

Comparison of Surgical and Transcatheter Treatment for Native Coarctation of the Aorta in Patients \geq 1 Year Old. The Quebec Native Aortic Coarctation Study.

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INTRODUCTION

In 1945, Crafoord et al and Gross independently reported successful surgical repair for coarctation of the aorta (1,2). Since then, several techniques for coarctation repair have been reported, including resection with end-to-end anastomosis, patch plasty with prosthetic material, homograft, and autologous subclavian artery and bypass grafting with prosthetic tube grafts or autologous vascular tissue. For more than 50 years, surgical repair has been the standard of care for aortic coarctation, with good acute and long-term results (3). Nowadays, surgical mortality is less than 1% in patients with simple coarctation, and surgical morbidity is low, including paradoxical hypertension, left recurrent laryngeal nerve paralysis, and phrenic nerve injury. Spinal cord ischemia or mesenteric arteritis with bowel ischaemia are exceedingly rare. Recoarctation after surgical repair in patients older than 1 year occurs in less than 10% of the cases, and the incidence of aneurysm formation at mid and long-term follow-up is low (about 5%) and varies depending on surgical technique. Incidence is highest with synthetic patch aortoplasty and lowest (0% in some series) when end-to-end anastomosis technique is used (4,5).

In 1982, balloon angioplasty was first used to treat aortic recoarctation (5). In this setting, results of percutaneous treatment showed a successful procedural rate higher than 75% with a low complication rate (6,7). Considering the higher risks related to a surgical reintervention, transcatheter approach has been accepted nowadays as the standard of care for aortic recoarctation (8). Balloon angioplasty of unoperated (native), coarctation was first described by Lababidi in 1983 (9), and has been shown to be equally effective as balloon angioplasty for recoarctation (10). The procedure produces a satisfactory gradient reduction in approximately 80% of patients, with an acute complication rate (including aortic dissections and rupture) comparable to that observed in recoarctation angioplasty

(10,11). However, restenosis occurs in 14% to 35% of cases (12), and the incidence of aortic aneurysm formation is highly variable depending on the series, ranging from 1% to 43% (11,13,14). Considering all these data, it is quite surprising that no large randomised studies have compared surgical repair with balloon angioplasty for the treatment of native aortic coarctation. In fact, only one study including 36 patients has compared surgical (16 patients) and percutaneous treatment (20 patients) for native aortic coarctation (15). In this prospective randomised study, reduction in peak systolic pressure gradient across the coarctation was similar immediately after both balloon angioplasty and surgery. However, restenosis at follow-up tended to occur more frequently in patients submitted to balloon dilation (25%) compared to surgical cohort (6%), and aneurysm formation was higher in the angioplasty group (20%) compared to the surgical group (0%). Although this study was small and statistically underpowered, such results raised some concerns about the appropriateness of balloon dilatation for unoperated aortic coarctation.

Primary stent implantation has been suggested as potentially superior to balloon angioplasty for the treatment of native aortic coarctation and aortic recoarctation. Stent implantation limits elastic recoil and potentially reduces aneurysm formation by reducing the amount of balloon stretch required. The incidence of suboptimal gradient reduction is low (<5%), as is the rate of restenosis (16,17). Although no comparative trial has been performed with surgical treatment, several groups have already claimed that this should be the standard treatment for aortic coarctation in adolescents and adults. However, the procedure has an incidence of about 5 to 10% of severe vascular access complications due to the large catheters used, and complications related to stent implantation (stent migration, balloon rupture) have been reported in 5 to 25% of cases. Recently, Agnoletti et al. have reported an incidence of complications related to aortic stent implantation of 25%, with 6% of cases needing urgent surgery (18). Also, even though anecdotic, cases of aortic rupture leading to patient's death have been reported following stenting (19,20). Despite the general acceptance of the idea that stents prevent aneurysm formation, some aortic aneurysms have been diagnosed at mid-term follow-up, with an incidence as

high as 17% in the patients who had had control angiography (21). In fact, no studies have systematically evaluated the presence of aortic aneurysms following stent implantation, and the exact incidence of such complication is unknown. Despite these complications and pitfalls catheter intervention (balloon angioplasty, with stent implantation in patients > 25 kg) has been adopted as the standard of care for aortic coarctation in many centres over the world, including ours and several others in the province of Québec. However, it seems advisable to undertake a study comparing this treatment with surgical repair, which has been demonstrated to be effective for more than 50 years.

This research proposal will compare surgical and percutaneous treatment for the treatment of native aortic coarctation in patients older than 1 year. This will be a retrospective study comparing the two strategies in all Quebec centres treating such type of patients. The results of this study will provide important data regarding the best therapeutic strategy for native aortic coarctation. Also, it could be the basis for the realisation of a prospective randomized study comparing the two treatment strategies.

