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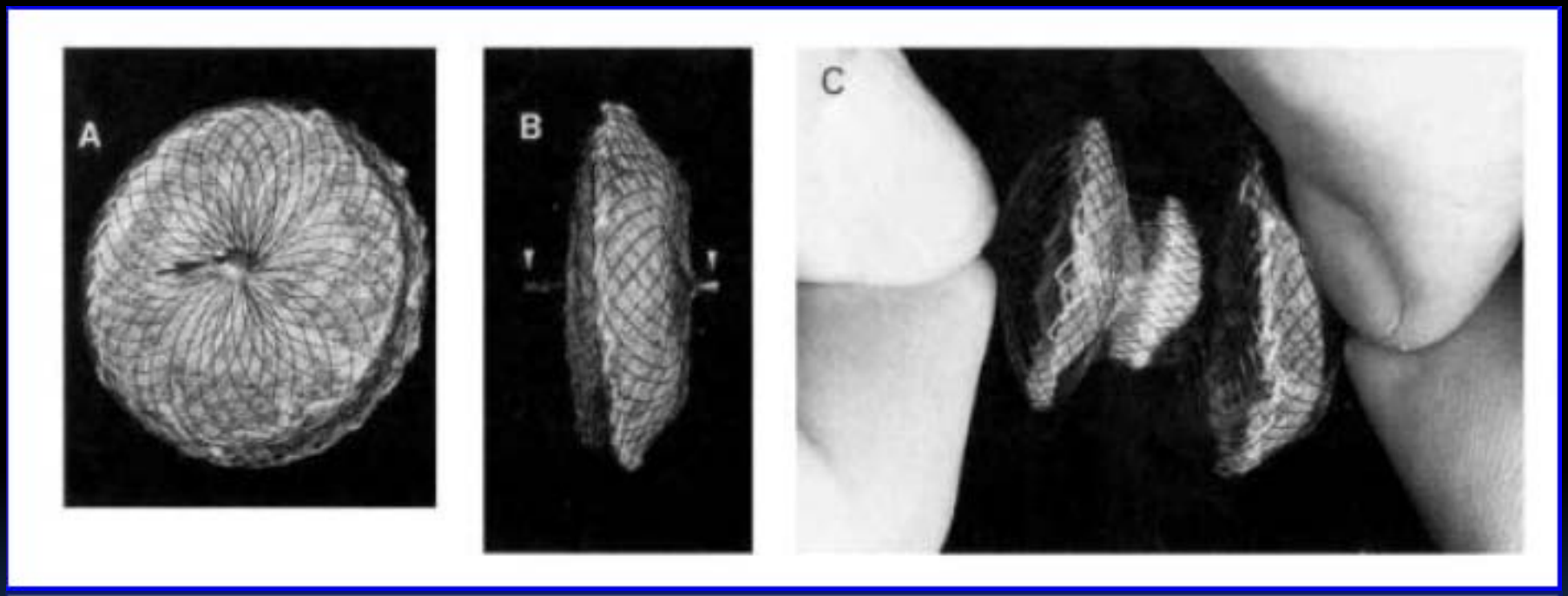
Amplatzer Occluders

- Mesh of Nitinol wires in 2 flat button shape with central connecting waist, filled with polyester



Nickel release after implantation of the Amplatzer occluder

Marcus W. Ries, MD,[a] Christoph Kampmann, MD,[b] Hans-Jürgen Rupprecht, MD,[a] Gudrun Hintereder, MD,[c] Gerd Hafner, MD,[c] and Jürgen Meyer, MD,[a] *Mainz, Germany*

Background Transcatheter closure of atrial septal defects is a new and less traumatic technique than open heart surgery. In recent years, patients with a patent foramen ovale sustaining potential paradoxical embolism have also become candidates for interventional closure devices. One of the more popular occluding devices is the Amplatzer septal occluder, which, like many other occluders, is made of nitinol. Nitinol-based alloys are widely used in medical products, for example, in orthopedics and orthodontics. However, the clinical use of nitinol, which contains 55% nickel, is still controversial because of concerns about its biocompatibility. Therefore, we examined the systemic nickel release after implantation of the Amplatzer occluder.

Methods and Results In 67 patients with no history of nickel sensitivity, blood samples were taken 24 hours before and 24 hours, 1, 3, and 12 months after occluder implantation. Nickel serum concentrations were measured by atomic absorption spectrometry; a value of <2 ng/mL of nickel was considered to be normal. A rise in mean serum levels of nickel was observed, from 0.47 ng/mL before implantation to 1.27 ng/mL (24 hours after), to a maximum of 1.50 ng/mL 1 month after implantation, which was statistically significant ($P = .008$ and $P = 0.022$, Wilcoxon Test). During follow-up, the values decreased to those measured before implantation.

Conclusions Nickel seems to be released from the device, causing a systemic rise in serum levels of nickel, possibly until a calcium-phosphate layer has formed on the passive oxide film of the device or until endothelialization is complete. Possible biological effects should be considered, particularly in young patients or patients with nickel hypersensitivity. (Am Heart J 2003;145:737-41.)

after Implantation of Amplatzer® Occluder

Department of Pediatrics, College of Medicine, Hallym University, Korea

Background

1. Transcatheter closure of patent foramen ovale (PFO), atrial septal defect (ASD) and patent ductus arteriosus (PDA) is a new and less traumatic technique than open heart surgery.
2. One of the more popular occluding devices is the Amplatzer® occluder which is made of nitinol(NiTi).
3. The possibility of nickel toxicity due to the high nickel content and possible dissolution during corrosion is a matter of concern

Purpose

1. To examine whether there is a systemic nickel release after implantation of Amplatzer® occluder in patients with PFO, ASD and PDA
2. To evaluate the safety of Amplatzer® occluder which is made of nitinol

Suudy population

March 2002 – March 2007
Department of Pediatrics, College of Medicine, Hallym University
Amplatzer® occluder(AGA medical, Golden Valley, MN, USA)
54 pts have undergone transcatheter closure
Blood samples were collected from 25 pts.
Pts. received no other type of metal implant

Gender	Female(%)	n=15(60)
	Male(%)	n=10(40)
Age	Mean age	25.5(Yrs)
	Range	9mos-51Yrs
Defect Type	ASDII	n=9 (36%)
	PDA	n=9 (36%)
	PFO	n=7 (28%)

Laboratory Analysis

Blood samples were analyzed using atomic absorption spectrometry (AAS, Kitachi5700, Hitachi, Japan).
Reference values for nickel
: female <0.6 ug/dl, male <0.51 ug/dl

Follow Up

December 2006 – June 2007
Random blood samples were obtained from 25 patients with Amplatzer® PFO, ASD, PDA occluder from at least 2days to 4-year and 7-month post closure period.

Results

All patients showed satisfactory clinical improvements and there was no echocardiographic evidence of complications.
During 4-year and 7-month post closure period, concentrations of nickel in serum were within normal range with values ≤0.2 ug/dl.

