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Application of Hemostatic Agent "Haemoblock" for Pocket Hematoma Reduction. Design of the PEGAS Study: a Multicenter Clinical Trial

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Pocket hematoma is a common complication of pacemaker implantations which prolongs hospitalization and may demand surgical revision in some cases. According to the data from different researchers PH rate varies from 2 to 7%. It depends on number of factors including a need for anticoagulation therapy. We present a review of design of multicenter clinical trial evaluating safety and efficacy of application of hemostatic agent "Haemoblock" for pocket hematoma reduction in patients taking oral anticoagulants.

Keywords: Pacemaker pocket hematoma; oral anticoagulants; haemoblock.

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Применение препарата "Гемоблок" для снижения риска формирования гематом ложа электрокардиостимулятора. Протокол многоцентрового клинического исследования ПЕГАС

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Гематома ложа (ГЛ) является известным осложнением процедур имплантации электрокардиостимулятора (ЭКС), приводящим к увеличению продолжительности нахождения в стационаре и, в некоторых случаях, к проведению хирургической ревизии ложа ЭКС. Частота ГЛ, по мнению разных авторов, составляет 2–7% и зависит от ряда факторов, в том числе от необходимости приема антитромботической терапии. В данной статье представлен анонс стартовавшего многоцентрового проспективного слепого рандомизированного плацебо-контролируемого клинического исследования по изучению безопасности применения отечественного гемостатического препарата «Гемоблок» при имплантации ЭКС и его эффективности в профилактике формирования ГЛ ЭКС у пациентов, принимающих оральные антикоагулянты.

Ключевые слова: гематома ложа электрокардиостимулятора; оральные антикоагулянты; гемоблок.

Как цитировать:

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INTRODUCTION

The pocket hematoma (PH), a common complication of pacemaker implantations, is detected in 2%–7% of cases [1, 2]. PH is clinically manifested by a sensation of local discomfort and pain and is associated with infiltration of the subcutaneous tissue [3]. Furthermore, this complication may require surgical intervention [2], which increases the risk of infection of the endocardial system [4] and prolongs hospitalization [5]. Hence, the search for ways to prevent bleeding from the pacemaker pocket is of great practical interest.

According to a study by Bernard M. et al., up to 50% of patients undergoing implantation of antiarrhythmic devices have indications for antithrombotic therapy, which elevates the risk of pacemaker PH significantly in them [6]. Several authors have proposed to perform a complete or partial withdrawal of these drugs for the period before the surgery and in the early postoperative period. In our opinion, such an approach in most cases is potentially hazardous to patients' health, especially in the case of patients who have previously undergone surgical correction of valve insufficiency or who have undergone percutaneous endovascular interventions. The strategy of continuing the intake of oral anticoagulants (OAC) without interruption or transition to bridge therapy before implantation has been demonstrated to be efficient and safe [7]. Meanwhile, patients taking OACs constitute a high-risk cohort of postoperative PH [8] and require particular alertness in this complication. The use of local hemostatic drugs is a promising method for increasing intraoperative hemostasis efficiency. All currently used and known local hemostatic agents aim to imitate specific stages of natural hemostasis and their acceleration or form a fibrin clot rapidly bypassing these stages [9]. Experience of using the topical hemostatic drugs to prevent PH in implanted devices is represented by a small number of studies that resulted in conflicting findings and had limitations associated with a small number of participants and a single-center design. Thus, the efficiency of the use of fibrin glue (24% PH in the control group versus 0% PH in the experimental group) was demonstrated in patients receiving heparin or warfarin [10]. Previously, a significant decrease in the frequency of PH of pacemakers was observed with local application of tranexamic acid (7.7% versus 26.5%) [11] and Arista AH® hemostatic powder (4% versus 9%) [12].

Another work studied the possibilities of the HemostatTM drug (which includes collagen and thrombin) for the implantation of pacemakers without discontinuation of OAC or when taking dual antiplatelet therapy. The results indicated a complete failure of hemostatic drugs compared with the use of vacuum drainage of the pacemaker pocket (8.5% of PH requiring surgical revision, 6.1% of infectious complications versus 0% of endpoints in the drainage group, n = 82 patients, p = 0.01 and p = 0.06, respectively) [13]. Therefore, the PerClot® polysaccharide hemostatic system was suggested to use. Due to dehydration of the pocket

contents, it was supposed to provide a high concentration of erythrocytes, platelets, and procoagulant proteins, creating a reliable matrix that stops bleeding. Meanwhile, the clinical use of PerClot® did not affect the frequency of PH in some cases. Further, it also caused a pronounced inflammatory response, which forced the study to be terminated early [14].

