Midterm safety and outcome of balloon angioplasty of native aortic coarctation in neonates and young infants and initial experience of prepartial dilatation using high-pressure noncompliant balloon

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ABSTRACT

Background : Balloon angioplasty (BA) for aortic coarctation in neonates and infants remains controversial due to high recurrence rate and vascular complications.

Aim : This study aimed to determine the safety and outcome of percutaneous treatment of coarctation in neonates and infants and to share the initial experience of strategy of prepartial dilatation with high-pressure noncomplaint balloon before final targeted dilatation using low-pressure compliant balloon.

Materials and Methods : Retrospective analysis of records of all neonates and infants aged <6 months who underwent BA either using only low-pressure balloon (Group A) or those with prepartial dilatation using high-pressure noncomplaint balloon followed by low-pressure compliant balloon (Group B) between July 2017 and February 2020 was performed. Demographic, clinical, echocardiographic, interventional, and follow-up data were collected for all.

Results : A total of 51 patients (41.2% neonates) were included in the study. Median age was 1 month 14 days (60.8% girls) and mean weight was 3.6 ± 1.5 kg. The mean peak trans-coarctation gradient was 53 ± 12 (34–80) mmHg. The final pressure gradient dropped to <10 mmHg in all cases of Group B and only in 26.3% (5) patients of Group A ($P < 0.001$). Recoarctation rate was 25.5% (13) overall and was significantly higher in Group A patients ($P < 0.001$), in those with borderline/mildly hypoplastic arch ($P = 0.04$) and in those with postprocedure gradient between 10 and 20 mmHg ($P = 0.02$). Median time to re-coarctation was significantly delayed in Group B ($P < 0.001$). There were no major complications or mortality in either group.

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Conclusions : BA in neonates and young infants has an excellent short and mid-term safety and efficacy. The recoarctation rate is significantly reduced as well as delayed with prepartial dilatation using high-pressure noncompliant balloon.

Keywords : Aortic coarctation, balloon coarctoplasty, neonates, noncompliant balloon, young infants

INTRODUCTION

Balloon angioplasty (BA) for aortic coarctation (AC) was first reported in 1983.[1] Despite low morbidity and complication rate, its role in neonates and young infants is controversial due to high restenosis rate, risk of aneurysm formation, aortic dissection, and limb complications.[2,3] It is the intervention of choice in cases of postsurgical recoarctation and native coarctation in older children.[4] In centers with limited neonatal cardiovascular surgical facilities, and in patients with high surgical risk, BA may form an effective and safe alternative in neonates and young infants. In our center, all cases of AC with or without associated cardiac anomaly in neonates and infants are primarily managed with BA due to the lack of neonatal cardiovascular surgical facility during the study period. We share our experience of this transcatheter procedure done in neonates and young infants aged <6 months and of strategy of prepartial dilatation of AC with the high-pressure noncomplaint balloon before final complete dilatation with low-pressure compliant balloon(s).

MATERIALS AND METHODS

Inclusion criteria

This single-center retrospective study included all neonates and infants <6 months of age who underwent transcatheter balloon coarctoplasty between July 2017 and February 2020. This also comprised patients with borderline or mildly hypoplastic aortic transverse arch (z score of transverse arch between −2 and −3) and all those with or without associated cardiac anomaly, irrespective of surgical intervention done subsequently. Written informed consent from the parent(s) was obtained in all cases. The ethical approval from the Institutional Ethics Committee was also taken.

Methods

Demographic and clinical presentation details were noted. All patients were evaluated in detail with transthoracic echocardiography (Philips iE33, Bothell, USA) including diameter of transverse arch and descending aorta at the level of diaphragm. Severe AC was defined as peak aortic arch gradient more than 20 mmHg with diastolic tailing of signal on continuous wave Doppler interrogation, in the presence of normal left ventricular ejection fraction. However, in those with left ventricular dysfunction (ejection fraction <50%), all were considered as severe coarctation of aorta irrespective of the gradient. The left ventricular ejection fraction was assessed by standard Simpson's method.

