientated, the operator gives post-hypnotic suggestions in order to deal with post-procedural pain and/or further ability in self-hypnosis (Workflow F).

The analgesic effect of hypnosis is due to an entrance block at the level of the dorsal horn of the spinal cord named "Gate control" hypothesis: this "gate" may be opened or closed by physical, emotional, cultural and behavioural factors [15].

It should be noted that in our centre several specialists of the electrophysiological team, both nurses and physicians, since the beginning of 2018, attended an hypnotic communication formative course. The result was that hypnotic communication began a daily practice in our lab. The acquisition of hypnotic skills made possible that the hypnosis was routinely applied by different professional figures in our daily practice. Every electrophysiological interventions (EP study, ablations and implants) had been managed by using hypnosis since 2018.

As far as concern S-ICD implantations, either the first operator or another physician/nurse circulating in the lab conducted the hypnotic communication.

In the hypnosis group a post procedural analgesic hypnotic conditioning was induced in order to provide analgesia lasting until the next day.

3.1. Measured parameters

In all patients enrolled the following parameters were measured:

1. Pain perception: was quantified using Numeric Rating Scale (NRS) score from 0 to 10 (10)
2. Anxiety: with a Score Scale from 0 to 10 (see supplementary Figs. 1 and 2 in the Appendix).
3. Real and Perceived Procedural length: the patients was questioned about the procedural estimated length after the procedure.
4. Hypnotic Communication support satisfaction. The patients expressed a value between Poor – Sufficient - Profitable – Excellent.
5. Type and dosage of administered drugs

Tests were administered before and after the procedure, once the full consciousness was restored in both Groups. The personnel involved in test administration following the procedure was blinded to patients Group assignment.

3.2. Statistical analysis

Continuous variables are expressed as mean and standard deviations or median and interquartile ranges, while categorical variables are reported as absolute values and frequencies. Comparison between hypnotic group and standard control group was made with T-Student test for continuous variables and Chi-Square test for categorical variables.

All statistical analyses were performed with SPSS 21 (SPSS Inc., Chicago, IL, USA) and statistically significant P-values were considered with a threshold<0.05.

4. Results.

Baseline characteristics of enrolled population are listed in Table 1. Thirty patients have been prospectively enrolled. According to the study protocol hypnotic communication have been offered to 15 patients. In 11 out of these 15 patients (73%) hypnotic communication was successful and they were allocated in Group B. The remaining hypnotic un-responder patients have been allocated in Group A together with patients whom hypnosis was not originally proposed. Consequently an "As Treated" analysis has been performed as previously pointed out in the Methods section. There were no statistical difference between the two study groups (See Table 1) according to baseline characteristics including the primary prevention indication. Baseline pharmacological therapy and antiarrhythmic drugs use were comparable among the two groups. Similarly procedure length was not affected by hypnotic communication (Group A 58,8 ± 6,9 min vs Group B 62,3 ± 9,8 min, p value 0,27, see Table 2). Hypnosis communication resulted in significant pain perception reduction (Group A 6,9 ± 1,6 vs Group B 1,1 ± 0,9, p value < 0,01). In Group B patients a painless procedure (NRS $\leq$ 2) was obtained in all cases (See Fig. 1). No differences were observed between the two study groups concerning the pre-procedural anxiety level (Group A 7 ± 1,4 vs Group B 6,6 ± 0,9, p value 0,37). In Group A patients, the friendly talk approach applied at the beginning of the procedure, led to a reduction of intraprocedural anxiety, while in Group B the reduction was greater because of the hypnotic communication protocol (Group A 3,5 ± 1,6 vs Group B 1,9 ± 0,5, p value < 0,01, See Fig. 2). In Group B patients an intraprocedural anxiety score $\leq$ 2 was observed in 10/11 patients while in 1/11 the anxiety score was 3. Moreover, a further advantage was also the reduction of the perceived procedural length (Group A 58,7 ± 13,4 min vs Group B 44,7 ± 5,5 min, p value < 0,01). All the Group B patients considered Profitable/Excellent the use of hypnosis in managing the procedure.

Concerning analgesic drugs no differences were observed in term of local Lidocaine dosage or Paracetamol (whose administration was similar in both Groups according to study protocol). No Midazolam or Propofol was used in Group B patients. On the other side the Fentanyl dosage was significantly lower in Group B patients (Group A 0,17 ± 0,05 mg vs Group B 0,11 ± 0,06 mg, p value < 0,01). In Group A 1 (5,3%) patient underwent endotracheal intubation with anesthesiologic support.

No periprocedural complications occurred in both Groups.

The mean time required for hypnosis induction was 4,5 ± 1,2 min.

In the post procedural setting an adjunctive dose of Paracetamol 1 gr was provided in all Group A patients while no analgesic drugs were required by Group B patients.

