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Subject: Stents Grafts.
Dr. Bogart Parra.
Interventional Cardiology
Venezuela.

STENT GRAFTS IN CORONARY INTERVENTIONS

Numerous academic reports have demonstrated the feasibility, safety and efficacy of stent grafts for the treatment of coronary perforations, coronary aneurysms, complex lesions (with ulcer or thrombus), lesions on venous grafts and also, in a more debatable case in intra-stent restenosis.

The first generation of grafts were stents covered with vein 1-2, followed with the current stents covered with biocompatible polymer membranes. The design used so far in my practice is the InSitu coronary Stent Graft which consists of an ultra thin ePTFE layer, biocompatible on a stainless steel 316L stent. The diameters for this stent start at 2.5mm and go up to 6.0mm, and the available lengths are 10, 13, 16, 19, 23 and 26mm, pre-mounted on a semi-compliant balloon. The evaluation in Venezuela of the feasibility and safety of this stent's implantation as well as its efficacy has been initiated.

An analysis of the predictive occlusion factors for the Stent Graft showed that the lesion's length, the vessel diameter, the minimum luminal diameter post Stent Graft implantation and the amount of pressure administered to the balloon to expand the stent were factors that played an important role as statistically significant in the prediction of occlusion.

A joint registry was made by the Heart Center's Cardiology and Angiology department, Siegburg and the Cardiovascular Research Foundation, New York (1997). It is important to emphasize some angiographic criteria suggested by the authors to implant a Stent Graft: vessels with a diameter >3.0mm and focal coronary aneurysms with more than 50% above the reference diameter. The intra-hospital results report 3 sub-optimal cases (4.5%) due to stent dislodgement, in one of the instances the stent was removed with a "microsnare" and in the other 2 cases the stent was able to be implanted in a site proximal to the lesion. Also the occlusion of secondary branches was reported for 13 patients (18.1%) causing 9 AMI (13%), 2 AMI Q and 7 AMI NO Q.

Long term follow up (159 +/- 49 days) yielded four cases of acute thrombosis (5.7%) between 7 and 70 days after implantation with three AMI Q and one death. Angiographic follow up made in 80% of the cases showed a restenosis rate of 31.6% with 26.8% being subject for TVR. Most of the restenosis occurred at the side of the stent (23.8% vs 8.8% in the center of the stent,

P<0.001). Intravascular ultrasound follow up found significant restenosis at the end of the graft in comparison with the center (P<0.001).

Stephan Baldus and collaborators reported one of the first significant registries on the treatment of de novo lesions of coronary venous grafts with the JO stent, executed in conjunction with three centers in Germany. They reported on the intra-hospital results as well as distant follow up of discharged patients for 190 patients with 127 lesions in venous grafts with a media of 11+/- 5 years (from 1-21 years). They compared this registry in a retrospective study and the authors concluded that there was a lower rate of complications during the procedures and a lower rate of sub-acute thrombosis, mortality and intra-stent restenosis during the follow up.

The authors' preliminary conclusion was that the use of the PTFE JO stent compared with standard stents (JO stent flex) in the treatment of venous coronary grafts was associated with a higher rate of complications and major events during intra-hospital observation and during the follow up with a similar angiographic restenosis.

It is common the embolization and/or dislodgement of the stent from the balloon, perhaps due to the inadequate "manual crimping", considering that the polymer layer in the "sandwich" produces a rigid system, rough and thick, provoking a challenging implantation from a technical point of view when compared to standard stents. Probably InSitu Technologies' Direct-Stent Stent Graft which is pre-mounted and is commercially available could diminish these challenges and complications. Other frequent complications are the occlusion of the side branches and the possible acute thrombosis of the stent. The first is an important limitation in the indication of the Stent Graft for lesions in the native coronary arteries. An explanation for the higher incidence of sub-acute thrombosis of the stent could be the late endothelialization of the PTFE, as it has been described in animal studies.

We believe that for coronary perforations the indication of Stent Grafts is irrefutable because when compared with surgery and venous grafts the PTFE Stent Graft represents a less invasive procedure, with more efficient and acceptable results. For aneurysms and/or pseudo-aneurysms the Stent Graft successfully "seals" the lesion and offers a satisfactory alternative to surgery. However, for arteries whose diameters are equal to or less than 3.0mm as well as long lesions (>15mm) the rate of complication and MACE at 6 months is high and a balance risk/benefit should be made.

