Federal Center for Cardiovascular Surgery
Astrakhan, Russia

Results of MAITRE (arguMents to Apply epInephryne for pocket hemaToma REduction) study

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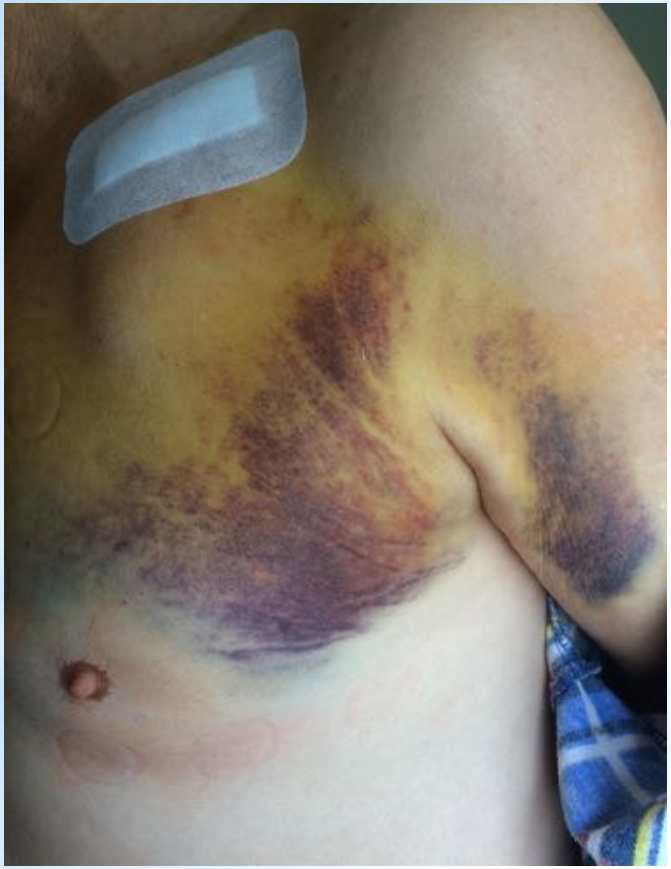
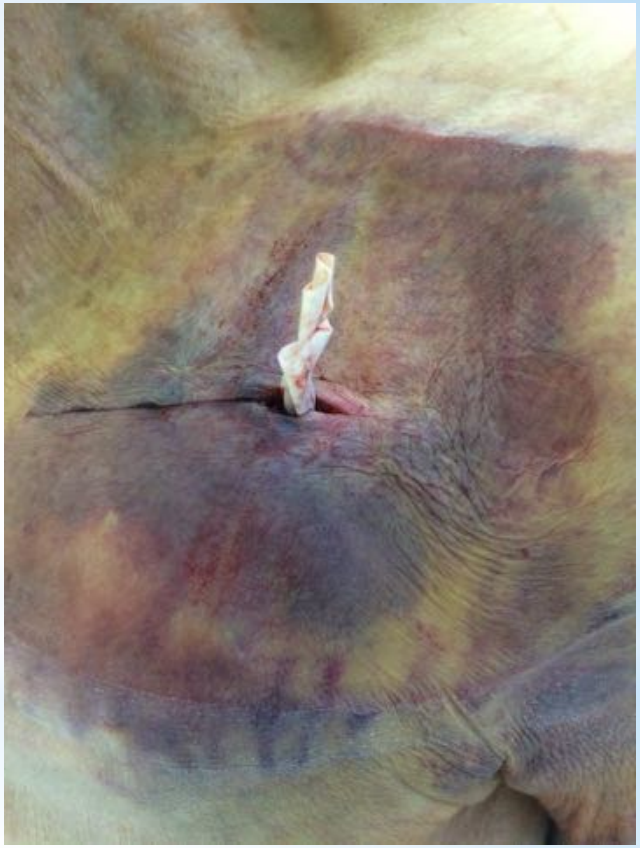
DISCLOSURES

There is no conflict of interest to declare.

Device Pocket Hematoma





Background

Pocket Hematoma After Pacemaker or Implantable Cardioverter Defibrillator Surgery*

Influence of Patient Morbidity, Operation Strategy, and Perioperative Antiplatelet/Anticoagulation Therapy

Uwe K. H. Wiegand, MD; Dominik Lefèvre, MD; Frank Bogunchewski, MD; Hendrik Bonnemeier, MD; Frank Eberhardt, MD; Herbert Schunkert, MD; and Frank Kock, MD

Study objectives: Pocket hematoma is a common complication after pacemaker or implantable cardioverter defibrillator (ICD) implantation. Thus, we investigated the influence of patient comorbidity, implantation strategy, operator experience, antiplatelet therapy, and anticoagulation therapy on hematoma rate.