5. Discussion

To the best of our knowledge this is the first study examining the use of hypnotic communication as periprocedural analgesia in S-ICD implantation in a prospective fashion. The main findings of the study are:

1) Hypnosis was successful in 73% of the patients comparable to what is reported in the literature about hypnosis susceptibility in a general un-selected population.
2) Hypnosis significantly reduced *peri*-procedural anxiety and consequently improved the psychological tolerance of the S-ICD implantation.
3) Hypnosis showed an analgesic synergistic effect, leading to a painless procedure in all the responder patients with a reduction of painkiller drugs use not only during the implant but also in the post-operative period.
4) No deep sedation/narcosis was required in hypnosis responder patients.

Furthermore the study showed that hypnotic communication did not impact on the real procedural length but it reduced significantly the procedural length perception and the technique was safe in all the patients.

This technique has been introduced in our lab in the early 2018 after having attended a specific course to learn the hypnotic communication. All the healthcare professionals involved in the EP program were trained. Very soon this methodology was applied to all the interventional electrophysiological procedures including S-ICD implantations [12]. In our experience hypnotic communication, during AF catheter ablation, was successful in reduction of intraprocedural anxiety with sparing of analgesic/sedative drugs [9]. In the recent past a wide range of trials have been carried out regarding the use of hypnosis both in percutaneous coronary intervention and in coronary artery bypass graft surgery [16,17] and in other minimally invasive surgical procedures [7]. However, few data are available evaluating the efficacy and safety of hypnosis during S-ICD implantation.

The present study showed that the use of hypnosis during S-ICD implantation was successful in 73% of patients, leading to a

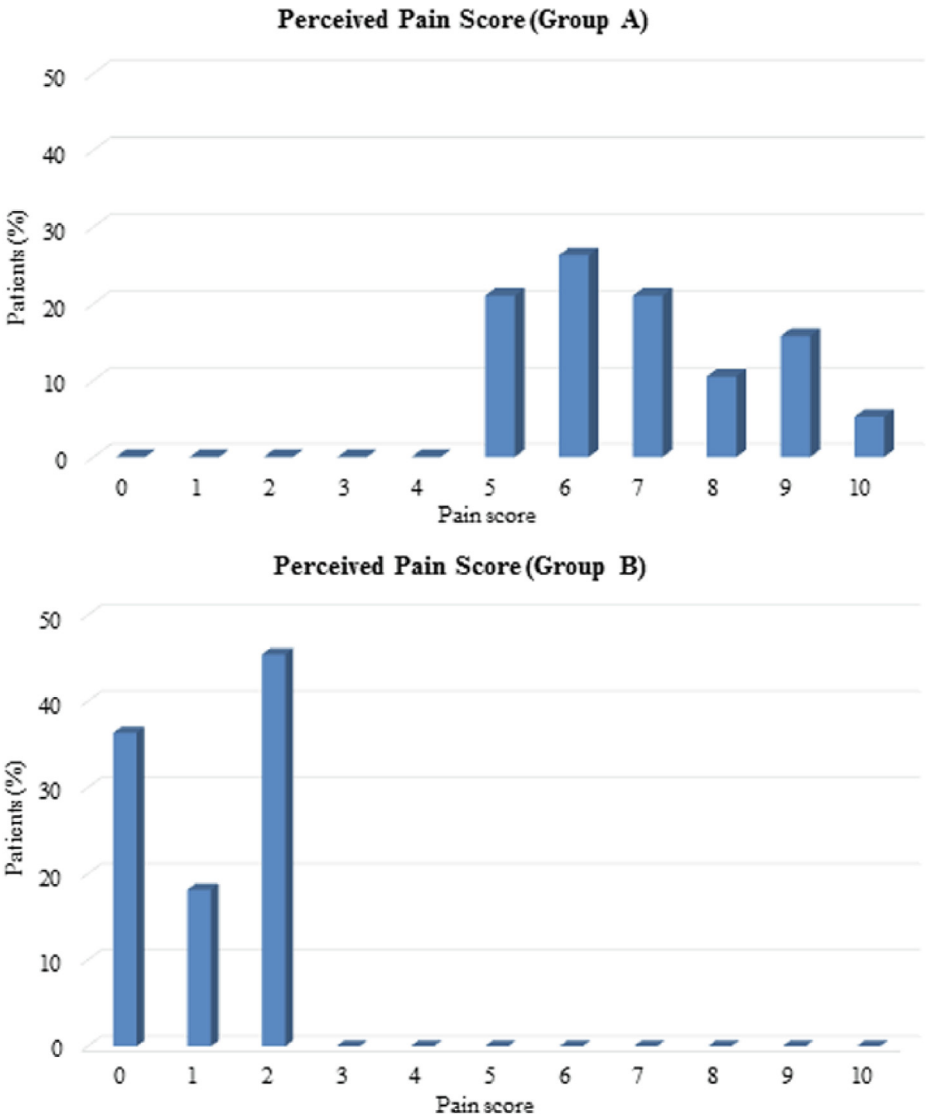

Fig. 1. Comparison of perceived pain score between the two groups of patients.

