Covered stents in patients with complex aortic coarctations

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Background There are limited data in the literature about the use of covered stent in patients with aortic coarctation.

Methods Between January 2004 and September 2006, we implanted covered Cheatham-Platinum stents in 33 patients with complex aortic coarctation (23 men, median age 13 years, range 6-66 years). Twenty subjects had native aortic coarctation, whereas 13 had recoarctation. All procedures were performed under general anesthesia and orotracheal intubation.

Results The stents used ranged from 22 to 45 mm in length. The mean fluoroscopy and procedure times were 14 ± 6 and 74 ± 15 minutes, respectively. After implantation, the gradient across the stenosis decreased significantly (pre stent: median value 39 mm Hg [range 20-75 mm Hg] vs post stent: median value 0 mm Hg [range 0-12 mm Hg] [$P < .0001$]). Vessel diameter increased from a median value of 5 mm (range 0-11) to a median value of 15 mm (range 10-25) ($P < .0001$). The stents were placed in the correct position in all subjects. No complications occurred, and on angiographic control, the stenoses had been relieved and the aneurysms completely excluded. During a median follow-up of 12 months (1-40 months), the results were stable without complications. One patient developed intrastent restenosis due to a significant endothelial proliferation that was successfully treated by high-pressure balloon angioplasty.

Conclusions Covered Cheatham-Platinum stents are promising tools for the treatment of complex aortic coarctation.
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Surgery or standard transcatheter approaches (balloon angioplasty or bare stent implantation) can be associated with significant morbidity and mortality in patients with complex aortic coarctations (ie, subatretic aortic coarctation or associated with aneurysm). Bare stents have been used in all sites in patients with congenital heart diseases, and large series and follow-up studies are reported in literature.[1-3] However, even with these stents, aneurysms may form, or aortic rupture may occur.[3]

Covered stents are currently widely used in the treatment of abdominal and thoracic atherosclerotic aneurysm in adults.[4] However, there is limited experience on the use of covered stents in congenital heart diseases,[5-9] a setting in which their role remains to be clearly defined.

In the present study, we report our experience of 33 patients in whom covered Cheatham-Platinum (CP) stents were used for the treatment of complex aortic coarctation.

Methods

The data of 33 patients (23 males) who underwent implantation of covered CP stents (NuMED, Hopkinton, NY) for complex aortic coarctation were collected prospectively between January 2004 and September 2006.

We defined as complex an aortic coarctation or recoarctation when it was subatretic, associated with an aneurysm, associated with an irregular wall, associated with dilation of the ascending aorta, associated with patent ductus arteriosus, or occurring in patients previously treated with the use of surgical patches.

The median age and weight at the time of the stent implantation were 13 years (range 6-66 years) and 60 kg (range 22-110 kg), respectively. Informed consent was obtained from all the patients or their parents.

Twenty subjects had native aortic coarctation: 7 had subatretic coarctation (Figure 1), 10 had severe aortic coarctation with irregular wall, 2 had an associated aneurysm, and 1 had an associated patent ductus arteriosus (Figure 2).

Thirteen subjects had aortic recoarctation: in 8 subjects, aortic recoarctation occurred after surgery. Two patients had an associated aneurysm; 3 had severe aortic recoarctation after

