

# Percutaneous dilatation of coarctation of the aorta, stenotic pulmonary arteries or homografts, and stenotic superior vena cava using Andrastents XL and XXL

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## Abstract

**Background:** Major vessel stenoses are currently successfully treated with stent implantation. Recently, new cobalt-chromium stents (Andrastents XL and XXL, Andramed, Germany) have been introduced into clinical practice. This alloy combines high biocompatibility with radial strength and flexibility.

**Aim:** To present our experience with the use of Andrastents XL and XXL for the dilatation of stenosed pulmonary arteries, coarctation of the aorta (CoA), and a stenosed superior vena cava (SVC).

**Methods:** The study group included 24 patients treated with 26 Andrastents. In 7 patients aged 23.3 (range 18–27) years, with the mean body weight of 64.7 (range 50–77) kg, prestenosing of a calcified pulmonary homograft was performed using 9 Andrastents XL or XXL (length of 30, 39, or 48 mm) before the Melody valve implantation. In one patient with a long and stiff stenosis, 3 stents were necessary. In 12 patients with native CoA aged 30.1 (range 9–55) years, with the mean body weight of 60 (range 25–105) kg, twelve Andrastents XL or XXL (length of 30, 39, or 48 mm) were implanted. In 4 patients with the right or left pulmonary artery stenosis close to the bifurcation (age 8.5 [range 6–10] years, body weight 27.3 [range 17–33] kg), 4 Andrastents 30 XL were implanted. In one child (age 7.5 years, body weight 21.7 kg) with a iatrogenic SVC stenosis (after 2 venous cannulations necessary for 2 surgical corrections of his double-outlet right ventricle), the stenosed site was dilated using Andrastent 21 XL.

**Results:** All procedures were performed successfully. No stent fractures were observed during the follow-up. The mean pressure gradient was reduced from 42.4 to 18 mm Hg (RVOT) in patients who underwent Andrastent and Melody valve implantation, from 54.1 to 13.2 mm Hg in patients with CoA, and from 49 to 21.7 mm Hg in patients with pulmonary artery stenosis. No aneurysm formation, stent migration, or rupture of the treated vessel during stent implantation were observed in any patient. The mean fluoroscopy time during stent implantation was 6.6 min in CoA, 8.8 min in pulmonary artery stenosis, 24.8 min during implantation of Melody valve (with prestenosing of RVOT with Andrastents) and 17.6 min during SVC dilation. Procedural outcomes (evaluated using noninvasive methods) remained favourable during the follow-up (0.5–21 months), with no complications observed.

**Conclusions:** Implantation of Andrastents XL or XXL is a very good therapeutic option in the treatment of major vessel stenoses.

**Key words:** congenital heart defects, percutaneous stent implantation

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## INTRODUCTION

Stent implantation plays an increasing role in dilating stenosed vessels in congenital and structural cardiovascular defects. A number of stent designs are currently available to use in the treatment of major vessel stenoses. However, only few of them have properties which allow their use in vessels with a diameter above 20 mm. Such stents should be characterised by flexibility (which allows their passage through curved vascular segments during implantation) and high radial strength allowing avoidance of elastic recoil. Recently, new cobalt-chromium stents (Andrastents XL and XXL, Andramed, Germany) have been introduced into clinical practice that seem to combine these characteristics. They were approved for the use in the European Union (CE mark) in 2009.

In this report, we present our initial experience with the use of these stents in dilating coarctation of the aorta, right ventricular outflow tract (RVOT) (calcified homografts), pulmonary arteries (PA), and the superior vena cava (SVC). To the best of our knowledge, it is the first published report on the use of Andrastents in clinical practice, although this issue has been debated on several occasions during international congresses [1–3].

## METHODS

This descriptive clinical study has been approved by a local ethics committee, and stent implantation procedures were performed upon obtaining patient or caregiver consent. The purpose of the study was to describe immediate efficacy of Andrastent implantation, possible complications, and early treatment outcomes. Stent implantation procedures were performed between June 2009 and February 2011. Inclusion criteria for the use of the stent in aortic, RVOT, and PA stenoses included pressure gradient above 20 mm Hg (by direct haemodynamic measurements) or, in case of PA and SVC stenoses, a lower gradient associated with markedly abnormal pulmonary flow distribution or resulting in symptoms of systemic venous congestion.