Design: Between 1990 and 2002, a total of 3,164 devices (pectoral pacemakers, 2,792; ICDs, 372) were implanted at our institution. Predictors of hematoma occurrence were determined prospectively and were analyzed by multivariate regression analysis. Operator experience was graded by individual implantation number, as follows: low, < 50; medium, 50 to 100; and high, > 100.

Results: The incidence of pocket hematoma was 4.9%, leading to prolonged hospitalization in 2.0% of all patients. Reoperation for pocket hematoma was required in 1.0% of patients. High-dose heparinization (hazard ratio [HR], 4.2), combined acetylsalicylic acid (ASA)/thienopyridine treatment after coronary stenting (HR, 3.2), and low operator experience (HR, 1.6) were independently predictive of hematoma development. Therapy with ASA alone did not increase the hematoma rate compared to patients who did receive antiplatelet or anticoagulation therapy (3.1% vs 2.9%, respectively; difference not significant). In patients with nonvalvular atrial fibrillation, postoperative high-dose heparinization substantially increased the hematoma rate (10.7% vs 2.9%, respectively; $p < 0.001$) without reducing the rate of arterial embolism within the first month after implantation (0.18% vs 0.21%, respectively; difference not significant). The infection rate (0.25% within 3 months after implantation) was not influenced by the presence of the pocket hematoma.

Conclusions: The use of high-dose heparinization and combined ASA/thienopyridine treatment are highly predictive for the occurrence of intraoperative bleeding and pocket hematoma in patients who have undergone pacemaker and ICD surgery. We propose recommendations for the management of antiplatelet and anticoagulation therapy in patients undergoing these interventions. *(CHEST 2004; 126:1177–1186)*

Key words: anticoagulation; antiplatelet therapy; arterial embolism; artificial pacemaker; hematoma; implantable cardioverter defibrillator

Abbreviations: aPTT = activated partial thromboplastin time; ASA = acetylsalicylic acid; ICD = implantable cardioverter defibrillator; INR = international normalized ratio; LMWH = low-molecular-weight heparin; UFH = unfractionated heparin

Complications of Device implantation Procedure

Complication	Age		*P*-value
	<70 years	≥70 years	
Hematoma	13 (5%)	7 (2.2%)	0.29
Pocket infection	7 (2.7%)	5 (1.6%)	0.59
Pneumothorax	2 (0.8%)	4 (1.3%)	0.72
Lead dysfunction/dislocation	11 (4.2%)	4 (1.3%)	0.21
Local wound fibrosis	0	3 (1.0%)	NA
Free wall rupture	0	1 (0.3%)	NA
Lead endocarditis	6 (2.3%)	0	NA

Kazım Serhan Özcan et al. *Pacemaker implantation complication rates in elderly and young patients*. Clin Interv Aging. 2013; 8: 1051–1054.

Background

Circulation
Arrhythmia and Electrophysiology

American Heart Association.

Risk of Hematoma Complications After Device Implant in the Clopidogrel Era

Ilana B. Kutinsky, Regina Jarandilla, Maralee Jewett and David E. Haines

Circ Arrhythm Electrophysiol. 2010;3:312-318; originally published online June 17, 2010;
doi: 10.1161/CIRCEP.109.917625

Background—Device implant pocket hematoma is a recognized complication after permanent pacemaker (PM) and implantable cardioverter-defibrillator (ICD) implantation. Pocket hematoma is associated with local discomfort, an increased risk of infection, and may require surgical intervention or lead to lengthier hospital stays. The purpose of the study was to identify the clinical factors associated with hematoma formation after PM or ICD device implantation.