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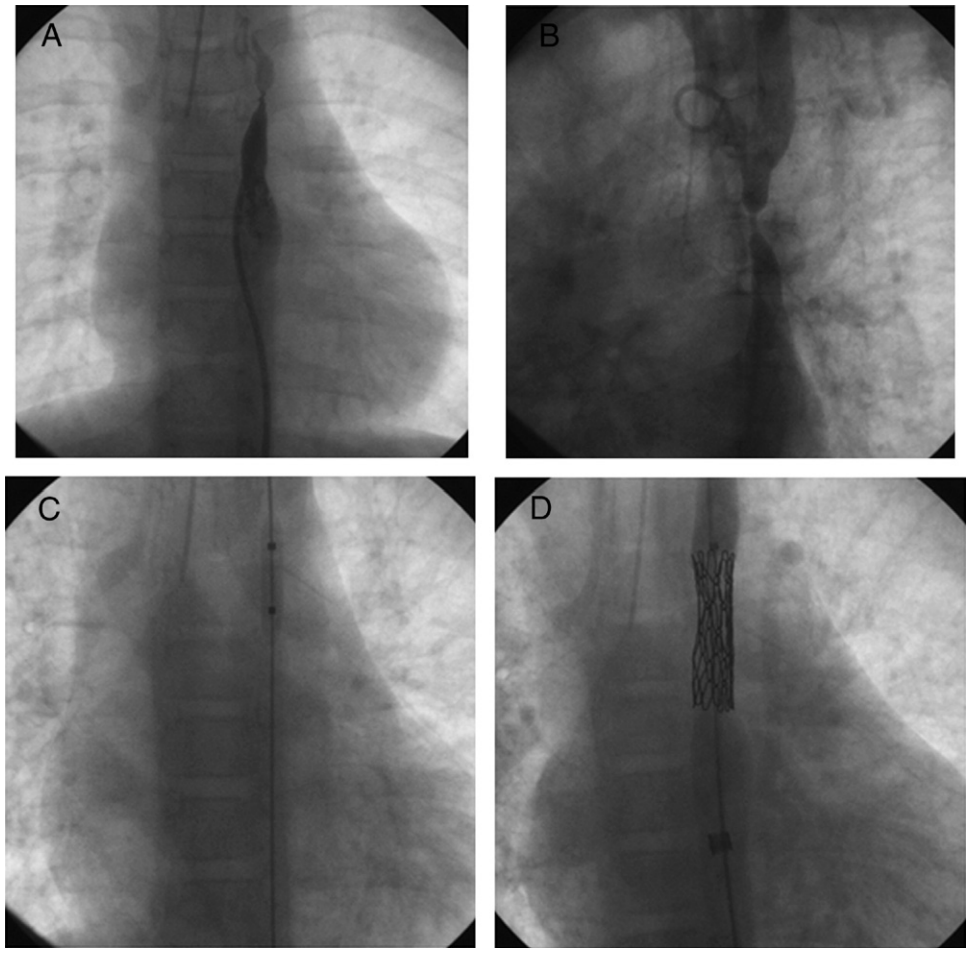
Figure 1



Subatretic native aortic coarctation. **A**, thoracic aortography in the anteroposterior view with the multipurpose catheter near the coarctation. **B**, thoracic aortography in the anteroposterior view with pigtail across the coarctation. **C**, Predilation by using balloon angioplasty. **D**, The stent is deployed and no residual stenosis is present.

having been treated surgically by the use of e-PTFE patch; finally, 3 of these patients had severe aortic recoarctation and an intimal irregularity of the aortic wall.

In another 5 subjects, recoarctation occurred after percutaneous treatment, and it was associated in all subjects with aneurysm formation. Of 5 subjects, 3 had a previous balloon angioplasty, whereas 2 had a stent implantation for subatretic aortic coarctation.