In all patients, Andrastents XL or XXL were implanted. Table 1 describes detailed patient characteristics, with patient numbering reflecting the order of implantation procedures. The mean patient age was  $23.1 \pm 12.9$  years, and body weight was  $53.7 \pm 21.9$  kg.

In 12 patients (age range 9–47 years, mean age 30.1 years, body weight 25–105 kg, mean 60 kg), intervention was performed due to a native coarctation of the aorta located within the aortic isthmus (Figs. 1A, B). A non-stenosed bileaflet aortic valve was present in 7 of these patients. In the patient # 5, ascending aortic and aortic arch hypoplasia was present that had been previously dilated surgically.

In 7 patients (age range 18–27 years, mean age 23.3 years; body weight 50–77 kg, mean 64.7 kg), pretesting of a calcified pulmonary homograft was performed before the Melody stented valve (Medtronic Inc.) implantation (Figs. 2A, B). In

4 patients, the homograft was implanted due to tetralogy of Fallot/pulmonary atresia with ventricular septal defect (VSD) (patients # 1, 4, 9, 15 in Table 1), in 2 patients due to transposition of the great arteries with VSD after a previous Rastelli procedure (patients # 3, 19 in Table 1), and in one patient due to critical pulmonic valvular stenosis (patient # 14).

In 4 patients (age range 6–10 years, mean age 8.5 years; body weight 17–33 kg, mean 27.3 kg), Andrastents were used to dilate the ostium of the right (RPA) or left pulmonary artery (LPA) (Figs. 3A, B). The LPA was dilated in 3 patients (# 6, 13, 20) and the RPA in one patient (# 2). In the patient # 20, the initial diagnosis was transposition of the great arteries, with anatomical correction in the neonatal period, followed by later (at the age of 2 year) surgical dilation of both PA using a patch. During cardiac catheterisation, stenoses of lobar branches of the RPA were found and dilated using balloon angioplasty simultaneously to Andrastent implantation to the LPA. Patients # 6 and # 13 underwent a surgical correction of double outlet right ventricle (DORV). Patient # 2 underwent common truncus arteriosus type II correction using a homograft. In this patient, both PA ostia were stenosed, with Andrastent implantation to the LPA and a 27 mm Genesis stent (Cordis) implantation to the RPA.

In one child (age 7.5 years, body weight 21 kg) following two previous surgical DORV corrections, with symptoms of SVC syndrome (patient # 24 in Table 1), an Andrastent was implanted into the stenosis site in the SVC (Figs. 4A, B).

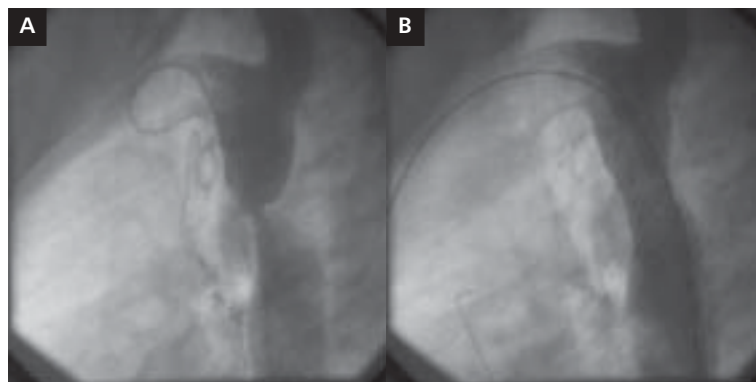
Andrastents (Andramed GmbH, Reutlingen, Germany) are constructed from a cobalt-chromium alloy. They have multicellular hybrid cell structure, constructed from 12 zig-zag elements. This stent design combines open and closed cell structures.

