SMART Control stents in femoropopliteal region

SMART Control stentovi u femoropoplitealnom regionu

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Abstract

Introduction/Aim. Occlusive disease of lower limb arteries have been so far traditionally best treated with bypass surgery, but we want to find minimally invasive approach that should be at least as good as conventional surgery, and hopefully better. The aim of this study was to evaluate SMART Control stents (Cordis, J&J) in Trans Atlantic Society Consensus (TASC) B and C femoropopliteal lesions during one-year follow-up.

Methods. Retrospective nonrandomized analysis included forty arteries in consecutive 40 patients who were stented with SMART Control stents. Primary patency at 12-month verified with Duplex Ultrasound and Acute Brachial Index (ABI) as well as freedom from Target Vessel Revascularization (TVR) were primary endpoints.

Results. Primary technical success at stent implantation was 100%. Mean ABI values were preprocedurally 0.50, postprocedurally 0.83, at one month 0.86, at six months 0.84, at one year 0.78. After one year 39 stents were patent (97.5%).

Conclusion. Excellent performance of the stent from technical point of view and a midterm results in vessel patency, as well as the absence of need for TVR were achieved. Yet, life expectancy in this cohort group of patients demands longer follow up data to draw a definite sustained positive conclusion.

Key words: femoral artery; arterial occlusive diseases; stents; prognosis.

Introduction

Well known factors influencing difficulties in any treatment of femoropopliteal arterial segment include different external and internal forces: proximity of major flexing points, large muscle masses around it, lack of high diastolic flow, etc. Apart from relatively recent phylogenetic origin, there are almost no collateral vessels along the entire course of the artery. From the very beginning of the endovascular approach to this territory, there were great many controversies about the issue of their true clinical benefit. Only recently, new papers on clinical trials about nitinol selfexpandable stents in femoropopliteal region really showed a substantial improvement in patency rates.

Uvod/Cilj. Okluzivne bolesti arterija donjih ekstremiteta tradicionalno su do sada najbolje lečene bypass hirurškom intervencijom, ali mi želimo da pronađemo minimalno invazivni pristup koji bi bio barem toliko dobar kao konvencionalna hirurgija, a možda i bolji. Cilj ovog rada bila je evaluacija SMART Control stentova (Cordis, J&J) kod Trans Atlantic Society Consensus (TASC) B i TASC C femoropoplitealnih lezija tokom jednogodišnjeg praćenja. Metode. Ovom retrospektivnom ne-randomizovanom studijom obuhvaćeno je 40 arterija kod uzastopnih 40 bolesnika kod kojih su postavljeni SMART Control stentovi. Primarna prolaznost u dobi 12 meseci, verificovana dupleks ultrazvukom i Ancle Brachial Index-om (ABI), kao i odsustvo potrebe za revaskularizacijom ciljne arterije (Target Vessel Revascularisation – TVR) bili su primarni konačni ciljevi. Rezultati. Primarni tehnički uspeh procedure ugrađenja stentova bio je 100%. Srednja ABI vrednost bila je preproceduralno 0.50, postproceduralno 0.83, posle jednog meseca 0.86, posle šest meseci 0.84, a posle jedne godine 0.78. Posle jedne godine 39 stentova bilo je prolazno (97.5%). Zaključak. Analiza je pokazala odlično ponašanje stenta sa tehničkog gledišta, odlične srednjoročne rezultate prolaznosti arterija, kao i odsustvo potrebe za TVR. Ipak, očekivani životni vek kod ove populacije bolesnika zahteva duže praćenje u cilju donošenja stabilnih pozitivnih zaključaka.

Ključne reči: a. femoralis; arterije, okluzione bolesti; stentovi; prognoza.
The aim of this study was to evaluate the safety, efficacy and performance of nitinol slotted tube SMART Control stents (Cordis, J&J) in patients presented with Trans Atlantic Society Consensus (TASC) type B and type C distal femoral and proximal popliteal artery lesions during one-year follow-up.