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Despite the ambiguity of the data on the possibilities of local hemostatic drugs in ensuring the prevention of PH of implanted devices, there is an active search for new pharmacological agents that can solve this problem. One of such agents is the Russian drug "Haemoblock" which exerts its hemostatic effect by forming a clot with blood plasma proteins (mainly albumin). A polyacrylic matrix complex is formed at stage 1 of the drug action, containing albumin molecules in the cells. At the next stage, albumin molecules reduce silver ions, forming polyacrylate anions with a strong bond with positively charged protein molecules. This structure is packed in several microlayers, creating a solid polymethacrylate film on the wound surface. Subsequently, the surface structure designed is replaced by fibrin, and the polyacrylate matrix is plasmolyzed within one day [15].

The Russian drug "Haemoblock" has already demonstrated its hemostatic potential in general surgical practice [16], orthopedics [17], and endoscopic interventions [16]. However, the possibilities of "Haemoblock" in preventing pacemaker PH have not been studied and may require further investigations. Therefore, we set out a new study to assess the safety of using the hemostatic drug "Haemoblock" during implantation of pacemakers to monitor its efficiency in preventing the PH of pacemakers in patients taking OAC.

STUDY DESIGN

The study will be conducted following the protocol, the rules of Good Clinical Practice, and the legislation of the Russian Federation. The clinical study protocol was reviewed and approved at a meeting of the Ethics Committee of the Ryazan State Medical University of the Ministry of Health of Russia (Protocol No. 18 of 08/25/2020).

Participants and planned sample size

This multicenter, prospective, blind, randomized, placebo-controlled clinical study will enroll patients aged 40–85 years with indications for implantation of a single- or dual-chamber pacemaker, taking OACs for at least seven days before surgery and at least seven days in the early postoperative period. The study design will not imply the choice of the preferred drug for anticoagulant therapy or change of the OAC at preparation for surgical treatment. Preferred dosing regimens for previously prescribed medications will be used according to the patient's clinical characteristics (comorbidity, risk of stroke) and the presence of risk factors for hemorrhage. OAC can be changed if the kidney pathology is detected and performed following current clinical guidelines [18].

The study will not include patients with hypoalbuminemia, severe arterial hypertension (systolic pressure ≥ 200 mm Hg and/or diastolic blood pressure ≥ 110 mm Hg), varying forms of coronary heart disease, severe chronic renal failure (creatinine clearance less than 40 ml/min), heart failure (left ventricular ejection fraction less than 35%), hemoglobin level less than 90 g/l; as well as those having verified impairments in one of the links of hemostasis (thrombocytopenia, abnormal values of prothrombin index, fibrinogen, and international normalized ratio above 3.0). Additional exclusion criteria include the need to take two or more antithrombotic drugs, the presence of known contraindications to the study drug administration in patients, the period of pregnancy and lactation, and participation in another study. Based on the optimal sample size calculation required to test the hypothesis (study power 80%, significance level 0.05), it is estimated to include at least 200 patients in the study.

Randomization

After signing informed consent, the patients will be centrally randomized using a random number generator. According to the randomization results, a control group and the leading group will be formed.

Pacemaker implantation

Before the surgery, the patient will be prevented from infectious complications by administering an antibacterial drug, according to the scheme adopted in each clinic, at least 30 minutes before the intervention. The pacemaker stimulation mode VVI(R) or DDD(R) is chosen according to the clinical recommendations of the All-Russian Society of Arrhythmology for electrophysiological studies, catheter ablation, and the use of implantable antiarrhythmic devices [19]. The surgery will be performed under local anesthesia. The pacemaker is implanted according to the generally accepted technique under the skin in the left or right subclavian region. The pacemaker pocket location is chosen by the surgeon individually. It is preferable to form a pocket in the subcutaneous tissue without damaging the fascia of the musculus pectoralis major. A gauze wad soaked in 15 ml of "Haemoblock" (leading group) or 15 ml of 0.9% NaCl solution (control group) is placed in the pocket formed. The wads are removed immediately before immersion of the pacemaker in the pocket.

