

What works best in congenital heart disease? Comparing two interventions for treatment of Aortic Coarctation

By Kaya Olczak, Maximilian Salcher and Huseyin Naci

Aortic coarctation is a congenital heart disease characterised by the narrowing of the aorta, commonly resulting in increased morbidity and decreased life expectancy. Despite a relatively low number of affected patients (3 to 4 cases per 10 000 live births) the follow-up after intervention procedures is expensive, due to required ongoing monitoring of disease progression and relapse, and possible late complications. The potential loss of a large number of life years through early death in young patients and high costs of follow-up have put this disease in the focus of the FP7-funded **CARDIOPROOF** project, in which LSE Health is leading on evidence synthesis and economic modelling.

How can aortic coarctation be treated and which treatment is best?

Initially only treated surgically, the quest for less invasive treatments has led to the development of two transcatheter interventions for aortic coarctation: balloon dilatation and stenting. Balloon dilatation involves the inflation of a balloon within the area of stenosis, stretching the walls of the aorta and increasing its diameter. This mechanism can, however, lead to aortic wall injuries and subsequent development of aneurysms. The implantation of a stent can theoretically prevent damages to the aortic wall and provide a more sustained relief of obstructions. At the moment, guidelines on aortic coarctation by the American Heart Association and the European Society of Cardiology do not provide a recommendation of which procedure to use. In collaboration with a team of cardiologists at the German Heart Institute in Berlin, we (Maximilian Salcher and Huseyin Naci) systematically collected and synthesised for the first time the evidence comparing the two available transcatheter interventions to answer the question: which intervention leads to better outcomes in patients with aortic coarctation?

Better immediate outcomes after stenting

Controlled trials, including the gold standard randomised controlled trials (RCT), were scarce or not at all existent to answer the research question. Therefore, a three-pronged analytic strategy was pursued: first, results of single-arm studies were pooled and overall estimates of the effectiveness of the two interventions obtained. Second, we analysed comparative studies that included both stenting and balloon dilatation. Finally, we conducted network meta-analysis, which includes both direct comparison between the two interventions of interest and indirect comparison of balloon dilatation and stenting via the third common treatment, surgery. Despite the limitations of the review due to the low standard of the evidence assessed, stenting appeared to achieve better immediate relief of the stenosis than balloon dilatation, and these results were consistent across all three analyses. We also found that significantly fewer patients who had undergone stenting than those that had undergone balloon dilatation experienced severe complications during hospital stay (for detailed results please refer to the **full publication**). Nevertheless, a “one treatment fits all” approach is not appropriate as the decision to perform one or the other intervention is informed by a multitude of factors, including the anatomy and shape of the patient’s aorta.

State of the evidence: room for improvement

The overall state of the evidence assessed was of low standard. There is widespread consensus that RCTs are the gold standard in evaluation research. Random allocation of participants to either an intervention or a control group, along with a protocol-driven controlled environment  ensures

internal validity: the observed treatment effect can be attributed to the treatment under investigation. Non-randomised studies, on the other hand, are exposed to risk of bias through the lack of random allocation of study participants. Although more than 7700 patients have undergone either balloon dilatation or stenting for treatment of aortic coarctation over the past 25 years, the evidence base for these interventions consists of mostly case series and single-arm studies, and no RCTs. The lack of rigorously conducted controlled studies suggests that there is room for improvement in the evidence base for interventional treatment of aortic coarctation. Future collaborations between clinical centres performing these interventions would significantly improve the current state of evidence and generate much needed information regarding the comparative effectiveness of balloon dilatation and stenting in patients with aortic coarctation.

Our systematic review of balloon dilatation and stenting for treatment of aortic coarctation highlighted some shortfalls in the evidence base on the comparative effectiveness of these two interventions. Available evidence suggests better immediate outcomes after stenting compared to balloon dilatation.

Further Information:

M Salcher, H Naci, T J Law, T Kuehne, S Schubert, M Kelm (2016) *Balloon Dilatation and Stenting for Aortic Coarctation: A systematic Review and Meta-Analysis*, *Circulation: Cardiovascular Interventions*, 9, 6, e003153.

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