

Original Article

Balloon angioplasty is preferred to surgery for aortic coarctation

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Abstract Objective: We sought to use techniques of decision analysis to compare values or preferences for balloon angioplasty versus surgery for treatment of aortic coarctation in children. **Background:** Balloon angioplasty and surgery for aortic coarctation have a differing spectrum and prevalence of outcomes and complications, making direct comparison difficult. **Methods:** From articles reporting treatment outcomes of native aortic coarctation from 1984 through 2005, we determined the baseline probabilities of successful treatment, complications, recoarctation and aneurysmal formation. Decision trees with baseline probabilities of these outcomes were formulated. Standard gamble interviews of medical professionals determined the preferences for the various outcomes. Final cumulative preference scores were further adjusted for both perceived mortality and procedural disutility. Sensitivity analyses determined threshold probabilities at which the score advantage changed. **Results:** Final preference scores for balloon angioplasty, with a mean of 0.8999, and standard deviation of 0.0236, were significantly higher than for surgery, at a mean of 0.8873, and standard deviation of 0.0246. The score advantage for balloon angioplasty did not change when adjusted for disutility, or mortality. Sensitivity analysis showed that even if the probability of periprocedural death or major complications for surgery was reduced to none, balloon angioplasty would still be preferred, except for neonates, where if surgical mortality were reduced below 4%, then surgery would be preferred. Probabilities for periprocedural death or major complications associated with balloon angioplasty would have to exceed plausible thresholds before surgery would be preferred. **Conclusions:** After accounting for preference-weighted probabilities of outcomes, balloon angioplasty is preferred over surgery for all plausible situations as the initial treatment for native aortic coarctation in children.

Keywords: Congenital cardiac surgery; interventional catheterization; decision analysis

PERCUTANEOUS TRANSCATHETER BALLOON ANGIOPLASTY was first used as an alternative to surgical repair for children with aortic coarctation in the early 1980s.^{1–4} There have only been two small prospective randomized controlled trials comparing surgical repair and balloon angioplasty for native aortic coarctation.^{5,6} This type of direct comparison is difficult, as the characteristics,

and potential complications of both procedures differ considerably, as well as the probabilities and values, preferences, or weightings of these outcomes. Clinical trials cannot simultaneously take into account these differences. Comparisons of non-randomized case series are also problematic for many reasons, including that the literature for surgery is not contemporary compared to balloon angioplasty. While analysis using methods of cost-effectiveness have been applied, formal comparisons of cost may not reflect the preferences of physicians and patients for different outcomes.^{7,8} The incorporation of these preferences

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into clinical decision-making based on the best available research evidence is the cornerstone of the practice of evidence-based medicine. Decision analysis is a useful method to incorporate the broad spectrum of outcomes and preferences into a comparison, together with determination of threshold values for changes in preferred approach. We present a decision analysis designed to determine whether balloon angioplasty or surgery would be the preferred treatment in childhood for native aortic coarctation across various age groups.

Methods

Formulation of the decision tree: A MEDLINE search was performed to identify published reports that examined the outcomes of children treated for native aortic coarctation. Search criterions included the following terms: "coarctation of the aorta", "balloon angioplasty", "surgery" or "surgical repair". Only articles published in English from 1984 through 2005 were used, restricting them to those examining primary repair or procedures for native aortic coarctation in children. Articles examining coarctation of the descending aorta, hypoplastic aortic arch, treatment of residual or recurrent coarctation, or the use of endovascular stents were excluded. The most recent article was used in situations where multiple articles were published using the same group of patients.

The results of the articles were stratified by age into 3 groups, neonates aged less than 3 months, children aged from 3 months to 12 years, and adolescents aged greater than 12 years. The probabilities of the following events were determined for each article

- perioperative death
- resolution of the gradient across the coarctation
- major and minor complication
- presence of residual or recurrent coarctation
- aneurysmal formation.

Individual decision trees were formulated for each article, and were combined to create a final decision tree for each age group. The contribution that each individual article made to the combined final decision tree was weighted based on the number of patients reported in that article, such that articles with a greater number of patients contributed more information to the baseline probabilities in the final decision tree. The probability of each of the events occurring was assumed to be independent of each other. The events occurred in either the periprocedural or follow-up periods.

Decision trees were formulated by referring to the initial branch point as the decision node, and dividing

Table 1. Major and minor complications for balloon angioplasty and surgical repair.

