MULTICENTRIC EXPERIENCE IN ARGENTINA WITH THE "CARDIA ULTRASEPT " DEVICE IN ATRIAL SEPTAL DEFECTS(ASD) CLOSURE.

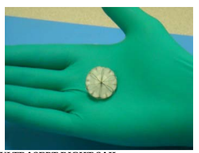
AUTHORS: Lucini, Victorio(*+^); Damsky Barbosa (*), Jesús; Ferrin, Liliana (**); Trentacoste, Luis(#+^);Marques Vitorino Adelia (*), Rivarola, Marcelo (#+^); De Dios Ana(*) , Granja, Miguel(+*^#).

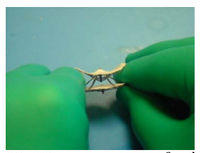
Hospital de Niños P. Elizalde(*), Hospital de Niños R. Gutierrez(#),Hospital Italiano(+), Sanatorio Mitre(^), Instituto de Cardiologìa de Corrientes(**).

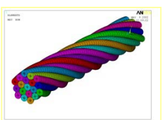
OBJECTIVE: Assessment of effectiveness and safety of the CARDIA ULTRASEPT ASD closure device, and short to medium term follow up of patients submitted to ASD closure with it .

MATERIAL AND METHOD: The ULTRASEPT is the VI generation of CARDIA ASD closure devices. It was carried out a retrospective analysis of 43 patients (pt) submitted to ASD Closure with this device between August 2010 and July 2012.
Data collection was done by patient´s Clinical Histories analyze.
We used the Ultrasept device in all pt.
The ULTRASEPT device is the last generation of CARDIA ASD closure devices. It has a ***double round disc design*** made of nitinol, covered with polyvinyl alcohol. It`s a self centering device, able to close ASD defects between 6-38mm. Outside diameter disc is 14mm larger than centering diameter (7mm per side)
Deliver Sheath: 9-14fr.
All the procedures were done under general anesthesia, and simultaneous Transesophageal Echocardiography.
Vascular access was femoral vein in all pt.
Heparin (100UI/kg) was given at the beginning of the procedure.
QP/QS were measured in all pt. with Ostium Secundum or Multifenestrated ASD. All pr. included in this study had significant left to right shunt (>2/1).
Patients with PFO have had history of TIA or STROKE without any concomitant disease that justified this event.
Balloon sizing with "stop flow" technique was done on pt with Ostium Secundum defects. In those pt. with a Patent Foramen Ovale (PFO) or a multifenestrated ASD, it wasn't done
During the quoted period, were submitted to the procedure 43 pt.
In the study it was assessed: **Effectiveness** of the implantation procedure and the **occurrence** of complications related to the procedure or the prosthesis used, and the persistence of residual shunt.

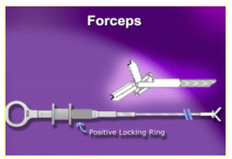

ULTRASEPT LEFT SAIL


ULTRASEPT RIGHT SAIL


LATERAL VIEW


Stranded-Wire Struts


Delivery SIstem



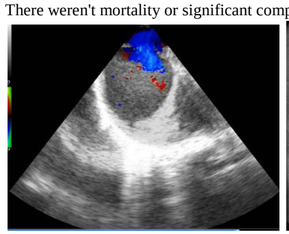
STUDY POPULATION	
Patients submitted	43pt.
Isolated Ostium Secundum ASD	32 pt.
Multiple or Multifenestrated ASD	5 pt.
PFO	5 pt.
Fontan fenestration	1 pt
Age: mean	25 y.o (range 3-69 y.o);
Weight: mean	47 kg. (range 12-83 kg).
Mean follow up	11.02m
Mean PAP	16.76mmHg
Asociated cardiac diseases	2pt .(1pt pulmonary stenosis and 1pt single ventricle)
ASD mean size	15mm

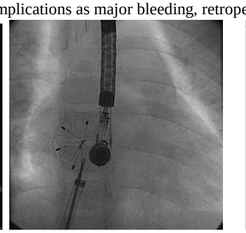
RESULTS	
Succesful implant	39 pt. (93%).
Non effective	3 pt .(7%).
-insufficient posteroinferior rim.	1pt.(2.3%)
-tear in the interatrial septum during procedure	1pt. (2.3%)
-embolized device	1pt. (2.3%
Mortality	0pt
Significant complication (retroperitoneal hematoma, major bleeding, erosion, vascular injury)	0pt
Device fracture	0pt.

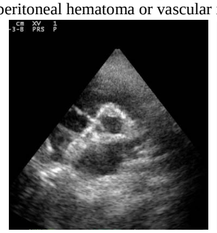
RESULTS:
Effectiveness: succesful implant 39 patients (93%).
Non effective procedure in 3 patients (6.9%):
1pt. (2.3%) the ASD couldn't be occluded due to insufficient posteroinferior rim.
1pt. (2.3%) had a tear in the interatrial septum during procedure (fig7), with unstable position of the device and significant residual shunt. The device was recaptured with a snare and the pt. sent to a programmed surgery.

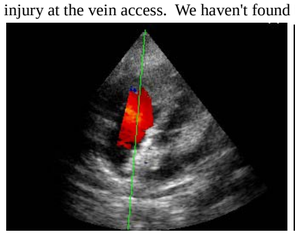
Complications: in 1pt. the device embolized at 24 hs, and was sent to surgery to retrieve the device and ASD closure, without complications.
One pt. had two ASD distant from each other. It was occluded the one with the biggest diameter and was left a 3 mm. defect without hemodynamic repercussion in the follow-up (FU).

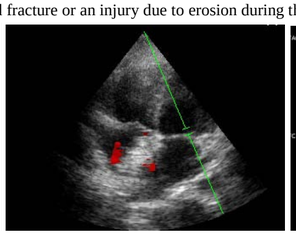
Residual shunt:
Transthoracic echo was done at 24hs, 1month, 3month and 6 month after procedure
97.6% (42pt) of the patient presented complete occlusion at 24hr control.
1pt presented residual shunt after procedure during follow up. It has 2 ASD distant each other. During the procedure It was closed the bigger defect, and the smaller remains patent without significant shunt
There weren't mortality or significant complications as major bleeding, retroperitoneal hematoma or vascular injury at the vein access. We haven't found fracture or an injury due to erosion during the short and medium term follow up.

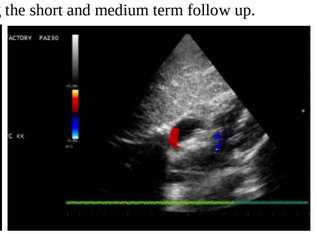

6yo. Pt. ASD 12mm (fig. 1)

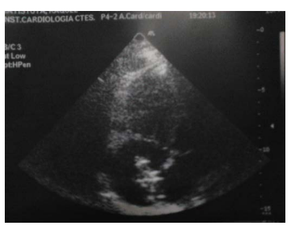

Fluoroscopic view after delivery (fig 2).


TEE after implant. (fig. 3)






3m. follow up. transthoracic eco (fig 4,5 and 6).


Unstable device after delivery (fig 7)

CONCLUSION: ASD closure with ULTRASEPT was safe, effective and well tolerated procedure, with very small number of major complication in our small series of patients.
Complete closure of the defect was achieved in the vast majority of patients at 24 hrs.