Methods

A retrospective nonrandomized analysis included the collected data from 40 arteries in the consecutive 40 patients. Primary patency at 12 months verified with Duplex Ultrasound and freedom from Target Vessel Revascularization (TVR) were final goals and primary endpoints. Acute Brachial Index (ABI) was measured before and immediately after the procedure, at 30 days, six months and one year. A drop of at least 0.15 in ABI was considered a secondary endpoint. A peak systolic velocity (PSV) of 150 cm/s or less was considered a success. A raise in PSV above 230 cm/s was indicated as a hemodynamically significant (> 50%) restenosis and also a secondary endpoint.

Antegrade approach with 6Fr sheath was performed in 27 of the patients. Crossover access was performed in 13 patients utilizing a long 7Fr Vista Brite (Cordis J&J) 45 cm arterial sheath. Lesions were approached with either soft or stiff Terumo hydrophilic 0.035" angled guide wire supported with straight or multipurpose 5Fr diagnostic catheter, and if not long (260 cm) one Terumo guide wire was available at the moment, after passing the lesion, 150 cm long one would be changed for an exchangeable 260 cm (Amplatz superstiff) guide wire. All the lesions were predilated with balloon dilatation catheters of 4 mm or 5 mm. Intentional subintimal recanalisation was not included in the study. Every patient received Heparin 100 IU per kg of body weight before the moment of the lesion traversing. Activated Clotting Time (ACT) was routinely monitored. The preferred ACT value to be reached was 250 sec. If postdilatational angiogram revealed less than 30% residual stenosis, without angiographic signs of dissection, those lesions were left alone and no stent implantation was considered an option. Every other outcome precluded stenting with SMART Control stent (Cordis J&J). Crossover placement of the stent through the sheath seemed to pass with no troubles in all the cases nevertheless the acuteness of the aortic bifurcation angle. Occasionally slight pullback of the sheath was necessary to straighten and pass through the kink on the sheath in the case of acute aortic bifurcation angle. Early sheath removal was always performed with either manual compression hemostasis (5 patients), Angio Seal (St Jude) (17 patients), or STARCLOSE (ABBOTT) (18 patients) closure device. Stent visibility was fair. Maneuverability and handling of the stent in the lesion was good. Postdilatation was performed in all the cases with a balloon matched to the artery diameter or max 10% larger and only within the stent struts. Every patient was prepared with tienopiridine derivate, clopidogrel or ticlopidin, continued for three months and aspirin 100 mg indefinitely.

Categorical variables are expressed as the number and percentage of the patients. Continuous variables are presented as an average ± SD, if appropriate. Stent patency rates were calculated on the basis of color-coded duplex sonography findings using Kaplan-Meyer survival analysis.

Results

There were 40 patients among who 31 were males and 9 females, mean age of who was 64.7 years ranging from 42 to 77 years. Considering risk factor distribution, 14 (35%) patients were diabetics, 30 (75%) had hyperlipidemia, 24 (60%) were hypertensive, and all of them were smokers, 35 (87.5%) active, and 5 (12.5%) former ones (table 1).

Table 1

<table>
<thead>
<tr>
<th>Characteristics of patients</th>
<th>n (%)</th>
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<tr>
<td>Total number</td>
<td>40 (100)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>male</td>
<td>31 (77.5)</td>
</tr>
<tr>
<td>female</td>
<td>9 (22.5)</td>
</tr>
<tr>
<td>Patients with</td>
<td></td>
</tr>
<tr>
<td>diabetes mellitus</td>
<td>14 (35)</td>
</tr>
<tr>
<td>lipid disorder</td>
<td>30 (75)</td>
</tr>
<tr>
<td>hypertension</td>
<td>24 (60)</td>
</tr>
<tr>
<td>Smokers</td>
<td></td>
</tr>
<tr>
<td>active</td>
<td>35 (87.5)</td>
</tr>
<tr>
<td>former</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>Age (yrs), mean (range)</td>
<td>64.7 (42–77)</td>
</tr>
</tbody>
</table>

According to Rutherford et al. 2, class II (moderate claudications) had 2 patients (5%), class III (severe claudications) had 26 (65%), class IV (ischemic rest pain) had 11 (27.5%) and class V (minor tissue loss) 1 patient (2.5%) (table 2).