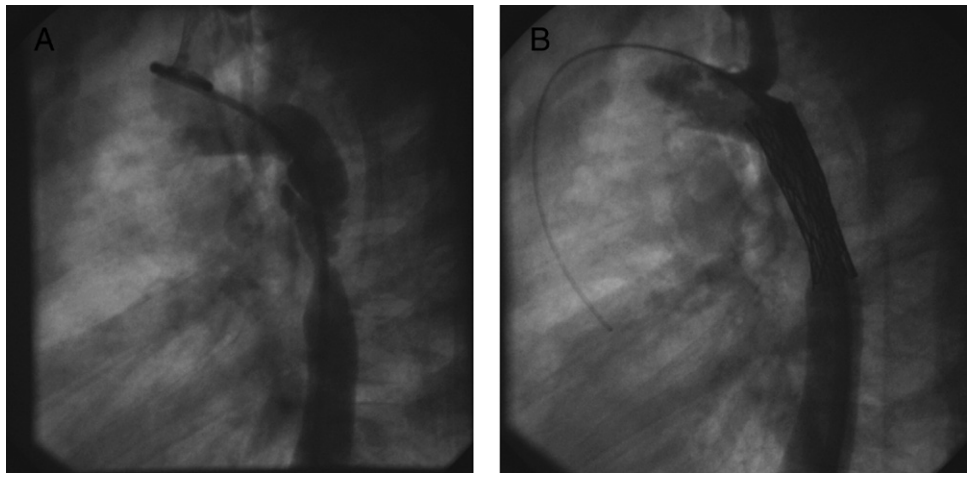
Implantation technique

The patients underwent general anesthesia and orotracheal intubation. Intravenous heparin (100 IU/kg, maximum of 5000 IU) was given immediately after femoral artery cannulation, which was achieved by using an 8F introducer. The stenotic segment was crossed by a 6F multipurpose catheter and a floppy guide wire (0.035-in. Terumo guide wire). The catheter was exchanged with a standard 0.035-in., 260-cm exchange guide wire for a pigtail catheter. The pressure gradient was measured between the 8F femoral sheath and the pigtail catheter located in the ascending aorta. Anteroposterior, 40° left anterior oblique and lateral angiograms were obtained with the holes of the pigtail catheter close to the stenotic area.

The following measurements were obtained from the angiography: (1) diameter and length of the stenotic area, (2) diameter of the descending aorta at the level of the diaphragm, (3) diameter of the aorta at the level of the subclavian artery, and (4) diameter of the transverse arch.

The diameter of the balloon was chosen to be equal to that of the distal arch at the level of the origin of the subclavian artery. If hypoplasia of the distal arch was present, the diameter of the transverse arch was used to choose the balloon. When a near atretic aortic coarctation was found, we performed predilation of the aortic segment by using coronary balloons. Furthermore, in these cases, we chose to dilate up to a maximum of 6 to 8 times the diameter of the stenotic area.

Figure 2



Native aortic coarctation with multiple-wall aneurysm. **A**, Descending aortogram in the lateral view. **B**, descending aortogram in the lateral view after implantation of a 29-mm covered stent showing a good result. Aneurysms are completely excluded.

The balloon catheter was chosen to be longer than the stent length. The length of the stent was determined by the distance from just beyond the left subclavian artery or the left common carotid if the left subclavian artery had been sacrificed in previous surgery, to about 10 to 15 mm beyond the site of the coarctation. BIB balloons (NuMED Inc, Cornwall, Ontario, Canada) or crystal balloons (BALT, Montmorency, France) were used. Mullins transseptal long sheaths (Cook Europe, Bjaeverskov, Denmark) were chosen to be 3F to 4F larger than the sheath needed for the balloons alone. Long sheaths ranging from 11F to 14F were used. The Mullins sheath was exchanged over a 0.035-in. stiff guide wire positioned in the ascending aorta or in the right subclavian artery. The length of the CP stents is covered with expanded polytetrafluorethylene. These stents have been previously described,[5-9] and they are available in lengths from to 22 to 45 mm. We used only the 8-zig covered CP stents.

The balloon with the stent was manually inflated in the correct position, up to the pressure recommended by the manufacturer, which was usually up to 4 to 6 atm. Angiographies were performed during and after the placement of the stent through the side arm of the sheath or by using a pigtail to asses the result and to rule out dissection or rupture of the aorta. Pressures were recorded after the procedure. Hemostasis was achieved by manual compression or surgical repair. All patients received cephalosporin for 24 hours and aspirin at a dose of 3 to 5 mg/kg once a day for 6 months after the implantation.

Postoperative care

To monitor the arterotomy site, gastrointestinal symptoms, and rebound hypertension, the patients were kept in hospital for 2 to 3 days after the procedure, after which they were discharged.

Follow-up protocol

During follow-up, patients underwent physical examination, including blood pressure measurements, electrocardiogram, and echocardiography, at 1, 3, 6 and 12 months. Spiral computed tomographic scan and ergometry were performed 3 and 12 months after the procedure.

Statistical analysis

All the data were reported as frequencies, means (SDs) or median with range as applicable. A paired Student *t* test was used to compare changes in pressures and diameters before and after procedure. All tests were 2-sided. $P < .05$ was considered as significant.

Results

The lengths of the stents ranged from 22 to 45mm. The mean fluoroscopy and procedure times were 14 ± 6 and 74 ± 15 minutes, respectively.

After implantation, the gradient across the stenosis decreased significantly (pre stent: median value 39 mm Hg (range 20-75 mm Hg) vs post stent: median value 0 mm Hg (range 0-12 mm Hg) ($P < .0001$). Vessel diameter increased from a median value of 5 mm (range 0-11) to a median value of 15 mm (range 10-25) ($P < .0001$).

