


PARAMETERS OF ALLERGIC REACTION AFTER IMPLANTATION OF DIFFERENT PATENT FORAMEN OVALE OCCLUDERS - A PILOT PROSPECTIVE RANDOMIZED STUDY

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PRIMARY ENDPOINT

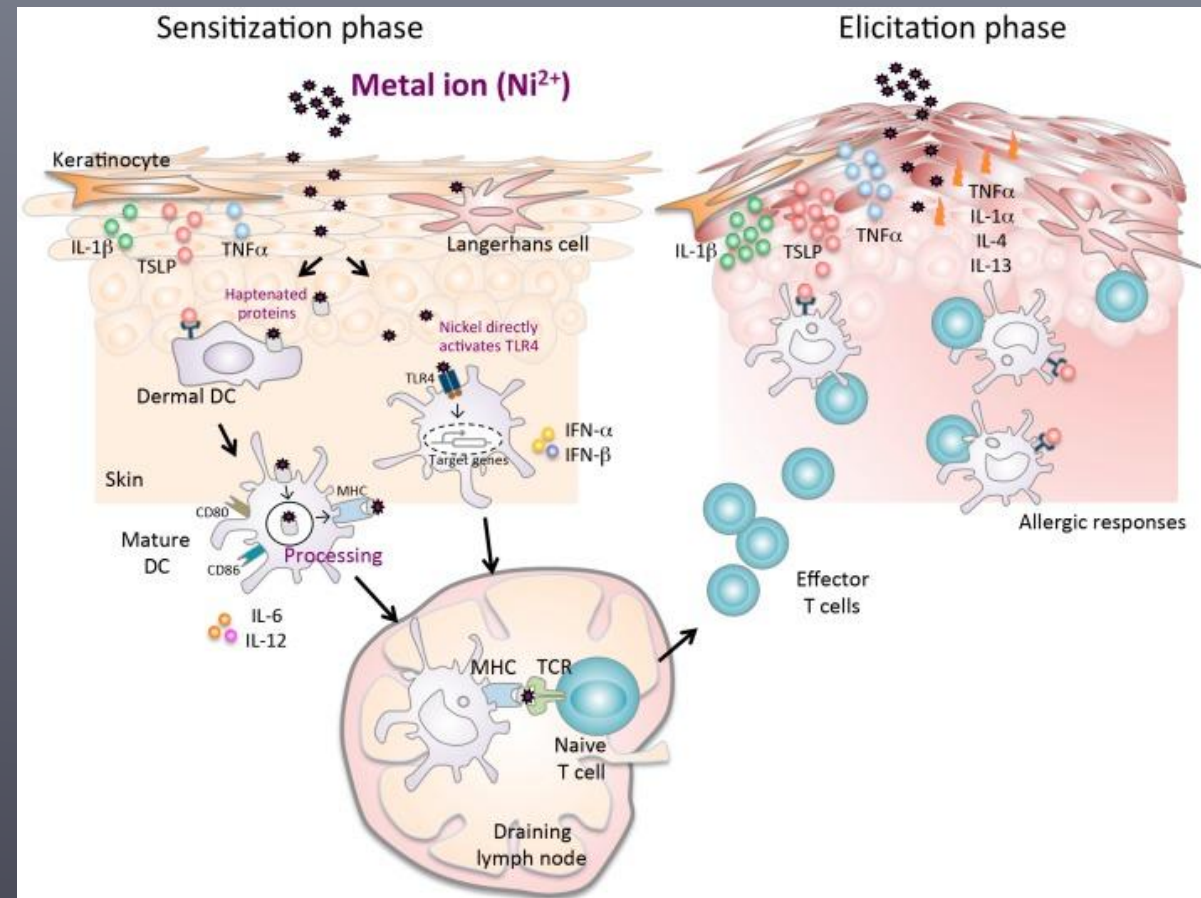
- ▶ To compare parameters of the allergic response after transcatheter closure of the patent foramen ovale (PFO) using three different types of nitinol occluders in a pilot randomized trial.
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METAL HYPERSENSITIVITY


- ▶ Nitinol – shape memory alloy
 - ▶ Nickel allergy prevalence - 8,6 % (Thyssen et al)
 - ▶ Titanium allergy prevalence – 0,6 % (Sicilia et al)
 - ▶ Dermatitis, fever, dyspnea, chest pain, palpitations, bronchospasm, pericardial effusion
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IMMUNOPATHOLOGICAL REACTIONS

- ▶ Type IV reaction (cell cytotoxic reaction).
- ▶ Delayed type hypersensitivity (12-48 h).
- ▶ T cells play a crucial role in these hypersensitivity reactions.
- ▶ Metallic ions work as haptens and bind to the surface of MHC.
- ▶ APCs migrate to draining lymph nodes where they present these haptens to naive T cells.
- ▶ Re-exposure to the same hapten induces a hypersensitive reaction.



