Transcatheter Treatment For Native Aortic Coarctation In Adult

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الخلاصة

١-**أهداف البحث:** التحري عن نتائج معالجة تخصر الشريان الابهر الاصيل في البالغين بواسطة التداخل القسطاري ومقارنة نسبة النجاح والمضاعفات بين استخدام البالون والشبكة ذات التوسع الذاتي.

٢-**خلفية البحث:**يعتبر التداخل الجراحي هو العلاج التقليدي لتخصر الابهر الاصيل الا انه انبثق مؤخرا العلاج بواسطة التداخل القسطاري كبديل للتداخل الجراحي والذي يعتبر الان العلاج الامثل في حالة معاودة التخصر بعد العملية الجراحية .ان استعمال البالون مع او بدون استعمال الشبكة في حالات التخصر الاصيل يبقى بحاجة الى دراسات اعمق.

٣-طرائق البحث:اجري لواحد وخمسين مريضا بالغا يعانون من تخصر الابهر الاصيل تداخلا قسطاريا وذلك في مركزين للقلب في بغداد للفترة بين كانون الثاني لسنة٢٠٠١ وحزيران لسنة ٢٠٠٤ .اجري التداخل بواسطة البالون لستة وعشرين مريضا بينما تم استخدام الشبكة ذات التوسع الذاتي لخمسة وعشرين مريضا.تم مراجعة وتحليل المعلومات الخاصة بالتصوير الوعائي والمتابعة لكل مريض من هؤلاء المرضى.

٤-**النتائج** :لقد خفض هذا الاجراء القسطاري فرق الضغط الجهازي عبر التخصر من ٦٨ ملم زئبق الى ٧.٥ ملم زئبقي مع زيادة في قطر التجويف الداخلي للتخصر اكثر من ضعفين بعد التداخل. وكانت نسبة النجاح الفوري متقاربة في حالتي المجموعة التي استخدمت فيها الشبكة ومجموعة البالون(٨٨%) مقابل (٨٤%) على التوالي.

لقد اصبح قرابة نصف عدد المرضى سويي الضغط الشرياني وبدون استخدام أي علاج مضاد لفرط ضغط الدم .لقد طرأت مضاعفات بسيطة وبصورة ملحوظة اكثر في مجموعة البالون مقارنة مع مجموعة الشبكة(٣٤%) مقابل (٢٨%) على التوالي.

المعلومات المتوفرة بعد ستة اشهر من المتابعة اظهرت ان مريضين في مجموعة البالون كانت لديهم زيادة ملحوظة في فرق الضغط عبر التخصر ،بينما اولئك الذين اجري لهم زرع شبكة ، كان مريضا واحدا منهم فقط قد احتاج الى تداخل قسطاري مرة اخرى بسبب النتائج الاولية الغير مثالية.

٥-**الاستنتاج:** ان التداخل القسطاري بواسطة البالون او الشبكة ذات التوسع الذاتي هو اجراء امين وفعال لتخصر الشريان الابهر الاصيل في البالغين. ولكي نؤكد هذه النتائج نوصي بدراسة لعدد اكبر من المرضى ولفترة اطول من المتابعة.

Abstract

Objectives: We sought to investigate the result of transcatheter treatment for native aortic coarctation in adult and compare the success rate and early complication rate between balloon angioplasty and self expandable stent.

***Background*:** Surgical repair was considered the conventional treatment for native aortic coarctation while balloon angioplasty emerged recently as an alternative to surgical repair and considered the treatment of choice in recurrent postoperative coarctation but its use with or without endovascular stent implantation for native coarctation remains controversial .

***Method*:** Fifty one patients with native coarctation underwent transcatheter intervention in two different cardiac centers in Baghdad between January 2001 and July 2004 , 26 patients underwent balloon angioplasty alone while 25 patients had endovascular stenting for coarctation. Hemodynamic , angiographic and follow up data were reviewed and analyzed for each patient.