In 67 pts, blood samples [illegible] before and 24hrs, 1, 3 and 12 mos after Amplatzer [illegible] implantation
No adverse effects in this [illegible]

Discussion

Potential Nickel Release
- cytotoxic effects
- Allergic reactions
- Carcinogenicity

No adverse effects in this study

Limitation

- However, further studies are needed to evaluate biological effects in patients with nickel hypersensitivity.

Conclusion

Nickel seems to be released from the Amplatzer® occluder. The dissolution of nickel from Amplatzer® occluder is minimal and systemic rise in serum levels of nickel are within normal range.
Implantation of the Amplatzer® occluder seems to be safe methods.

Congenital Heart Disease

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Nickel Allergy in Interatrial Shunt Device-based Closure Patients

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KEYWORDS
Congenital Heart Disease • Device • Allergy

ABSTRACT

Background. The possibility of nickel toxicity has been raised with interatrial shunt closure devices constructed of nitinol. This study is aimed to assess the potential adverse symptoms in terms of incidence, duration, and significance, in patients with interatrial shunt and nickel allergy who underwent nitinol device-based closure.

Methods. We prospectively enrolled 46 consecutive patients (mean age 35 ± 28.8 years, 30 female) over a 12-month period referred to our center for catheter-based closure of interatrial shunts. Patients were investigated for previous hypersensivity to nickel and were required to test potential nickel allergy with cutaneous patch test (TRUE test) before device implantation. Routinely, clinical visit with laboratory examinations, and TTE were scheduled at 1, 6, and 12 months.

Results. Nine patients (19.5%, mean age 31.3 ± 13.2 years) had proved symptomatic and instrumental nickel allergy as showed by cutaneous patch skin test but preferred to be implanted. All patients underwent successful transcatheter closure with an immediate occlusion rate of 100% without intraoperative complications. Between the 2nd and 3rd postoperative day, 8 out of 9 patients developed a sort of 'device syndrome' that included concurrent chest discomfort, exertional dyspnea and asthenia, and mild leukocytosis. The syndrome was treated with Prednison and Clopidogrel and in all was resolved after 1-week therapy. Interestingly, none of the patients without nickel allergy developed postclosure symptoms ($P < .001$).

Conclusions. In conclusion, nickel allergy is still a problematic issue in patients scheduled for transcatheter closure of intracardiac shunts; however, our brief study suggests that nickel allergy is not per se a contraindication to nitinol device closure.

Accepted in final form: July 24, 2007.

Nitinol Device

- Nitinol consists of 55% nickel and 45% titanium and is used in numerous medical applications due to its shape memory property.
- Disadvantages of nitinol include nickel release into blood. Some patients are allergic to nickel.
- Nickel release mechanism: friction (rubbing of wires against each other in the wire mesh) or corrosion.

Nanofusion Platinum-Coated Nitinol

- Platinum is biocompatible, non-corrosive, non-allergic
- Nano Fusion is a technique by which layers of Platinum atoms are put on top of the Nitinol wire by a process of Plasma deposition.
- One layer by layer is created such that the total thickness of the platinum layer is about 2500 angstroms (25 microns)

Cocoon Occluders

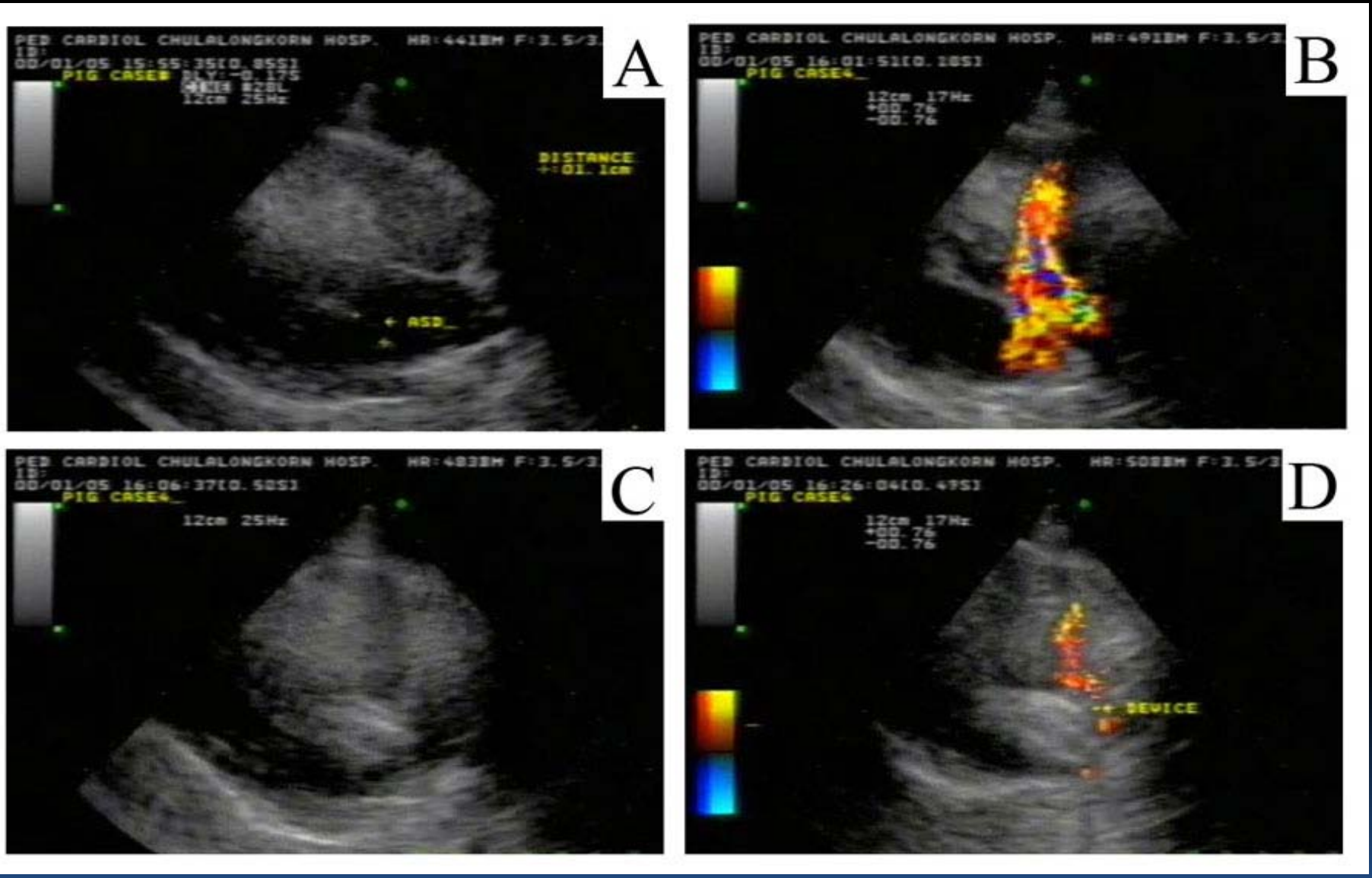
- The COCOON occluders are braided from platinum coated nitinol wire mesh.
- Platinum is proven to be an excellent non-corrosive and non-allergenic and bio-compatible material.
- The devices are filled with polypropylene to enhance thrombogenicity.
- The platinum coating enhances the radio opacity of the device.
- The platinum coating prevents nickel release into the blood stream after device implantation overcoming the disadvantage of nitinol.

