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Compassionate use of the PASCAL system for transcatheter tricuspid repair: a prospective, multicentre, first-in-man study

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AIMS
Transcatheter edge-to-edge repair of severe tricuspid regurgitation (TR) has been shown to be afeasible and safe treatment option for selected patients at prohibitive surgical risk. Large tricuspid leafletcoaptation gaps and severe leaflet tethering represent challenging anatomic conditions that may limit theefficacy of transcatheter repair techniques. The purpose of this first-in-man experience was to investigate theprocedural feasibility of the novel PASCAL transcatheter repair system (Edwards Lifesciences, Irvine, CA, USA).

METHODS AND RESULTS
Nine patients with severe symptomatic TR were treated with the PASCAL system in acompassionate use program at 3 sites. All patients suffered from severe right heart failure (NYHA III-IV)due to severe TR and were deemed inoperable by the institutional heart teams. The procedures were performedvia the right femoral vein under general anesthesia using transesophageal echocardiographic guidance.Procedural success was defined as reduction of at least one TR grade. If simultaneous grasping of two tricuspidleaflets was not achievable due to a large coaptation gap and/or severe leaflet tethering, the system allowed forindependent leaflet grasping - usually the anterior or posterior tricuspid leaflet first, followed by grasping of theseptal leaflet.Treated patients (age: 78 ± 6 yrs) were considered to be at intermediate surgical risk (EuroScore II: 6 ± 7). Oneprocedure remained unsuccessful primarily due to difficult imaging conditions (no device placed), in theremaining 8 patients a total of 14 PASCAL devices (2 devices/patient in 6 patients, 1 device/patient in 2 patients)were placed in the tricuspid valve, 8 in the anterior-septal and 6 in the postero-septal position. A successfulprocedure with TR reduction by one grade was achieved in 8 patients. Applying a 5 grade scheme, the meantricuspid regurgitation grade was reduced from 3.9 ± 1.0 to 1.8 ± 0.5 without relevant increase in tricuspidgradients (mean gradient 1.2 ± 0.8 mmHg). Independent leaflet grasping was used for 12 of 14 PASCAL devicesto overcome large coaptation gaps and leaflet tethering. During in-hospital stay, a single leaflet device attachment was observed in one patient, which was managed conservatively. No other complications were observed during or following the procedure. Of note, we did not observe pericardial effusions, TR worsening or acute worsening of right ventricular function.

CONCLUSIONS
Severe TR with large leaflet coaptation gaps can be successfully treated in selected patients withthe use of the novel transcatheter PASCAL repair system, which incorporates a spacer and enables independentleaflet grasping in challenging tricuspid anatomies. A 30-day clinical follow-up will be presented.