***Result*:** The procedure acutely reduced the transcoarctation systolic pressure gradient from 68±23 to 7.5±11 mmHg with increase in minimal luminal diameter of coarct segment more than two folds post intervention . The immediate success rate was comparable in stent and balloon group 88% versus 84% respectively .Nearly half of our patients become normotensive without antihypertensive medication before discharge. Minor complications found to be significantly higher among balloon group as compared to stent group 34% versus 28%.On six months follow up two patients in balloon group had significant increment in pressure gradient while those who underwent stent implantation only one patient had reintervention because of suboptimal initial result.

Conclusion:balloon angioplasty with or without endovascular stenting is safe and effective nonsurgical approach for native aortic coarctation in adult. Large sample size and longer follow up is recommended to confirm this result.

Introduction

Coarctaion of aorta is a narrowing usually in the region of the *ligamentum arteriosum*. It may be discrete or tubular or associated with hypoplasia of the aortic arch and isthmus (1).

It was first described by Prussian anatomist Johann Friederich Meckel in the 1760 (2).

There is a strong association between coarctation and bicuspid aortic valve with a reported incidence up to 85%, necessitating replacement in 5%.(4). A bicuspid valve is the usual cause of Aortic stenosis or incompetence with coarctaion. A close association was also reported between coarctation and congenital anomalies of the mitral valve, patent ductus arteriosus , ventricular septal defect, and atrial septal defect.

It has been estimated that if left untreated , up to 90% of patients with isolated coarctation will die before 50 years of age as a result of acute or chronic heart failure, bacterial endocarditis , aortic rupture or dissection, intracranial hemorrhage, hypertension , premature coronary artery diseases and valvular heart disease (5).

Surgical repair is considered the conventional treatment for native aortic coarctation (6).It has improved the prognosis for patients with this malformation, although the long term result after coarctation repair may not be completely satisfactory (7).

Late restenosis and aneurysm formation have been disturbing sequelae of surgical repair and surgical procedure itself may be associated with significant morbidity and mortality(6).

Recently percutaneous balloon angioplasty with or without endovascular stent has been used as an alternative to surgical repair. Balloon angioplasty appears to be effective in recurrent post operative coarctation and is now considered the treatment of choice for this condition .The use of balloon angioplasty with or without balloon expandable stent for native coarctation however is more controversial (8).

Aim of the study :

1- to evaluate the result of balloon angioplasty with and without endovascular stent in native aortic coarctation in adult.
2- to study the early effect of transcatheter intervention on hypertension state and its control.
3-to compare the immediate success rate and early complication rate between balloon angioplasty and self expandable stent in the treatment of native aortic coarctation.

Patients and methods

Between January 2001 and July 2004, 51 patients with coarctation of aorta presented to Ibn Al-Bitar center for cardiac surgery and Iraqi center for heart diseases in Baghdad underwent transcatheter intervention for native aortic coarctation .
In the first center 26 patients underwent balloon angioplasty without stenting while in the second center 25 patients underwent direct stenting with self expandable stent with post stenting balloon dilatation .

***Inclusion criteria*:** All adult patients (more than 18 years old) with native aortic coarctation,those with recoarctation after surgical repair were excluded.

Data collection and measurement

1-Clinical data : data such as age, sex, body weight, body surface area ,associated cardiac defects, balloon size ,complications and antihypertensive treatments were reported for each patient.
2-Cardic catheterization data:
a*-hemodynamic data* : invasive blood pressure (peak systolic blood pressure were measured above and below the areas of coarctation before and after the intervention in both stent and balloon group.Peak to peak systolic pressure gradient before and after intervention was calculated as peak systolic pressure in ascending aorta minus peak systolic pressure in descending aorta.
b*- angiographic data* : all cineangiogram were reviewed and the diameter of the following regions were recorded prior to angioplasty , isthmus(area between the *left subclavian artery* and *ligamentum arteriosum*), the coarctation site itself and the descending aorta at the level of the diaphragm .Coarctation segment diameter after intervention was also recorded. All measurements were corrected for magnification using the known diameter of the angiographic catheter.