Pre-Clinical Experience

Animal Model Synopsis

- Location
  - Faculty of Veterinary Sciences, Mahidol University
- Lead Investigator
  - Pornthep Lertsapcharoen, M.D
    - Department of Pediatrics, Faculty of Medicine, Chulalongkorn University
- Total Cases
  - 12 cases (20-30kgs)

Transthoracic Echocardiography

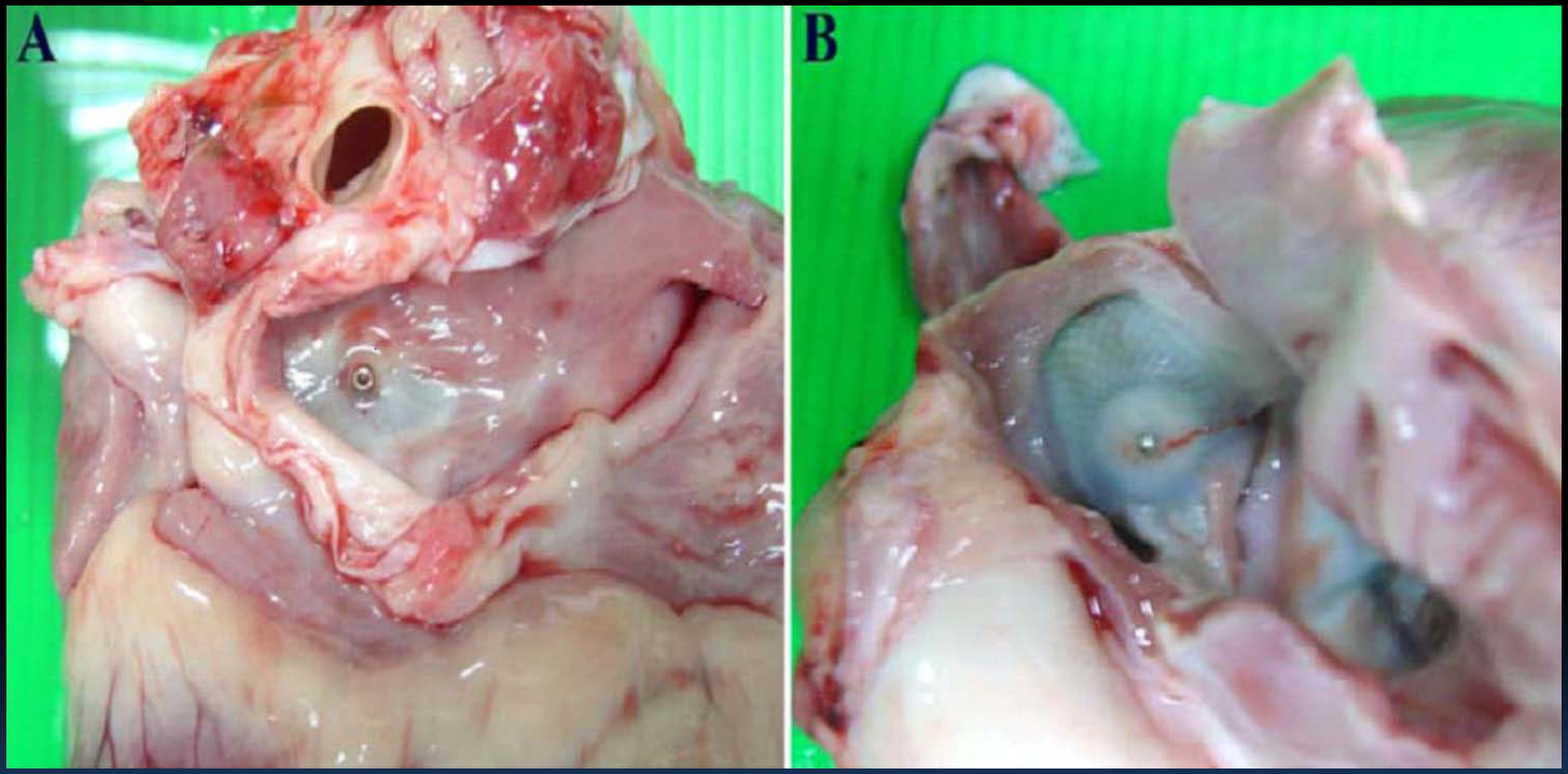


Results in ASD device

Case	Weight (kg)	Balloon catheter (mm)	ASD size (mm)	Device size (mm)	Echo Residual ASD	Complication	Sacrifice (days after)	Autopsy finding	Remarks
1	28	12	12	12	no	no	immediate	Good alignment	
2	28	12	10-11	12	no	Died from A. fibrillation	immediate	good	
3	28	12	10	10	no	no	7	good	
4	28	12	12	12	no	no	7	good	
5	30	10	9	8	no	no	38		
6	28	12	12	12 PDA6/8	no	Abnormal respiration	7	good	+ PDA 6/8 mm
7	28	12	12	12 PDA6/8	no	Apnea and cyanosis needed CPR	7	good	+ PDA 6/8 mm
8	25	12	12	12	no	no	29	good	Deployed without fluoroscope
9	25	12	12	12	no	no	28	good	
10	25	10	10	10	no	no	42	good	
11	25	9	9	8	no	no	42	good	
15	20	10	10	10	no	no	36	good	

Postmortem pictures

- 42 days after device implantation



Right Atrial View

Left Atrial View

Results in PDA device

Case	Weight (kg)	Device size (mm)	Complication	Sacrifice (days after)	Autopsy finding	Remarks
6	28	ASD 12 PDA 6/8	Abnormal respiration	7		ASD+PDA devices
7	28	ASD 12 PDA 6/8	Apnea and cyanosis needed CPR	7		ASD+PDA devices
12	23	PDA 6/8	No	7		
13	27	PDA 6/8	Died 1 day after	1	Closed to RCA	
14	24	PDA 6/8	no	7		
16	24.5	PDA 6/8	no	7		
17	23	PDA 6/8	no	7		
18	22	PDA 6/8 PDA 4/6	Convulsion 1 hr after	1	Closed to RCA	2 PDA devices
19	23.5	PDA 6/8	no	7		
20	34.5	PDA 6/8 PDA 4/6	no	7		2 PDA devices

