

Comparison of Two Transvenous Temporary Pacemaker Fixation Methods: FIX-IT Trial

Comparação entre 2 Métodos de Fixação de Marca-passo Provisório Transvenoso: FIX-IT Trial

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ABSTRACT

Introduction: the necessity for temporary pacemaker (TP) goes through several scenarios. Some patients require the device to complete an infection treatment, regain the pace after myocardial infarction, or while awaiting the release of the definitive device by the health care provider. Regardless of the TP passage technique, good electrode fixation is essential, avoiding dislocation and the necessity for repositioning, among other complications.

Objective: to compare two forms of TP fixation, one under direct fixation to the skin and the other keeping the venous introducer connected to the plastic protection through the pacemaker electrode lead. **Methods:** Forty patients were randomized, 20 in each group. Data regarding the procedure time, electrode lead position, command thresholds, sensitivity, and complications were recorded. The primary outcome considered was the necessity for repositioning or exchange of transvenous TP and secondary any complication without the necessity to reposition it. **Results:** There were no significant differences in the total duration of the procedure between the groups in the initial position of the electrode and the access route used. The group with plastic protection had a higher primary outcome (60%) than the direct fixation group (20%; $p = 0.0098$). There were no differences regarding the secondary outcome ($p = 1.0$). The group with plastic protection also had more total complications compared to the other group ($p = 0.0262$). **Conclusion:** Direct fixation of the pacemaker electrode lead was safer concerning the fixation with plastic protection, reducing complications such as electrode dislocation requiring repositioning or replacement without increasing the procedure time.

KEYWORDS: Artificial pacemaker; Artificial heart stimulation; Sutures.

RESUMO

Introdução: A necessidade de marca-passo provisório (MPP) transita por diversos cenários. Alguns pacientes necessitam do dispositivo para completar um tratamento de infecção, recuperar o ritmo após infarto do miocárdio ou enquanto aguardam liberação do dispositivo definitivo pela operadora de saúde. Independentemente da técnica de passagem do MPP, a boa fixação do eletrodo é fundamental, evitando-se deslocamentos e necessidade de reposicionamento, entre outras complicações. **Objetivo:** Comparar duas formas de fixação de MPP, uma sob fixação direta na pele e outra mantendo-se o introdutor venoso conectado à proteção plástica por todo cabo-eletrodo do marca-passo. **Métodos:** Randomizaram-se 40 pacientes, 20 em cada grupo. Registraram-se dados referentes ao tempo do procedimento, posição do cabo-eletrodo, limiares de comando, sensibilidade e complicações. Consideraram-se como desfecho primário a necessidade de reposicionamento ou troca do MPP transvenoso e secundário qualquer complicação sem a necessidade de reposicioná-lo. **Resultados:** Não houve diferenças significativas na duração total do procedimento entre os grupos na posição inicial do eletrodo e na via de acesso utilizada. O grupo com a proteção plástica apresentou desfecho primário maior (60%) em relação ao grupo de fixação direta (20%; $p = 0,0098$). Não houve diferenças em relação ao desfecho secundário ($p = 1,0$). O grupo com proteção plástica também apresentou mais complicações totais em relação ao outro grupo ($p = 0,0262$). **Conclusão:** A fixação direta do cabo-eletrodo do marca-passo se mostrou mais segura em relação à fixação com proteção plástica, reduzindo complicações como deslocamentos do cabo-eletrodo que necessitem de reposicionamento ou troca desse, sem aumento no tempo do procedimento.

PALAVRAS-CHAVE: Marcapasso artificial; Estimulação cardíaca artificial; Sutures.

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INTRODUCTION

The necessity for a definitive pacemaker goes through several scenarios, and some patients need to remain under the use of a temporary pacemaker (TP) either to complete an infection treatment, regain the pace after myocardial infarction or even awaiting the release of the definitive device by the health care provider.