In conclusion, we consider that the implantation of the Stent Graft is a feasible and safe procedure with high rates of success for the initial procedure. For native coronary arteries it has the limitation related to the occlusion of branches and subsequent AMI. It also has a higher rate of late sub-acute thrombosis that could be present in the first or second month. The most important predictive factors for the thrombus formation are the lesion's length (>20mm), reference diameters equal to or less than 3.0mm, a reduced lumen and a deployment pressure of the stent of <16 ATM.

To avoid sub-acute thrombosis we suggest the implants of Stent Graft to be made in arteries with a higher diameter, guided by intravascular ultrasound, high inflation pressure, prolonged inflations and dual drug therapy (Clopidogrel) and Aspirin for no less than 6 months post-procedure. The usefulness of the Stent Graft to prevent intra stent restenosis has not been studied. Its indication in aneurysms (Figure 3 and 4), pseudo-aneurysms and fistulae is controversial. Its indication is irrefutable and is the best choice for coronary perforations.

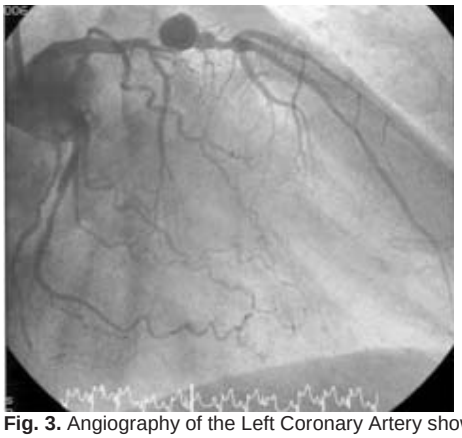


Fig. 3. Angiography of the Left Coronary Artery showing an aneurysm at the proximal segment of the LAD (10 mm).

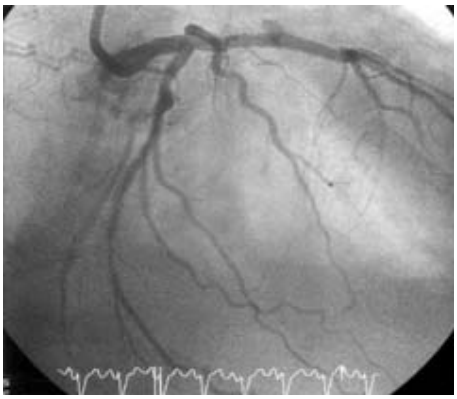
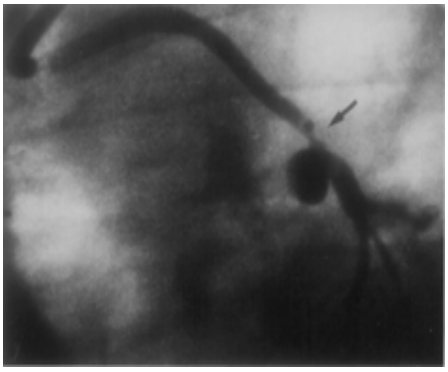


Fig. 4. Angiography after the implant of an InSitu Direct-Stent Stent Graft 3.0 x 26 mm sealing the aneurysm



Fg 1. *Case 1. 90% obstruction and aneurysm of Saphenous Vein Graft in LAD.*

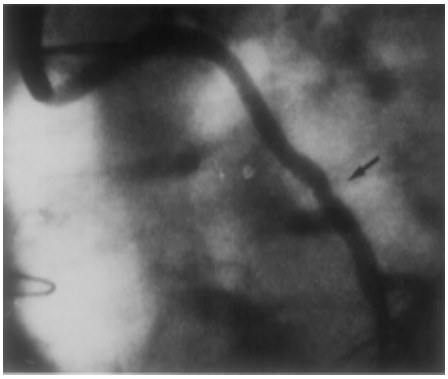


Fig 2. After Stent Graft implantation

- InSitu Stent Graft
- - Aneurismas.
- - Perforación.
- - Rupturas