SA Heart

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South African Society of Cardiovascular Intervention

SASCI POSITION STATEMENT ON USE OF LEFT ATRIAL APPENDAGE OCCLUSSION DEVICES

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Percutaneous closure of the left atrial appendage is a reasonable option to consider in patients with atrial fibrillation with a CHADS score >1 and who are unable to take any form of oral anti-coagulant therapy due to contra-indications. (1).

However the main concern about the use of these devices is peri-procedural complications at the time of implantation in particular. The FDA initially approved and subsequently withdrew approval of the Watchman device used in the Protect-AF study because of a concerns about safety at the time of implantation (primary safety 7.4%/100 patient years vs 4.4% in the control group) – those being significant pericardial effussion causing haemodynamic compromise, stroke, air embolism and device dislodgement (2). Safety events however were significantly better with increasing operator experience as was seen in the Protect-AF Continued Access Registry (primary safety end point 3.7%/100 patient years)(3). A second study, the Prevail Study (not as yet published)(4), was subsequently done with significantly better safety outcomes (primary safety end point 2.2%/100 patient years). The Watchman device is expected to receive FDA approval in the latter half of 2014. Importantly review of the safety events showed that the highest complication rates occurred during implantation of the operators first 3 devices (12.3% versus 5.9% subsequently).

There are currently no randomised control studies of the Amplatzer Cardiac Plug, only registry data which shows similar procedural safety outcomes compared to the Watchman device. Initial European experience 7% serious complication rate and the European Prospective Observational Study 2.9% (5,6,7,8).

Therefore safety at the time of implantation is absolutely imperative. Both Boston Scientific (Watchman) and St Jude (Amplatzer Cardiac Plug) have strict training criteria that must be met before an operator is allowed to be considered trained. These include doing a 2 day training course at an approved center in Europe involving lectures, getting to use the device in a dry lab, using the device in a simulator and attending/watching devices being implanted. Thereafter an online examination has to be passed. Subsequently procedures **must** be done with the attendance of a proctor, requiring a minimum a 3-10 proctored procedures before being "signed off" to do the procedure. However this is at the proctor's discretion. This training regime is imperative to ensure proper patient selection and safe device implantation and is very similar to what is expected of doctors who are starting a TAVI programme.

The procedure is guided by Trans-esophageal echocardiography (TEE). The TEE operator needs to be an integral part of the training program, requiring the same exposure as the operator.

SASCI would like to stress the importance that both doctors and the industry comply with these training guidelines.

Suitable patients, particularly during early operator experience, would be those with a CHAD-Vasc score > 2 and a high HASBLED score (>4), or other contra-indications for oral anti-coagulant therapy, **and** who are not particularly frail and /or have a limited life expectancy.

SASCI supports the use of LAA occluder devices in appropriately selected patients when performed by appropriately trained operators.

References

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