Follow up

Before discharge, all patients underwent complete clinical evaluation including blood pressure measurement , echocardiography , and chest films.
The patients with stent were placed on aspirin for 3- 6 months and followed after one month by fluoroscopy screening for stent recoil and at 6 months aortogram done for assessment of restenosis.After 6 months all patients had full clinical examination ; transthoracic echo-doppler study.

Statistical analysis

Data were collected and analyzed using SPSS version 10 for windows (SPSS , Chicago, Illinois, and USA). Difference between groups were examined by independent *t*- test and for comparison of means .

Multiple logistic regression analysis was done to compare different factors with a success rate , Chi-square test or Fisher exact probability test was used to detect

significance of relations between various variable. P- value less than0.05 was considered statistically significant .

Results :

1-*Description of study sample*:

Fifty one patients with native aortic coarctations proved by cardiac catheterization study were included . 38 were male and 13 were female , male to female ratio was 3:1 . The mean age at time of intervention was 26±8 year (range 18-54). The mean ± one standard deviation for the weight ,height and body surface area were shown in table 1.

Forty seven patients (92%) had hypertension , the remaining four were normotensive patients. Regarding types of coarctation the majority has discrete coarctation (86.3%) while tubular type was present in seven patients (13.7%) only . Nearly half of our patients had associated cardiac defects (complex coarctation) as shown in table 2 . Bicuspid aortic valve was the commonest association(58%), among other cardiac defects shunt lesion such as PDA,VSD ,ASD are present in 25 % of patient.

As shown in table 3 there was no statistically significant difference in baseline characteristic, pre interventional angiographic and hemodynamic data between stent and balloon group.

2. ***Hemodynamic and angiographic result***:

The procedure acutely reduced the peak to peak systolic coarctation gradient from (68±23 to 7.5±11) mmHg after intervention (p =0.0001).

The systolic pressure in ascending aorta reduced significantly from (166±30 to 137±27) mmHg (p=0.0001). The minimal luminal diameter of coarct segment increased more than two fold post intervention from (7.3±2.3 mm to 16±3 mm) (p=0.0001).

The systolic pressure in the descending aorta raised significantly also from (99 ±20 to 120±4) mmHg (p=0.001).

On the other hand there was no statically significant difference in post procedural angiographic and hemodynamic changes between stent and balloon group see figure 2.

3.***The procedural success***:
The procedural success rate was slightly higher in stent group as compared to balloon group. But it didn't reach statistical significance (88 % versus 84%) .

4. ***Effect of intervention on blood pressure control***
More than one third of our patients with coarctation were severely hypertensive on two or more antihypertensive drugs before intervention. This was reduced to only 5.9 % after the procedure (p=0.001) . Nearly half of the patients became normotensive without antihypertensive medication after the procedures see table 9. This change in the blood pressure control after the procedure was highly significant statistically when compared to the preprocedural level see table 4.

5. ***post procedural complication***:
There was no major complication such as death or event that mandate urgent surgical intervention in both stent and balloon group . Regarding the rates of other minor complication there was 28% among stent group as compared to 34% among balloon group which was statistically significant (p=0.02).table 5.
Slipped stent was higher among the stent group while minor intimal tear was greater in balloon group. Vascular access complications and prolonged chest pain were nearly equal in both groups. Hypertensive crisis was seen in only one patients after the procedure in balloon group.

6.*Short term follow up*:
Regarding stent group there was no stent recoil as seen by fluoroscopy one month after the procedure . Six month after the procedure , angiography was done for twenty stented patient which showed no significant instent intimal hyperplasia or increase in pressure gradient in all patients except one patient who underwent reintervention with balloon angioplasty after six months because of poor initial results .
Regarding balloon group the available follow up data with echocardiography and Doppler study showed only two patient out of twelve who had pressure gradient greater than 20 mmHg across coarctation, both of them had tubular type of coarctation.