Methods and Results—The subjects of this prospective observational study were 935 consecutive patients at Beaumont Hospital who underwent implantation of a PM or an ICD. Clinical characteristics and anticoagulant/antiplatelet drug use were recorded. A pocket hematoma was documented in 89 of 935 patients. Significant predictors of device pocket hematoma included ongoing clopidogrel therapy (18.3% on therapy, 10.5% recently discontinued, and 7.9% off therapy; $P<0.001$) and use of intravenous heparin (22.0% on therapy versus 8.2%; $P<0.0001$). Patients in whom clopidogrel was discontinued >4 days before device implantation had no hematoma. Hematomas occur more frequently in patients receiving ICDs than those receiving PMs. Device pocket hematoma was associated with an increased median length of hospital stay (4 days [interquartile range, 1 to 9] days with versus 2 days [interquartile range, 1 to 6] days without hematoma; $P=0.004$) and increased late complications or surgical intervention.

Conclusions—The use of clopidogrel or intravenous heparin significantly increased the risk of hematoma at the time of PM or ICD implantation. By withholding clopidogrel before surgery, the excess risk of bleeding complications may be reduced. (*Circ Arrhythm Electrophysiol.* 2010;3:312-318.)

Key Words: pacemaker ■ implantable cardioverter-defibrillator ■ complications ■ hematoma ■ anticoagulation ■ clopidogrel ■ heparin ■ enoxaparin

Materials and Methods

arguM**ents to** A**pply ep**I**nephryne for pocket hema**T**oma** RE**duction**

MAITRE is a single-center, randomized, double-blind, placebo-controlled clinical study in two compared groups of patients with implanted single and dual-chambered pacemakers.

GOALS:

- to show efficacy of epinephrine as a component of local anesthesia during pacemaker implantation;

- to evaluate a possibility of epinephrine usage as a component of local anesthesia during pacemaker implantation for pocket hematoma prophylaxis.

Study Design

Patient Selection

Inclusion Criteria:

- A signed informed consent for participation in the study;
- men and women aged from 40 to 70 with indications for single and dual-chamber pacemaker

Exclusion Criteria:

- individual epinephrine and/or lidocaine intolerance;
- known contraindications for studied drugs administration;
- Severe arterial hypertension: SBP ≥ 200 mm Hg and/or DBP ≥ 110 mm Hg;
- unstable IHD;
- disturbances in any hemostasis mechanisms: number of thrombocytes, PT, fibrinogen, INR, tourniquet test;
- LV EF (Simpson) <35%;
- pregnancy and lactation;
- chronic kidney insufficiency: creatinine level higher than 110 micromoles per liter.

Patient Registration Card

Patient registration number
Group of randomization (A, B)
Case Study number
Surgeon Name
Age, years
Gender (m/f)
LV EF (Simpson), % (note the date of the latest TTE)
BMI
BSA
Volume of Anesthetic solution, ml
Implantation date
Pacemaker type
Venous Access (S, SP, P)
Device pocket localization (subcutaneous, subfascial, intramuscular)
Fluoroscopy time
Fluoroscopy dose
Drainage Removal (days after procedure)
Ultrasound Study (Pocket Hematoma +/-)
Hemostatic Agents Administration on the third day after procedure (name)
Length of hospital stay (after a procedure)
Antiplatelet/anticoagulant administration before procedure
Local vasopressor epinephrine effects (+/-)

Study Design

Indications for pacemaker implantation, a signed informed consent

Randomization

a) *Choice of a Surgeon*
b) *Choice of a study group*

A group

Lidocaine Solution 0,25% -150 ml

+

0,1% epinephrine solution - 1,0 ml

B group

Lidocaine Solution 0,25% -150 ml

+

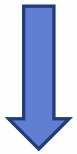
saline solution - 1,0 ml (placebo)

Study Design

Pacemaker Implantation

Postoperative Follow-up
Pocket Ultrasound Study (3 -5 days after procedure)

Statistical analysis



Conclusions, clinical implementation

The analysis of Study Endpoints

Primary Endpoint:

- *Pocket Hematoma*

Secondary Endpoints:

- *Drainage insertion during the procedure*
- *Drainage prolongation*
- *Hospital stay days*
- *Cerebral vascular events*
- *Bleeding, pericarditis, tamponade*
- *Infectious complications*
- *Implanting Surgery Poll*

Early End of Study

The study could come to an early end for a patient:

- in case of the patient's refusal to participate;
- according to the decision of a researcher in case of:
  - adverse effects;
  - violation of the study protocol;
  - non-related to pocket hematoma need to perform surgical revision

