Published in final edited form as:

Catheter Cardiovasc Interv. 2018 September 01; 92(3): E175–E184. doi:10.1002/ccd.27531.

Transcatheter Pledget-Assisted Suture Tricuspid Annuloplasty (PASTA) to create a double-orifice valve

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Abstract

Objectives—Pledget-assisted suture tricuspid valve annuloplasty (PASTA) is a novel technique using marketed equipment to deliver percutaneous trans-annular sutures to create a double-orifice tricuspid valve.

Background—Tricuspid regurgitation is a malignant disease with high surgical mortality and no commercially available transcatheter solution in the US.

Methods—Two iterations of PASTA were tested using trans-apical or trans-jugular access in swine. Catheters directed paired coronary guidewires to septal and lateral targets on the tricuspid annulus under fluoroscopic and echocardiographic guidance. Guidewires were electrified to traverse the annular targets and exchanged for pledgeted sutures. The sutures were drawn together and knotted, apposing septal and lateral targets, creating a double orifice tricuspid valve.

Results—Twenty-two pigs underwent PASTA. Annular and chamber dimensions were reduced (annular area, $10.1 \pm 0.8 \text{ cm}^2$ to $3.8 \pm 1.5 \text{ cm}^2$ (naïve) and $13.1 \pm 1.5 \text{ cm}^2$ to $6.2 \pm 1.0 \text{ cm}^2$ (diseased); septal-lateral diameter, $3.9 \pm 0.3 \text{ mm}$ to $1.4 \pm 0.6 \text{ mm}$ (naïve) and $4.4 \pm 0.4 \text{ mm}$ to $1.7 \pm 1.0 \text{ mm}$ (diseased); and right ventricular end-diastolic volume, $94 \pm 13 \text{ ml}$ to $85 \pm 14 \text{ ml}$ (naïve) and $157 \pm 25 \text{ ml}$ to $143 \pm 20 \text{ ml}$ (diseased)). MRI derived tricuspid regurgitation fraction fell from $32 \pm 12\%$ to $4 \pm 5\%$.

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CONFLICTS OF INTEREST

ABG serves as a proctor for Edwards Lifesciences and St Jude Medical, which manufacture transcatheter heart valves.

VCB is a consultant for Edwards Lifesciences and for Abbott Vascular, and his employer has research contracts for multicenter investigation of transcatheter aortic and mitral devices from Edwards Lifesciences, Abbott Vascular, Medtronic, St Jude Medical, and Boston Scientific.

No other author has a financial conflict of interest related to this research.

Results were sustained at 30 days. Pledget pull-through force was five-fold higher ($40.6 \pm 11.7\text{N}$ vs $8.0 \pm 2.6\text{N}$, $p < 0.01$) using this strategy compared to single puncture techniques used to anchor current investigational devices. Serious complications were related to apical access.

Conclusions—PASTA reduces annular dimensions and tricuspid regurgitation in pigs. It may be cautiously applied to selected patients with severe tricuspid regurgitation and no options. This is the first transcatheter procedure, to our knowledge, to deliver standard pledgeted sutures to repair cardiac pathology.

Keywords

Tricuspid valve regurgitation; Transcatheter electrosurgery; Tricuspid Annuloplasty; Structural heart disease

BACKGROUND

Tricuspid valve regurgitation is a common, progressive, malignant disease associated with increased mortality independent of left ventricular function or pulmonary artery pressures (1,2). Outcomes worsen with increasing severity of tricuspid regurgitation (1).

Isolated surgery for tricuspid regurgitation is rarely performed (3), and is associated with a higher mortality than for any other single valve (4). Re-operations for failed tricuspid repair have an in-hospital mortality of 35% (5). Surgical outcomes for organic tricuspid regurgitation are worse than for functional tricuspid regurgitation, and replacement has a higher mortality than repair (6,7). There are no commercially available transcatheter options in the US.

We propose a percutaneous pledget-assisted suture tricuspid annuloplasty (PASTA) to create a double-orifice tricuspid valve. The surgical precedent for PASTA comes from Hetzer's double orifice suture technique, which has been performed in more than 90 patients with severe organic and functional tricuspid regurgitation with no reoperation after 8.7 years (8).

We report PASTA in animals. We tested 1) transcatheter delivery of trans-annular double-bite pledgeted sutures; 2) pull-through force of pledgeted sutures; 3) a technique to exchange guidewire for suture; 4) a muscular interventricular septal bite to anchor the septum directly; and 5) use of off-the-shelf commercially-available medical equipment to perform a closed-chest beating heart suture annuloplasty. To our knowledge this is the first true transcatheter cardiac surgery procedure, accomplishing repair using only sutures and pledgets rather than anchors and metallic implants.

METHODS

Animal experiments and necropsy

Procedures on Yorkshire swine were approved by the NHLBI animal care and use committee and conducted per contemporary NIH guidelines. Anesthesia was induced and maintained with mechanical ventilation and inhaled isoflurane. Jugular and femoral sheaths

were placed percutaneously and aspirin, heparin, amiodarone, and metoprolol were administered.

Careful assessment for structural compromise, thermal and mechanical injury, and histology were performed after necropsy.