Procedure

All procedures were done through femoral arterial access with insertion of 3F (French)/4F pediatric vascular sheath, under conscious sedation. Unfractionated heparin (100 IU/Kg) was administered in all patients immediately after the vascular access was obtained. The coarctation segment was crossed retrogradely in all except one case, using 0.035" or 0.025"J-tip Glidewire (Terumo, Somerset, NY, USA) or 0.014" coronary wire and end hole guide catheter advanced thereafter. After obtaining the invasive pressure gradient across the coarctation segment, the guide catheter was exchanged for Pigtail catheter in ascending aorta for obtaining baseline aortogram at shallow left anterior oblique fluoroscopic view. In one infant (5 months), due to failure to cross retrogradely, the coarctation segment was crossed antegradely through radial arterial access and initial dilatation done with noncompliant (NC) coronary balloon, followed by subsequent dilatation with compliant balloon through femoral arterial route. The arterial accesses were obtained without ultrasound guidance.

Balloon selection and use

The maximum size of balloon used was 80%–100% of diameter of descending thoracic aorta at the level of diaphragm. The graded sequential dilatation was done in all cases. In all cases, 2–4 inflations of balloon catheter were done using diluted (1:2) contrast, for short inflation time of 10–15 s. In the initial 19 (37.2%) patients, only low-pressure (Mini-TyshakII™; NuMed, Hopkintown, NY, USA) balloons were used throughout the procedure, and these were assigned into Group A. For the remaining 31 (62.7%), which formed the Group B, we changed the strategy and used high-pressure NC coronary balloons of smaller caliber for initial dilatation up to 50%–60% of planned maximum dilatation diameter, followed by low-pressure compliant balloon for subsequent required dilatation(s) in the same setting. The pressure used for inflation was up to the nominal burst value of a particular balloon used. It was 3–3.5 atmospheres in case of compliant balloon and 10–12 atmospheres for NC balloons. Hand inflation was not used in any of the cases.

Postprocedure protocol

After the procedure, check aortogram, to assess the degree of dilatation and any development of possible aortic dissection/aneurysm, was obtained with pigtail catheter passed over wire already parked in the ascending aorta. Endpoint was drop in pressure gradient across the coarctoplasty segment to at least <20 mmHg and preferably <10 mmHg and anatomical dilatation on post-BA aortogram. Postprocedure, heparin infusion at 40 IU/Kg was administered in patients with diminished or absent lower limb arterial pulses till complete restoration of latter.

Follow up

Postprocedure follow-up clinical, blood pressure recording, and echocardiography were done at 24 h, 1 week, 1 month, and 3 months and periodically thereafter. Recoarctation was diagnosed when the mean aortic arch gradient was more than 20 mmHg with diastolic tailing and corroborated by significant systolic noninvasive blood pressure difference between upper and lower limbs. Re-intervention details, if any, were noted.

The data were expressed as frequency, mean, median, range, and standard deviation. Comparison of parameters between the groups was performed with Student's *t*-test and Fisher's exact test, as appropriate and Kaplan–Meier survival analysis for time to reintervention was done. Statistical analysis was performed using SPSS version 24.0 (IBM Corp., Armonk, NY,USA). A $P < 0.05$ was considered statistically significant.

RESULTS

During the study period, out of 53 patients of AC in neonates and infants <6 months, 51 underwent transcatheter balloon coarctoplasty. We excluded two patients with significant hypoplastic transverse arch of aorta (z score of transverse arch <–3), confirmed by computed tomography cardiopulmonary angiography. Out of 51 cases, twenty-one (41.2%) were neonates and the remaining were young infants (1–6 months). The baseline demographic and clinical characteristics of the two groups were comparable to each other [Table 1]. Minimum follow-up duration was 18 months with 39 (79.6%) cases being followed up for 36 months. Out of 35 patients with left ventricular dysfunction, 15 (40%) had severe left ventricular dysfunction with left ventricular ejection fraction <30%.

The procedural and outcome measures between the two groups have been elaborated in Table 2. Immediate reduction in pressure gradient across the coarctoplasty segment was seen in all cases. In 37 (72.5%) patients, it dropped below 10 mmHg, while in remaining 14 (27.5%), it persisted between 10 and 20 mmHg. In all cases of Group B, the final pressure gradient dropped to <10 mmHg, as compared to only in 5 (26.3%) belonging to Group A ($P < 0.001$). Up to 3 and 4 sequential dilatations were required in 15 (29.4%) and 2 (3.9%) cases, respectively.