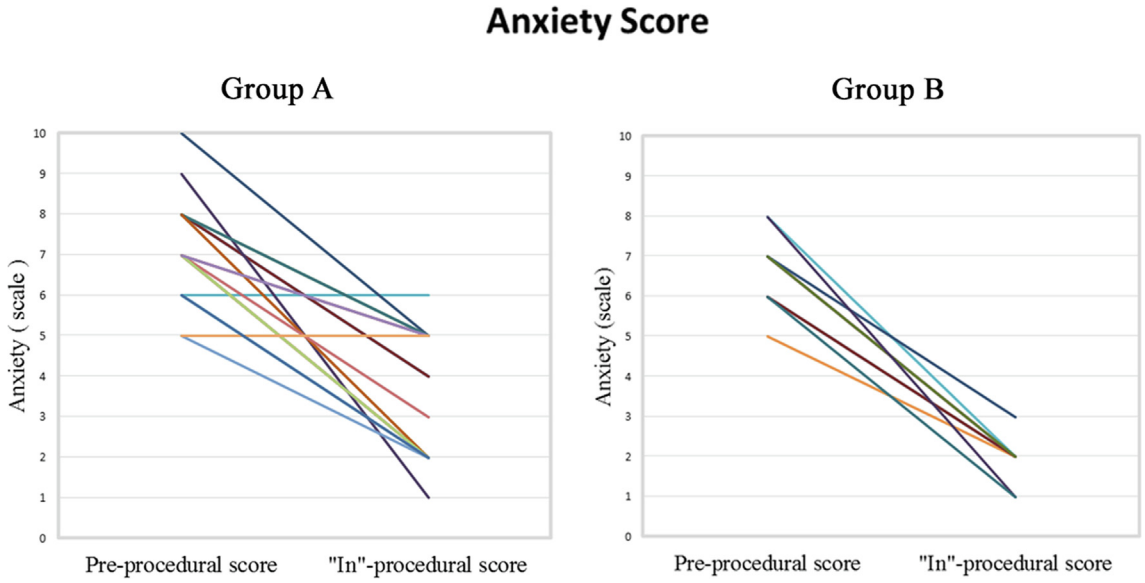

Fig. 2. Comparison of anxiety score between the two groups of patients.

Table 1
Baseline characteristics differences between the two groups.

Clinical characteristics	Group A (n = 19 pts)	Group B (n = 11 pts)	P-value
Age	53,3± 13,6	57,3± 11,8	0,42
Male sex	13 (68,4%)	9 (81,8%)	0,42
Body Mass Index	24,2± 2,1	24,3±1,3	0,96
Hypertension	9 (47,4%)	4 (36,4%)	0,56
Diabetes	6 (31,6%)	1 (9,1%)	0,21
Heart failure	1 (5,3%)	0 (0%)	1,00
Stroke/TIA	1 (5,3%)	1 (9,1%)	1,00
Heart disease			0,21
No Structural HD	2 (10,5%)	2 (18,2%)	
Ischemic HD	6 (31,6%)	4 (36,4%)	
Dilated HD	8 (42,1%)	2 (18,2%)	
Right Ventricle Arrhythmogenic HD	2 (10,5%)	2 (18,2%)	
Valvular HD	1 (5,3%)	1 (9,1%)	
Ejection fraction	30,2± 18,7	22,1± 18,6	0,26
Primary prevention	16 (84,2%)	8 (72,7%)	0,45
Antiplatelet	2 (10,5%)	0 (0%)	0,26
Beta-blockers	16 (84,2%)	8 (72,7%)	0,45
ACE inhibitor	13 (68,4%)	7 (63,6%)	0,79
Amiodarone	3 (15,8%)	2 (18,2%)	0,87
Anticoagulant	12 (63,2%)	4 (36,4%)	0,16

Table 2
Procedural parameters difference between the two study groups.

Procedural Parameters	Group A (n = 19 pts)	Group B (n = 11 pts)	P-value
Real procedure length (min)	58,8± 6,9	62,3± 9,8	0,27
Perceived procedure length (min)	58,7± 13,4	44,7± 5,5	<0,01
Midazolam [mg]	2,05± 1,19	0	<0,01
Fentanyl [mg]	0,17± 0,05	0,11± 0,06	<0,01
Propofol [mg]	87,00± 29,1	0	<0,01
Anxiety score pre procedural	7± 1,4	6,6± 0,9	0,37
Anxiety score intra procedural	3,5± 1,6	1,9± 0,5	<0,01
Max perceived pain score	6,9± 1,6	1,1± 0,9	<0,01

tolerable procedure, with a reduced anxiety level and sparing of analgesic drugs. Considering our responder patients rate, to further improve the hypnosis induction rate, a good patient selection, identifying the most sensitive psychological profile using Spiegel's Hypnotic Induction Profile [18], Stanford Scale of Hypnotic Susceptibility [19] and Harvard Group Scale of Hypnotic Susceptibility can be used [20]. Moreover, it should be taken into account that the level of suggestibility would have a biphasic pattern, higher in childhood and in the elderly.