The rate of pacemaker implantation per million inhabitants in Brazil is substantially lower than in neighboring countries, despite the progressive increase in total implantation of these devices in the last decade¹. Population aging and the consequent degenerative diseases of the heart excito-conductor system will increase the demand for implantation of these devices shortly. The current economic crisis and chronic underfunding of the Unified Health System (UHS), in contrast, will hinder meeting this growing demand. This scenario will culminate in a more significant number of patients admitted to emergency services awaiting electronic heart device implantation. Many of these patients stay in the hospital for days, weeks, and even months, mostly on transvenous TP. Therefore, implantation techniques of these systems in a practical way, ensuring safe ventricular stimulation and avoiding future complications, are essential.

Several techniques for implantation of TTPs have been described: (i) under direct vision, with the aid of radioscopy; (ii) with the aid of intracavitary electrogram; (iii) blind, with electrode lead under stimulation with maximum energy^{2,3}. Temporary pacemaker implantation is described using active fixation electrode and connected to a permanent external pacemaker generator to the skin; however, the material required for this implant modality is not available in the vast majority of emergency services^{4,5}.

There is no definition on the best implantation form. There is little material in the literature comparing the techniques^{6,7}. It is up to the doctor to choose, according to his experience, not only the way of passage, but also the way of fixing the electrode lead. On the other hand, it is essential to minimize possible complications related to the procedure, such as those related to venepuncture, infections, myocardial perforations, arrhythmias, electrode displacement, among others².

In this study, it will compare two TP electrode lead clamping techniques, evaluating several variables, including displacement and loss of command.

METHODS

A unicentric randomized study was performed, dividing 40 patients who required urgent TTP implantation into two groups, 20 in each branch. Patients were randomized as soon as they agreed and signed the consent form. Before randomization, the project was submitted and approved by the institution's ethics committee (CAAE: 57695016.4.0000.5483, Opinion Number: 1.754.718).

Group 1 was submitted to the direct fixation of the electrode lead over the skin, without the aid of an introducer, or a plastic protective cover (Fig. 1). In group 2, the electrode lead was maintained with the vascular introducer connected to the respective plastic protective cover of the TP passage material (Fig. 2).

The electrode lead fixation of group 1 was made with 3.0 nylon wire. After the electrode was positioned in the heart, the venous introducer was removed and then the initial fixation was performed on the insertion of the electrode lead in the skin with a U-point followed by three common bailarinas (without to suture the skin) interspersed with



Figure 1. Direct fixation

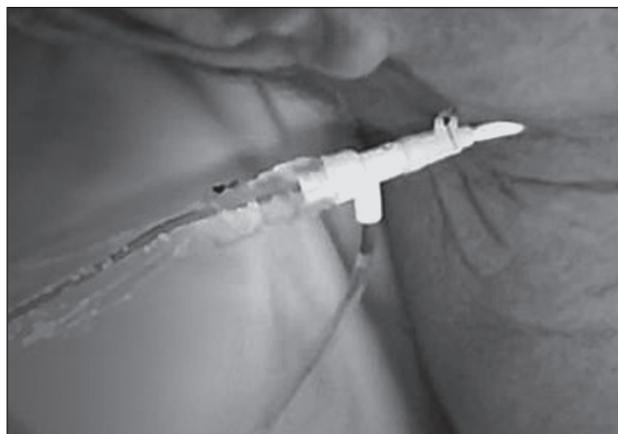


Figure 2. Fixing with plastic protection

another three with a stitch on the skin, where the needle end of the wire was crossed giving a small spot on the skin under the electrode. At the end of each bailarina, as well as at the initial U-point, a double knot was made followed by two other single knots. The distance from the electrode-wire insertion to the last bailarina was always less than 2 centimeters.

The patients in group 2 did not have their electrode leads fixed directly to the skin, but kept with the respective vascular introducer present in the material available for passage, and this was connected with the plastic protection around the electrode lead, fixing the set (electrode lead and plastic protection) through a lock at its opposite end to the introducer. Only one point remained in fixing the introducer with the skin. There was no suture of the electrode lead directly to the skin, involving plastic protection.