Table 2

<table>
<thead>
<tr>
<th>Rutherford class patients distribution</th>
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<tr>
<td>Rutherford class</td>
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<tr>
<td>Class II (moderate IC*)</td>
</tr>
<tr>
<td>Class III (severe IC*)</td>
</tr>
<tr>
<td>Class IV (rest pain)</td>
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<tr>
<td>Class V (minor tissue loss)</td>
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* Intermittent claudications

Lesion severity distribution was as follows: Trans Atlantic Society Consensus (TASC) B lesion type in 14 (35%) patients, and TASC C lesion type in 26 (65%) patients, while 27 (67.5%) lesions were total occluded.

Full lesion length coverage with stent struts was achieved in 38 (95%) arteries. The remaining were longer, more or less diffusely diseased arteries.

Lesion mean length was 80.65 ± 14.35 mm with mean arterial diameter of 5.45 ± 0.3 mm. Mean stent length was 90.5 ± 11.97 mm. The number of patent crural runoff vessels was 1.625 ± 0.42 mm (table 3).

Only the arteries stented with single stent were enrolled in the study. All stents were 7 mm (9) or 8 mm (31) in diameter. Average stent length was 90.5 ± 11.97 mm ranging.

Mean ABI value raised from preprocedural 0.50 to postprocedural 0.83, 0.86, 0.84 and 0.78 at one, six and twelve months respectively (Table 4). Only two patients presented with drop in ABI of more than 0.15 (0.64 and 0.59 respectively) after six months but without signs of major clinical deterioration. Also, routine duplex controlled examinations revealed that their peak systolic velocities (PSV) in popliteal artery were 150 cm/sec and 170 cm/sec respectively, which drove us to the crural disease progression as a cause of ABI failure. The worst clinical outcome appeared in the patient who could hardly walk but the control revealed ABI of 0.92. The reason of this complication was aggravated hiparthrosis in the ipsilateral leg.

At one year check up one stent was unpatent in a diabetic patient with heavily compromised crural runoff (ABI = 0.38). All other stents did not show duplex signs of significant PSV rise.
to test this hypothesis. We will test all the stents for fractures mostly. Still, our study did not definitely last long enough to perform any kind of morphological control (angiography or computerized tomography, e.g.) we do not really know if and when the stents are patent according to duplex PSV of the operator, and generally more acceptable.

## Discussion

Literature data inconsistency was historically predominant feature of endovascular surgery in femoropopliteal region. Until recently, actually until newer generation of self-expandable nitinol stents showed up in the field, there was strong hesitation in vascular surgical community when referring this cohort of patient population to endovascular repair was an issue.

Mewissen in his very important study evaluated safety and efficacy of selfexpandable SMART nitinol stents in patients with chronic limb ischemia (CLI) demonstrating type B or C TASC lesions in the femoropopliteal (FP) arterial segment. In the series of 137 lower limbs with chronic limb ischemia, secondary to TASC A (n = 12) or TASC B, C (n = 125) lesions in the femoropopliteal artery were treated with Cordis SMART selfexpanding nitinol stents. The mean lesion length was 12.2 cm. The technical success was 98%. Within the follow-up period (mean, 302 days), 24 limbs were diagnosed with hemodynamic stent failure. The primary stent patency rates were 92%, 76%, 66%, and 60% at 6, 12, 18, and 24-months, respectively. These results truly represent a breakthrough in SFA revascularization strategies.