Balloon angioplasty	Surgical repair
Major complications <ul style="list-style-type: none"> ● Aortic perforation or rupture ● Arrhythmia with cardiopulmonary arrest ● Cardiac perforation ● Stroke 	Major complications <ul style="list-style-type: none"> ● Spinal cord injury ● Arrhythmia with cardiopulmonary arrest ● Stroke
Minor complications <ul style="list-style-type: none"> ● Vascular obstruction or transaction ● Arrhythmia ● Haemorrhage ● Seizures ● Allergic reaction to contrast dye 	Minor complications <ul style="list-style-type: none"> ● Wound infection ● Arrhythmia ● Chylothorax ● Haemorrhage ● Phrenic or laryngeal nerve injury ● Seizures ● Respiratory complications

the tree into the two different options for treatment options, namely balloon angioplasty versus surgical repair. Within each arm, the tree continues to branch out. Each branch is referred to as a "chance node," and represent points where different events, such as complications, periprocedural death, aneurysms and recoarctation, may occur. Each chance node is also assigned a probability, which represents the probability of each event occurring. These probabilities are based on the weighted data from the articles. The first chance node represents the probability of periprocedural death, followed by the chance nodes for the probabilities of a successful procedure, leaving a residual gradient less than 20 millimeters of Mercury, major and minor complications, recurrent coarctation, and aneurysmal formation. Major and minor complications for balloon angioplasty and surgery are defined in Table 1, based on findings in the reviewed literature. Recurrent coarctation was defined as a recurrence of a gradient across the repair site of greater than 20 millimetres of mercury based on blood pressure or angiographic measurements in a successfully treated patient, or an increase in the residual gradient after an initially unsuccessful procedure. In the decision tree, branching stops at end nodes which represent different combinations of the various events. In other words, a patient with a successful repair, no major complications, no minor complications, no recoarctation and no aneurysmal formation, would represent one complete branch to the end node.

Determination of preferences: Preference scores are scores representing subjective preferences in a quantitative fashion. Preference scores were determined by

a standard gamble interview. A perfect outcome is assigned a preference score of one, while certain death is assigned a preference score of zero. All other combinations of outcomes are assigned scores between these two values based on the standard gamble interview.

During the process of interviewing, hospital staff determined the preference scores due to their familiarity with management of aortic coarctation, potential complications, and outcomes. Fifteen individuals were interviewed, specifically 3 staff cardiologists, 5 cardiology fellows, 4 cardiovascular research assistants, and 3 experienced nurses working in our clinic for paediatric cardiology. Individuals were given the situation of a child of a particular age with isolated native aortic coarctation. At the start of the interview, individuals were asked to estimate what they believed to be the percentage mortality associated with each option for treatment for each of the age groups. They were then asked to state which option they favoured, either perfect surgery or perfect balloon angioplasty. An initial standard gamble interview was done to determine the amount of "disutility" associated with the alternative procedure. For example, if an individual stated that they would prefer a perfect balloon angioplasty over a perfect surgery, they were then asked whether they would prefer a perfect surgery with no residual gradient and no complications as opposed to a perfect balloon angioplasty but associated with 5% chance of periprocedural death. If they responded to this choice that they would prefer surgery, the choice was re-presented, but with a 1% chance of death. The chance of death was likewise adjusted up or down until the individual felt that the two choices were equivalent, with neither preferred. The chance of death associated with the point of equivalency was, in this situation, taken as the "disutility" associated with surgery. Respondents were then randomized to start with end nodes for either balloon angioplasty or surgical repair. They were asked to rank the end nodes, representing combinations of outcomes, for each procedure from the most to the least favourable, and standard gamble questions were given to determine the percentage chance of death associated with a perfect procedure which would be equivalent to the combination of outcomes represented by each end node.

Data analysis: To determine which option for treatment had the greatest final preference score, the preference scores of each end node were multiplied by the baselines probabilities of each event associated with that end node, and summed back to the initial decision node. The final cumulative preference scores for each treatment option were compared using paired t tests. To determine the

effect of disutility associated with the initial biased preference, the disutility was subtracted from all final end nodes for that decision option and the adjusted preference scores were summed back to the decision node. This analysis was likewise performed with adjustment for perceived mortality, and both disutility and perceived mortality together. One-way sensitivity analysis was performed for mortality and disutility-adjusted final preference scores. Sensitivity analysis consists of varying the probabilities of each event for one procedure while holding the probabilities for the alternative procedure constant, until a threshold is reached at which the final cumulative preference score difference indicates a change in the preferred option. This type of analysis is important in exploring the robustness of the analysis, particularly if the baseline probabilities are felt to be inaccurate or not contemporary. If the threshold values are beyond what would be considered plausible, then the conclusions are supported with confidence.