Procedures were performed in local anaesthesia in adults and in general anaesthesia in children. A diagnostic cardiac catheterisation was performed before the intervention in all cases. Detailed measurements of the stenosed vessels and pressure gradients before and after the procedures were made. Femoral artery access was used for coarctation of the aorta, and femoral vein access was used in the remaining cases. After crossing the stenosis site and advancing a superstiff catheter through the stenosis, a long Mullins sheath (Cook, Denmark) of an appropriate diameter was introduced. Following catheterisation, we did not use a hemostatic device to close the punctured vessel in any of the patients. Stent implantation was performed following precise angiographic delineation of the stenosed site. Stents were manually mounted on a balloon catheter. For implantation, it was necessary to use vascular sheaths that were 2 F larger compared to the size required for the used balloon catheter. We used BIB (Numed), Powerflex (Cordis), and Maxi LD (Cordis) balloons (for details see Table 1). Andrastents are available in two sizes: XL, which may be dilated to the diameter of 25 mm, and XXL, which may be dilated to the diameter of 32 mm. Comparison of

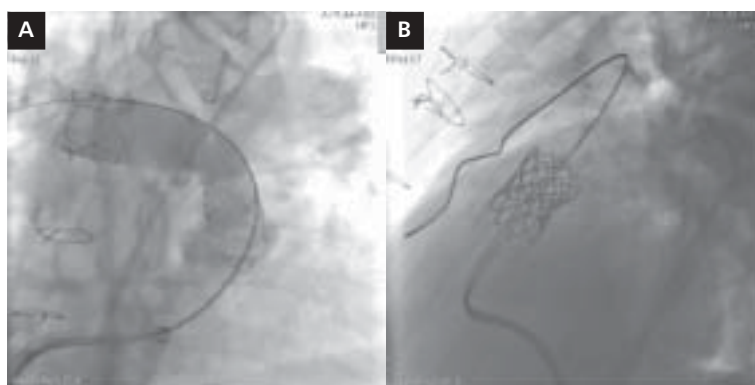
**Table 1.** Characteristics of the 24 patients treatment using 26 Andrastents XL and XXL

Patient no.	Sex	Age [years]	Weight [kg]	Implantation site	Stent	Balloon	Gradient [mm Hg]		Follow-up [months]
							Before	After	
1	M	20	77	PT	39XL	BIB 10/20	54	25	21
2	M	6	17	RPA	30XL	P-Flex 10	96	49	19
3	M	25	77	RVOT/PT	39XXL	BIB 11/22	27	24	14
4	M	18	54	RVOT/PT	39XXL	BIB 11/22	26	11	14
5	F	51	70	CoA	39XL	MaxiLD 16	30	3	12
6	M	9	30	LPA	30XL	MaxiLD14	23	10	12
7	F	19	47	CoA	39XXL	MaxiLD 16	49	26	12
8	F	39	54	CoA	39XL	MaxiLD 14	43	15	11
9	F	24	53	RVOT/PT	39XXL	BIB 11/22	32	8	10
10	M	47	75	CoA	39XXL	BIB 10/20	60	1	9
11	F	16	51	CoA	48XL	MaxiLD 14	46	19	7
12	M	31	83	CoA	48XXL	BIB 11/22	85	26	7
13	F	10	33	LPA	30XL	MaxiLD 16	4	0	7
14	F	27	72	PT	30XXL	BIB 11/22	48	21	6
15	F	22	50	RVOT/PT	2 × 39XXL 1 × 49XXL	BIB 11/22	58	14	6
16	F	22	55	CoA	39XL	BIB 18	31	0	6
17	F	15	41	CoA	39XL	MaxiLD 15	59	0	5
18	M	41	105	CoA	30XL	MaxiLD 14	66	26	5
19	M	27	70	RVOT/PT	39XXL	BIB 10/20	52	23	4
20	M	9	29	LPA	30XL	MaxiLD 15	73	28	2
21	M	41	54	CoA	39XL	MaxiLD 16	37	7	1
22	M	9	25	CoA	30XL	P-Flex 12	89	22	0.5
23	F	17	45	CoA	30XXL	P-Flex 12	47	20	0.5
24	M	7.5	21	SVC	21XL	P-Flex 12	9	1	0.5
Mean ± SD		23.1 ± 12.9	53.7 ± 21.9				47.7 ± 23.5	15.8 ± 12.2	