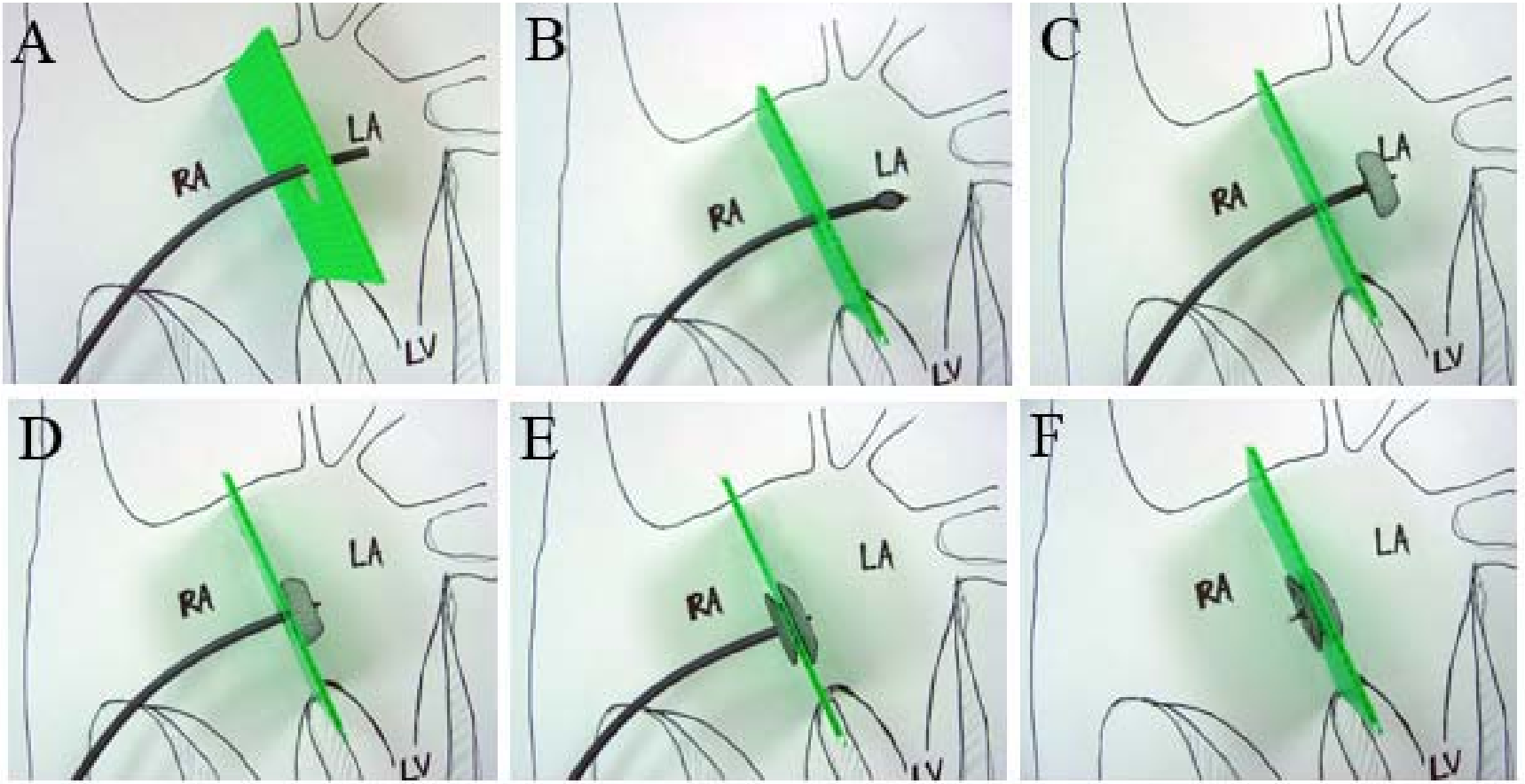
Human Experience

Clinical Trials-Synopsis

- Location
  - Faculty of Medicine, Chulalongkorn University
- Lead Investigator
  - Pornthep Lertsapcharoen, M.D
    - Department of Pediatrics, Faculty of Medicine, Chulalongkorn University
- Objectives
  - Study the effects of Cocoon ASD device in human population
  - Compare the level of nickel in the blood before and after device implantation