OBJECTIVES

1. To compare the acute results and complications obtained by surgical repair and transcatheter treatment (balloon angioplasty +/- stent implantation) of native aortic coarctation.
2. To compare the mid-term outcomes regarding reintervention rate, aneurysm formation, and residual hypertension of patients who had surgical repair vs those who underwent transcatheter treatment.

STUDY DESIGN

Multicenter retrospective study including all patients older than 1 year old who have undergone an intervention (surgical or percutaneous) for the treatment of isolated native aortic coarctation during the last 6 years in all Quebec hospitals such type of treatment.

INCLUSION CRITERIA

Patients older than 1 year who underwent surgical or percutaneous treatment of a native aortic coarctation in Quebec hospitals during the last 6 years (from January 1998) and who have at least one month follow-up.

EXCLUSION CRITERIA

1. Patients younger than 1 year
2. Patients who had other concomitant cardiac pathologies for which surgery and/or transcatheter treatment was foreseen at the same time or within the next 5 years following aortic coarctation repair or dilatation.
3. Aortic arch hypoplasia (Z value < -2) or long-segment coarctation not amenable to balloon angioplasty.
4. Patients who have been lost at follow-up, with less than 1 month follow-up.

STUDY ASSESSMENT

I. Preintervention

Baseline data at the time of intervention, including age, sex, weight, height, history of hypertension, medication, left ventricular hypertrophy, presence of all other coexisting cardiac abnormalities, and all available data about anatomic and functional severity of aortic coarctation will be recorded. All these data will be recorded by reviewing the medical records of the patients.

II. Intervention and acute results

The type and date of intervention (surgical vs percutaneous), as well as the hospital stay will be recorded for all patients.

In case of surgical treatment, the technique used will be specified.

In case of transcatheter treatment, technical details of balloon angioplasty (maximal diameter of the balloon used/diameter of descending aorta) and stent implantation (type of stent, maximal diameter of the balloon used to expand the stent/diameter of descending aorta) will be recorded.

III. Acute and subacute complications

All the complications that occurred within the first 30 days of the intervention (including per-procedure complications, even those not leading to any consequences) will be recorded. Each complication have to be dated and commented on detail in the case-report form.

All complications will be evaluated by an investigator team composed of at least one interventional cardiologist or pediatric cardiologist, and one cardiac surgeon.

Major complications will be defined as those requiring urgent reintervention, those leading to any sequelae, those hemorrhagic ones requiring blood transfusion and those leading to patient's death.

IV. Follow-up

At the latest follow-up available in the medical record of the patient, the presence of clinical symptoms, hypertension, medical treatment, systolic transcoarctation gradient by Doppler measurement, and arm-leg gradient by cuff measurement will be recorded. Upper limb blood pressure at the latest follow-up will also be recorded. If any complications including reintervention occurred during follow-up, it will be dated and recorded with detailed comments.

If the patient has not been followed at the same institution that performed the aortic coarctation treatment, and some information is missing, a clinical evaluation by one of the investigators will be necessary. If not, the patient will not be included in the study.

If any aortic imaging techniques have been used during the follow-up to evaluate the results of the intervention and to look for the presence of aortic aneurysms, the results of these tests will be provided in the case-report form. If no imaging techniques have been used during the mid to long-term follow-up (≥ 1 year), the investigators strongly suggest performing contrast-enhanced magnetic resonance imaging or multislice computed tomographic angiography for the evaluation of aneurysm formation at the level of the coarctation repair/dilatation. As stated in the introduction section, aortic aneurysm appears in 5% to 20% of the cases following aortic coarctation repair (surgical or percutaneous, with or without stent implantation), and the presence of such complication leads to an increased risk of aortic rupture and death (3). Therefore, the use of an imaging technique during follow-up should be considered as clinically indicated, and not for research purposes.

Aneurysms will be defined as either a dilation at the coarctation site with a diameter $>150\%$ of the aortic diameter at the level of the descending aorta or a discrete saccular dilation at the site of the coarctation of >2 mm. All images will be analysed by two experienced physicians (one pediatric cardiologists and one radiologist).

SAMPLE SIZE AND STATISTICAL ANALYSIS

The medical records of all patients diagnosed with aortic coarctation treated in the last 6 years (January 1998 - March 2004) in the CHUL of Quebec, Montreal Children's Hospital, Montreal Heart Institute, Quebec Heart Institute, and Sainte-Justine hospital will be reviewed. The total number of patients in all centres will be about 120. Assuming a drop-out of 25% of reviewed cases who did not fulfil the inclusion criteria, the final number of patients included will be about 90 (about 40% of them treated by dilation, and 60% by surgery).

Discrete variables will be expressed as proportions and continuous variables as means \pm standard deviation, or median with its interquartile range. The chi-square test will be used to compare categorical data, and the student's t-test or the Mann-Whitney test will be used to compare continuous variables.

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