BIOMARKERS

- ▶ IgE – product of mast cells, early hypersensitivity marker (type I reaction)
 - ▶ Eosinophils - release several cytotoxic cationic granule proteins in allergic disease.
 - ▶ ECP – product of crystalloid secondary granules of eosinophils, effectors of inflammation.
 - ▶ IL-1, IL-6 – cytokines, produced by interaction between helper T-cells and APCs (e.g. macrophages), maximum plasma concentration 3-5 h after stimulus.
 - ▶ CRP
 - ▶ WBC
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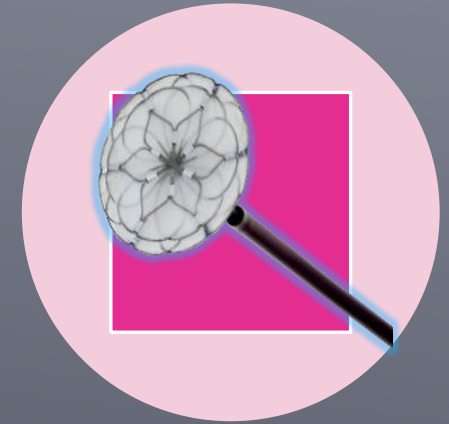
OCCLUDER TYPES



1. AMPLATZER® (ABBOTT®)
DEVICE MADE OF NITINOL
WITH WIRE TREATMENT TO
REDUCE NICKEL EXCRETION
AND POLYESTER FABRIC




2. FIGULLA® (OCCLUTECH®)
DEVICE MADE OF TITANIUM
OXIDE-COATED NITINOL AND
PET-PATCH




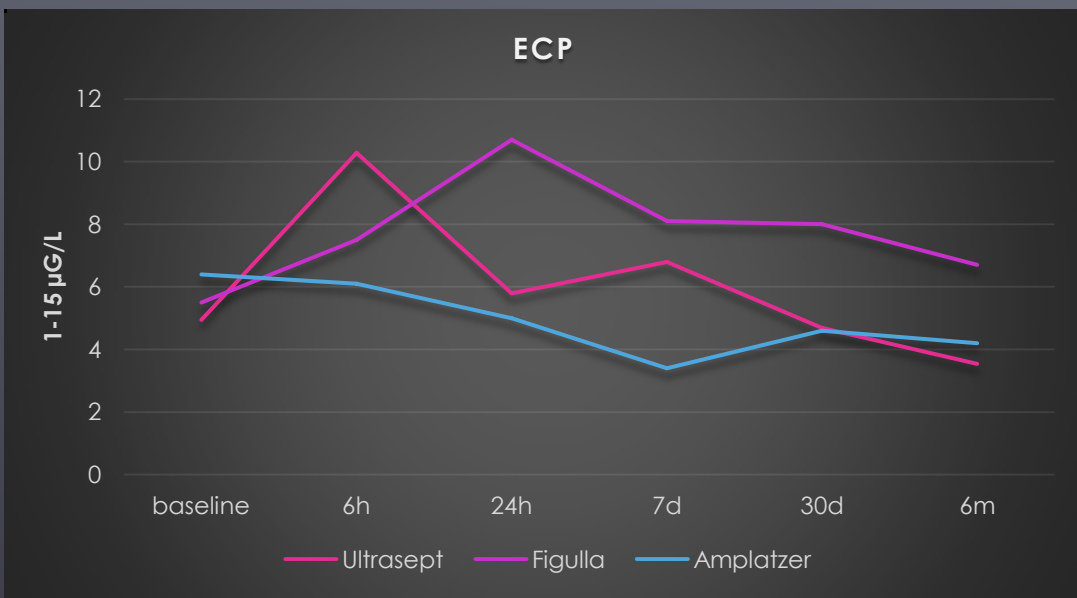
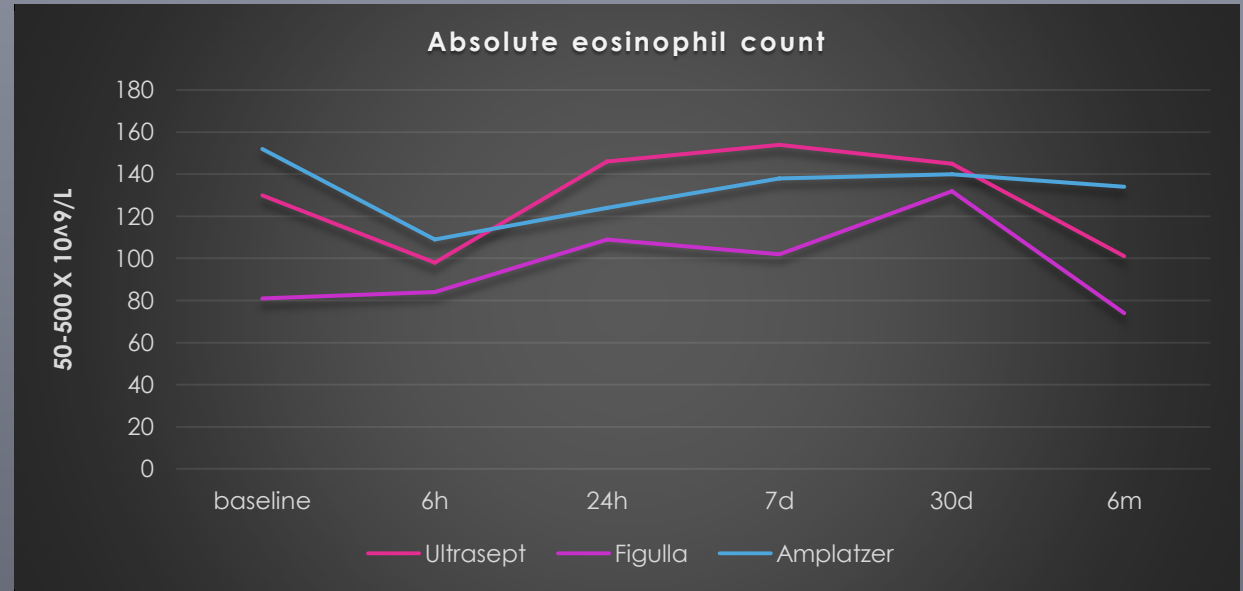
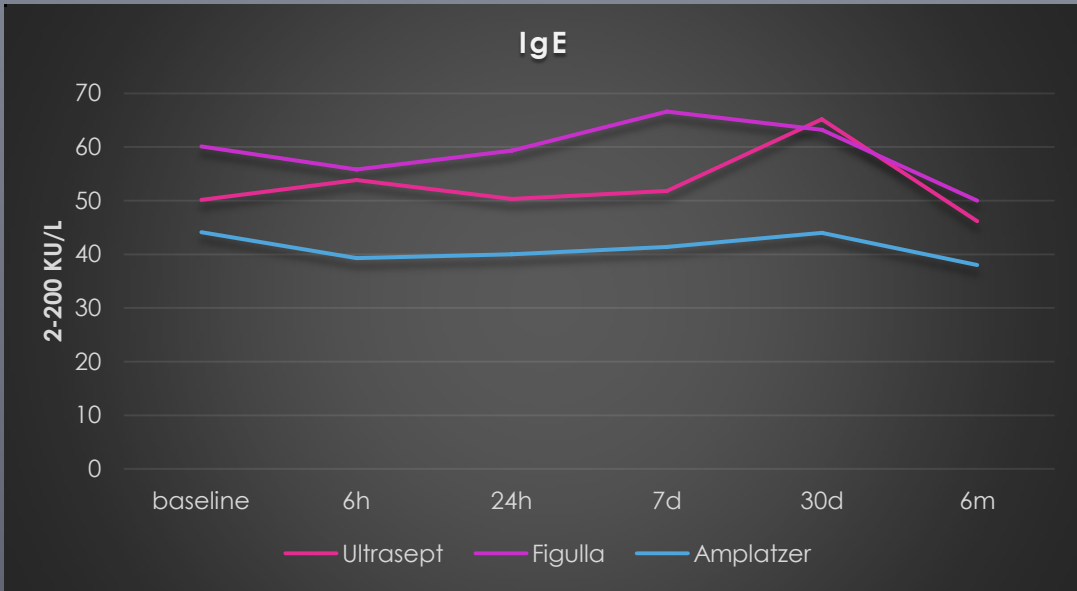
3. ULTRASEPT® (CARDIA®)
DEVICE WHICH CONSISTS OF
NITINOL COATED WITH
POLYVINYL ALCOHOL