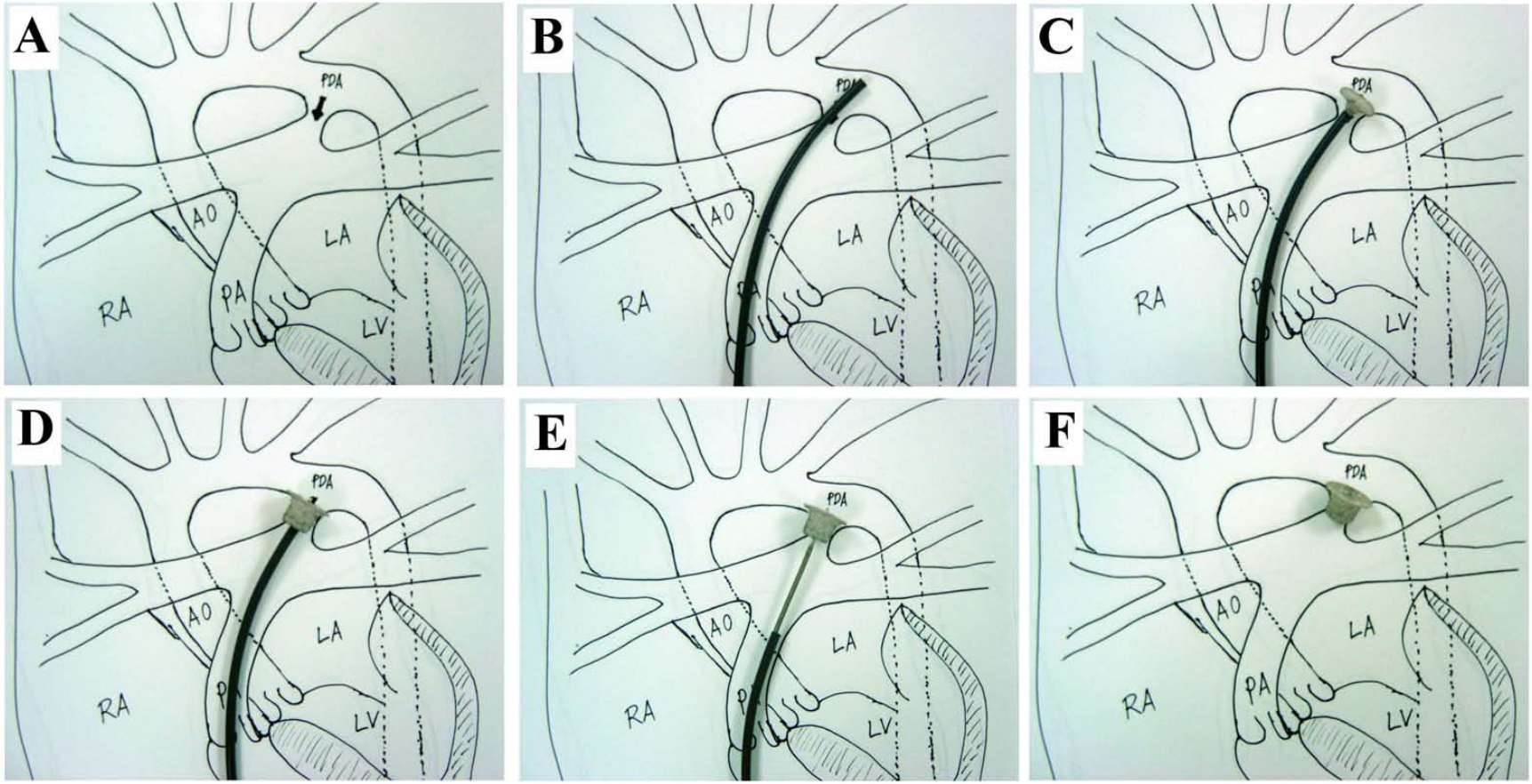
ASD Summary

- ASD 31 cases
- 10 males, 21 females
- Age 4-59 years (median 11 yrs)
- Weight 13.7-90 kg (mean 33 kg)
- ASD diameter by TEE 10-30 mm (19.7 + 4.8)
- Device size 14-34 mm (23.4 + 4.6)
- TTE study at day 1, 7, 30, 90, 180



PDA Summary

- PDA 30 cases
- 7 males, 23 females
- Age 11 months-65 years (median 9 yrs)
- Weight 4.2-58 kg (mean 19 kg)
- PDA diameter 2.9-15.1 mm
  (5.1 + 2.4)
- Device size 6-18 mm (7.7 + 2.5)



Results

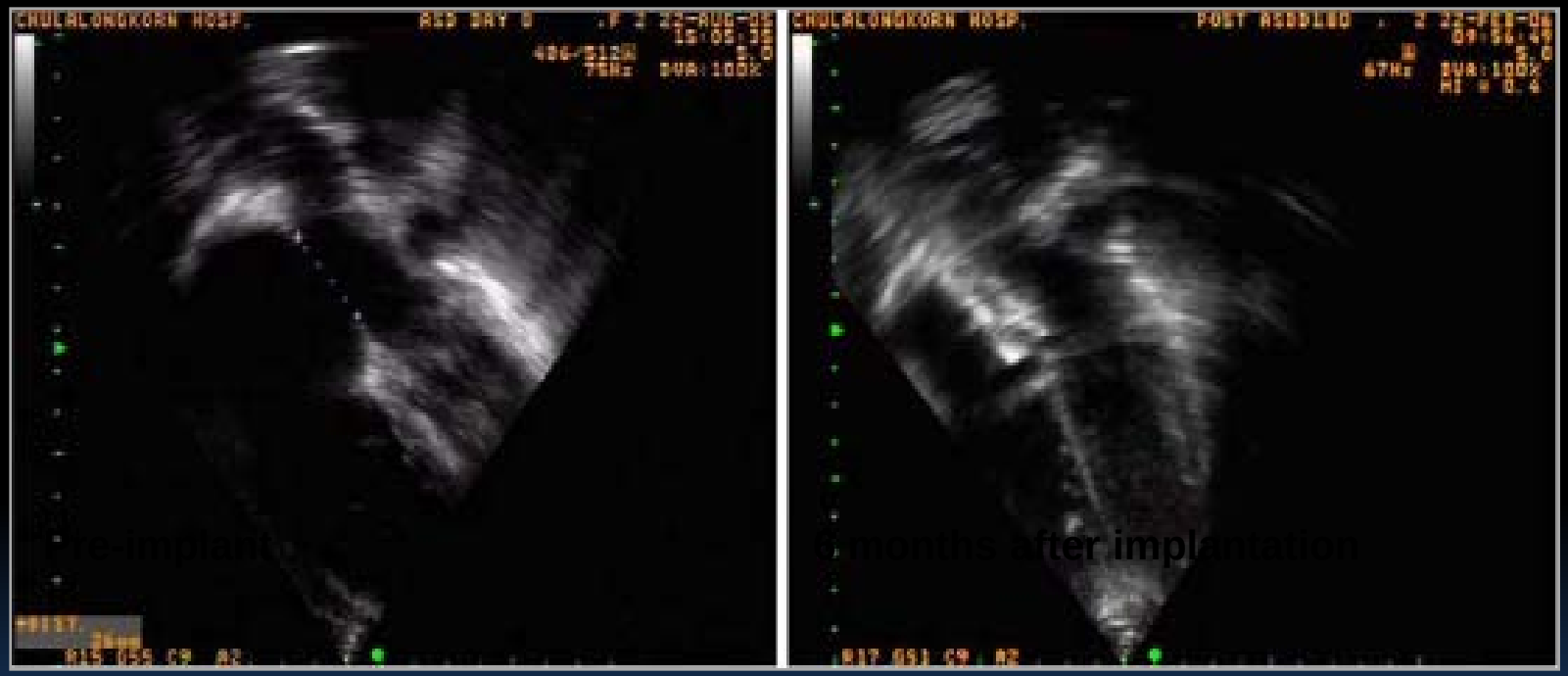
- ASD and PDA devices were successfully implanted in all cases
- ASD 29/31 complete closure 1 month after implantation
- PDA 29/30 complete closure at day 0 (1 at day 30)