The material used up to the 20th randomized patient was a 6F temporary bipolar stimulation catheter of Dispomedica® (Hamburg, Germany) without active myocardial fixation, with a non-valved vascular introducer. From the 21st patient, an update of the same material was used, which was then disposed of a vascular valve introducer. Importantly, in both groups, the final dressing was performed by keeping the outer portion of the electrode lead coiled and attached with adhesive material (micropore, adhesive tape, etc.) so as to avoid direct accidental traction on the insertion point on the skin (group 1) or about the introducer (group 2).

Three techniques of TP passage were used: the first through direct vision by radioscopy in a hemodynamic laboratory, the second by the bedside with the aid of intracavitary electrograms and the third by the bedside, but blindly, without the assistance of electrograms. TP passthrough mode was not randomized. Preference was

given to the passage of TP with the aid of radioscopy in a hemodynamic laboratory. However, at the discretion of the team and depending on the urgency and/or severity of the case, the bedside passage was performed with or without the aid of intracavitary electrograms.

Information was collected regarding patient age, paying source, days of hospitalization until randomization, the provenance of another service, previous TP use, previous antibiotic use, the reason for TP implantation, passage mode, the access route, the electrode end position and the procedure time. At the end of the passage, the initial assessment was performed for sensitivity and command threshold. This evaluation was repeated twice a day for all days when the patient was using this device. The deadline for the use of TP was set at 15 days. After this period, if the patient still needed temporary stimulation, a new TP would be implanted in place of the previous one, and the patient's follow-up in the study would be terminated (Fig. 3). All patients submitted to TP implantation were referred to the intensive care unit (ICU) of the same hospital and remained there under standardized care while in need of temporary stimulation. Chest radiograph was performed daily to control electrode placement with EKG.

The primary outcome was defined as any complication requiring pacemaker electrode replacement or repositioning. A secondary outcome was defined as any complications in which there was no need to change or reposition.

The collected data were submitted to statistical analysis with a professional of the area. Statistical analyses were performed using the chi-square test and the nonparametric Mann-Whitney U test, and those with p-values less than 0.05 were defined as statistically significant results.