The choice of venous approach and electrode fixation system (active, passive) is determined by the surgeon individually. Electrocoagulation is actively used intraoperatively. Before suturing the subcutaneous tissue,

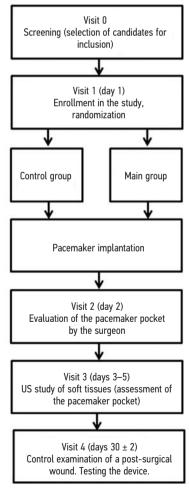


Fig. 1. Study design

the pocket is irrigated with 5 ml of "Haemoblock" solution without subsequent rinsing. In the presence of diffuse bleeding, which, according to the surgeon, can lead to a hematoma of the pacemaker pocket, a Bülau drain is installed. In all cases, after implantation, bed rest is prescribed following the clinic's standards of patient management, but not less than 3 hours [20]. Upon the patient's return to the ward, a cold compress with a load is applied to the postoperative wound area for 60 minutes.

Management of patients in the early postoperative period

The study design does not provide bridge therapy or discontinuation of the OAC before and after the pacemaker implantation. It is forbidden to prescribe hemostatic treatment in the first two days after the pacemaker implantation. On day three after implantation, it is allowed to prescribe an intravenous drip-feed infusion of 100 ml of the aminocaproic acid solution and/ or 5 ml of tranexamic acid solution intravenously. With severe bleeding from the pacemaker pocket and the need to maintain drainage, antibiotic therapy continues until the Bülau drain is removed. If necessary, in the first two days after implantation, drainage of the pacemaker pocket is allowed in a dressing room. All manipulations performed, including drainage and hemostatic therapy, are registered in the patient's medical care. All patients undergo ultrasound study of soft tissues on days 3-5, verifying the presence of fluid (blood) in the pacemaker pocket and counting the volume of accumulated fluid. The follow-up period for patients will be 30 \pm two days after the pacemaker implantation (Fig. 1).

Study indicators

The primary endpoint is the presence of free fluid (blood) in the pacemaker pocket in the early postoperative period, diagnosed by soft tissue ultrasound. In addition, the presence of a hematoma (fluid) in the pocket before the US study can be verified after the operating surgeon's examination, which detects palpable infiltration that smooths the pacemaker contour and the presence of a fluctuation effect.

Secondary endpoints include intraoperative installation of Bülau drain, duration of the Bülau drain, the need for postoperative drainage of the pacemaker pocket, imbibition of soft tissues on the side of pacemaker implantation, hemostatic therapy, exceeding the average number of bed-days, cerebral stroke, transient ischemic attacks,

bleeding, pericarditis, cardiac tamponade, and infectious complications.

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Research methods

Patients will undergo general clinical diagnostics following the nosological standard. Obligatory components of the examination are diagnostics of hemostasis pathology (complete blood count with platelet count, prothrombin index, fibrinogen, international normalized ratio), determination of the blood level of albumin, verification of the status of renal failure (creatinine clearance), and heart failure (echocardiography with left ventricular ejection fraction measurement according to Simpson), US study of soft tissues around the pacemaker pocket.

Statistical processing of the research materials will be performed using the methods of parametric and nonparametric analysis. The accumulation, correction, and systematization of the initial information and visualization of the results obtained will be performed in Microsoft Office Excel 2010 spreadsheets. Statistical analyses will be performed using the IBM SPSS Statistics 23 program. To assess the effect of the study drug on the endpoints, the odds ratio will be calculated, and a correlation analysis is planned.

STUDY TIMING

AND EXPECTED RESULTS

The study was registered with the USA National Institute of Health (NCT04559646). The enrollment of patients had been started, and the first randomization was performed on September 28, 2020. Thus, the research base will be fully formed by the end of 2021, and the first results will be presented in quarter 1 of 2022. The use of the hemostatic drug "Haemoblock" during the pacemaker implantation is expected to reduce the risk of PH formation in patients taking OAC.

ADDITIONAL INFORMATION

Conflict of interest. The study's sponsor was the "Moscow Regional Scientific Research Institute of Blood," which provided the drug "Haemoblock" to research centers free of charge. No additional financial remuneration was provided to the research participants.

Consent for publication. Written consent was obtained from the patient for publication of relevant medical information.

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