Total re-coarctation rate was 25.5% (13 patients). It was significantly higher in Group A than B ($P = 0.01$). Median time period to develop re-coarctation was

Table 1: Patient characteristics

	Total (*n*=51), *n* (%)	Group A (*n*=19), *n* (%)	Group B (*n*=32), *n* (%)	*P*
Age (months/days), median (range)	1 month 14 days (1 day-5 months 26 days)	1 month 24 days (1 day-5 months 26 days)	2 months 7 days (1 day-5 months 16 days)	0.37
Weight (kg), mean±SD (range)	3.6±1.5 (1.8-6.6)	3.5±1.4 (1.8-6.6)	3.7±1.1 (2.3-6.1)	0.57
Gender				
Male	20 (39.2)	7 (36.8)	13 (40.6)	0.79
Female	31 (60.8)	12 (63.2)	19 (59.4)	
Upper limb hypertension	48 (94.1)	17 (89.4)	31 (96.8)	0.33
Congestive heart failure	15 (29.4)	8 (42.1)	7 (21.9)	0.12
Left ventricular dysfunction	35 (68.6)	14 (73.7)	21 (65.6)	0.55
Borderline/mild arch hypoplasia	10 (19.6)	5 (26.3)	5 (15.6)	0.35
Diameter of descending aorta (mm), mean±SD (range)	6.7±0.9 (5.3-8.5)	6.5±0.9 (5.3–8.1)	6.9±1.0 (5.3-8.5)	0.15
Peak gradient across coarctation segment (mmHg), mean±SD (range)				
Echocardiographic	53±12 (34-80)	52±12 (38-78)	55±13 (34-80)	0.68
Angiographic	47±10 (30-70)	44±9 (32-66)	49±10 (30-70)	0.42
Associated cardiac lesions	35 (68.6)	14 (73.6)	21 (65.6)	
Shunt lesions				
VSD	13 (25.5)	7 (36.8)	6 (18.8)	0.15
ASD	14 (27.4)	6 (31.6)	8 (25)	
PDA	11 (21.6)	4 (21.1)	7 (21.9)	
APW	2 (3.9)	1 (5.3)	1 (3.1)	
Obstructive lesions				
BAV with severe AS	14 (27.4)	5 (26.3)	9 (28.1)	0.89
Valvular PS	2 (3.9)	1 (5.3)	1 (3.1)	

SD: Standard deviation, VSD: Ventricular septal defect, ASD: Atrial septal defect, PDA: Patent ductus arteriosus, APW: Aortopulmonary window, BAV: Bicuspid aortic valve, AS: Aortic stenosis, PS: Pulmonary stenosis

2 months (15 days–3 months) in Group A and 5 months (4–6 months) in Group B patients ($P < 0.001$). Univariate analysis showed that re-coarctation was significantly earlier in Group A patients ($P < 0.001$), in those with borderline/mildly hypoplastic arch ($P = 0.04$) and in those with postprocedure gradient between 10 and 20 mmHg ($P = 0.02$). Nine out of 10 (90%) patients of borderline or mildly hypoplastic aortic arch required repeat dilatation as compared to only 6 (14.6%) cases with normal arch ($P = 0.04$). Kaplan–Meier survival analysis for time to re-coarctation was significantly earlier in Group A than Group B in overall as well as in neonates and young infants separately [Figures 1-3]. In all cases of re-coarctation, repeat balloon coarctoplasty was done using high-pressure NC coronary balloon, irrespective of the group they originally belonged to. None of the patients with re-coarctation required surgical coarctoplasty. Figure 4 shows fluoroscopic images of pre and postballoon dilatation of the coarctation segment of a 30-day-old infant of Group B.

The left ventricular function and heart failure improved dramatically in all cases. No patient had any major complications like perforation, dissection, or aneurysm of aorta. Blood transfusion was required in six (11.7%) patients, puncture site hematoma which resolved with compression was seen in two (3.9%) patients. Four (7.8%) patients developed femoral arterial occlusion warranting prolonged administration of heparin despite which only monophasic flow could be established in two (3.9%) of them. However, none of the patients had threatened limb. There was no mortality in either group. There was no significant difference in the complications between the two groups. Meantime for discharge was 3 (2.5–4) days. Hypertension normalized in all but two (3.9%) cases at 6 months postprocedure.