Characteristics of the Patients

	Group A (Epinephrine)	Group B (Saline Solution)	P value
Patients, no (n=133)	75	58	0,2
Male/female-no.(%)	43/32 (57%/43%)	29/29 (50%/50%)	0,19
Average age, years	60 (55;65)	62 (56; 65)	0,3
BMI	29,2 (26,4; 33,1)	30,7 (26,8; 34,7)	0,2
Diabetes Mellitus	5 (7%)	6 (10%)	0,3
LV EF (Simpson), %	58 (53; 61)	58 (53; 60)	0,2
Medications – no. (%)			
antiplatelet therapy	12 (16%)	8 (14%)	0,5
anticoagulant therapy	22 (29%)	22 (38%)	0,4
combined AP/AC therapy	2 (3%)	1 (2%)	0,2
no hemostatic drugs	39 (52%)	27 (47%)	0,3

Results

From April 2014 to April 2015 we randomized and performed pacemaker implantation on 133 eligible patients.

	Group A	Group B	P value
Single-chamber pacemaker implantation	23 (31%)	19 (34%)	0,3
Dual-chamber pacemaker implantation	52 (69%)	39 (66%)	0,5
Subcutaneous pocket localization	62 (83%)	54 (93%)	0,2
Subfascial pocket localization	10 (13%)	4 (7%)	0,2
Intramuscular pocket localization	3 (4%)	0	0,4
Venous Access:			
cephalic	29 (39%)	38 (66%)	0,2
subclavian puncture	41 (55%)	18 (31%)	0,4
combined access	5 (6%)	2 (3%)	0,2

Average Procedure Time was 38 (35; 60) min

Results

The primary end-point was registered in 7 patients

Patients	1	2	3	4	5	6	7
Study group	A	B	A	A	A	A	A
Age	64	64	64	66	64	57	69
Gender	male	female	male	male	male	male	male
BMI	34,5	27,2	28,4	21,6	42,9	31,7	34,1
AP/AC intake	-	AC	AC	AC	-	AC	AC
Pacemaker type	DR	DR	VR	DR	DR	VR	VR
Device Pocket localization	Subcutan.	Subcutan.	Subfasc.	Subcutan.	Subcutan.	Subcutan.	Subcutan.
Venous access	cephalic	puncture	cephalic	puncture	puncture	puncture	cephalic

Pocket Hematoma Risk in A group was 0,09 (9 %), in B group – 0,02 (2%).
OR = 5, 95% CI: 2.1-7.3, p=0.003

Results

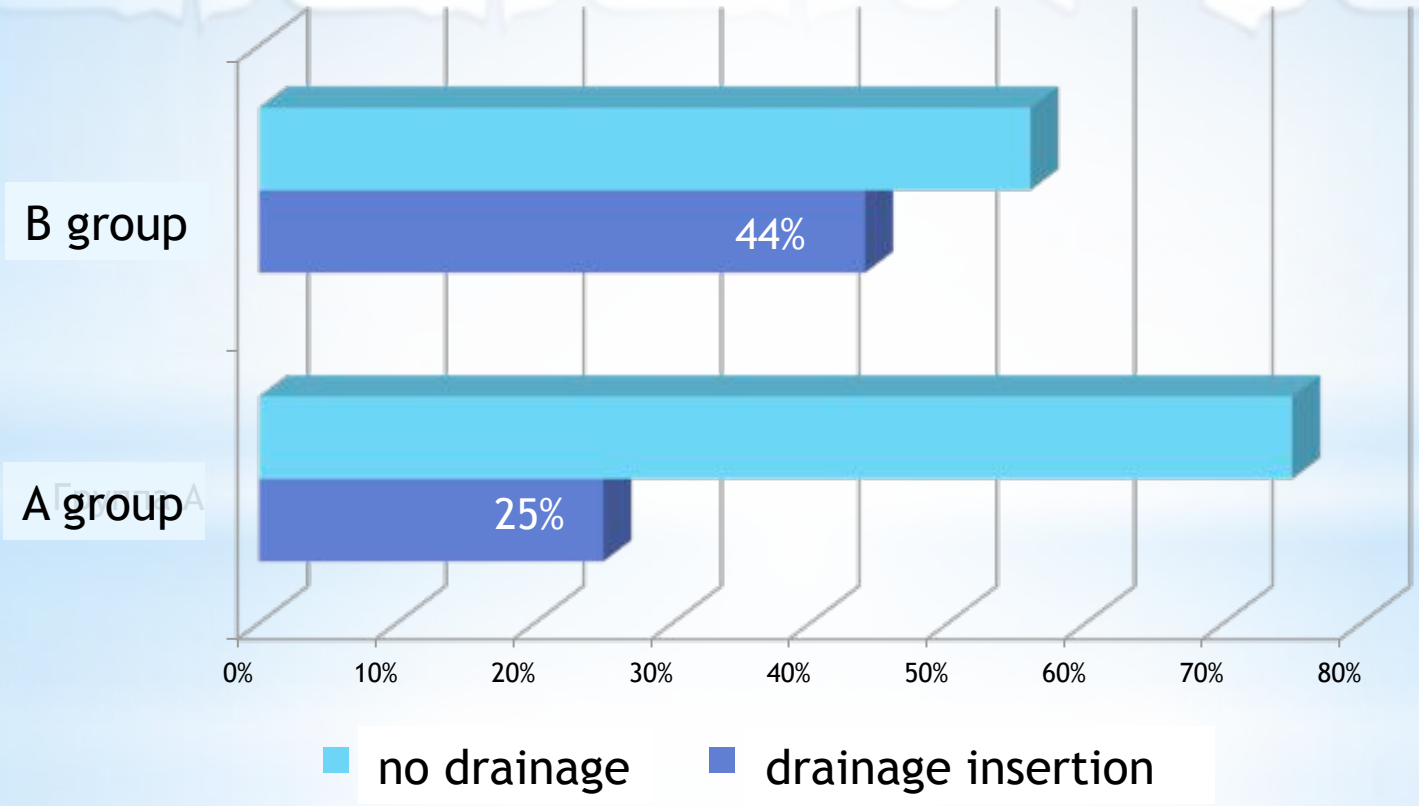
Secondary end-points:

- lead dislodgement– 2 pts (2%)*
- pneumothorax – 2 pts (2%)*
- length of hospital stay:
  A group - 5 (4; 5) days, B group - 5 (4; 6) days, p=0,3*
- drainage was inserted in 43 procedures (32%):
  in A group – 25%, in B group – 44%**
- pocket draining duration didn't exceed 2 days and it was ≈ 1 day in both groups*

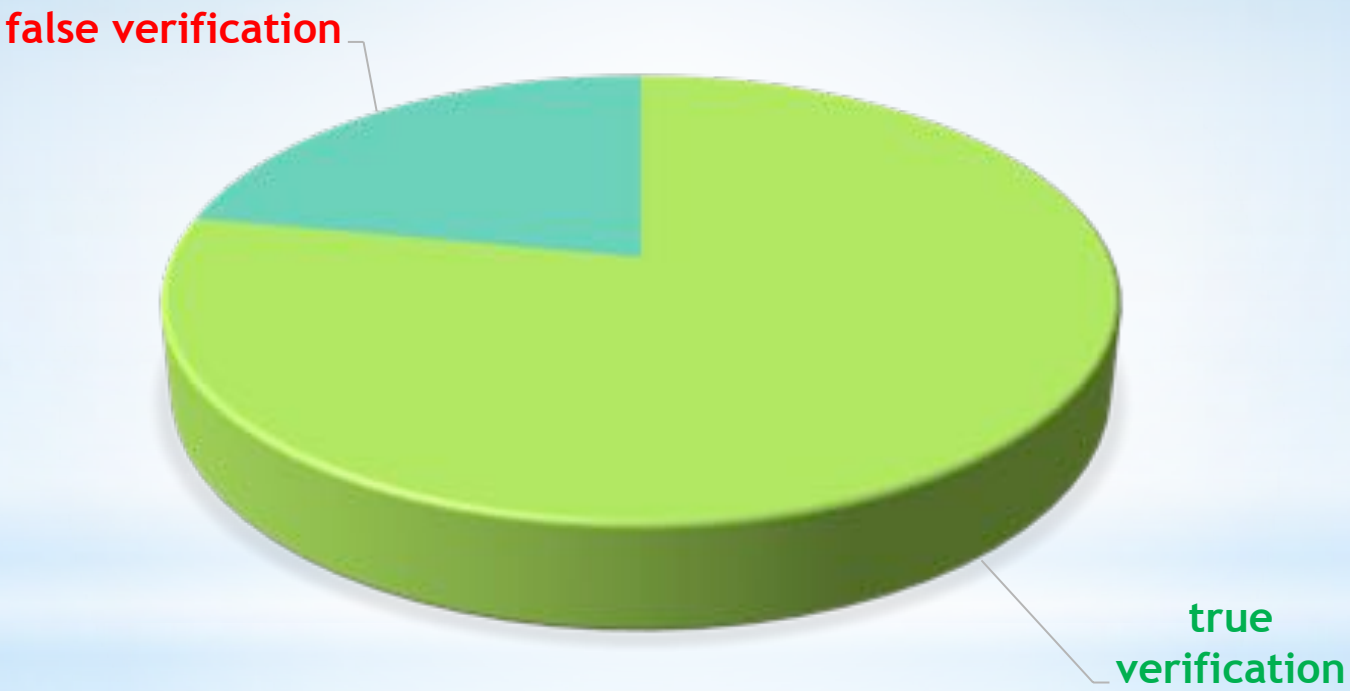
**there are no relations between the studied groups (p>0,1).*