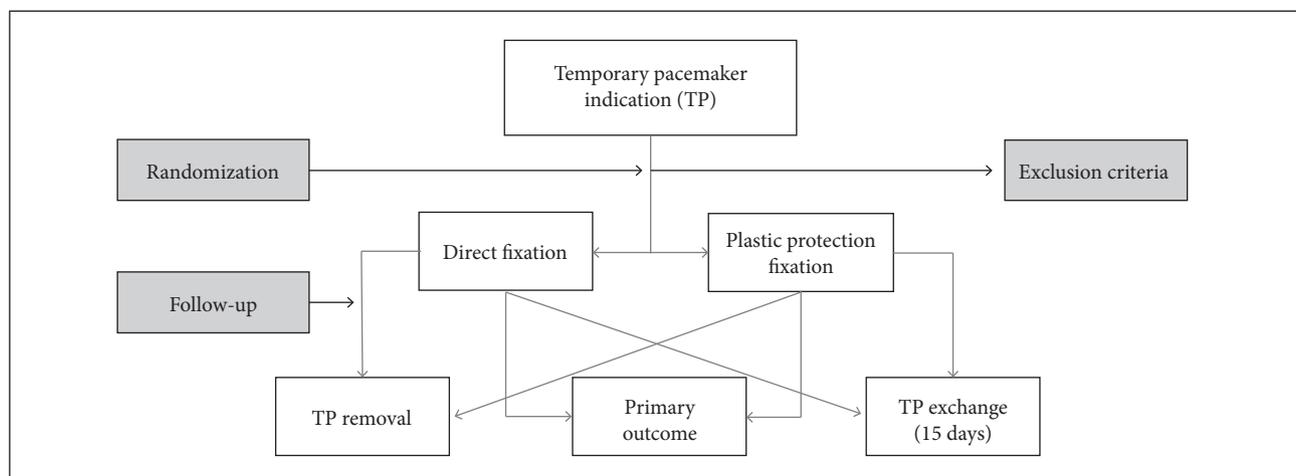


Figure 3. Study Design

RESULTS

Forty patients were randomized between October 2016 and July 2017 in a single service, dividing 20 patients in each branch (group 1: direct fixation: group 2: fixation with plastic protection). Randomization was performed as soon as TP passage was indicated, immediately after patients' informed consent. No statistically significant differences were observed between the groups regarding age, gender, paying source, length of hospital stay before randomization, the provenance of another service, previous TP use, previous antibiotic use and escape rate (Table 1). Even having the preference for passing TP under direct hemodynamic view, there were no significant differences between the groups regarding the mode of TP passage. Only one case of bedside blind passage was observed in group 2 after the patient presented cardiopulmonary arrest due to hypoxia and progressed to asystole after cardiopulmonary resuscitation.

The most commonly used access route was the right subclavian vein, a service preference, in order to keep the left side free for implantation of the definitive device. However, the left subclavian veins and the right and left internal jugular veins were also used, depending on the clinical condition of the patient and the access route available at the time of implantation. Nevertheless, no significant differences were observed regarding the access route used between the groups (Table 1).

The initial position of the electrode was also evaluated; In cases of bedside implanted TP, this evaluation was performed with chest radiograph in three incidences. Although the predominant initial position in group 1 was the right ventricle (RV) apex and in group 2 the subtricuspid region, there were no statistically significant differences between groups concerning the TP electrodeposition (Table 1).

All implantation was performed by at least two team members, one with experience in the procedure. Although the total time of the procedure was slightly longer in group 1,

Table 1. Baseline of patients.

	Direct fixation (group 1)	Fixing plastic protection (group 2)	P-value
Age (years)	71.55 (53-90)	74.65 (64-84)	0.34
Gender	75% (15) male 25% (5) female	70% (14) male 30% (6) female	0.7233
Paying Source	55% UHS. 35% supplementary health. 5% private, 5% partner	70% UHS. 25% supplementary health, 5% Partner	0.7411
Length of stay to randomization (days)	3.3 (0-39)	2.45 (0-15)	0.966
Provision of another service	8 patients (40%)	13 patients (65%)	0.1134
Previous TP	8 patients (40%)	7 patients (35%)	0.744
Time with TP (days)	11.33 (2-35)	12 (2-22)	0.52
Previous ATB	7 patients (35%)	6 patients (30%)	0.7357
Prior ATB Time (days)	5.71 (0-20)	6.17 (0-13)	0.774
TP Pass Indication	55% TAB, 20% AB 2°G, 15% SND, 5% asystole, 5% Others	70% TAB, 15% AB 2°G, 5% SND, 5% preoperative, 5% others	0.7743
TP Pass Mode	70% scopy, 30% IE	60% scopy, 35% IE, 5% blind	0.7411
Access vein	60% RSV, 30% LVSC, 10% RIJV	75% RSV, 15% LVSC, 5% RIJV, 5% LIJV	0.5013
Electrode position	40% apex RV, 30% subtricuspid, 15% low septum, 10% average septum, 5% RV sidewall	40% subtricuspid, 25% apex RV. 10% VSRV, 10% low septum. 5% average septum, 5% RV sidewall, 5% without information	0.7257
Procedure Time (min)	30% 16-30 min, 30% 31-45 min. 15% 46-60 min, 15% 1-15 min. 10% +60 min	35% 16-30 min, 30% 31-45 min, 25% 1-15 min, 10% +60 min.	0.5376

ATB = antibiotic; AB 2°D = 2nd degree atrioventricular block; TAB = total atrioventricular block; SND = sinus node disease; IE = intracardiac echocardiogram; TP = provisional pacemaker; UHS = Unified Health System; RV = right ventricle; RIJV = right internal jugular vein; LIJV = left internal jugular vein; RSV = right subclavian vein; LVSC = left subclavian vein; VSRV = RV output path.

justified by the time required for direct attachment of the electrode to the skin, there were no significant differences regarding the total duration of the procedure between groups (Fig. 4, Table 1).