Three patients (5.8%) had Turner's syndrome. Associated cardiac lesions included large ventricular septal defect requiring intervention in 6 (11.7%), small ventricular septal defect not requiring intervention in 7 (13.7%), large aorto-pulmonary window in 2 (3.9%), ostium secundum atrial septal defect requiring no urgent intervention in 7 (13.7%), small patent ductus arteriosus (PDA) in 9 (17.6%), large PDA requiring intervention in 2 (3.9%), bicuspid aortic valve with severe valvular aortic stenosis requiring balloon valvuloplasty in 14 (27.4%),

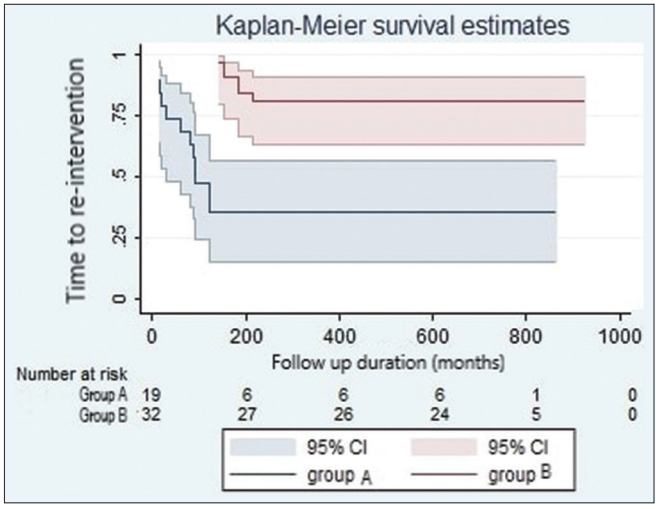

Figure 1: Overall time to recoarctation for the two groups

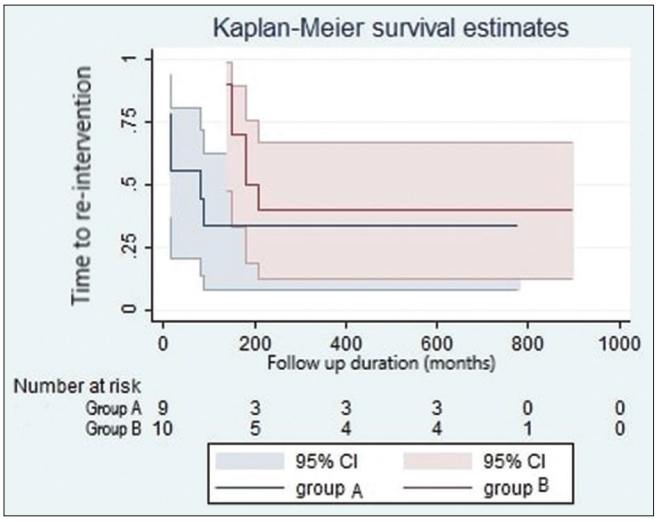

Figure 2: Time to recoarctation for the two groups among neonates

Table 2: Comparison of procedural and outcome measures

	Total (*n*=51), *n* (%)	Group A (*n*=19), *n* (%)	Group B (*n*=32), *n* (%)	*P*
Balloon size (mm), median (range)	7 (5-8)	6 (5-8)	7 (5-8)	-
Number of inflations (median)	2	3	2	-
Fluoroscopic time (min), mean±SD	5.2±1.2	5.2±1.2	4.8±0.8	0.15
Total procedure time (min), mean±SD	30.6±4.8	32.2±4.4	30±4.2	0.08
End point AC gradient <10 mmHg	37 (72.5)	5 (26.3)	32 (100)	<0.001
End point AC gradient 10-20 mmHg	14 (27.5)	14 (73.7)	0	<0.001
Average hospital stay (days)	2.6	3	2.7	0.12
Average follow-up duration (months), mean±SD, median (range)	28±4.5, 30 (18-36)	26±4.5, 30 (18-36)	28±4.5, 30 (18-32)	0.09
Re-intervention (total)	13 (25.5)	9 (47.4)	4 (12.5)	0.01
Re-intervention (neonates) (*n*=9+12)	7 (33.3)	5 (55.6)	2 (16.7)	<0.001
Re-intervention (1-6 months) (*n*=10+20)	6 (20)	4 (40)	2 (10)	<0.001
Interval to re-intervention (days), median (range)	90 (15-210)	80 (15-120)	165 (140-210)	<0.001