In this study, Group B patients showed an advantage in terms of intra-procedural anxiety reduction and a good tolerance of the procedure. Previous similar results have been already published in the electrophysiological field [9,12] and also in a paper regarding ophthalmological surgery [21]. The anxiety reduction in Group B was superior to what observed in Group A. Noteworthy is also the fact that the anxiety reduction in Group B was due only to hypnotic communication. Conversely in Group A patients, the anxiety reduction was less evident and obtained using specific drugs and in some of them was not measurable because of deep sedation/narcosis that "per se" eliminated consciousness.

In addition to the anxiety reduction, the hypnotic mediated analgesia may be clinically relevant especially in patients undergoing S-ICD implantation. This effect is not related to the activation of the opioid system, unlike other non-pharmacological techniques (acupuncture) but it has been related to a possible synergistic effect with opioid drugs [15]. In fact Casiglia [22] demonstrated that the hypnotic analgesia is based on the "Gate Control" phenomenon with a block of the pain transmission at the level of the dorsal horn of the spinal cord. In fact during an experimental model applying a "cold pressure test", hypnosis was able to abolish the consequent vasoconstriction phenomenon confirming that the level of block was below the cerebral cortex, not involving the conscious control.

In our study in patients responder to hypnosis a painless procedure (NRS $\leq$ 2) was obtained in all 11 cases with a standard analgesic protocol including Paracetamol 1 gr and local Lidocaine with a mean Fentanyl dose of 0,17 mg (min 0,1 mg, max 0,25 mg). Conversely Group A patients showed an higher perceived procedural pain (Mean Pain Scale was 6,9) and in fact, a larger amount of analgesic drugs had to be used in this Group, in particular an higher dose of Fentanyl, the adjunctive use of Midazolam, Propofol and in one case narcosis. The larger amount of sedative drugs in Group A, determined in these patients a higher rate of oxygen support in reason of deep sedation and in one case *endo*-tracheal intubation was needed. No complications related to hypnosis were reported.

According to our results it seems that hypnosis may play a role as adjunctive analgesic strategy during S-ICD implantation. It is noteworthy the fact that sedative drugs were not used to avoid the interference with the patients conscious control that is necessary to hypnosis induction and maintenance. This aspect may be appealing in all patients who may have comorbidities, that may contraindicate the use of specific drugs or deep sedation.

It should be also noted that the patients under hypnotic status experienced also a reduction of the perceived procedural length. Interestingly, the implementation of hypnotic communication in the workflow of the procedure, did not affect the procedural time and the required time to reach the hypnotic status was short (about 4,5 min). The absence of statistical difference in the total procedural time between the two groups may be due to the fact that the time spent for hypnotic communication is balanced by a better pain control during the procedure.

The consequence of the study results is a very good tolerance of the procedure in the hypnosis group confirmed by the fact that all of the patients considered profitable or excellent the hypnotic communication support. We can speculate that hypnosis benefits observed in this study focusing on a commonly "painful" procedure, such as S-ICD implantation, may be transferred to any device implantation.

In conclusion, our study reinforces the important beneficial effects of hypnosis in patients undergoing S-ICD implantation. It allows to perform a painless procedure, with a reduction of intra-procedural anxiety, time perception and use of analgesic drugs.

6. Limitations

The first limitation is the small sample size but it considers a single centre experience that can be transferred in a multicentre study that can corroborate the results. This is not a randomized trial, however patients were enrolled in a prospective fashion with 1:1 allocation ratio. Selection bias cannot be excluded but they should be balanced between the two groups.

27% of the patients did not respond to hypnosis. Anyway our hypnosis inducibility is comparable to what is reported in the literature about hypnosis susceptibility in the general population. However it should be noted that the hypnotic induction profile test to select the patient on the basis of their hypnotic susceptibility was not used. In the four non responder patients the failure may be attributed to a particular personality having a self-structured hyper-controlled behavior making difficult the relaxation and/or a poor compliance with distrust on medical advices. In one case the failure may be due to a language barrier (African native with

poor Italian comprehension). Finally, considering the bias of an "As Treated" analysis of our study, it should be stated that the unselected subgroup of patients enrolled and the consecutive enrollment approach should have mitigated this bias.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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