11:00

783-3 A New and Simple Method for Transcatheter Occlusion of Patent Ductus Arteriosus and Residual Shunts: Retrievable Coil Device

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For occlusion of patent ductus arteriosus (PDA) the currently used coil devices are not safe because of lack of deployment precision and retrievability. In 1992 we developed a new intravascular occlusion technique using memory-shaped retrievable stainless steel coils (Duct-Occlud, Pfm, Cologne). A snap-in mechanism keeps the coil attached to the core wire before final detachment. The new occlusion technique, therefore enables precise placement of coils.

We report first clinical results of transcatheter occlusion of PDA using the new coil device. From November 1992 to August 1994 all patients (n = 59, aged 4 months to 21 years, 4.5–64 kg) with a PDA underwent a transcatheter occlusion procedure. In 52 patients a coil implantation was successful. A balloon dilatation of a valvar pulmonary stenosis (n = 1) and a coarctation of aorta (n = 1) was successfully performed in the same session of PDA occlusion. In the remaining 7 patients coil implantation was not possible because of too small (PDA-diameter < 0.5 mm, n = 4) or too large (smallest PDA-diameter > 3 mm, n = 3) ductus size. The rate of total occlusion 6 months after implantation was 88%. Early complete occlusion (within 24 hours) was demonstrated in 39 cases (75%), delayed (within 6 months) occlusion in 7 (13%) cases. In 6 patients a residual shunt (1 moderate, 5 small) remained, in 2 of them a second coil (coil-in-coil-technique) was implanted 1 year after first attempt with following complete occlusion within few minutes. In all coil implantation procedures neither embolization of coils nor major complications occurred. No flow disturbances in descending aorta or pulmonary artery or mechanical hemolysis were registered.

Conclusion: Our first clinical results demonstrate the new transcatheter coil occlusion technique as a highly effective and very safe method. This technique seems to be the method of choice for occlusion of small and medium sized PDA.

11:15

783-4 Follow-up Results of Transvenous Occlusion of Patent Ductus Arteriosus with the Adjustable Buttoned Device

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During a 4-year period ending July 1994, 81 patients underwent transcatheter occlusion of patent ductus arteriosus (PDA) with the adjustable buttoned device at 22 institutions around the world under an IRB-approved custom-made device protocol. The device is a modified version of the Sideris' buttoned device for atrial septal defect closure. The patients were 11 mo to 65 years (median, 7.0 years) with weight range of 7.2 to 90 kg (median, 19 kg). The PDAs measured 1 to 15 mm (median, 4 mm) at the narrowest diameter; fifteen were larger than 8 mm and three larger than 10 mm with a Qp:Qs range of 1.3 to 3.2. They were occluded with devices measuring 15 to 35 mm; all but 10 were delivered via #7-French sheaths. Ten devices ≥ 25 mm were delivered to the implantation site via #8-French sheaths. 78 of 81 (96%) were implanted at first attempt. In all three with device dislodgment, the device was retrieved via the sheath and two of these underwent PDA occlusion with larger devices and third patient had elective surgical closure of PDA. Small residual shunts detected by color Doppler were present in 31 (39%) patients.

Forty-one patients were followed for 1 to 24 months (8 ± 7 mo) with clinical, chest x-ray and echo-Doppler evaluation. None required repeat intervention. The device was found intact on chest x-ray and echo. No evidence for thromboembolism, endocarditis or hemolysis was found nor was there evidence for descending aortic or left pulmonary artery obstruction. Percent incidence of residual shunt by color Doppler gradually decreased and was 39, 21, 15, 13 and 0% respectively at 1 day, 1, 6, 12 and 24 months following device implantation.

Based on these data it is concluded that 1) transvenous occlusion of PDA is feasible, effective and safe, 2) small-sized sheaths (7-French in most, 8-French in some) are adequate for all ductus sizes, 3) all types of PDAs (conical, tubular and short) and both long and short PDAs can be occluded because of the adjustable button loop design of the device, 4) further improvement/miniaturization may eventually result in extending the procedure to neonates and premature infants.