PATIENT POPULATION AND METHODS

- ▶ 39 patients (21 women and 18 men).
 - ▶ Age 29-72.
 - ▶ Three groups according to the type of implanted occluder.
 - ▶ Parameters: plasma CRP levels, full blood count including eosinophils, IgE, eosinophilic cationic protein (ECP), fibrinogen and a panel of cytokines.
 - ▶ Measured at baseline (24 hours before the procedure) and 6 hours, 24 hours, 7 days, 1 month and 6 months after occluder implantation.
 - ▶ Only patients with normal baseline levels of IgE, eosinophils, ECP, and CRP were included for the final analysis (group 1 n = 7, group 2 n = 9, group 3 n = 6).
 - ▶ Procedural success 100 %.
 - ▶ No major complications.
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RESULTS

- ▶ No significant changes in plasma levels of IgE and eosinophils were detected during the follow-up among the 3 groups of patients.
 - ▶ The ECP values differed statistically among the individual groups 7 days after the procedure ($p = 0.025$), there were no significant deviations in the other observed times.
 - ▶ No measurable increase in interleukins 1 and 6 was detected.
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„p“ level	Baseline	6h	24h	7d	30d	6m
IgE	0,921	0,973	0,935	0,679	0,739	0,769
Eosinophils	0,474	0,616	0,974	0,300	0,906	0,125
ECP	0,625	0,141	0,556	0,025	0,078	0,711

Figure 1 – statistical analysis at a 95 % confidence level

CONCLUSION

- ▶ Comparing 3 types of PFO occluders, there were no significant differences among selected parameters of the allergic response.
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THANK YOU FOR ATTENTION!



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