SD: Standard deviation, AC: Aortic coarctation

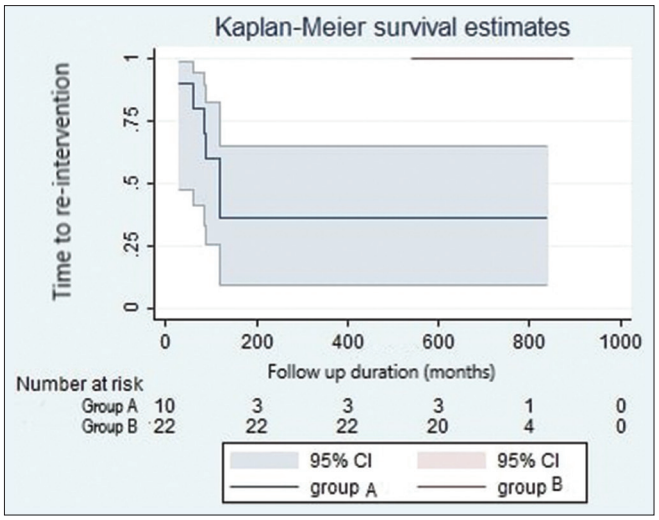

Figure 3: Time to recoarctation for the two groups among young infants (1–6 months)

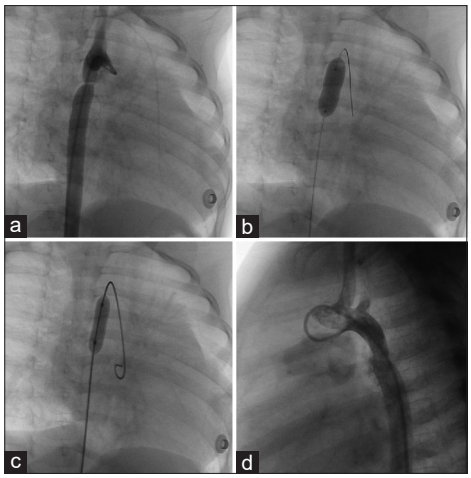

Figure 4: (a) Aortic angiography of a 30-day-old male infant with Coarctation of aorta. (b) Dilatation with high-pressure 5 mm × 15 mm noncompliant coronary balloon (NC Quantum Apex; Boston Scientific, Natick, MA) over 0.014" Run-through coronary wire (Terumo, Somerset, NY) and inflated up to 10 Atm. (c) Dilatation with low-pressure 7 mm × 20 mm compliant balloon (Mini-TyshakII™; NuMed, Hopkintown, NY, USA) over 0.025" J tip Glidewire (Terumo, Somerset, NY, USA) and inflated up to 3.5 Atm. (d) Aortic angiography postballoon coarctoplasty

and valvular pulmonary stenosis requiring balloon valvulolasty in 2 (3.9%) cases. Four patients (7.8%) had right aortic arch.

DISCUSSION

Coarctation of aorta is the sixth most common congenital cardiovascular defect with the incidence of 4%–6% and reported prevalence of approximately 4 per 10,000 live births.[5,6] The standard recommended treatment of native AC is surgery until 4–6 months of age, balloon coarctoplasty thereafter at any age, and stent coarctoplasty in older children weighing more than 25 Kg.[4] Latest Indian guidelines recommend surgery in neonatal AC with or without aortic arch hypoplasia (Class I), balloon coarctoplasty in critically ill neonates with high risk for surgery (Class IIa), surgery (Class I) or BA (Class IIa) in infants with coarctation, and BA in re-coarctation (Class I).[7] The mean survival age of unrepaired coarctation is 35 years with nearly 75% mortality by 46 years of age.[4] Availability of early management modalities such as balloon dilatation and endovascular stent placements has greatly altered the natural history of untreated coarctation which otherwise, in long term, predisposes to earlier death, higher incidence of ischemic heart and atherosclerotic diseases, heart failure, endocarditis, cerebrovascular accidents, spontaneous rupture or dissection of aorta and rupture of Berry's aneurysm.[8]