Lugmayr et al. evaluated effectiveness of nitinol stents (Symphony, Boston Scientific) in patients with lesions in the superficial femoral and popliteal arteries assessing midterm results in 54 extremities in 44 patients for treatment of short, less than 6 cm, complex stenoses (n = 32) and occlusions (n = 22). The mean duration of follow-up was 27 months. The primary 1 year patency rate was 87%, and 1 year secondary patency rate was 91%. The primary 3-year patency rate was 76%, and the secondary patency rate was 87%. The study was very nicely conducted and long term followed up, but the issue was only a portion of real life problems within territory of SFA. The point is that not a vast majority of patients are presented with such a short diseased artery segments. This could also be the drawback of our study, although our lesions were slightly longer.

It seems that concern about eventual stent fractures could not be justified in the scenario of relatively shorter lesions stenting, less than 10 cm, requiring single stent mostly. Still, our study did not definitely last long enough to test this hypothesis. We will test all the stents for fractures during further follow-up period.

Systematic stenting versus selective use of Palmaz stents was not approved as presented in the paper by Becquemin et al. though some other authors challenge this statement within the nitinol stents. Our opinion is that we are closer to the selective stenting until much more data show clear benefit, taking into account a high money value for nitinol stents, as well. SIROCCO I & II trials caused slight disappointment in the world of endovascular surgery. These trials could not transfer brilliant outcomes of DES from coronary territory, but at the same time they expressed excellent performance of nitinol BMS indeed. This drives us to the fact that SFA and especially its biomechanics itself is actually the limiting factor much more than simple extrapolating the restenosis process from other vascular territories, e.g. coronary.

What about diffuse disease or very long lesions, TASC D? Well, we ought to be honest and accept the fact that apart from eventual possibility to perform endovascular treatment of these lesions, the reasonable approach is still surgical one, although some advocate that approach to any kind of SFA disease. Especially in the lesions requiring multiple long stents, we must count on stent fractures and, moreover, extremely modulated biomechanics along the course of the whole artery, particularly true for diabetic population according to the paper of Sabeti et al.

One could postulate that we should not comment on the issue of long lesions, and that might be true, but in our institution, vascular surgeons still avoid endovascular approach to long SFA lesions.

Our results are encouraging and correlate with other most recently cited papers. Considering the approach, either antegrade or contralateral crossover have their pros and cons. It is our opinion that regular utilization of closure devices in these procedures should be mandatory in which case the antegrade approach should be the easier, less cumbersome and safer, at least due to lower ionizing radiation for the operator, and generally more acceptable.

Another issue in our series is important. A vast majority of arteries accepted stents of 8 mm diameter. For most of them, it was between 20 and 25% or even 30% oversizing the artery lumen according to QVA (Quantitative Vessel Analysys). Although some patients claimed certain discomfort during the first month after the procedure, very few showed any clinical problem in patency yet. Still, we will test this in a 24-month control having in mind the concern of some authors that this could possibly lead to stent fracture due to chronic strain and fatigue of the material.

There are, of course, some drawbacks of this study. First, the lack of randomization we are quite aware of. Second handicap is the one of ABI at rest, particularly in diabetic patients, but it seemed easy for routine orientation control, followed by duplex examination. The fact that the vast majority of stents are patent according to duplex PSV of 230 cm/s does not mean that at least some of them has already been restenosed, yet, not significantly. Since we did not perform any kind of morphological control (angiography or computerized tomography, e.g.) we do not really know that proportion. Therefore, it seems to be another drawback.
Conclusion

We achieved 100% patency rate in the intermediate 6-month follow up and 97.5% in a 12-month follow-up. More important is what will be the result in 24- or maybe 48- or 60-month follow-up. Further clinical studies of SFA stenting will give us more information like what kind of stents, what design, what force resistance should they express in different parts of adductor channel for instance, etc. At the same time, additional molecular, biochemical, and pathological studies are needed in order to understand the particularity of restenosis in SFA. Also, considering life expectancy in this population, we need sustained high patency rates for a longer periods.

REFERENCES


The paper was received on December 11, 2007.