Type II endoleaks in the era of endovascular aneurysms sealing (EVAS): single center experience.

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The Nellix device is a novel sac anchoring graft designed to treat aorto-iliac aneurysms by obliterating the aneurysm sac, thus eliminating the endoleaks space. Primary endpoint is to assess the immediate technical success and type II endoleaks incidence rate, while second endpoint is to evaluate morphologic changes of Nellix endograft itself during follow-up.

MATERIALS and METHODS: In the last 8 years two hundred and fiftyeight patients were submitted to endovascular treatment for AAA with different endoprothesis. Of this group, forty (15.5%) were treated by using the NELLIX endograft in a period from December 2013 to December 2015 (one case in emergency). All patients (mean age 75 years) were classified as American Society of Anesthesiologists score (ASA) III (70%) and ASA II (30%). In patients treated with different endografts, a patent IMA was embolized to prevent type II endoleaks in 58 (26.6%), while in 14 coils were released inside the sac (6.4%). Our inclusion criteria were according to the Nellix Instructions For Use (IFU). Two pairs of lumbar arteries were present in 25% of patients, 3 pairs in 40% and 4 pairs in 35%. A patent Inferior Mesenteric Artery (IMA) was identified in 75% of all cases. The amount of polymer infused in the endobags was between 26 and 90 ml; the endobags filling pressure ranged from 180 to 200 mmHg. In two patients (6.7%) a covered stent was implanted to achieve a better configuration of the graft. Average procedural time was 120 minutes while average contrast media quantity was 70 ml. Angio-CT scan control was performed at 30 days (24 patients) and Angio-MRI controls were performed at 30 days (25 patients), 6 months (25 patients) and 12 months (12 patients) High resolution Duplex scans and contrast enhancement were scheduled before the discharge and at 30 days, 6 and 12 months for all patients.

RESULTS: in all patients the Nellix endograft was successfully implanted, with 0% aneurysm related-mortality. All patients but one were discharged in the fifth postoperative day. Either both intraoperatively as well as in the postoperative period and during follow-up only one type I (2.5%) endoleak was recorded in the Nellix group while in the other group, 33 patients (15.3%) developed a type II endoleaks. Ten of these endoleaks (30.3%) were discovered within the first 12 months whether the remaining 23 (69.7%) were diagnosed late during follow-up. In 10 of this group a reintervention was needed. In the immediate postoperative day, an acute obstruction of a Nellix stent occurred (2.5%) and treated with intraluminal thrombolytic therapy while type I is still not treated. During follow-up, all Nellix grafts remained patent no modification of the endobags and no change of the Nellix stents position were recorded and a sac shrinkage was recorded in 75% of those cases with a 12 months follow-up; finally no volumetric changes were registered either in the suprarenal aorta as at the aortic wall.

DISCUSSION AND CONCLUSIONS: Type II Endoleaks are considered a major concern in EVAR. It negatively affects efficacy and early/late outcomes justifying the long-term surveillance after EVAR and giving an account of the need for secondary interventions. Questions remain regarding the timing, indications, and best method of treatment. More than 20% of patients undergoing EVAR develop a type II endoleaks, but only a minority needs a reoperation, because the relationship between these endoleaks and the rupture risk is not still clear. The final effect of this new system is minimize potential longitudinal and lateral movements and subsequently prevent type I endoleaks while the AAA sac filling should be able to block the retrograde flow through collateral arterial pathways (LA and IMA) preventing Type II endoleaks. This new concept of Nellix sealing seems to be able to resist the sideways forces, minimizing not only the endograft migration but also complications as endoleaks. In this study, no morphologic changes inside the graft itself or in the longitudinal position of the covered stents inside the aneurysmal sac were registered in all those patients submitted to angio-MRI during the entire follow-up. After placement of the Nellix system, aneurysm sac shrinkage was observed in 75% of cases with a 12-months follow-up as a result of the modification of intraluminal thrombus. EVAS seems to be effective to prevent type II endoleaks so that, in this preliminary experience, the incidence rate at was nil in all patients with 12 months of follow-up.