In neonates and young infants, while BA is the recommended management for postoperative recoarctation, it remains controversial in native coarctation.[9,10] This variation in management strategies is due to high restenosis rate, risk of aortic aneurysm/dissection/rupture, and vascular complications in native lesions on this age group.[2,3] Dilation of recoarctation is thought to be safer with reduced predisposition to rupture due to the layered protection by the encompassing surgical scar tissue. However, one of the studies demonstrated equivalent acute results of balloon dilatation in native and recurrent coarctation and noted that acute aortic tears do not occur with dilation of native coarctation.[2] The immediate reduction in pressure gradient with BA was 100% in our study, comparable to other studies that have shown early success rate ranging from 88% to 100% in neonates and infants with congestive heart failure (CHF) or cardiogenic shock.[11-13]

BA in neonates and infants has been reported to have variable recurrence rate. The restenosis rate requiring reintervention was 100% in 10 infants in one study, who underwent balloon dilatation or stent implantation after a median period of 12 weeks.[10] In another study, recoarctation rate was 83% and reintervention was done in 35%, out of which 37.5% developed aneurysms.[3] In the study by Liang *et al.*, BA was done for native coarctation in neonates and infants with CHF with a re-coarctation rate of 44%.[14] However, in our center, the total re-intervention rate was 25.5% after a median period of 3 months and was significantly lower in Group B than A ($P < 0.001$). The reintervention rate showed significance among neonates when compared with young infants ($P < 0.001$).

In the study by He *et al.* in 37 neonates and young infants, coronary balloons (3–6 mm) and regular Cordis balloons (6–8 mm) were preferred to peripheral vascular balloons. They had demonstrated significant reduction in gradient and increase in mean coarctation diameter

after balloon dilatation in this population with only 6 patients (16.2%) requiring repeat dilatation at an interval between 5 and 18 months.[11] Two of their patients had developed small aneurysms postdilatation.[11] There was no recoarctation or vascular complication in young infants when NC balloon was used in Group B in our study. Another study that has utilized coronary balloons for dilatation in 44 infants has shown reintervention rate of 20.45% with early age of presentation as a significant risk factor. However, details of size of balloon, nature, and number of inflations have not been mentioned.[15]

Our strategy of using a high-pressure NC balloon of smaller size for initial dilatation followed by final dilatation with larger low-pressure balloon has significantly reduced recurrence rate without increase in the risk of other complications. It is presumably due to more effective breakage of posterior shelf of coarctation segment as well as controlled initial intimal and medial tear, without increasing risk of aortic complications. The high-pressure NC balloons used in our study were compatible with the same 4 F sheath used for low-pressure balloon, thus not increasing risk of sheath-induced arterial injury and/or occlusion.

The significant risk factors for recoarctation were neonatal age group, Group A patients, immediate residual gradient of more than 10 mmHg across coarctoplasty segment and presence of borderline/hypoplastic arch. Similar to our study, risk of re-coarctation was higher in neonates and infants with CHF whose post-BA systolic pressure gradient was more than 10 mmHg in the study by Liang *et al.*[14] They also noted that a coarctation diameter of <3 mm resulted in restenosis.

The incidence of coarctation is as high as 12% in patients with Turner's syndrome, and due to inherent genetically predisposed aortopathy, they are more prone to complications such as aortic aneurysm, dissection, and rupture.[16,17] In our study, we had three cases of Turner's syndrome, with none developing any procedure-related aortic complication.

The limitations of our study include lack of comparison with surgically managed cases in neonates and young infants. Ours is a retrospective study comparing two different strategies which has its inherent biases. More prospective randomized studies in these age groups with long-term follow-up for delayed recurrence are required to establish the efficacy of use of high-pressure NC balloon dilatation as an effective strategy for the treatment of AC.

CONCLUSIONS

Balloon coarctoplasty in neonates as well as young infants has an excellent short and mid-term safety. In neonates, although surgical repair has been shown to be an effective procedure in terms of reintervention in other studies, in a resource-constrained setup, balloon coarctoplasty may be considered as a safe and effective alternative. In both neonates and young infants, initial partial predilatation with high-pressure NC balloons of lower caliber is significantly effective in reducing the rate of as well as time for reintervention, with no increase in the complication rate. However, further studies are required to recommend this strategy as the therapy of choice in this subgroup of population.

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Conflicts of interest

There are no conflicts of interest.

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