Serum Nickel Test Result

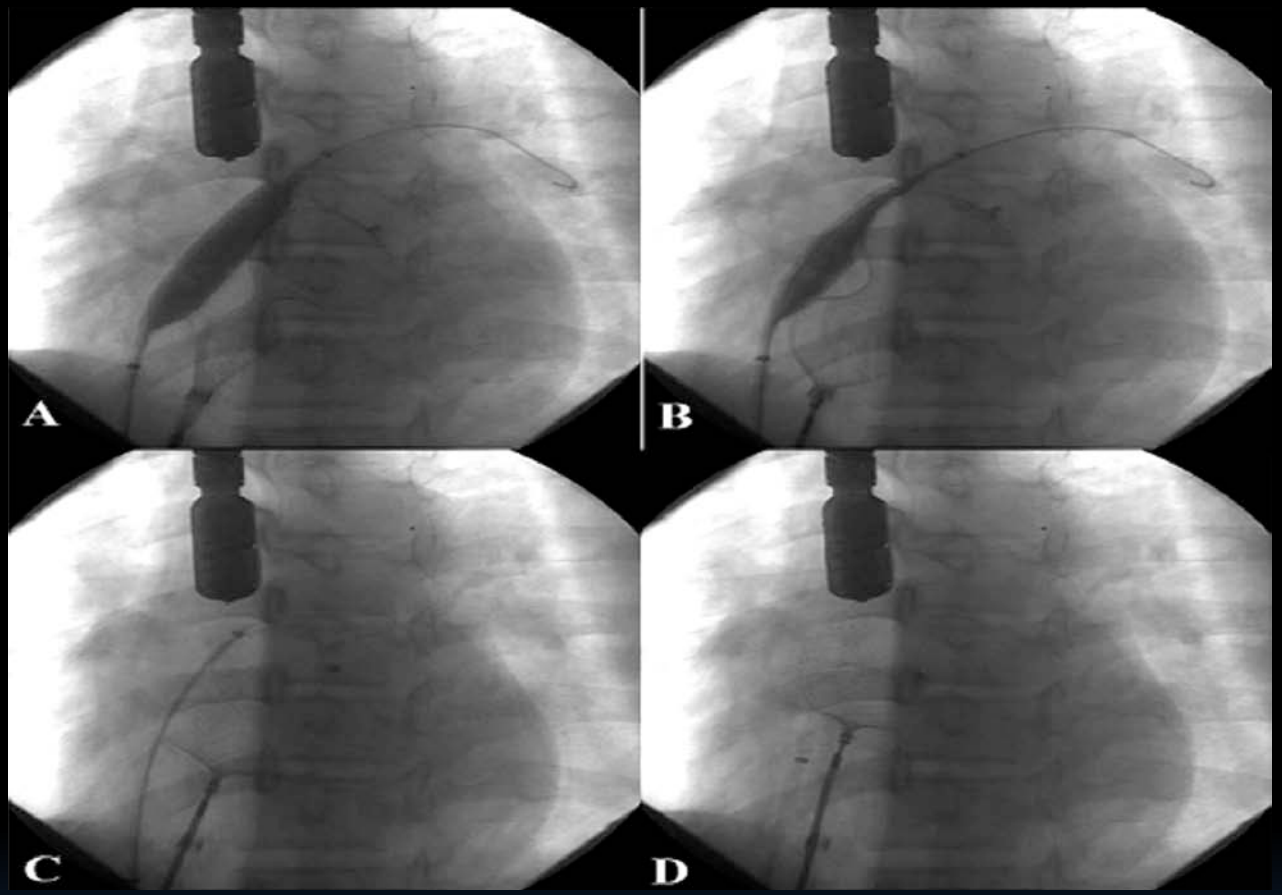
- Sample Size - 50 patients
- Sample Timeline - Before, 1, 3, 7, 30, 90 and 180 days
- Measurement Technology – Atomic Absorption Spectrometry
- Mean Serum Nickel Level – 0.65, 0.63, 0.67, 0.55, 0,53 and 0.42 ng/ml
- Conclusion – No statistical difference before/after Cocoon device implantation

Echo pictures

- Echocardiographic study showing the ASD that was closed with 30 mm device.



Balloon Assisted Technique



- A 15 mm balloon valvuloplasty catheter was used to assist the deployment of 30 mm ASD device in a 14-year-old girl with an ASD size of 26 mm measured by TEE

Publications

Original Contribution

Self-Expanding Platinum-Coated Nitinol Devices for Transcatheter Closure of Atrial Septal Defect: Prevention of Nickel Release

*Pornthep Lertsapcharoen, MD, *Apichai Khongphatthanayothin, MD, †Suphot Srimahachota, MD, ‡Ruenreong Leelanukrom, MD

ABSTRACT: Background. A variety of nitinol-containing devices for transcatheter closure of atrial septal defects (ASD) has been widely used. However, there is concern about the release of nickel after nitinol device implantation. In this study, a platinum-coated nitinol device was braided from nanoplatinum-coated nitinol wires in order to prevent nickel release. The serum nickel levels before and after device implantation and the 1-year results were evaluated. **Methods.** Thirty-one patients, aged 4–59 years, and weighing 13.7–90.0 kg, underwent transcatheter closure. Blood samples for serum nickel levels were taken before, 1 day, 1 week, 1 month and 3 months after implantation. **Results.** Twenty-nine (93.6%) patients had a successful implantation. The mean ASD diameter was 19.7 ± 4.8 mm (range 10–30 mm). Procedure-related complications included transient brachial plexus injury in 1 patient, and transient dysrhythmia in 4 patients. All 29 patients had complete closure within 1 month after implantation. The mean serum nickel levels at baseline and at 1 day, 1 week, 1 month and 3 months after implantation were 0.65 ± 0.28, 0.63 ± 0.18, 0.67 ± 0.34, 0.55 ± 0.16, 0.52 ± 0.14 ng/ml, respectively. There was no significant difference in serum nickel levels before and after implantation. There were no device-related complications at 1-year follow up. **Conclusions.** Transcatheter ASD closure using a platinum-coated nitinol device can be performed safely and successfully with good outcomes. Nano-coating of platinum on nitinol wires can prevent nickel release following device implantation.

J INVASIVE CARDIOL 2008;20:279–283

Key words: atrial septal defect; transcatheter closure; platinum-coated nitinol device; nickel release

Nitinol, an alloy composed of 55% nickel and 45% titanium, has been widely used in medical products. With its superelastic and shape-memory properties, nitinol has generated new models of occlusion devices for transcatheter closure of atrial septal defects (ASD) and various other cardiovascular defects. These nitinol devices not only yielded excellent results, but also made for easy and safe device implantation. However, there is a concern about release of nickel after implantation of nitinol devices,[1,2] especially in patients with nickel allergy.[3-5] This is where platinum-activation of nitinol by nanotechnology has a role. By a process called plasma deposition, ultra-thin layers of platinum atoms are deposited on the surface of nitinol wires. The platinum layers prevent nickel release, but do not change the superelastic and shape-memory properties of nitinol. This concept has produced a new ASD occlusion device model that should resolve the nickel release problem.

The purpose of this study was to evaluate the 1-year results of platinum-coated nitinol device use in percutaneous transcatheter closure of ASDs and to study the difference in serum nickel levels before and after ASD closure with this device.

From the *Division of Pediatric Cardiology, Department of Pediatrics, †Division of Cardiology, Department of Medicine, ‡Department of Anesthesiology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand.

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Methods

The study protocol and informed consent form were approved by the ethics committee of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. All patients or their guardians gave written consent for their participation in the study.

Patient population. Patients > 3 years of age who had a secundum ASD and right ventricular volume load by transthoracic echocardiography (TTE) and in whom defect closure was indicated were invited to participate in the trial. Patients were excluded who had associated cardiac defects that needed open-heart surgery and in whom TTE demonstrated an ASD size > 30 mm and septal rims < 7 mm from the right pulmonary vein, coronary sinus, superior vena cava, inferior vena cava and mitral valve.