***relations between the groups are statistically significant (p<0,05).*

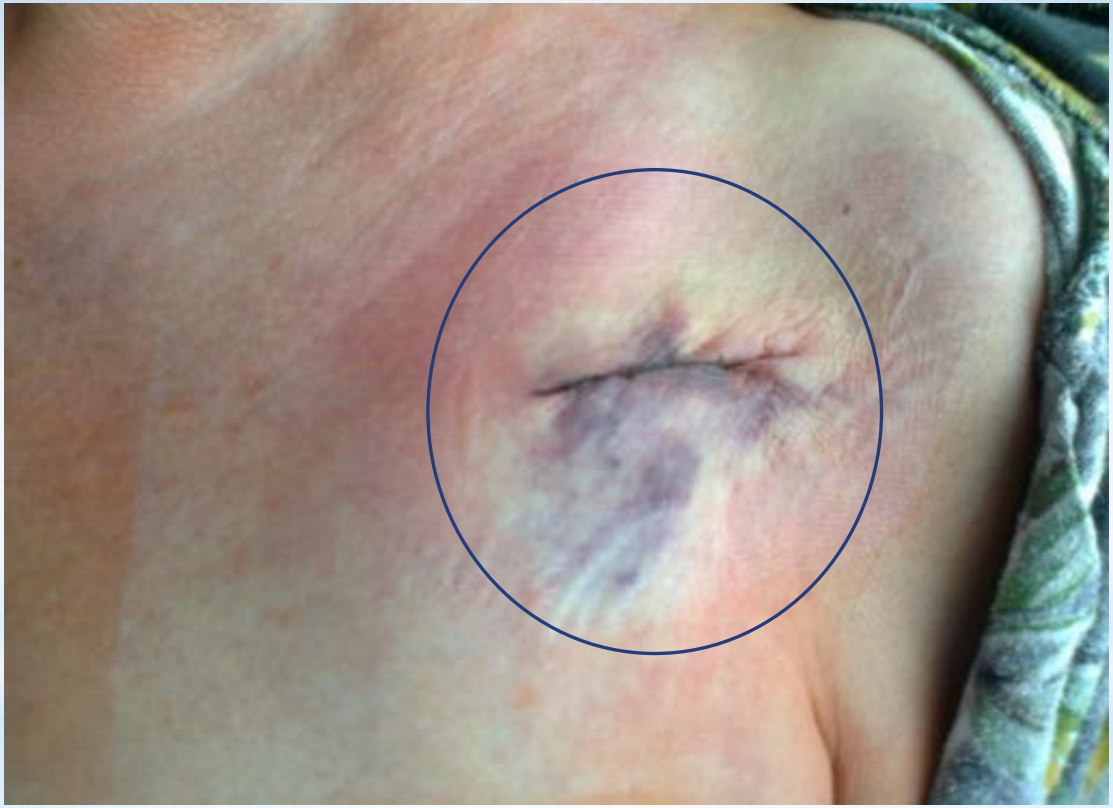
Secondary End-point - Pocket draining duration n=43 (32%)