Results

Decision tree: A total of 104 published articles were used in the formulation of the decision tree and the determination of the event probabilities. Of these, 7 articles from 3 different groups involved follow-up of the same groups of patient, and thus only the most recent article was used. Only 2 of the articles were based on prospective randomized control trials.^{5,6} The remainder of the articles were case series. Overall, we used 97 articles, with a combined total of 4,963 patients. Duration of patient follow-up ranged from 1 month to 20 years, with a mean of 4.6 years. The citations for the articles are provided in the accompanying Appendix. Of the articles, 28 reported results of balloon angioplasty in 959 patients, and 68 reported on surgical repair in 4,004 patients. Of the 4,004 patients undergoing surgical repair, 1,601 underwent primary end-to-end anastomoses, 615 patch repair, 1,425 subclavian artery flap repair, and 363 used other types of repair, including extended end-to-end anastomosis. The baseline probabilities of periprocedural death, successful procedure, major and minor complications, recoarctation and aneurysms are shown in Table 2. Unavoidably, associated cardiac anomalies were found in 89% of the neonatal population. Ventricular septal defect, atrial septal defect, and patency of the arterial duct were the most common, making up 32%, 5%, and 20% of the associated lesions, respectively. Within the populations of children and adolescents, associated anomalies were found in 50% and 15% of patients, respectively. In addition, more complex lesions were found within

Table 2. Percent baseline probability of events stratified for each age group and procedure, as pooled from the medical literature reviewed*.

	Neonates	Children	Adolescents
Balloon angioplasty			
Perioperative death (<i>pBPeriDeath</i>)	9	0.5	0
Successful procedure (<i>pBSuccess</i>)	86	89	86
Major complications (<i>pBMajor</i>)	1	1	0.2
Minor complications (<i>pBMinor</i>)	13	13	3
Recoarctation (<i>pBRecoarct</i>)	11	10	13
Aneurysms (<i>pBAneurysm</i>)	0.1	0.3	3
Surgical repair			
Perioperative death (<i>pSPeriDeath</i>)	10	4	3
Successful procedure (<i>pSSuccess</i>)	87	95	97
Major complications (<i>pSMajor</i>)	0.1	0.1	< 0.1
Minor complications (<i>pSMinor</i>)	1	5	1.0
Recoarctation (<i>pSRecoarct</i>)	6	2	0.7
Aneurysms (<i>pSAneurysm</i>)	0.1	0.8	0.2

*The probabilities as they appear in the decision tree are shown in parentheses.

the neonatal age group than the other two age groups. The final decision tree is shown in Figure 1.

Preferences: At the time of the interview, the initial bias of all persons interviewed favoured a perfect balloon angioplasty over a perfect surgery. Individuals reported that they thought that estimated periprocedural mortality within the neonatal age group was 2.0%, with a range from 0.5 to 10% for balloon angioplasty, and 3.0%, with a range from 0.5 to 9.0% for surgical repair. Similarly for children, the median perceived mortality was 1.0%, ranging from 0.1 to 5.0%, for balloon angioplasty and 1.0%, ranging from zero to 10.0%, for surgical repair. In adolescents the median perceived mortality was 1.0%, ranging from 0.1 to 15.0%, for balloon angioplasty and 1.5%, ranging from zero to 11.0%, for surgical repair. Perceived mortality was not statistically significantly different between the procedures for any age group.

The decision analysis was performed for each individual interviewed to give the final cumulative preference scores for each procedure and, thus, the preferred option for treatment of that individual. Within the neonatal age group, balloon angioplasty was preferred to surgical repair, having a mean final preference score of 0.8999, and standard deviation of 0.0236 for balloon angioplasty versus 0.8873 and standard deviation of 0.0246 for surgery (*p* less than 0.001). For the children, a similar trend was seen, with balloon angioplasty significantly preferred over surgical repair, with a mean of 0.9746 and standard deviation of 0.0292 versus 0.9433 and standard deviation of 0.0285 (*p* less than 0.001). Within the adolescents, balloon angioplasty was also significantly preferred, at a mean of 0.9784 and standard deviation of 0.0300, over surgical repair,

which scored a mean of 0.9588 and had a standard deviation of 0.0255 (*p* less than 0.001). When the cumulative preference scores were adjusted for disutility, perceived mortality, and both perceived mortality and disutility, similar statistically significant trends were also seen, with balloon angioplasty always being preferred (Fig. 2).