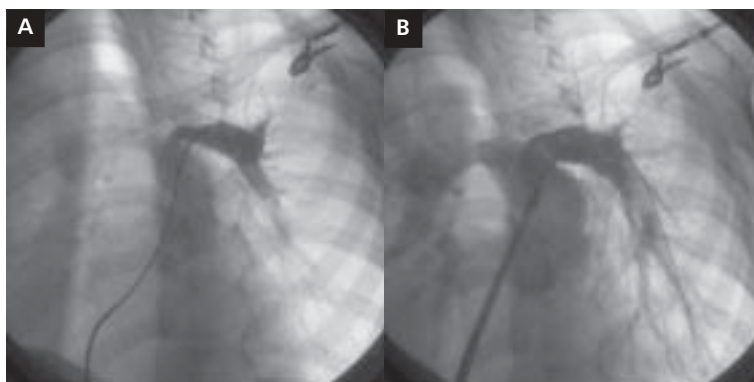
M — male; F — female; RVOT — right ventricular outflow tract; PT — pulmonary trunk; CoA — coarctation of the aorta; LPA — left pulmonary artery; RPA — right pulmonary artery; SVC — superior vena cava; BIB — balloon in balloon catheter; P-flex — Powerflex balloon catheter; MaxiLD — MaxiLD balloon catheter



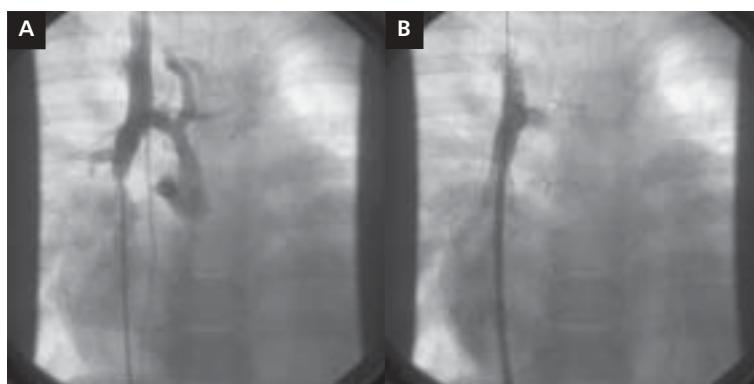
**Figure 1.** A 14-year-old male with congenital coarctation of the aorta. Aortography in a LAO 90 degree view; **A.** Before implantation; **B.** After implantation of an Andrastent 30 XL



**Figure 2.** A 20-year-old man following surgical correction of tetralogy of Fallot, with a calcified homograft showing evidence of both stenosis and regurgitation; **A.** Angiographic image (LAO 30 + SU 10 view) of the pulmonary artery following homograft prestenting using an Andrastent 39 XL (contrast agent injected through the Multitrack catheter); **B.** Fluoroscopy (LAO 90 degrees view). The same patient following implantation of a stented Melody valve into the previously implanted Andrastent (note the difference between less radioopaque Andrastent structure compared to that of the CP stent, on which the Melody valve is mounted)



**Figure 3.** A 9-year-old boy with a significant left pulmonary artery stenosis following surgical double outlet right ventricle correction. Pulmonary angiography (LAO 30 + SU 10 view); **A.** Before implantation; **B.** After implantation of an Andrastent 30 XL



**Figure 4.** A 7.5-year-old boy with a iatrogenic stenosis of the superior vena cava (following two surgical double outlet right ventricle corrections performed using cardiopulmonary bypass). Angiography of the superior vena cava in a PA view; **A.** Before implantation; **B.** After implantation of an Andrastent 21 XL

**Table 2.** Comparison of technical characteristics of different stents

Stent	Genesis XD	Intrastent LD	Andrastent XXL	CP(8Z)
Length [mm]	38	35	48	45
BIB* (15 mm profile) [F]	10	10	10	11
Wire thickness [inches]	0.010	0.011	0.011	0.013
Length [mm] at 12 mm diameter	33.2	35	46.5	42.7
Radial strength at 2 mm compression	4.4	5.4	6.9	6.9
Max. diameter [mm]	18.5	26	32	28

\*Sheath size required for the stent inserted using a balloon-in-balloon (BIB) catheter with the optimal diameter of 15 mm

selected technical characteristics of the stents used to dilate major vessels is shown in Table 2. Both Andrastent sizes (XL and XXL) are available with the length of 13, 17, 21, 26, 30, 39, 48, and 57 mm.