The mean of TP initial command values was also analyzed. The value was slightly lower in group 2 compared to group 1: 0.93V vs. 1.53V ($p = 0.01$) (Fig. 5). The initial sensitivity analysis was hampered by the peculiarities between each patient and the fact that some did not have an escape heart rate susceptible to sensitivity analysis, so this variable was not considered in the study.

The primary outcome, that is, any complication that led to electrode lead replacement or repositioning was significantly higher in group 2 than in group 1 ($p = 0.0098$) (Fig. 6). In all patients who presented the primary outcome, there was displacement of the electrode with loss of ventricular capture at maximum energy. One patient from group 2 presented, besides the displacement of the electrode lead with loss of ventricular command, low energy phrenic stimulation, motivating the repositioning of the TP (Fig. 7). No significant differences were observed between groups regarding the number of device implantation days until the primary outcome.

Still, regarding the primary outcome, the result was analyzed after the material update from the 21st patient, coincidentally leaving 10 patients in each group to be randomized. Despite the higher number of patients who reached the primary outcome in group 2 compared to group 1 (70 vs. 30%), no statistically significant difference was observed in this subgroup ($p = 0.074$) (Fig. 8).

Regarding the secondary outcome, there were no significant differences between the groups ($p = 1.0$) (Fig. 9).

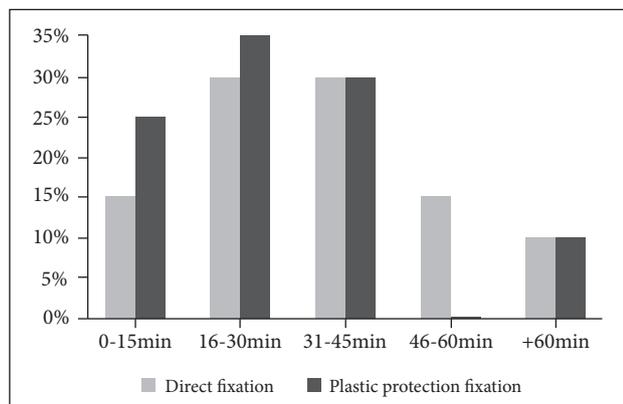


Figure 4. Procedure time ($p = 0.5673$).

However, there were differences in the cause that led to the outcome: while in group 1 there were two patients with electrode lead displacement requiring inversion of stimulation polarity, a pneumothorax, and a puncture site hematoma, in group 2 there was electrode displacement in two patients, one with high energy phrenic stimulation and the other with persistent ventricular arrhythmias due to the presence of the electrode. Summing up all the complications that led to the primary and secondary outcomes, it is clear that electrode lead displacement appears as the most frequent complication ($p = 0.0262$).

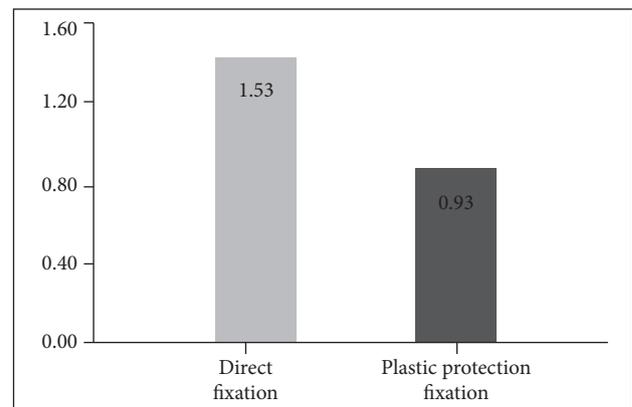


Figure 5. Initial Command Threshold Average ($p = 0.01$).

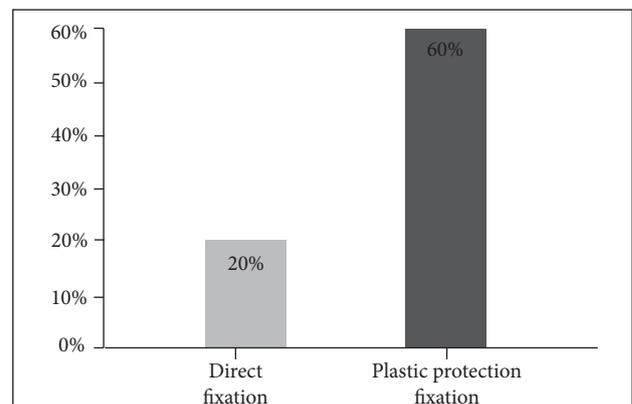


Figure 6. Primary outcome ($p = 0.0098$).