One-way sensitivity analysis: One-way sensitivity analysis was performed on disutility and perceived mortality adjusted cumulative preference scores for all three age groups. As the probabilities of aneurysmal formation, a successful procedure, minor complications, or recurrent coarctation for either surgery or balloon angioplasty were varied between 0 to 100%, balloon angioplasty continued to be preferred throughout all age groups. Likewise, any reduction in the risk of periprocedural death or major complications associated with surgical repair did not alter the preference for balloon angioplasty, even when the risk of death or major complications with surgery within the child and adolescent age group reached zero. Within the neonatal age group only, when the periprocedural mortality for surgery fell below 4%, surgery became the preferred option. When the risk of periprocedural death with balloon angioplasty was greater than to 8%, 9%, and 15% within the groups of neonates, children, and adolescents, respectively, surgery was then preferred. When the risk of major complications with balloon angioplasty was greater than 52%, 76%, and 66% within these groups, respectively, surgical repair was then preferred. None of the published articles reviewed had a risk of periprocedural death with balloon angioplasty greater than 10%, or a risk of major complications greater than 50%. It would also be unlikely that even a contemporary series of

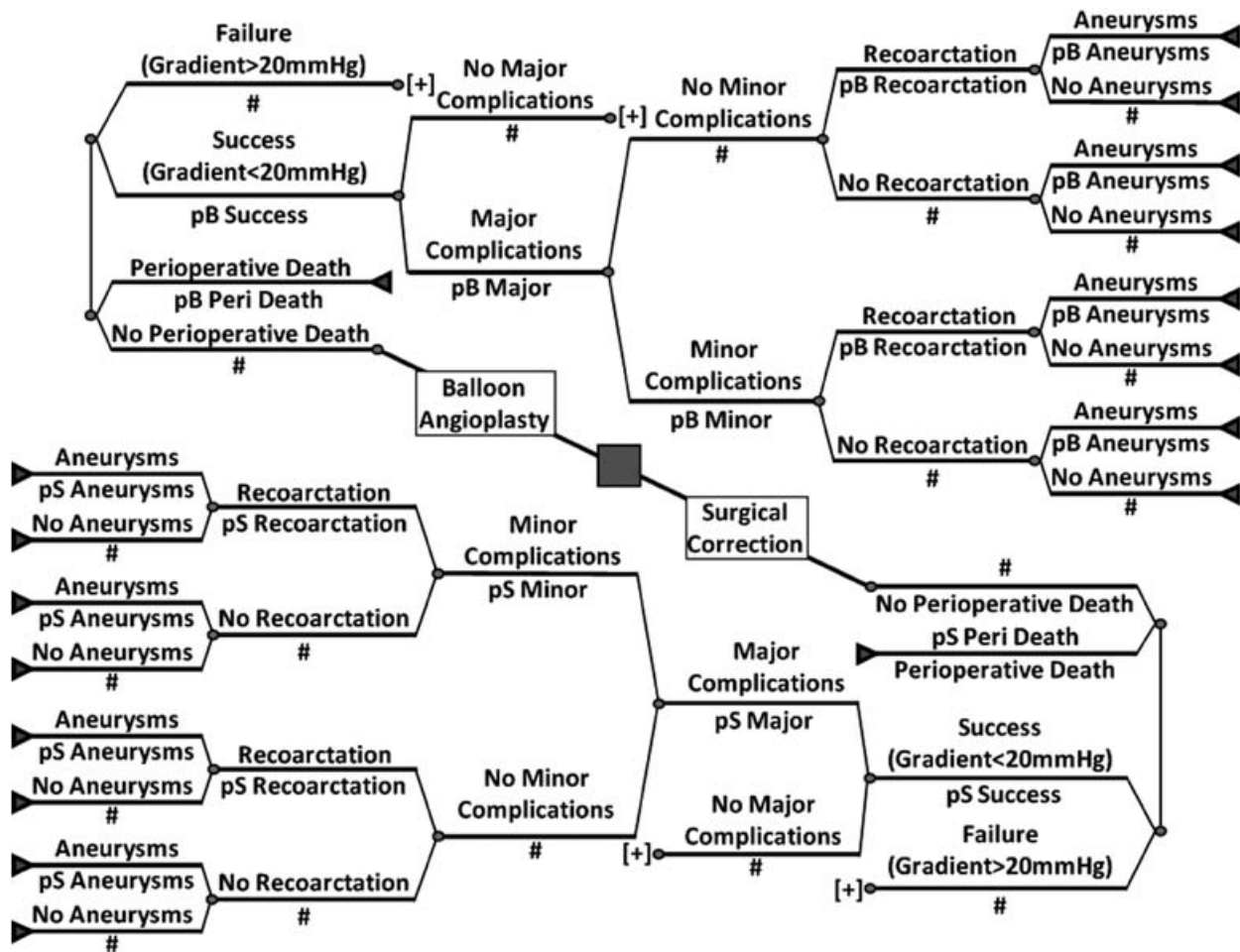


Figure 1. Diagram of decision tree – only selected branches are fully extended, collapsed branches (+) are similar in patterns to those that are fully extended. Circles represent chance nodes and triangles represent end nodes.