Implanting Surgery Poll

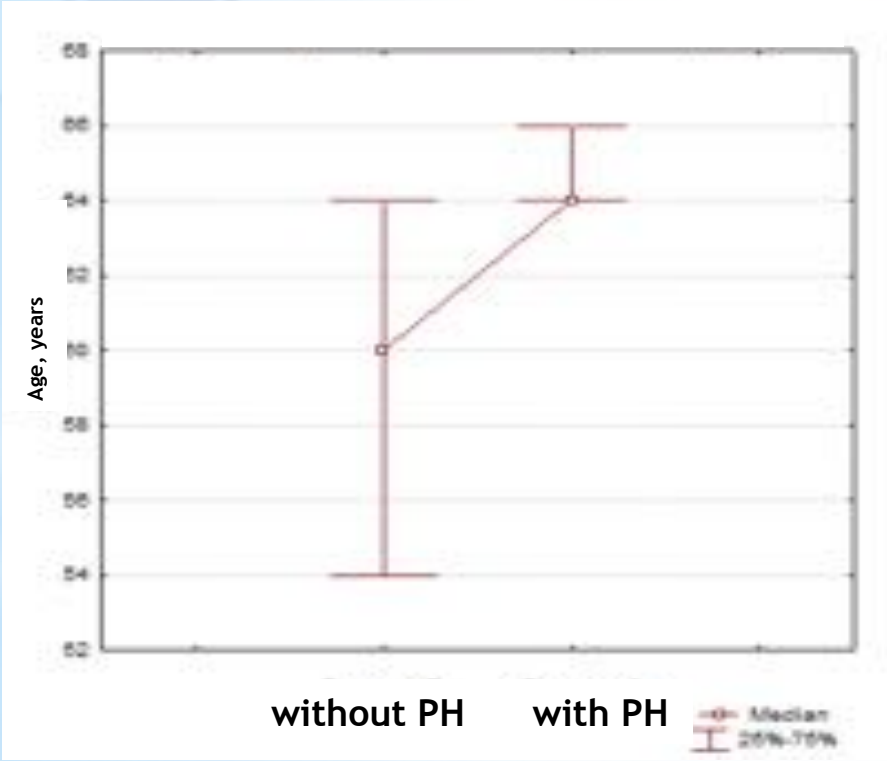


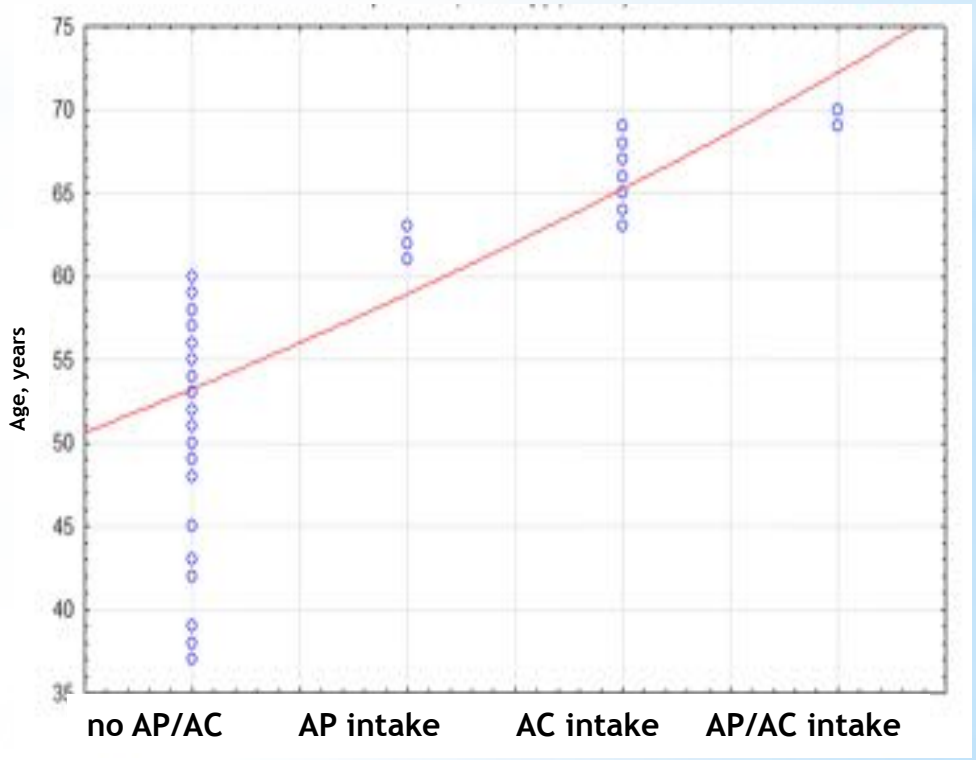
Epinephrine Effects



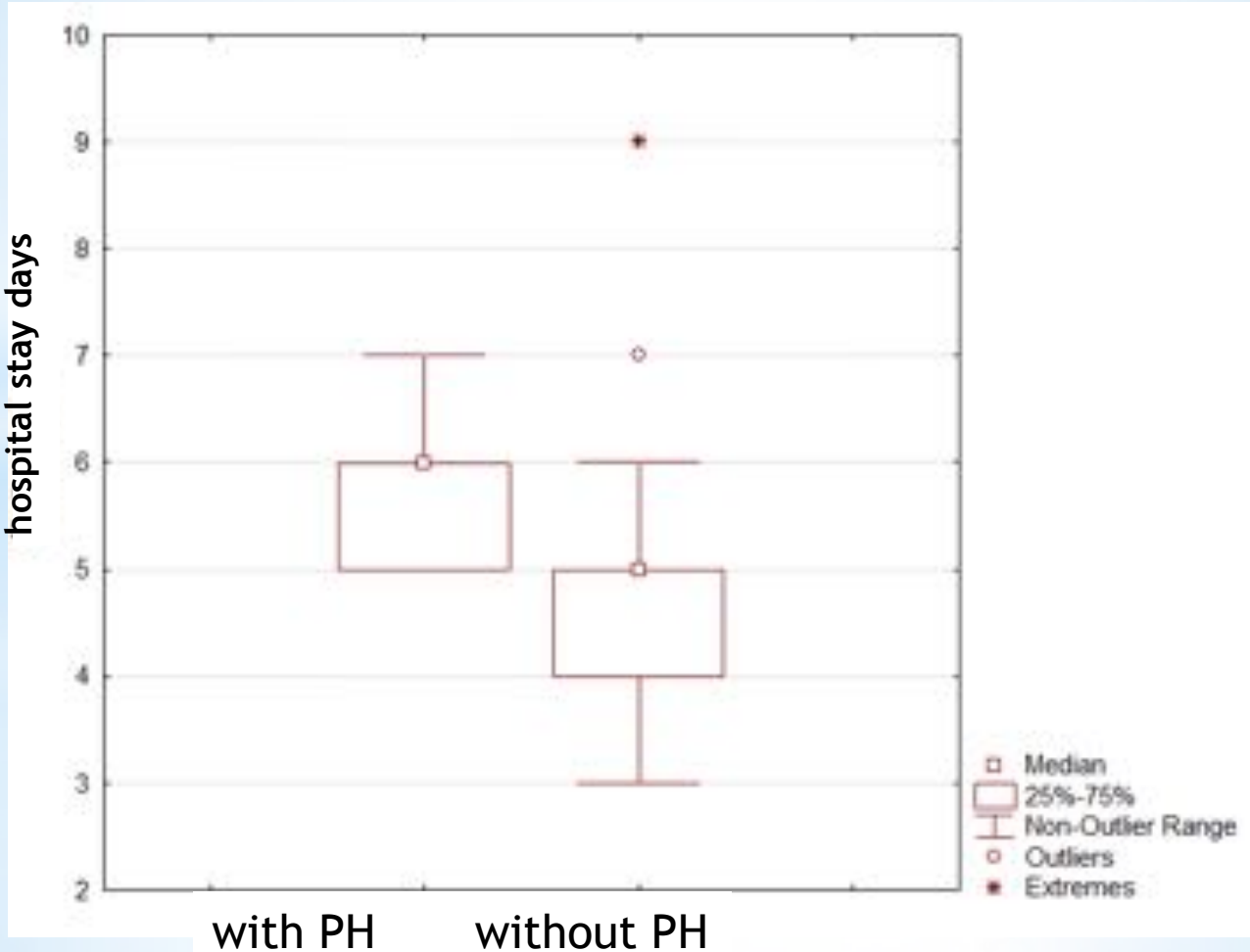
BP and HR monitoring didn't show any significant systemic epinephrine effect.
We registered a local epinephrine effect as a circular skin paleness above pacemaker pocket in the area of anesthetic solution injection.

Characteristics of the Patients with Pocket Hematoma





Length of hospital stay



Conclusions:

1. Epinephrine administration as a component of local anesthetic solution during a pacemaker implantation is safe and doesn't lead to any serious adverse effects.

2. Epinephrine administration as a component of local anesthetic solution during a pacemaker implantation doesn't decrease the risk of pocket hematoma creation which is probably connected with local vasopressor epinephrine effects and delayed capillary bleeding in a device pocket.

3. It is possible that a risk of pocket hematoma increases with ageing.

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THANKS FOR YOUR ATTENTION!