Tables and figures

Table 1 Patient characteristics (n=51)

Male	38	74.5%
Female	13	25.5%
Age in years	26±8	18-54
Weight (kg)	64±12	35-95
Height(cm)	162±12	125-185
Body surface area {square meter}	1.6±0.2	0.9-2.1
Hypertension	47	92%
Lv dysfunction	5	9.8%
Discrete coarctation	44	86.3%
Tubular coarctation	7	13.7%
Isolated coarctation	26	50.9%
Complex coarctation	25	49.1%

Table 2
Associated cardiac defects

Type of defect	No
Bicuspid aortic valve	18
Aortic regurgitation	9
Aortic stenosis	3
Mitral valve prolapse +MR	3
Patent ductus arteriosus	3
Ventricular septal defect	3
A-V canal	1
ASD secundum	1
Subaortic ridge	1
Isthmus arch hypoplasia	1

Table 3
Base line characteristics of both Stent and Balloon group

	Stent	Balloon	p-value
Age (yrs)	28±9	23±7	0.07
Weight(kg)	66±15	63±9	0.39
Height(cm)	164±13	160±10	0.28
Body surface area(m2)	1.6±0.27	1.6±0.13	0.73
Male	19	19	0.53
Female	6	7	0.65
Hypertension	24	23	0.6
Lv dysfunction	2	3	0.65
Discrete coarctation	21	23	0.5
Tubular coarctation	4	3	0.75
Isolated coarctation	16	10	0.15
Complex coarctation	9	16	0.12
Ascending aorta peak syst.(mmHg)	170±28	163±32	0.39
Descending aorta peak syst.	98±21	101±19	0.52
Pressure gradiant across coarctation	72±24	65±21	0.27
Coarctaion diameter(mm)	8±2	6.5±2.3	0.11
Balloon size(mm)	19±1.9	17±3	0.12
Balloon /aorta ratio	1±0.9	0.95±0.1	0.18

Table 4
Comparison of blood pressure state pre and post intervention

Item	Preintervention	Post intervention
Normotensive	4 (8%)	29 (56.9%)
Hypertensive 1	28 (54.8%)	19 (37.2%)
Hypertensive 2	19 (37.2%)	3 (5.9%)
Total	51 (100%)	51 (100%)

p-value 0.0001

Table 5
Early post-procedural complications in both stent and balloon group

Type of complication	Stent group	Balloon group
Vascular access	2	2
Minor intimal tear	0	5
Prolong chest pain	1	1
Slipped stent	4	0
Paradoxical hypertension	0	1
Total	7 28%	9 34%