The stents were placed in the correct position in all subjects. No complications occurred, and angiographic controls showed that the stenoses had been relieved and the aneurysms completely excluded. During a median follow-up of 12 months (1-40 months), the results were stable without complications.

There were no differences in either early or follow-up results between subjects with native aortic coarctation when compared to patients with recoarctation.

Only 1 patient showed a significant increase of obstacle at the level of the aortic isthmus 1 year after treatment due to severe intrastent stenosis related to endothelial proliferation. In fact, the diameter of the vessel reduced

Table I. Characteristics of patients and follow-up data

No	Name	Diagnosis		Age at procedure (y)	Preprocedure systemic pressure at rest	Systemic blood pressure at rest at latest follow-up (mm Hg)	Antihypertensive therapy at follow-up	Blood pressure response at exercise testing at follow-up
1	BV	Subatretic native		27	140/90	110/90	No	Normal
2	GC	Recoarctation after balloon angioplasty	A	12	140/85	115/75	No	Normal
3	BP	Recoarctation after surgery (e-PTFE patch)		29	160/70	120/70	No	Normal
4	SL	Recoarctation after bare stent	A	27	140/70	110/80	No	Normal
5	SA	Recoarcation and after bare stent	A	20	150/70	120/80	No	Normal
6	PMP	Subatretic native		12	140/60	115/70	No	Normal
7	VB	Recoarctation after surgery	A	14	140/70	110/60	No	Normal
8	TA	Recoarctation after surgery (e-PTFE patch)		9	150/60	120/80	No	Normal
9	CL	Recoarctation after balloon angioplasty	A	14	145/70	110/75	No	Normal
10	CP	Subatretic native		38	170/80	120/80	No	Normal
11	RF	Recoarctation after surgery	A	45	180/100	140/90	Yes	Hypertensive
12	UA	Native and patent ductus arteriosus		17	160/90	130/80	No	Normal
13	LF	Native	IW	18	160/100	130/80	No	Normal
14	MM	Native	IW	16	170/90	120/80	No	Normal
15	CD	Subatretic native	A	7	160/90	120/80	Yes	Hypertensive
16	BP	Native	A	35	170/70	120/80	No	Normal
17	GS	Subatretic native		6	160/80	100/60	No	Normal
18	AN	Native	IW	12	150/70	125/70	No	Normal
19	EM	Subatretic native		17	160/90	110/80	No	Normal
20	AA	Subatretic native		11	160/95	130/80	Yes	Hypertensive
21	LM	Recoarctation after surgery	IW	14	150/75	110/85	No	Normal
22	CL	Native	IW	12	140/60	120/70	No	Normal
23	LM	Native	IW	13	180/90	130/80	Yes	Hypertensive
24	PA	Native	IW	10	140/75	115/65	No	Normal
25	DG	Native	IW	12	150/80	130/60	Yes	Hypertensive
26	SF	Recoarctation after surgery (e-PTFE patch)		16	190/100	130/90	Yes	Hypertensive
27	DPG	Native	IW	26	180/70	140/80	Yes	Hypertensive
28	RR	Native	A	38	150/90	120/80	No	
29	AV	Recoarctation after surgery	IW	19	170/70	140/70	Yes	Hypertensive
30	GM	Recoarctation after balloon angioplasty	A	7	130/70	100/70	No	Normal
31	NJ	Native	IW	19	160/70	110/70	No	Normal
32	DAA	Native	IW	18	200/100	130/90	No	Normal
33	DA	Recoarctation after surgery	IW	25	160/80	140/80	Yes	Hypertensive

A, Aneurysm; *IW*, irregular aortic wall.

from 12 mm at stent implantation to 8 mm. He was successfully treated by high-pressure balloon angioplasty using a 12 × 40 ultrathin balloon (Boston Sci Ltd, Cork, Ireland) dilated up to 12 atm. Nine subjects required antihypertensive drugs at follow-up due to the occurrence of systemic hypertension during exercise testing (Table I). In all patients needing drugs, β-blockers were 2used.

Discussion

Aortic coarctation in adulthood in patients with an associated aneurysm, in subjects with near-atretic aortic histmus, or in subjects with recurrent pathology, is a very challenging clinical problem.