Following stent implantation procedure, all patients underwent follow-up clinical evaluations (physical examination, ECG, and echocardiography) initially every 3 months (during the first year after the implantation) and semiannually thereafter. An imaging study (angiography, MRI or CT angiography) was planned in all patients at 2 years following the implantation.

## RESULTS

We used 26 Andrastents in 24 patients. All procedures were performed successfully. No stent migration, stent fracture, or aneurysm development in the treated vessel were observed in any patient. A significant dilatation of the stenosed site was obtained in all cases. Mean pressure gradient (by direct measurements) decreased from  $47.7 \pm 23.5$  to  $15.8 \pm 12.2$  mm Hg. In one patient with a long, narrowed and calcified homograft following the repair of tetralogy of Fallot, three Andrastents (length 39, 39, and 49 mm) had to be successively implanted (patient # 15 in Table 1).

In patients with coarctation of the aorta, pressure gradient by direct invasive measurements before Andrastent implantation ranged from 31 to 89 (mean 54.1) mm Hg, compared with 3 to 26 (mean 13.2) mm Hg after the implantation. Total fluoroscopy time ranged from 4 to 13 (mean 6.6) min. Elective stent redilatation was performed in two patients at 9 and 12 months, respectively (patients # 7 and # 8).

In patients undergoing pretesting of the calcified homograft before the Melody valve implantation, pressure gradient across the homograft ranged from 26 to 58 (mean 42.4) mm Hg, compared to 8 to 25 (mean 18) mm Hg after the implantation. Total fluoroscopy time including the Melody valve implantation ranged from 18 to 41 (mean 24.8) min.

In patients with PA stenosis, pressure gradient before the implantation ranged from 4 to 96 (mean 49) mm Hg, compared to 0 to 49 (mean 21.7) mm Hg after the implantation. Total fluoroscopy time ranged from 8.7 to 36.7 (mean 8.8) min.

In the child with stenosed SVC, venous pressure gradient decreased from 9 to 1 mm Hg, along with resolution of head

and face oedema. Total fluoroscopy time during this procedure was 17.6 min.

Follow-up noninvasive evaluations showed a good effect of the procedure in all patients, with no increase in pressure gradient. The patients remained in good clinical condition and no complications were observed. The duration of follow-up ranged from 0.5 to 21 months.

## DISCUSSION

Use of stents to dilate large vessels requires appropriate technical characteristics of these devices, primarily in regard to radial strength and stability of the implanted stent. First such stents that were widely introduced into clinical practice were steel Palmaz stents [4] with a closed-cell design. Although effective, they were associated with a number of disadvantages, including stiffness and sharp margins resulting in relatively numerous complications that finally resulted in withdrawal of these stents [5]. A new generation of these stents, named Genesis, was characterised by similar radial strength as compared to the Palmaz stents but these stents were much more flexible [6]. Next, a stent with an open-cell design was introduced, known as Intrastent. These stents were similar to the Genesis stents in regard to radial strength and flexibility, but also had an important advantage of no shortening during dilatation, a significant flaw of other stents [7]. A major advantage was the introduction of Cheatham Platinum (CP) stents, initially designed for dilating coarctation of the aorta [8, 9]. These stents were constructed from a platinum-iridium alloy, had rounded margins and produced much less complications as compared to other stents [10]. They were also characterised by large radial strength and flexibility. Next innovation was the introduction of covered stents which have a bare metal framework similar to all stents described above but are covered with an additional external layer. In covered CP stents and Advanta V12 stent, this is a polytetrafluoroethylene layer. A potential advantage of these stents is the protection afforded to the vessel wall in case of its rupture, and an ability to exclude concomitant aneurysmal lesions. A disadvantage is the risk of adjacent side branch closure in case of stent migration. Generally, experience with the use of covered stents is not large [11, 12].

