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Left Atrial Appendage Closure in Atrial Fibrillation Patients

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Abstract

In the real world experience with large scale multicentre registries that have proven efficacy and safety of left atrial appendage closure. Despite the fact that scientific societies agree with the benefits of left atrial appendage closure if oral anticoagulation is at high bleeding risk, the current clinical practice guidelines published by the European Society of Cardiology assigns a low level of recommendation (IIb-B) for patients with atrial fibrillation who have a contraindication to long-term oral anticoagulation. It is important to point out that guidelines are recommendations of clinical behaviour, produced through a systematic process, in order to assist doctors and patients in deciding the most appropriate assistance modalities in specific clinical circumstances and that they are not mandatory. In this review we analysed the importance of this methods in treatment of atrial fibrillation patients [1].

Keywords: Atrial fibrillation; Left atrial appendage closure; percutaneous procedure; Warfarin; Bleeding risk; Guidelines

Introduction

After being only a surgical procedure in the late 40s of the previous century1, Since 2002, with the Plaato device, interventional cardiologists have been able to close the left atrial appendage in order to prevent, in patients with nonvalvular atrial fibrillation,cerebral infarction in alternative to oral anticoagulation, especially in patients with some sort of contraindication to these drugs [2]. From that year there has been a slow but constant growth of the procedure in terms of number of procedures and in terms of device evolution. In terms of number of procedures the last United States national registry, we have had an increase of physicians and hospitals performing left atrila appendage closure from 30 to more than 1200 and from 20 to over 400, respectively, in the past two years [3]. Italy confirms this increasing trend in 2019 with a 16 % increase in the total number of procedures in comparison to the previous year and a total number of procedures in the same year that is over 1000, almost tripling since 2014 [4]. The turning point for the procedure was in 2009; in that year we have the publication of a multicenter randomized clinical trial named PROTECT AF, which compared the left atrial appendage closure with the Watchman left atrial appendage occluder device (Boston Scientific, United States) vs conventional treatment with oral anticoagulation with warfarin. In this trial the non-inferiority of the percutaneous procedure for the primary composite endpoint of stroke, cardiovascular death or systemic embolism was proven [5]. And five years later, the PREVAIL trial, a clinical randomized trial with a similar study design to the PROTECT AF trial, achieved the same results regarding efficacy; the big difference was a success rate of 95% and significantly less common complications, demonstrating that experience in this procedure is of top importance and that skilled operators are a must, expecially in a procedure where we are not treating an acute disease, but we are trying to avoid events related to atrial fibrillation [6]. Therefore the procedure has to be performed in the best setting and the operator experience is a milestone. Moreover the long-term follow-up results are very positive. In the PROTECT AF trial at almost 4 year the follow-up demonstrated that the patients have significant benefit in the composite primary endpoint (8.4% vs 13.9%; hazard ratio = 0.61;

95% confidence interval, 0.38-0.97; P = .04) respect to the control group with oral anticoagulation with warfarin [7]. But the main result was that also all-cause mortality improved in the invasive arm in comparison to the conservative one (12.3% vs 18%; hazard ratio = 0.66; 95% confidence interval, 0.45-0.98; P = .04). But what happens if we compare left atrial appendage closure with the new oral anticoagulants. A randomized clinical trial, the PRAGUE-17, compared LAAO with these novel direct-acting oral anticoagulants, and proved, even in this case, the non-inferiority of the interventional procedure compared to novel anticoagulants for what concerns the prevention of cardiovascular, neurological or hemorrhagic events associated with atrial fibrillation [8]. These data are confirmed in the real world experience with large scale multicentre registries that have proven efficacy and safety of left atrial appendage closure. Among these the EWOLUTION registry for the Watchman device demonstrated a 98.5% success rate, and a 2.7% rate of complications [9]. Accordingly the multicentre registry of the Amulet device (Abbott, United States) demonstrated a 99% success rate and a 3.2% rate of complications [10]. These results are much better that in the early series telling us once more the importance of operator experience and are consistent with many other studies published. Despite the fact that scientific societies agree with the benefits of left atrial appendage closure if oral anticoagulation is at high bleeding risk, the current clinical practice guidelines published by the European Society of Cardiology assigns a low level of recommendation (IIb-B) for patients with atrial fibrillation who have a contraindication to long-term oral anticoagulation [11]. It is important to point out that guidelines are recommendations of clinical behaviour, produced through a systematic process, in order to assist doctors and patients in deciding the most appropriate assistance modalities in specific clinical circumstances and that they are not mandatory. What is mandatory is to choose the best treatment option for the specific patient that we have in front of us and that no clinical trial, however well designed, can consider in all his peculiarities. Trials are trials and real world is real world and no trial can ever consider all the variables that a single patient may present. We will have to wait for the conclusions of 2 ongoing large scale randomized clinical trials of LAAO vs direct-acting oral anticoagulants, the CHAMPION-AF for the Watchman Flx, Boston Scientific and the CATALYST, Amulet, Abbott in order to establish the interventional procedure of left atrial appendage closure against s technique in patients without contraindications to novel oral anticoagulation. In conclusion, we can absolutely state that left atrial appendage closure is safe and effective. The data we have say that its utility is sure in patients with atrial fibrillation who cannot take oral anticoagulation to prevent the occurrence of strokes for high bleeding risk. In some cases the interventional procedure has demonstrated a reduction in mortality rate compared to oral anticoagulation. It is therefore of great importance to be aware of this opportunity for patients, avoiding, especially after bleeding under therapy with novel oral anticoagulants to try another one, rather than going directly to left atrial appendage closure. In the future results from upcoming trials should go in this direction making the interventional procedure the one of choice for effectiveness and safety in our everyday patients with non valvular atrial fibrillation at high risk of stroke and bleeding and maybe for cost effectiveness matters, even in patients not at high bleeding risk.

Conflicts of Interest

Abbott official Proctor for structural heart disease interventional treatments.

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