p-value 0.021

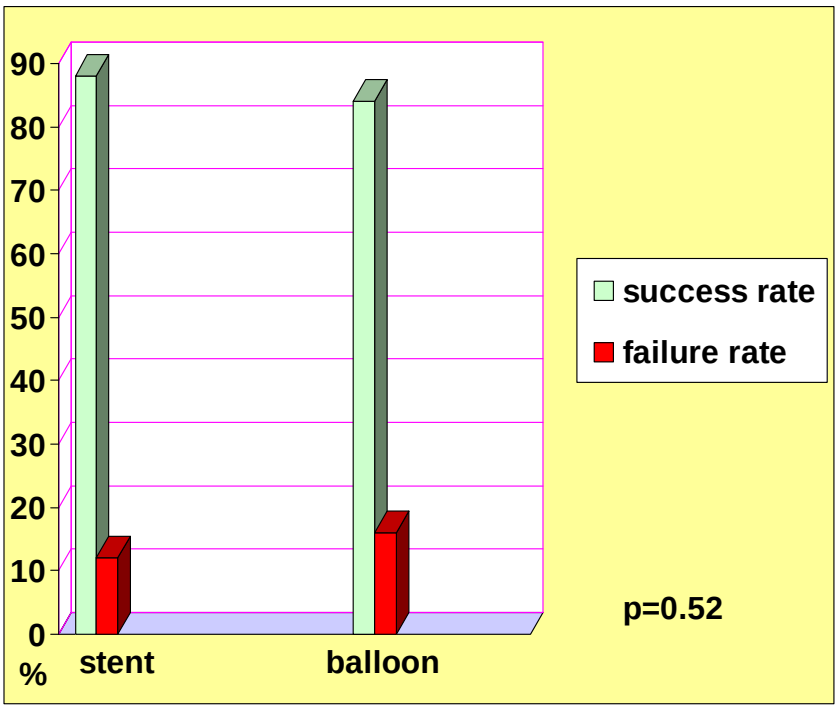

Figure 1. success rate in balloon and stent group

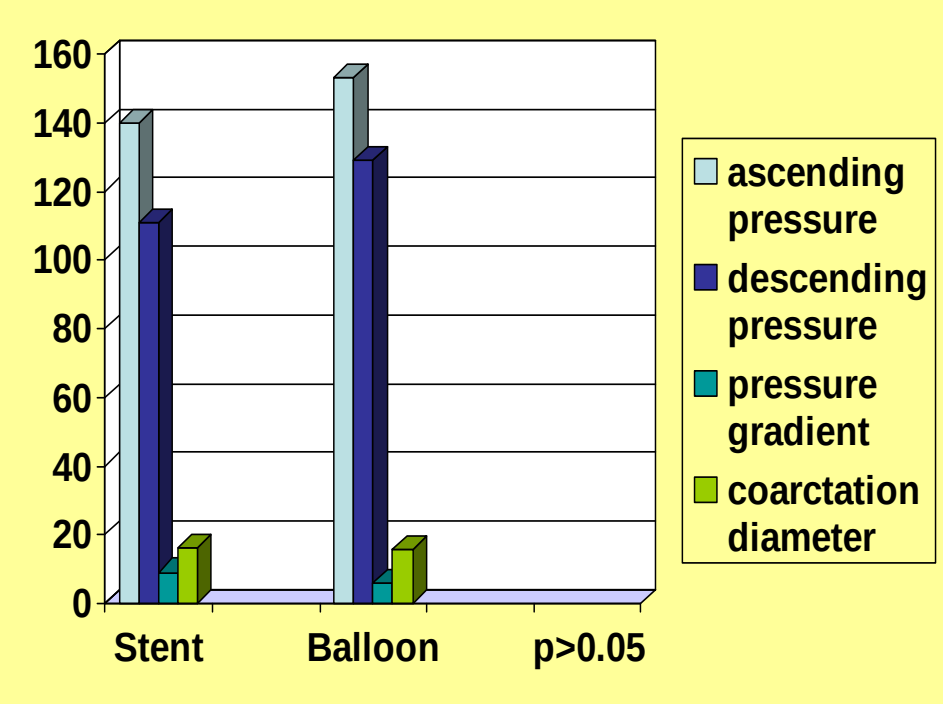

Figure 2 :post procedural hemodynamic and angiographic data in stent and balloon group

Discussion

In this study the immediate hemodynamic and angiographic results after balloon dilatation with or without stent implantation were favorable. post dilatation gradient less than 20 mmHg were obtained in 84% and 88 % of patients in balloon and stent group respectively .

Large series of studies reported a comparable excellent initial result after balloon angioplasty with or without stent implantation (6,9,11,14,15).

McCrindle et al reported the acute result of 422 balloon dilatation for native aortic coarctation performed in 25 institutions, success rate ranged 78-91 % (3).

Hamdan et al study reported an excellent initial result in 32 of 33 stented patient with aortic coarctation (11).

In Multiple logistic regression analysis , only greater ratio of balloon to aorta diameter and discrete type of coarctation could be entered significantly into the final regression model. After controlling for these two variables no other factor was significantly and independtly associated with early success rate .This is in agreement with Ovaert et al who reported a greater ratio of balloon to aorta diameter was independently associated with early success.(16)

The effect of intervention on BP control , our study showed that the blood pressure was normalized without antihypertensive therapy in 25 patients (50%).

Only 43% of patients remains on antihypertensive drugs and those who need two or more antihypertensive drugs were reduced significantly from 19 patients(37%) to three patients only(5.9%) after interventions p=0.0001. These findings concur with the report by Schrader et al (17) who reported a 79 % rate of normalization of blood pressure after coarctation angioplasty in adolescents and adults . The higher rate of normalization of blood pressure in this study as compared with our study was probably because the mean age at time of intervention of this study was younger than that in our

study .Wells et al reported 46% rate of normalization of hypertension after repair in adult (18).