It is still debated which stent type, bare metal or covered, is superior. This dilemma has not been solved with the recent publication of the European Society of Cardiology guidelines for the management of grown-up congenital heart disease patients [13]. Our own experience in the interventional treatment of coarctation of the aorta includes more than 200 patients [14]. Our present findings show high utility and efficacy of Andrastents in dilating various vessel stenoses but also indicate similar technical properties of these stents as compared to widely used CP stents (Table 2). It seems that the design of Andrastents, combining open and closed cell structures, has the respective advantages of both, i.e. flexibility and ability to adapt to vessel curvatures are combined with high radial strength. In case of prestenting calcified homografts before implantation of a Melody stented valve, the use of Andrastents allows determining whether potential stent fracture involves the Melody valve stent or not, as the latter is mounted on a CP stent.

Another important practical issue is a lower cost of Andrastents as compared to CP stents [15].

## CONCLUSIONS

Implantation of Andrastents is a very attractive and effective therapeutic option in the treatment of major vessel stenoses. However, further data regarding long-term outcomes of this treatment are necessary.

**Conflict of interest:** none declared

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# Przezskórne poszerzanie koarktacji aorty, zwężonych tętnic płucnych (lub homograftów) i żyły głównej górnej za pomocą Andrastentów XL lub XXL

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## Streszczenie

**Wstęp:** Zwężenia dużych naczyń aktualnie skutecznie leczy się za pomocą implantacji stentów. Ostatnio do praktyki klinicznej wprowadzono nowe stenty kobaltowo-chromowe (Andrastent XL i XXL). Powyższy stop zapewnia wysoką biokompatybilność oraz połączenie wysokiej siły odśrodkowej stentu z jego giętkością.

**Cel:** Celem pracy było przedstawienie własnych doświadczeń w zastosowaniu Andrastentów XL i XXL w poszerzaniu koarktacji aorty (CoA), zwężeń gałęzi tętnicy płucnej (TP), zwapniałych homograftów w pozycji płucnej i żyły głównej górnej (SVC).

**Metody:** Leczeniem objęto 24 pacjentów, u których wszczepiono 26 Andrastentów. U 7 z nich w wieku 23,3 roku (18–27 lat), o masie ciała 64,7 (50–77) kg przed implantacją zastawki płucnej na stencie Melody dokonano prestenowania zwapniałego homograftu za pomocą 9 Andrastentów XL lub XXL o długości 30, 39 lub 48 mm. U 1 pacjenta z długim niepodatnym zwężeniem wszczepiono 3 stenty. U kolejnych 12 osób w wieku 30,1 roku (9–55 lat), o masie ciała 60 (25–105) kg z wrodzoną CoA dokonano implantacji Andrastentów XL lub XXL o długości 30, 39 lub 48 mm. U kolejnych 4 pacjentów w wieku 8,5 roku (6–10 lat) i o masie ciała 27,3 (17–33) kg zastosowano stenty XL 30 do prawej bądź lewej gałęzi płucnej blisko jej odejścia od pnia płucnego. U 1 dziecka w wieku 7,5 roku, o masie ciała 21 kg zwężoną jatrogenie SVC (po dwóch kaniulacjach związanych z operacją przeprowadzoną w krążeniu pozaustrojowym) poszerzono tę zmianę za pomocą Andrastentu XL 21.

**Wyniki:** Wszystkie zabiegi ukończono pomyślnie, uzyskując spadek gradientu ciśnień w przypadku CoA z 54,1 do 13,2 mm Hg; poszerzania RVOT (homograftu) z 42,4 do 18 mm Hg, gałęzi TP z 49 do 21,7 mm Hg i zwężenia SVC z 9 do 1 mm Hg. Podczas implantacji nie stwierdzono ani jednego przypadku migracji stentu, jego pęknięcia czy powstania tętniaka. Średni czas fluoroskopii wynosił w przypadku: implantacji Andrastentu do CoA — 6,6 min; implantacji zastawki Melody (z prestenowaniem Andrastentem RVOT) — 24,8 min, poszerzania gałęzi TP — 8,8 min i poszerzania SVC — 17,6 min. W dalszej obserwacji (od 0,5 do 21 miesięcy) stan pacjentów pozostawał dobry, w badaniach nieinwazyjnych utrzymywał się dobry wynik zabiegu i nie zanotowano powikłań.

**Wnioski:** Przezskórne poszerzanie zwężonych dużych naczyń za pomocą Andrastentów stanowi bardzo dobrą opcję terapeutyczną.

**Słowa kluczowe:** wrodzone wady serca, przezskórna implantacja stentów

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