surgical outcomes would report no mortality and no major complications.

Discussion

When reviewing the literature, there are only two randomized clinical trials comparing primary transcatheter balloon angioplasty and surgical repair for aortic coarctation. In a small randomized clinical trial of 36 patients, Shaddy et al.⁵ studied 36 patients between 3 and 10 years of age, and found that both procedures were equally successful in reducing the gradient across the site of coarctation, with no significant difference in the initial complication rates between the two procedures. Neurological complications, with 1 patient with paraparesis and another with paralysis of the vocal cords, occurred in the surgical group, and there was a statistically significant increase in aneurysmal

formation, at 20% versus zero, and recurrent coarctation, at 25% versus 6%, with balloon angioplasty. A long-term follow-up study of the same population found that only half of the patients undergoing balloon angioplasty patients were free from aneurysm or reintervention, compared to 87% of surgical patients.⁹

Hernandez-Gonzalez et al.⁶ also conducted a small multi-centric randomized clinical trial involving 58 patients between the ages of 1 and 16 years who were randomized to either angioplasty or surgical repair. The success rates were comparable between the two groups. Recurrent coarctation was significantly more likely in those undergoing balloon angioplasty, at 50% versus 21%, while more serious post-operative complications were found to occur in those undergoing surgical repair.

Both clinical trials showed that balloon angioplasty was comparable to surgery, although the

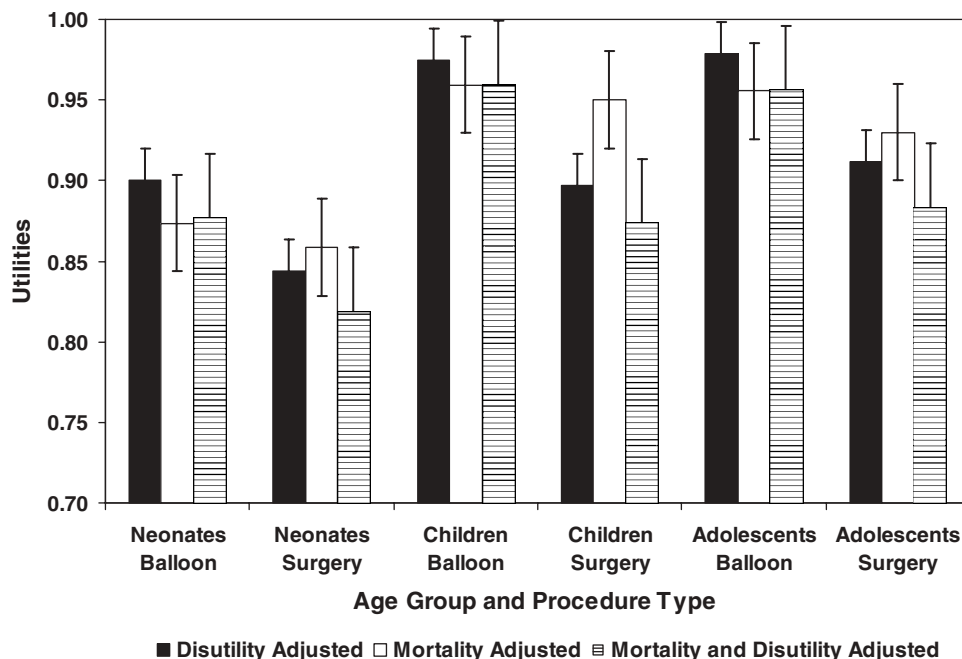


Figure 2.