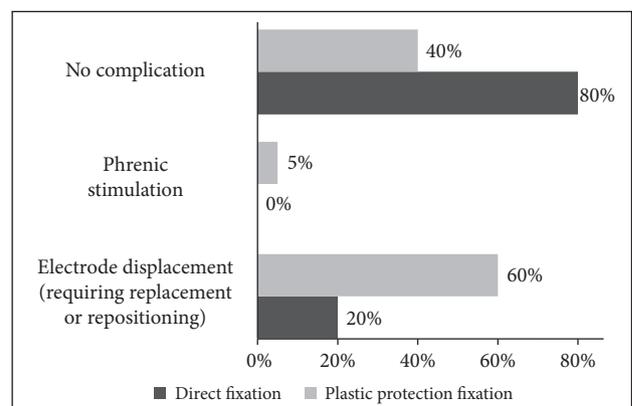


Figure 7. Complications primary outcome ($p = 0.0225$).

(Fig. 10). There were no patients with hemothorax, cardiac tamponade, venous thrombosis, or temporary stimulation system infection in the present study.

There were a total of four deaths during patient follow-up, two in each group. None of the deaths was directly related to the TP implantation procedure, nor problems related to temporary artificial cardiac stimulation. In group 2, both deaths were due to septic shock secondary to nosocomial pneumonia, as was one of group 1 deaths. The other death in this group was due to complications from cardiogenic shock.

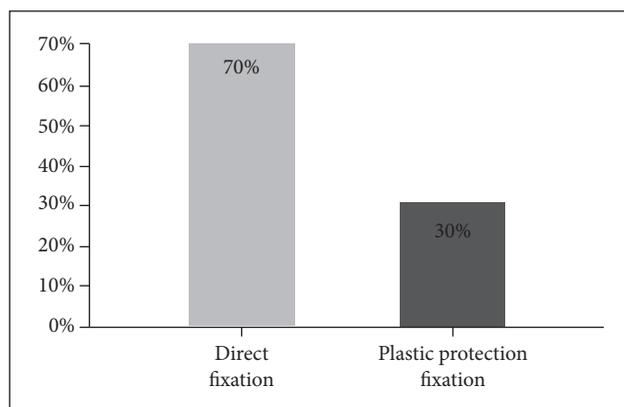


Figure 8. Primary outcome after 20th patient ($p = 0.074$).

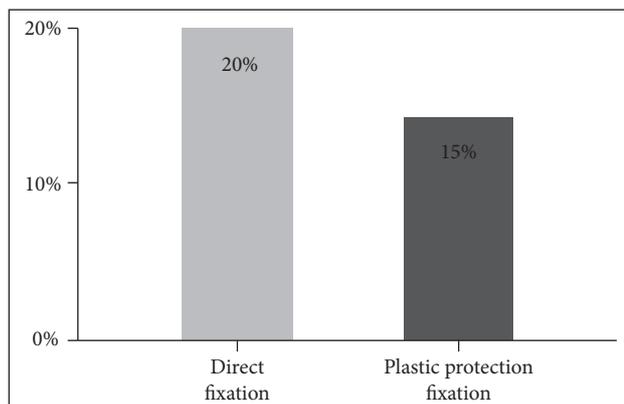


Figure 9. Secondary outcome ($p = 1.0$).

