Editorial

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Pulmonary Artery Stents-Still "Off Label"

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In this issue of Korean Circulation Journal, Ko et al.[1] report on the effectiveness and safety of percutaneous implantation of pulmonary arterial stents in congenital heart disease between 1999 and 2010 in one institute. Since Dr. Mullins recognized the potential for stents to treat pulmonary arterial stenosis effectively which were compared to the surgical methods, many reports about these experiences have been reported. Most of the studies demonstrated the effectiveness of pulmonary arterial stenting by increasing pulmonary artery size, reducing pressure gradients, decreasing right ventricular pressure and improving the disparity in pulmonary arterial blood flow.[2-5] However, there are few reports with long-term follow-up data in a large population of patients, especially no multicenter, randomized controlled studies as Ko et al.[1] noted. Therefore, in spite of the efforts of many doctors, the use of stents to treat pulmonary arterial stenosis is still considered "off label"-i.e., not approved by the Food and Drug Administration, even though the investigational device exemption (IDE) was obtained by Dr. Mullins' efforts. Recently, Law et al.[6] reported a long-term follow-up study including Dr. Mullins' very first human implantation of stents in the pulmonary artery. They confirmed that intravascular stents maintained their safety and efficacy over 15-20 years in relieving branch pulmonary artery stenosis. However, the follow-up of this study also has limitations, that is, 18 of 68 patients were lost to follow-up less than 5 years after stent implantation.

Current issues in pulmonary arterial stent implantation including jailed side branches, redilation of the stent, stenting at early age such as infancy and stent fracture. In Law's study,[6] 27 of 55 stents (49%) resulted in partial or complete jailing of a side branch. Only 5/27 (19%) of the jailed vessels had complete occlusion of the jailed side branch and the group of patients with a compromised side branch flow still had a sustained reduction in right ventricular pressure; thus, jailing of a side branch may be acceptable if the gain is greater than the loss of flow to the jailed vessel. Nevertheless, we should try to use an open-cell stent such as the Mega LD or Maxi LD (EV3, Plymouth, MN, USA) in case of unavoidable jailing side branches. Regarding further stent dilation or additional stent implantation, several studies[6-8] confirmed its safety and effectiveness, and Stapleton et al.[7] found that patients who had their initial stents placed before age 10 years had an increased risk of needing further interventions at subsequent catheterizations. Initial vessel diameter or percent change in vessel diameter post stent were not associated with increased risk for repeat interventions. Stanfill et al.[9] showed that stent implantation in infants was safe and effective, and serial redilation was also possible. However, they emphasized that efforts should be made to implant large stents with adult diameter potential in children who will not require further cardiac surgery and small- or medium-sized stents in carefully selected infants who will ultimately require future cardiac surgery. Stent fracture is rare and asymptomatic in pulmonary artery stenting, but frequently occurs in the right ventricle to pulmonary artery conduit stent, and it may cause conduit restenosis or stent fragment embolization. Although fluoroscopy remains the gold standard to diagnose stent fractures, lateral projection chest radiographs may improve detection.[10]

The study of Ko et al. showed us the effectiveness and safety of percutaneous implantation of the pulmonary artery stent in short term result as many previous reports have done. It is not a long term follow-up result, also not a randomized controlled study compared to a surgical treatment. Among the 42 patients, only 8 patients had follow-up angiography. The study did not cover the current issues of pulmonary artery stent mentioned above. The authors worried about harmful vessel damage in using the Genesis stent (Cordis, Warren, NJ), but this was not correct because the Genesis stent

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can be introduced through an 8F sheath with a 14-16 mm balloon catheter. They implanted a stent in a 0.5 year-old infant, and we really want to know what the indication was, what kind of stent was used, what was the follow up result, etc. To add strength to this study, they should give us more detailed information about the complicated cases, and then we would share their painful experiences and might avoid the same complications in our practices.

In conclusion, the effectiveness and safety of the pulmonary artery stent for pulmonary artery stenosis are definitely accepted in many centers caring for a large number of patients with congenital heart disease. However, its use is still considered "off label". This means we should try to report on the detailed long term follow-up of patients who underwent pulmonary artery stent implantation to achieve an approval from the FDA.

REFERENCES

1. Ko HK, Kim YH, Yu JJ, et al. *Effectiveness and safety of percutaneous transcatheter implantation of pulmonary arterial stent in congenital heart disease. Korean Circ J 2012;42:40-5.*
2. Fogelman R, Nykanen D, Smallhorn JF, McCrindle BW, Freedom RM, Benson LN. *Endovascular stents in the pulmonary circulation: clinical impact on management and medium-term follow-up. Circulation 1995;92:881-5.*
3. McMahon CJ, El-Said HG, Grifka RG, Fraley JK, Nihill MR, Mullins CE. *Redilation of endovascular stents in congenital heart disease: factors implicated in the development of restenosis and neointimal proliferation. J Am Coll Cardiol 2001;38:521-6.*
4. O'Laughlin MP, Slack MC, Grifka RG, Perry SB, Lock JE, Mullins CE. *Implantation and intermediate-term follow-up of stents in congenital heart disease. Circulation 1993;88:605-14.*
5. Shaffer KM, Mullins CE, Grifka RG, et al. *Intravascular stents in congenital heart disease: short- and long-term results from a large single-center experience. J Am Coll Cardiol 1998;31:661-7.*
6. Law MA, Shamszad P, Nugent AW, et al. *Pulmonary artery stents: long-term follow-up. Catheter Cardiovasc Interv 2010;75:757-64.*
7. Stapleton GE, Hamzeh R, Mullins CE, et al. *Simultaneous stent implantation to treat bifurcation stenoses in the pulmonary arteries: Initial results and long-term follow up. Catheter Cardiovasc Interv 2009;73:557-63.*
8. Tomita H, Nakanishi T, Hamaoka K, Kobayashi T, Ono Y. *Stenting in congenital heart disease: medium- and long-term outcomes from the JPIC stent survey. Circ J 2010;74:1676-83.*
9. Stanfill R, Nykanen DG, Osorio S, Whalen R, Burke RP, Zahn EM. *Stent implantation is effective treatment of vascular stenosis in young infants with congenital heart disease: acute implantation and long-term follow-up results. Catheter Cardiovasc Interv 2008;71:831-41.*
10. Breinholt JP, Nugent AW, Law MA, Justino H, Mullins CE, Ing FF. *Stent fractures in congenital heart disease. Catheter Cardiovasc Interv 2008;72:977-82.*

http://dx.doi.org/10.4070/kcj.2012.42.1.8