Median final preference scores adjusted for mortality, disutility and both mortality and disutility distributed among the various age groups and procedures.

complications inherent to each treatment option differed considerably and varied in their frequency and severity. These differences may greatly impact on decisions concerning management and preferences. As a result, it is difficult directly to compare balloon angioplasty and surgical repair.

Decision analysis has been used successfully to evaluate complex and dissimilar options for treatment in a wide variety of clinical situations.¹⁰ Decision analysis, through the use of utilities or preferences, places a quantitative value on very different outcomes, allowing them to be compared. It also allows one to account for the severity and frequency of the different complications inherent to each procedure. The methods for undertaking a decision analysis have been described in the literature.^{11–14}

Our decision analysis indicates that balloon angioplasty was the preferred treatment of native aortic coarctation throughout the age range for childhood. Sensitivity analysis revealed that only increases in major complications and periprocedural death associated with balloon angioplasty outside the ranges currently cited within the literature affected the preference for angioplasty. Within the literature, the risk of major complications for balloon angioplasty ranges from zero to 10%, and it is doubtful that it will ever be greater than 50%. As a result, this threshold value is likely of little clinical significance. A periprocedural mortality of greater than 10% was found to be another threshold

value. Our review of the literature found that the periprocedural mortality rate with balloon angioplasty in the neonatal population was approximately 9%. It was noted, however, that aortic coarctation in the neonatal age group was more frequently associated with other congenital cardiac abnormalities. As a result, the reported complication rates and periprocedural mortality rates in neonates may not be an accurate reflection of that associated with balloon angioplasty of isolated native aortic coarctation. It would also be unlikely that even a contemporary series of surgical outcomes would report no mortality and no major complications, which, even if achieved, would still not cause surgery to be the preferred option.

Our results must be viewed in light of some limitations. The estimates for the probabilities of outcomes were based on review of the literature, and hence are subject to publication bias. Over the recent past, there have not been as many articles published on surgical correction of aortic coarctation as compared to balloon angioplasty. As a result, the outcomes of surgical repair are not contemporaneous to those reported for balloon angioplasty, and may overestimate the probability of adverse outcomes, although this was explored through use of sensitivity analysis. Newer techniques with improved outcomes, such as extended end-to-end repair, were represented in only a minority of included reviews. Additionally, mortality and adverse outcomes

may be underestimated in patients having balloon angioplasty because of the treatment bias for surgery in those with other associated complex defects, especially within the neonatal population. During our analysis, we varied these probabilities of the various complications and outcomes occurring from zero to 100%, accounting for all possibilities. As a result, even though estimates of probabilities may not be accurate reflections of present day results, they are accounted for within the sensitivity analysis. In addition, the number of articles relevant to each age group varied. Fewer articles examining the use of balloon angioplasty were found at the extremes of age, that is for neonates and adolescents.

The preference scores were obtained from medical professionals at a single institution. Although surgeons did not participate, the only difference they would be expected to have from other providers of health care might be a bias towards surgery, and lower estimates of periprocedural mortality associated with surgery. The remaining preferences are obtained in an unbiased manner as to procedure, and it would be unlikely that their results would be different. It would be interesting to see if these preference scores differed amongst various institutions or specialties, and how these values and the decision process vary when applied to parents and legal guardians of patients with this diagnosis. It was not currently feasible to educate a large number of parents with regards to the pathophysiology, complications, and outcomes for aortic coarctation. As a result, we interviewed only medical staff familiar with aortic coarctation and its management, complications, and outcomes.

More recently, endovascular stents are now being used as an adjunct to balloon angioplasty in older patients with aortic coarctation, and this may further improve the outcome of patients treated with interventional cardiac catheterization.¹⁵⁻¹⁸ George *et al.*⁸ compared balloon angioplasty with endovascular stenting versus surgical repair of aortic coarctation. Surgical repair was successful in all cases, and endovascular stenting was associated with a 10% initial rate of failure. No complications were seen with either procedure.

Our study is the first to use decision analysis systematically to evaluate the comparison of transcatheter balloon angioplasty and surgical repair of native aortic coarctation across all age groups of childhood. We show that balloon angioplasty appears to be the preferred initial treatment of

non-neonatal aortic coarctation, though the findings concerning native coarctation treatment in neonates remain controversial.

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