Minimally invasive mitral ring adjustment one year after implantation

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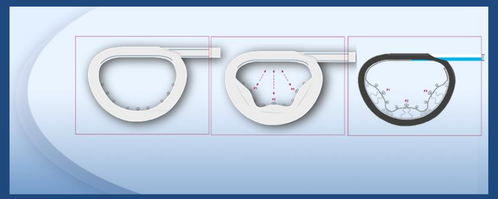
Objective

We want to prove the safe and effectiveness of a mitral surgical ring whose size, once implanted, is adjustable either at the time of surgery or during the follow up without redo surgery. This first adjustment experience demonstrate that the purpose for which this innovative device has been conceived is valid and proven by clinical data

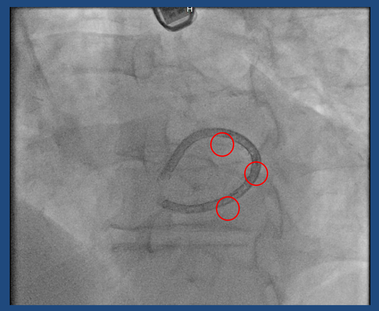
Methods

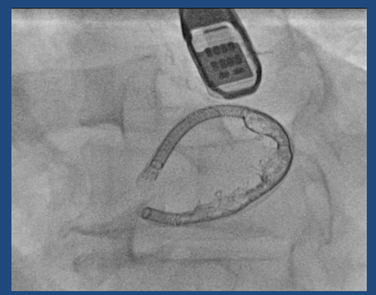
Kalios is an adjustable mitral surgical ring, implantable either traditionally or through minimally invasive approach. It consists in a classical surgical ring with three stents implanted in the posterior portion, corresponding to P1, P2 and P3. These stents will permit the adjustment of the device once implanted through a control centre implanted subcutaneously and connected to the ring.

A special device consisting of a catheter with three separated lumen ending in three expandable balloons is inserted through the subcutaneous device in order to set each balloon on a different portion of the posterior portion of the ring (P1, P2 and P3). The balloons are inflated in order to expand the corresponding stents in the manner needed to adjust the diameter of the ring on the prolapsing portion. The procedure is echo-driven. The maximum adjustment reduces the effective orifice area by 15%.









Conclusion

The possibility to entirely reconsider the status of the patient at each follow up is a big opportunity and will contribute to change the classic way to survey the preliminary markers of mitral regurgitation facing the possibility to act to prevent left ventricle function impairment.

This must also be considered as an improvement of the standards of care with an evident cost-effectiveness impact, thus the patients do not require surgery with prolonged post-operative stay, rather they face a rapid recovery.

Results

Our case reports the success of the adjustment of the mitral ring of a patient implanted one year before, who developed severe mitral regurgitation as a consequence of ventricular enlargement due to myocardial infarction. The procedure of adjustment ran easily with no complications in a hybrid operating room taking one hour of time and the result was immediately patent, with a return to the result obtained at the implant