Device design. The device was braided from platinum-coated nitinol wires into 2 circular discs (acting as left and right atrial discs) with a central connecting waist (stenting at the ASD), and filled with 3 circular polypropylene sheaths (each was sewn at the rim of the right atrial disc, the central connecting waist and the left atrial disc, respectively) to enhance thrombogenicity (Figure 1). Although the structure of the device appears similar to the Amplatzer septal occluder *(AGA Medical, Golden Valley, Minnesota)*, the surface composition of the nitinol wires that was platinum coated, including the fabric used for occlusion, are different. The loading system consisted of a small tube that acted as a loader and a delivery cable that could be connected with the device by

Transcatheter Closure of Patent Ductus Arteriosus with a Self-Expanding Platinum-Coated Nitinol Device

Pornthep Lertsapcharoen, MD, Apichai Khongphatthanayothin, MD, Vidhavas La-orkhun, MD, Kanyalak Vithessonthi, MD, *Suphot Srimahachota, MD

ABSTRACT: Background. An occluding device for closure of patent ductus arteriosus (PDA) was developed from meshed nitinol wires coated with platinum for prevention of nickel release after implantation. **Objectives.** Our purpose was to assess the immediate and short-term results of transcatheter PDA closure with this device. **Methods.** Sixty patients (13 males and 47 females) underwent catheter-based PDA closure. The age ranged from 9 months to 65 years, with a median age of 4 years. The weight ranged from 4.2–65 kg, with a median of 15.2 kg. The mean PDA diameter at the narrowest segment was 4.7 ± 2.2 mm, with a range of 2.0–15.1 mm. Eighteen cases had serial blood samples for serum nickel analysis taken before and at 1, 3 and 30 days after device implantation. **Results.** The devices were successfully deployed in all 60 patients. There were no serious procedural complications. Color Doppler demonstrated complete occlusion rate of 78.3%, 90.0% and 100% at 1 day, 1 month and 1 year after implantation, respectively. There was no statistical difference in serum nickel concentrations between pre- and post-implantation. **Conclusion.** Transcatheter PDA closure using a platinum-coated nitinol device can be performed safely and successfully. There was no evidence of nickel release or nickel reaction after device implantation. This device model may be an alternative for PDA closure, especially in patients with potential nickel allergy.

J INVASIVE CARDIOL 2009;21:286–289

Key words: patent ductus arteriosus; transcatheter closure; platinum-coated nitinol device; nickel release

Nitinol, an alloy composed of 55% nickel and 45% titanium, has been widely applied in many medical implant products. During the past decade, a variety of nitinol-containing devices were designed and studied for catheter-based closure of atrial septal defect (ASD), patent foramen ovale (PFO) and patent ductus arteriosus (PDA). At present, Amplatzer occluders (nitinol-containing devices) have been used worldwide for transcatheter closure of ASD, PFO and PDA. A large amount of literature exists indicating excellent outcomes, even in very large defects.[1-8] For the nickel component in nitinol alloy, transient release of nickel into the circulation was demonstrated after ASD and PFO closure with the Amplatzer occluder (*AGA Medical Corp., Plymouth, Minnesota*).[9,10] There were a number of reported cases about systemic allergic reaction after closure of ASD, PFO[11-13] and PDA[14] with a nitinol-containing device. Thus, nickel release after nitinol device implantation is a concern, especially in patients with a history of nickel allergy. With nanotechnology, ultrathin layers of platinum coated on the surface of nitinol can avoid exposure of the nickel-containing alloy to the bloodstream and also prevent nickel release after device implantation. This concept presents an innovative model of a nitinol-based PDA occlusion device that is platinum-coated for prevention of nickel reaction after implantation. This device may be an alternative for PDA closure, especially in patients who have clinical evidence of nickel allergy, or in those who would like to avoid the possible adverse effects from nickel reaction.

The purpose of this study was to evaluate the immediate and short-term outcomes of transcatheter PDA closure with a platinum-coated nitinol device and to study the serial serum nickel concentrations before and after device implantation.

From the Division of Pediatric Cardiology, Department of Pediatrics, and the *Division of Cardiology, Department of Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand.

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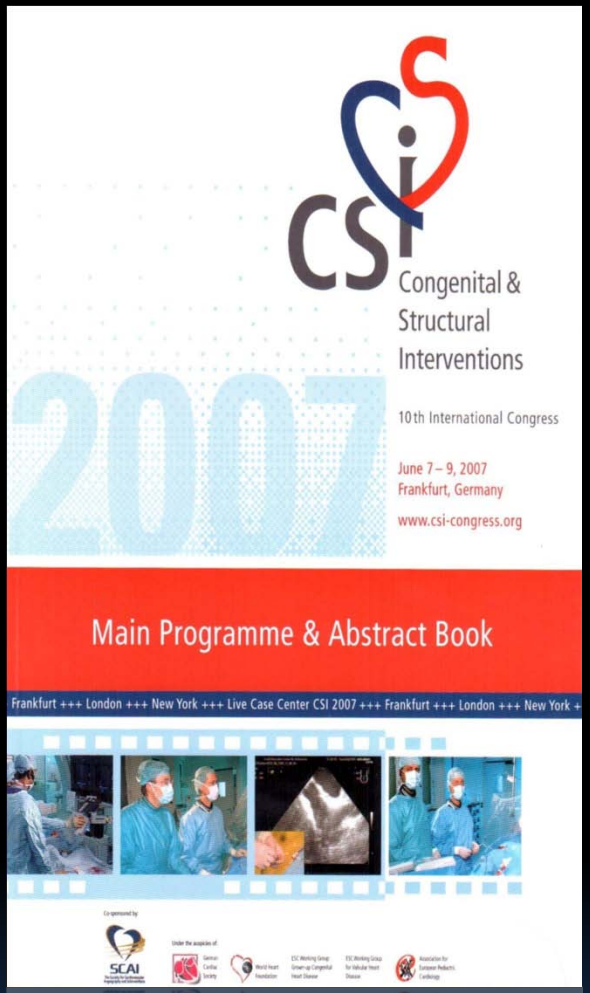
Methods

Patient population. The study protocol and informed consent form were approved by the ethics committee of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. The consent forms were signed by the patients or their parents for participation in the study. Patients beyond the neonate age who were diagnosed by clinical and echocardiographic findings with a PDA requiring closure were invited to participate in the study. Between August 2005 and April 2008, 60 patients (13 males and 47 females; 49 pediatric and 11 adult cases) were enrolled in the study. The median age was 4 years (range: 9 months to 65 years). The median weight was 15.2 kg (range: 4.2–65 kg).