In fact, in these cases, surgical procedures can be hazardous in regard to hemostatic control of large intercostals arteries; furthermore, incidence of postrepair paraplegia is greater than in simple aortic coarctation,[10] in particular when an aneurysm is present because of the need to sacrifice intercostal arteries.

Standard percutaneous techniques appear promising, but they can be associated with major limitations. In fact, limiting factors of angioplasty alone are recoil of the vessel with recurrence of stenosis and vascular injury with consequent vessel dissection or aneurysm formation.[11,13] The use of bare stents has solved the first problem, but aneurysm formation still remains an issue, the reported incidence being up to 5%.[2,3,12-15] Furthermore, Palmaz stents have sharp edges and are associated with the risk of vessel dissection. In our earlier experience,[3] 1 subject died due to vessel dissection, and 2 subjects treated with bare stents for near-atretic aortic coarctation developed an aneurysm of the aortic wall at the level of the stent.

These drawbacks may be overcome with the use of covered CP stents. These stents have rounded edges that are less traumatic to the native vessels. Furthermore, the ePTFE protects the stenotic and diseased segment, particularly when a subatretic segment is being treated. To obtain a good result, it is of paramount importance to use a covered stent of sufficient length to straddle the diseased tissue completely.

There are not a large amount of data about the use of covered CP stents in the management of aortic coarctation.[5-9,12,16-19] Ewert et al[16] reported their experience with the use of 60 CP stents. Eleven patients (median age 40 years, range 8-67 years) were treated with a covered CP stent for subatretic aortic coarctation in 6 cases, native coarctation in 2 cases, aortic recoarctation in 2 cases, and aortic recoarctation and aneurysm in 1 case. Qureshi et al[7] implanted covered stents into 4 subjects with aortic coarctation. Two of these subjects had had a previous balloon dilation with subsequent recoarctation and aneurysm formation. They were both successfully treated with covered CP stents, 1 with a 34-mm and the other with a 39-mm stent.

Pedra et al[17] used covered CP stents and self-expandable stent graft in 9 patients. The procedure was successful in all subjects. However, these authors reported the development of wall aneurysm in 2 patients despite the use of covered stents.

Tzifa et al[9] reported a multicenter experience of 30 patients (mean age 28 years, range 8-65 years) treated by using covered CP stents. During a median follow-up of 12 months, all stents were patent and in good position. Minor problems were encountered in 2 subjects, whereas 4 more patients needed subsequent balloon dilation after the initial procedure. Finally, in 43% of the subjects, the antihypertensive medication was either decreased or stopped.

In addition, there are single case reports on the use of covered stents.[5,8,18] Furthermore, there are rare reports of self-expanding stents being used to treat aneurysms in patients who were previously surgically treated for aortic coarctation.[19] However, in these cases, no recoarctation was present. Finally, Ovaert et al[11] published the successful implantation of graft Jomed stents in 5 patients, 2 of whom had postangioplasty aneurysm formation.

In our series, which to our knowledge is the largest single-center experience reported in literature, we used covered CP stents to treat patients with complex aortic coarctation. The procedure was successful in all cases, and results were stable during a median follow-up of 12 months. Only 1 subject showed intrastent restenosis due to significant endothelial growth.

Finally, no data has been reported on subjects in whom a covered stent was placed within a previous bare stent. We treated 2 subjects with this situation without problems.

However, there are some concerns about their use. The main one is the possibility of occluding side branches, especially in the case of the spinal artery. However, the spinal artery usually originates below the level of the ninth thoracic vertebra and, in particular, in the aorta below the diaphragm.[20] Therefore, spinal artery occlusion is unlikely to occur.

A potential concern could be related to the occurrence of embolization of a covered stent. If this situation occurs with a bare stent, it can be dilated in the abdominal or thoracic aorta without major problems because branching arteries remain patent. If this is the case while using a covered stent, many problems may occur if important arteries are closed by the ePTFE coverage. Therefore, implantation has to be performed very carefully.

Another concern is related to the use of CP stents in growing children. In fact, these stents are covered with ePTFE, which potentially limits the extent to which they can be redilated. However, we used only 8-zig stents, and the ePTFE covering it is quite an elastic material and

is usually quite abundant. Furthermore, it gives no inflammatory reaction. For all these reasons, we believe that these stents are capable of being redilated up to an adult size.