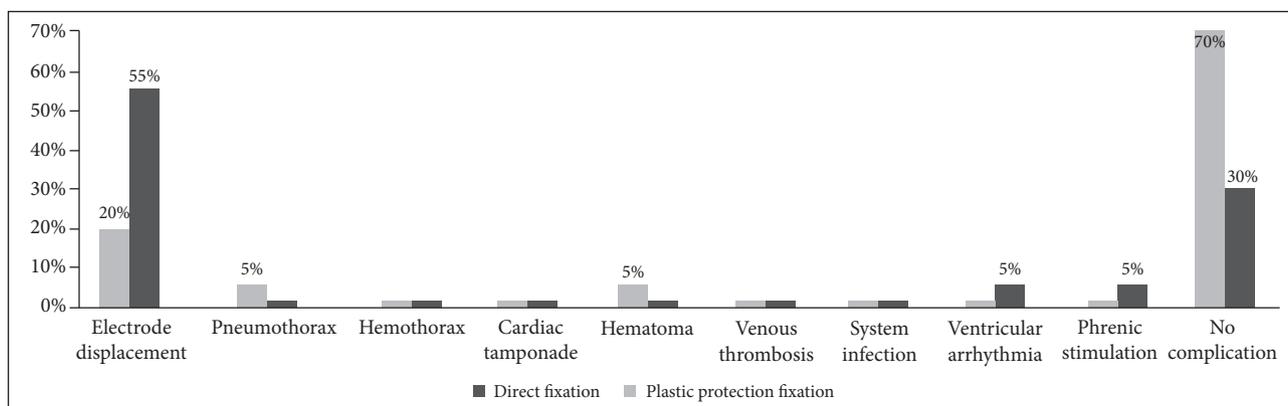


Figure 10. Combination primary and secondary outcome ($p = 0.0262$).

DISCUSSION

The present study revealed that patients who had TP fixed directly to the skin had a lower primary outcome, that is, any complication that resulted in the replacement or repositioning of the electrode lead compared to the group that had TP fixed with the plastic protection set and vascular introducer. There is a much more substantial amount of electrode dislocations in group 2 compared to group 1, proving that the TP fixation method with only the plastic protection and the vascular introducer increase the risk for displacements. Importantly, all patients who reached the primary outcome had electrode displacement, which makes this complication the most common in the TP setting. As previously described, after the 20th randomized patient, there was an update of the material used, with a new valved vascular introducer that, in theory, would help stabilize the TP electrode lead due to its friction with the valve rubber (especially in patients with group 2). The result of the analysis of this subgroup showed that, despite the greater tendency of dislocations and, consequently, primary outcome in group 2 after updating the material used, there was no statistically significant difference between the groups. However, it should be noted that in this subgroup, only a sample of 10 patients was used in each branch of the study, which loses its statistical power in the analysis.

It was decided not to use active fixation electrode leads in this study since these electrodes are not available in most services, but a passive fixation electrode of a brand very present in the national market. Thus, we tried to portray the reality available in the vast majority of intensive care and emergency services.

Analysis of total TP implantation time between groups was also relevant. The initial hypothesis was that the removal of the vascular introducer followed by the points used for fixation in group 1 patients would imply a longer procedure time compared to group 2; However, the results show that there was no statistically significant difference between the groups regarding the total procedure time (Table 2, Fig. 4). In this case, it should be noted that TP implantation was performed by a minimum of two people, at least one with extensive experience in this procedure, which may have contributed to this similarity between the groups.

Regarding the initial command threshold, despite the difference between the groups in their mean (Fig. 5), it is essential to consider that the values did not determine the outcome of the primary outcome analysis, mainly because the mean value group 2 was lower than group 1.

If, on the one hand, unicentric work limits the number of randomized patients in the study, on the other

hand, they submit them to standardized ICU care of the service, thus minimizing any differences in care with TP in the follow-up.

CONCLUSION

This is the first work that determines the best TP fixation methodology when comparing two widely used fixation techniques. It is concluded that, due to the necessity to use TTP, the direct fixation of the electrode lead to the skin after endocavitary implantation results in a significantly lower rate of complications, such as electrode lead dislocation, avoiding the necessity for repositioning or replacement of the device. It is noteworthy that, for higher statistical power in the analysis of groups (and subgroups), a more significant number of randomized patients is required.

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