11:30

783-5 Intravascular Stents in Systemic Venous and Systemic Venous Baffle Obstructions

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For the management of systemic venous and systemic venous baffle obstructions, both surgery and isolated balloon dilation of are often unrewarding. Since 1991 we have managed such obstructions with intravascular stents. Twelve pts aged 3 mths–20 yrs (mean 8.2 yrs), have had 21 stents implanted in 13 systemic venous obstructions: 9/13 in central veins and 4/13 post atrial baffles for TGA. 12/13 obstructions were acquired and 1/13 congenital. 8/13 obstructions were symptomatic (SVC syndrome 6/8) and 5/13 were asymptomatic.

Immediate Results: Obstruction was complete requiring transeptal needle perforation in 4/13. Post-stent implantation, the diameter of the obstruction increased from 2 ± 2.4 mm (range 0–8.5 mm) to 11.4 ± 3.7 mm (range 7.6–20 mm, $p < 0.001$). The gradient decreased from 10.8 ± 8.1 mmHg (range 0–20 mmHg) to 0.9 ± 1.3 mmHg (range 0–4 mmHg, $p < 0.001$). There was residual angiographic obstruction in 1/13 pts. Symptoms resolved in 6/8 and improved in 2/8 symptomatic pts. No complications were incurred.

Follow-up Results: 6/13 obstructions were restudied 2–13 mths post stent implantation. All stents remain patent with no stent fracture or compression. No stents required redilation. Neointimal hyperplasia was seen in 5/6 stents. Differences between immediate post stent and follow-up lumen size (13 ± 4.7 mm vs 11 ± 4.7 mm) and gradients (1 ± 1.6 mmHg vs 0.7 ± 1.2 mmHg) were not significant. In 1 pt, with 4 serial stents, 1 stent had 'unlocked' and rotated, but remained unobstructed.

Conclusions: Stent implantation in systemic venous obstructions is safe and effective, even where obstruction is complete. Longterm follow-up is required to determine if neointimal proliferation will require redilation. We postulate intravascular stents will become the treatment of choice for selected systemic venous and systemic venous baffle obstructions.

11:45

783-6 Complications of Pediatric Cardiac Catheterization: A Prospective Study

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A study of adverse events related to diagnostic (DIAGN) or interventional (INTERV) cardiac catheterizations was undertaken beginning January 1, 1987 through December 31, 1993 involving 4,952 studies. Patient ages ranged from 1 day to 20.6 years. There were 1,472 (29.6%) INTERV procedures, 3,117 (62.7%) DIAGN (angiographic and hemodynamic) and 381 (7.7%) electrophysiologic (EP) studies. A number of patients underwent both INTERV and EP studies at the same procedure.

One or more complications were reported in 498 (10.1%) patients. Major complications (death n = 35, cardiac arrest n = 7, cardiac perforation n = 7, complete heart block n = 14, ventricular tachycardia or fibrillation n = 7) were reported in 70 (1.4%) cases: 63% percent of deaths occurred in pts < 1 year old. Minor complications occurred in 476 cases including 183 (38.4%) arterial complications, with residual pulse weakness after therapy in only 14 (2.9%) pts. The incidence of complications was 9.5% in DIAGN (56 major; 268 minor), 11.6% in INTERV (25 major; 164 minor), and 7.4% in EP studies (8 major; 29 minor). Age, type of cardiac catheterization and complications are as follows:

Age	All Patients # Compl./Total	DIAGN # Compl./Total	EP # Compl./Total	INTERV # Compl./Total
<1 mos	78/471 (16.5%)	59/399 (14.8%)	1/9 (11.1%)	18/64 (28.1%)
1–6 mos	80/497 (16.1%)	51/356 (14.3%)	0/9 (0%)	29/135 (21.5%)
6 mos–1 yr	68/465 (15.0%)	49/352 (13.9%)	2/5 (40%)	17/109 (15.6%)
>1 yr	271/3,519 (7.7%)	139/2,010 (6.9%)	26/358 (7.3%)	107/1,164 (9.2%)

Pediatric cardiac catheterization is not a risk free procedure, and the incidence of major complications is low. However, with incrising INTERV procedures the incidence of major/minor complications may increase.