Finally, there is the issue of intrastent restenosis that occurred in one of our patients, and that has to be investigated in the follow-up.

The main limitations of our report are related to the relatively small number of patients treated and the lack of data about very long-term follow-up. Nevertheless, considering our experience and published data, we believe that covered CP stents are very useful tools for complex aortic coarctation.

Finally, probably even in "simple" coarctation, use of covered CP stents may increase the safety of procedure over either short- or long-term periods. However, randomized studies of bare versus covered stents should be performed in order to address this issue.

References

1. Mullins CE, O'Laughlin MP, Vick III GW, et al. Implantation of balloon-expandable intravascular grafts by catheterization in pulmonary arteries and systemic veins. Circulation 1988;77:188-9.
2. O'Laughlin MP, Perry SB, Lock JE, et al. Use of endovascular stents in congenital heart disease. Circulation 1991;83:1923-39.
3. Chessa M, Carrozza M, Butera G, et al. Results and mid–long-term follow-up of stent implantation for native and recurrent coarctation of the aorta. Eur Heart J 2005;26:2728-32.
4. Taylor PR, Gaines PA, McGuinness CL, et al. Thoracic aortic stent grafts—early experiences from two centres, using commercially available devices. Eur J Vasc Endovasc Surg 2001;22:70-6.
5. Forbes T, Mastisoff D, Dysart J, et al. Treatment of coexistent coarctation and aneurysm of the aorta with covered stent in a pediatric patient. Pediatr Cardiol 2003;24:289-91.
6. Ewert P, Abdul-Khaliq H, Peters B, et al. Transcatheter therapy of long extreme subatretic aortic coarctation with covered stents. Catheter Cardiovasc Interv 2004;63:236-9.
7. Qureshi SA, Zubrzycka M, Brzezinska-Rajszys G, et al. Use of covered Cheatham-Platinum stents in aortic coarctation and recoarctation. Cardiol Young 2004;14:50-4.
8. Gunn J, Cleveland T, Gaines P. Covered stent to treat co-existent coarctation and aneurysm of the aorta in a young man. Heart 1999;82:351.
9. Tzifa A, Ewert P, Brzezinska-Rajszys G, et al. Covered Cheatham-Platinum stents for aortic coarctation. Early and intermediate results. J Am Coll Cardiol 2006;47:1457-63.
10. Kirlklin/Barrat-Boyes. Cardiac surgery. 3rd ed. Philadelphia: Churcill Livingstone; 2003. p. 1315-77.
11. Ovaert C, Benson LN, Nykanen D, et al. Transcatheter treatment of coarctation of the aorta: a review. Pediatr Cardiol 1998;19:27-44.
12. De Giovanni JV. Covered stents in the treatment of aortic coarctation. J Interv Cardiol 2001;14:187-90.
13. Fawzy ME, Awad M, Hassan W, et al. Long-term outcome (up to 15 years) of balloon angioplasty of discrete native coarctation of the aorta in adolescents and adult. J Am Coll Cardiol 2004;43:1062-70.
14. Suarez de Lezo J, Pan M, Romero M, et al. Immediate and following findings after stent treatment for severe coarctation of aorta. Am J Cardiol 1999;83:400-6.
15. Cheatham JP. Stenting of coarctation of the aorta. Catheter Cardiovasc Interv 2001;54:112-25.
16. Ewert P, Schubert S, Peters B, et al. The CP stent—short, long, covered—for the treatment of aortic coarctation, stenosis of pulmonary arteries and caval veins, and Fontan anastomosis in children and adults: an evaluation of 60 stents in 53 patients. Heart 2005;81:948-53.
17. Pedra CA, Fontes VF, Esteves CA, et al. Use of covered stents in the management of coarctation of the aorta. Pediatr Cardiol 2004;26:431-9.
18. Khan MS, Moore JW. Treatment of abdominal aortic pseudoaneurysm with covered stents in a pediatric patient. Catheter Cardiovasc Interv 2000;14:445-8.
19. Ince H, Petzsch M, Rehders T, et al. Percutaneous endovascular repair of aneurysm after previous coarctation surgery. Circulation 2003;108:2967-70.
20. Connolly JE. Prevention of spinal cord complications in aortic surgery. Am J Surg 1998;176:92-101.