

### **Non-routine using of the Amplatzer Occluders and the Amplatzer Plugs in children**

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Background: Occasionally, some of medical devices used to treat congenital cardiac lesions in the cardiac catheterization laboratory are used on an off-label and non-routine basis. This article discusses about non-routine practice of the Amplatzer atrial and ventricular septal occluders and plugs. Methods: In a prospective study, from November 2006 to December 2011, used Amplatzer occluders and plugs in a pediatric cardiology ward were reviewed. Data were collected and analyzed. Results: The children (n=442) were catheterized to close their defects by using the Amplatzer devices. The mean age and body weight of the patients was  $5.87 \pm 4.2$  years (range 1 month-17 years) and  $20.94 \pm 13.73$  (range 2-87) kg. Routine using devices counts were 428 patients (96.8%) and non-routine ones were 14 (3.2%). Non-routine, off-label using indications and used devices were the Amplatzer Vasculer Plug 1 and 4 (coronary fistula occlusion in three patients, the left ventricle pseudoaneurysma occlusion in one patient, atypical PDA occlusion in one patient, anomalous pulmonary venous drainage occlusion in one patient), the Amplatzer Ductal Occluder I and II (perimembraneous VSD occlusion in one patient and muscular VSD occlusion in three patients), the Amplatzer Muscular VSD Occluder (very large PDA occlusion in two pulmonary hypertensive patients, the RPA to LA fistulous connection closure in one patient), the Amplatzer Septal Occluder (very large aortopulmonary window closure in one patient). The devices were successfully implanted in all of extra-ordinary or difficult, extreme cases. Conclusions: The use of a medical device outside of its approved label is commonly referred to as "off-label use." This study showed that the problem of off label, non-routine using the devices exists in pediatric cardiology. Percutaneous closure of defects with the non-routine Amplatzer devices is safe and effective with high success rate and high follow-up term outcome.