Fawzy et al , showed blood pressure was normal without medication in 27 patients (75%) at follow up one year after angioplasty and only 10 patient (27%) needed drug therapy(19). In another study 30% of patient with surgically treated aortic coarctation remains hypertensive despite correction of their lesion (20). The cause of persistent hypertension following repair or dilatation is unclear but is related to the age at time of repair and the duration of preoperative hypertension(21).

The pressure gradient post intervention was the only factor that predict normal pressure at time of discharge in our regression model.

Regarding Complications in our study, there was no periprocedural or early post procedure death in both stent and balloon group.This is comparable to some large studies where no acute mortality related directly to the procedure has been described (3).

In other study balloon angioplasty was occasionally associated with death in 0.7% (22).

Regarding minor complications, it was significantly higher among balloon group as compared to stent group 34% versus 28% respectively p=0.02. This can be explained from studying table 12 which showed minor tear greater in balloon group, expected finding due to mechanical injury to the intima and media of the aortic wall at site of coactation by inflated balloon which is unavoidable especially in a very severe coarctation .

In all these five patients with intimal tear , coarctation diameter before intervention was less than five mm. In those patients with most severe obstructive lesions, there appear to be more invagination of the wall from the media rather than intraluminal shelf which could be enlarged through dilatation (tearing) within the shelf(3).

Sohn et al using IVUS immediately after dilatation for native coarctation demonstrated that despite high incidence of dissection detected by IVUS many vessels remodel and decrease in size or disappearance of intimal flap and dissection space(23)

Four cases of slipped stent had been described in this study because of direct stenting was used in most of our patients (80%) without predialtation. This made the stent to be released over the narrowed segment liable for forward or backward slipping from narrowed to the dilated segment.This can be prevented by predialating the coarctation segment prior to stenting to make the narrowed area more suitable for stent deployment or use of balloon mounted stent instead of self expandable stent .

Vascular access complication was the third most important complication in this study, it have been reported in up to 19% of patients in other studies(24,25,26).

It is related probably to the use of a large vascular sheath specially with a stent deployment . this type of complication is preventable with further improvement in size, contour of angioplasty catheter delivery system and by use of arterial sheaths of acceptable size and or use of recently introduced closure devices(angioseal and vasoseal) for sealing the puncture site at the end of the procedure (27).

Short term follow up : there were two patients out of twelve in balloon group has significant increased in pressure gradient (more than 20mmHg) on follow up Echo-doppler study six months after intervention , both of these patient has tubular type of coarctation on initial angiography. While those patients who underwent endovascular stenting no one has significant increment in pressure gradient on follow up catheterization after six month . This difference can be explained by the fact that the stent were designed to opposes the recoil of elastic vascular stenosis which probably greater in long segment narrowing than in discrete lesion (3) , so the stent may become extremely useful in patient with tubular lesion by producing a vessel wall support.

On the basis of these data, we are optimistic that transcatheter aortic balloon angioplasty with or without endovascular stent deployment offer an acceptable alternative to surgical repair , it also offer a significant advantage regarding mortality rate and avoiding intubations , general anaesthesia and thoracotomy, it minimizes blood loss and shortens the duration of hospitalization considerably.

Conclusion and Recommendations.

Transcatheter balloon angioplasty with or without stenting is a safe and effective method for relief of native aortic coarctation and offers an acceptable alternative to surgical treatment.

As far as the success rate is similar in balloon and stent group, it is wise to reserve stents for those patients with tubular coarctation or after major dissection.

Predilatation prior to stent deployment is safe and useful to prevent slipping of the stent.

The earlier the intervention , the better is the prognosis regarding the left ventricular function and blood pressure control.

Mortality and morbidity is fairly low with transcatheter intervention and the present complications are minor and preventable in the majority of cases.

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