

Clips and chutes: combined solutions to combined problems



Sameer Gafoor^{1,2*}, MD

1. Swedish Heart and Vascular Institute, Seattle, WA, USA; 2. CardioVascular Center Frankfurt, Frankfurt, Germany

Schaefer et al¹ tackle an important problem – patients with left ventricular apical aneurysms who also have severe mitral regurgitation (MR). They do this through the unique combined approach of the Parachute[®] left ventricular partitioning system (CardioKinetix, Inc., Menlo Park, CA, USA) with the MitraClip

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percutaneous mitral leaflet repair system (Abbott Vascular, Santa Clara, CA, USA). The combined need for Parachute and MitraClip is not great – the authors state that in a 30-month period they were able to screen only 49 Parachute patients in a high-volume centre, of whom 35% did not meet the anatomic criteria. Of these patients, only six had severe mitral regurgitation (12% of the original cohort). Whilst this number is very small, this technique is a very important step forward.

MitraClip for secondary mitral regurgitation in patients who were candidates for surgery was studied in the randomised EVEREST II trial², where 27% of patients had secondary mitral regurgitation: MitraClip was at least as good as surgery in these patients with secondary MR. In Europe, MitraClip use has continued in non-operative patients with severe secondary MR and has been studied in multiple registries (e.g., the TRANscatheter Mitral Valve Interventions [TRAMI] Registry³ and the ACCESS-Europe

A Two-Phase Observational Study of the MitraClip[®] System in Europe [ACCESS-EU]⁴), with a higher procedural success rate than in the EVEREST II trial. Randomised studies are in progress. Of note, a recent meta-analysis encompassing 875 patients in nine studies covering MitraClip for secondary MR showed net improvement in the six-minute walk test, NYHA functional class, and reverse remodelling⁵.

Geometrical remodelling after myocardial ischaemia/infarction can lead to the presence of a left ventricular aneurysm. Suggested therapeutic options included changing the LV geometry to reduce wall stress, improving compliance, and improving LV filling pressures. This was attempted with surgical aneurysmectomy, which for many fell out of favour following the Surgical Treatment for Ischemic Heart Disease (STICH)⁶ trial. However, this trial has been criticised on many issues, including patient selection (a broad range of baseline end-systolic volume index, extent and severity of baseline aneurysm, and viability of anterior wall) and adequacy of end-systolic volume index reduction. The Parachute device is a percutaneous non-thoracotomy non-cardiopulmonary bypass method to partition the ventricle and exclude the aneurysm with good results in a carefully selected patient population^{7,8}.

* Corresponding author: Seckbacher Landstrasse 65, 60389 Frankfurt am Main, Germany.
E-mail: s.gafoor@cvcfrankfurt.de

Technically, a combined approach has its advantages. In this setting, the patient has to go through one visit for both approaches and a single access is used. The use of venous access here allows for a decrease in vascular complications and also extends the indications to patients with peripheral vascular disease (where a traditional femoral arterial Parachute implantation would have been more difficult). The 24 Fr MitraClip sheath is a large-bore steerable sheath that allows fine-tuned movement in multiple directions.

However, there are important technical issues which the reader should be aware of before performing such a combined procedure. Although the Parachute procedure can be performed under conscious sedation, the operators felt that the combined procedure required general anaesthesia. Transoesophageal echocardiography is used. Positioning the Parachute may be easier with the MitraClip delivery system, but this requires operators to be familiar with this system in advance (risk of chordal and subvalvar apparatus interference). Insertion of the Parachute in this system can potentially entrap air, which must be avoided. Even in this very skilled group, there was a rip in the interatrial septum and a tear in the anterior mitral leaflet, both of which required additional device therapy. After the Parachute has been implanted, mitral regurgitation often increases: this may be due to cardiac output increase or perhaps due to interaction with the papillary muscles, which may make MitraClip implantation more difficult – the formerly “clip-pable” patient may be less than straightforward after the Parachute release. In addition, this points to a greater emphasis on pre-procedural planning – the echocardiographer and interventionalist should evaluate the echocardiogram together before the case and expect potential changes in mitral regurgitation, leaflet coaptation, tenting angle, and also the expected TEE probe position after the Parachute has been implanted. In addition, the team in charge of sedation should be prepared for and react to a potentially greater level of mitral regurgitation after Parachute implantation.

The article goes over the haemodynamics of implantation in great detail. After Parachute implantation, there was an improved cardiac output and aggravation of MR (increase in v-wave and LA pressures). The MR increase may be due to cardiac output but may also be due to further displacement of the basal papillary muscle as a result of interaction with the Parachute device. After the MitraClip was implanted, there were increases in multiple good haemodynamic parameters (cardiac output [CO], cardiac index [CI], stroke volume [SV], stroke work index [SWI]) and decreases in other haemodynamic parameters (systemic vascular resistance index [SVRI], left atrial pressure [LAP], pulmonary capillary wedge pressure [PCWP]). Aside from the changes in mitral regurgitation, the end results are similar to a prior paper with just Parachute implantation benefit⁹, showing how much the aneurysm exclusion has a benefit on haemodynamic outcomes. However, this may not tell the full story: even with the best of planning and performance, there may be late increase in mitral regurgitation – as seen in patient #6 – where two more clips and a duct occluder had to be implanted.

Combined therapies raise issues of order and time between interventions. When there is combined aortic stenosis and severe mitral regurgitation in a non-operative patient, most operators would attempt transcatheter aortic valve implantation (TAVI) first and then monitor the mitral valve for improvement before attempting mitral valve intervention in a second setting (in this case the two processes are interdependent). This allows the ability to “wait-and-see”, restricting a second intervention to those patients where this is absolutely necessary (an option not usually offered in traditional cardiac surgery due to the need for a second sternotomy). In this case the Parachute portion has to be performed first as it would be technically difficult after MitraClip placement. Due to the increased mitral regurgitation post-Parachute, the case is made that the combined interventions should occur in the same setting, as there is little likelihood of delayed improvement.

One additional point from this article is how two different interventions, one for heart failure and one for mitral regurgitation, could be performed together to treat a single patient for improved outcomes. Although European guidelines¹⁰ have evolved to include the MitraClip device, this does not address other new or combined interventions that may impact on secondary MR in the context of heart failure. This is even more important currently as there are now evolving options for percutaneous mitral annuloplasty, mitral valve replacement, and ventricular restoration. It is imperative that clinical trialists, guideline writers, and regulators do not judge procedural success or failure based on one intervention when it can – or should be – part of a combined staged treatment strategy. We strongly encourage this group to publish follow-up results on these patients.

We live in times when advancements are happening not only in percutaneous mitral leaflet repair but also in ventricular restoration and percutaneous mitral annuloplasty. We congratulate the authors for seeing a new use for a device that was already being used in a patient population that needed both therapies. MitraClip has faced some difficulties in proving its worth for functional mitral regurgitation compared to surgery, but combined approaches open the pathway for combined benefit. It is up to physicians to see how these different technologies can sometimes be used concurrently for the best benefit.

Take-home points from combined Parachute-MitraClip implantation:

- Patient selection is key to procedural success – all criteria must be fulfilled for both interventions.
- General anaesthesia and transoesophageal echocardiography are recommended.
- Careful evaluation of haemodynamics with right heart catheterisation may add additional information.
- Mitral regurgitation often increases after Parachute implantation.
- Evaluation of septum and leaflets is even more important after combined intervention.
- Careful follow-up is recommended.

Conflict of interest statement

The author has no conflicts of interest to declare.

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