Device design. The system consists of an occlusion device, a delivery cable and a loader. The device is braided with nitinol wires, nanocoated with platinum and filled with 5 polypropylene sheaths to enhance thrombogenicity (Figure 1). A delivery cable can be connected to the proximal end of the device with a screw connection for controlled release. The device is tubular in shape, with a diameter 2 mm larger at the distal end than at the proximal end. A thin disc is located on the distal end, which has a diameter 4 mm larger than that of the distal end. The size of the device is indicated by the diameter of its smaller proximal end. We demonstrated the safety and successful occlusion results with this device in our previous animal experiment.[15] Although this device appears similar to the Amplatzer Ductal Occluder,



Transcatheter Closure of Atrial Septal Defect with Self-Expandable Platinum-Coated Nitinol Device: Prevention of Nickel Release

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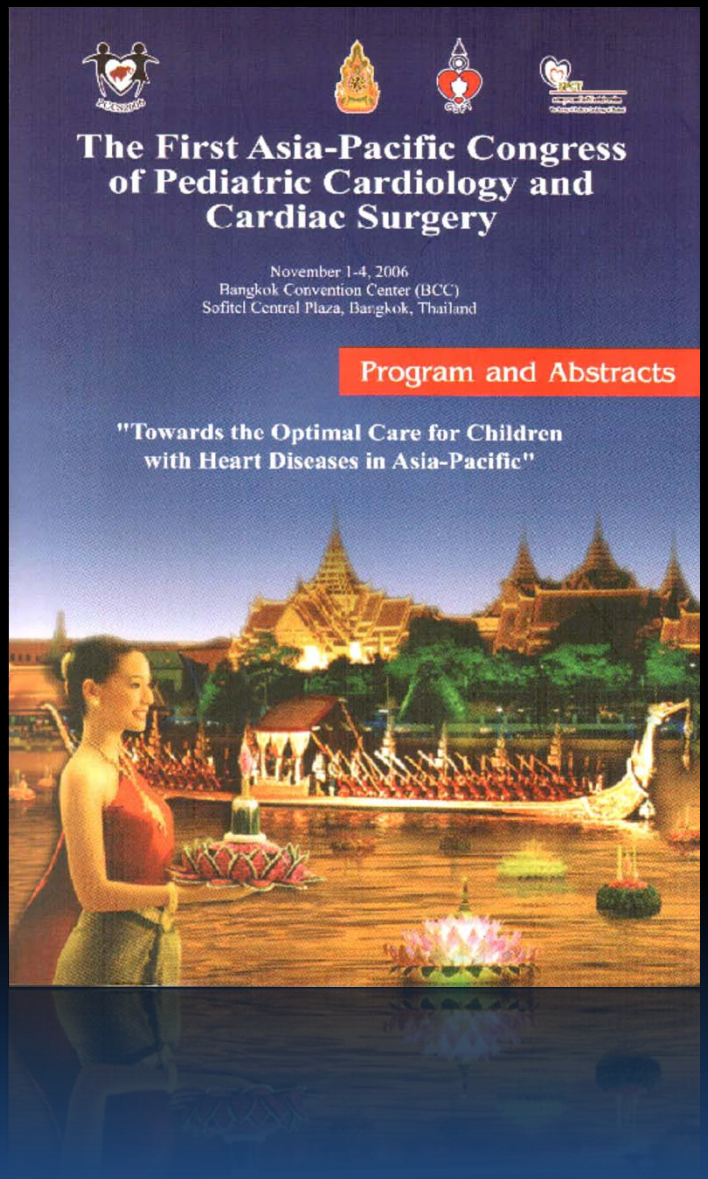
[1]Division of Pediatric Cardiology, Department of Pediatrics
[2]Division of Cardiology, Department of Medicine
[3]Department of Anesthesiology

Background: Recently, nitinol-containing occluding devices for transcatheter atrial septal defect (ASD) closure have been widely used. However, there are some concerns about nickel release after nitinol device implantation that may induce reaction in the patients especially in those with nickel allergy. In this study, the ASD device was braided from nanoplatinum-coated nitinol wires. Nano-coating of platinum on nitinol wires prevents nickel release by covering the exposed surface but maintains the super-elastic and shape-memory properties of the nitinol alloy.

Objectives: Our purpose was to assess the immediate and short-term results of transcatheter closure of ASD secundum using self-expandable platinum-coated nitinol ASD closure devices and to evaluate the serum nickel level before and after device implantation.

Methods and Results: Between July 2005 and May 2006, 31 patients (10 males and 21 females) underwent attempted transcatheter ASD closure. The median age was 11 years, ranged from 4 to 59 years. The median weight was 33 kg, ranged from 13.7 to 90 kg. Blood samples for nickel level were collected at before and at day 1, 7, 30 and 90 after device implantation. Twenty nine (93.6%) patients had successful implantation. Dislodgement of the device requiring emergent operation occurred in 1 patient and failure to deploy device in the other one. The procedure-related complications included transient brachial plexus injury in 1, transient complete heart block in 1, and transient junctional rhythm in 3 patients. The mean ASD diameter measured by transesophageal echocardiogram was 19.7 + 4.8 mm, ranged from 10 to 30 mm. The mean diameter of the device was 23.4 + 4.6 mm, ranged from 14 to 34 mm. There was no device–related complication during follow-up. All of the 29 successful patients had complete closure within 1 month after device implantation. There was no significant difference in serum nickel level before and after implantation.

Conclusion: Transcatheter ASD closure using self-expandable platinum-coated nitinol device can be performed safely and successfully. Nano-coating of platinum of nitinol wire can prevent nickel release after implantation.



FP47

TRANSCATHETER PLATINUM-COATED NITINOL OCCLUDING DEVICES: PREVENTION OF NICKEL RELEASE

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Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand

Background: Recently, Nitinol-based alloys are widely used in medical products, including transcatheter occluding devices in cardiac intervention. However, possibility of systemic nickel release leading to a rise in serum concentrations of nickel after device implantation should be concerned. In this study, the atrial septal defect (ASD) and patent ductus arteriosus (PDA) occluding devices were braided from Nitinol wires and coated with Nanoplatinum. With Nanotechnology, layers of platinum were coated on the surface of meshed Nitinol wires in order to prevent the exposure of Nitinol alloy to the blood after implantation.
Objective: Our purpose was to evaluate the change in serum nickel concentrations in the patients before and after transcatheter ASD and PDA closure with platinum-coated Nitinol occluding devices.
Method: In 50 patients (25 ASD cases and 25 PDA cases), blood samples were taken during the cardiac catheterization before and at 1, 3, 7, 30, 90 and 180 days after device implantation. Blood samples in 104 normal adult populations were also included. Serum nickel concentrations were measured by atomic absorption spectrophotometry.
Results: The mean serum nickel levels were 0.65, 0.63, 0.67, 0.55, 0.53 and 0.42 ng/ml, before and at 1, 7, 30, 90 and 180 days after device implantation in the ASD group; and 0.59, 0.57, 0.56, 0.55, 0.61 and 0.46 ng/ml, before and at 1, 3, 7, 30, 90 and 180 days after device implantation in the PDA group; respectively. The mean level in 104 normal populations was 0.67 ng/ml. There was no statistical difference in serum nickel concentrations before and after device implantation in both the ASD and PDA groups. The serum nickel levels in the 50 patients were not significant different from those in the normal populations.
Conclusion: Layers of platinum coated on the surface of meshed Nitinol-wires are able to cover the exposed surface of the Nitinol alloy. Prevention of serum nickel release by using platinum-coated Nitinol occluding devices is possible.

Cocoon
Septal Occluder

Cocoon
Duct Occluder

- Certified by Thai FDA.
- CE approval obtained in 2010.
- Over 2000 devices implanted in Thailand, Vietnam, Sri Lanka, India since 2008.

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Thank you.