PASTA Procedure Overview

PASTA reduces the tricuspid valve orifice by apposing septal and lateral targets on the tricuspid annulus using percutaneously delivered pledgeted sutures. We selected two specific annular targets for PASTA, one at the mid-anterior leaflet, and another at the posterior-septal leaflet commissure, avoiding the AV node and Bundle of His. Because there is no anatomic septal annulus, the septal pledget target incorporates interventricular septal myocardium between the base of the septal leaflet and the coronary sinus. The result is a double-orifice tricuspid valve. [FIGURE 1A–E].

PASTA Tools and Techniques

In vivo procedures in swine were guided by X-ray fluoroscopy and intracardiac echocardiography using only marketed equipment. We tested both trans-apical (via percutaneous 12Fr right ventricular sheath, 10cm *Fast-Cath*, St Jude) and trans-jugular (using a deflectable 8.5Fr jugular Agilis small curl sheath) approaches. A separate trans-jugular sheath was used for snaring.

We use established transcatheter electrosurgery techniques to traverse annular and myocardial tissue (9–11). A pair of 0.014" guidewires (Confianza Pro 9, Asahi-Intecc) are directed to each target using curved catheters (5–6Fr mammary, JR4, and multipurpose) through a trans-apical or trans-jugular sheath [FIGURE 2A+E, FIGURE 3]. Each guidewire is insulated with a 0.035" polymer jacketed wire convertor (Piggyback, Teleflex Vascular Solutions) to concentrate current delivery at the guidewire tip. The guidewire shaft is clamped to a unipolar electrosurgery pencil (Valleylabs FX, Medtronic Covidien) set at 30W cutting mode and advanced under brief (0.5–1.0s) electrification. The guidewire tips are snared and externalized through a jugular sheath. The traversing guidewire pairs are spaced 5–10mm apart to accommodate pledgets and to distribute force along the annulus. A 0.014" 'marker' guidewire (ATW, Cardinal) in the right coronary artery helps avoid perforating the right coronary artery during annular traversal and is used to estimate distance between annular bites. A loop snare (15mm Amplatz Gooseneck, Medtronic) in the coronary sinus ostium identifies the crossing target at the septum.

Teflon pledgets (7x3x1.5mm, 9x4x1.5mm Ethicon) are mounted on braided polyester suture (84" size 0 Ethibond EXCEL, Ethicon), chosen for tensile strength and low thrombogenicity in cardiovascular surgery. Surgical steel suture (3-0 Ethicon) is tied to the pledget to impart radiopacity. Pledgeted suture is connected to the guidewire using a half-hitch knot, tightened with forceps, crimped with sterile pliers, and threaded through the annulus [FIGURE 2B+F, SUPPLEMENT FIGURE S1A].

From a trans-apical approach, the free suture ends from the first traversal are tied to the tips of the guidewires advanced through the opposite annular target and are withdrawn back

through the apical sheath [FIGURE 2C]. The final pledgets are attached and secured using alternating half-hitch knots delivered using a transapical laparoscopic knot pusher (3mm × 36cm, Mediflex, Islandia, NY) and free suture ends are cut *in situ* (Surecut, Sentreheart, Redwood City, CA) [FIGURE 2D]. From a trans-jugular approach, the suture topology is different. Pledgets are mounted on the externalized suture ends and then tied together, pushed onto the annulus, and tightened using a Cor-Knot (31cm, SLI Solutions)[FIGURE 2G+H].

Percutaneous RV apical access and closure

For the trans-apical approach, closed chest needle access to the right ventricle was obtained under biplane fluoroscopy, targeting a pigtail catheter in the right ventricular apex and marking the apical left anterior descending artery with a guidewire. A 12Fr × 10cm sheath was secured.

To allow apical sheath removal after PASTA was completed, anticoagulation was reversed with protamine. The sheath was replaced with a nitinol cardiac occluder (Amplatzer Duct Occluder 10/8 or Amplatzer Ventricular Septal Defect Occluder 8mm, St Jude).

Tricuspid regurgitation animal model

A model pathologically mimicking clinical functional tricuspid regurgitation was created by combined right ventricular pressure and volume overload (12) after 30 days. Homemade nitinol stents (2.5 × 8cm) were implanted across the pulmonary valves of naïve swine, creating free pulmonary regurgitation. Simultaneously, polyvinyl alcohol microspheres (500–700 μ m Embospheres, Merit Medical) were infused into the pulmonary arteries until the mean pulmonary artery pressure doubled acutely.

Pull-through force

To prevent avulsion of sutures, we tested different pledget strategies in freshly explanted swine hearts. Transcatheter suture mimics have involved a single trans-annular “bite” (13). We compared this strategy with a double trans-annular bite used in PASTA. Pledgeted sutures were fed through a single tricuspid trans-annular bite at both septum and free wall in five naïve swine hearts. The pull-through force (Model ZPH; Imada, Northbrook, IL) was compared to four non-survival and four 30-day PASTA explants where a pledget was secured to annular targets at two bites [SUPPLEMENT FIGURE S1B+C]. The *in vivo* bites were made using radiofrequency perforation with a guidewire and *ex vivo* bite with a 2-0 curved needle.

Imaging and analysis

MRI was performed at 1.5 T (Aera, Siemens, Erlangen, Germany) before and after PASTA. Steady-state free precession MRI measured right sided chamber size and function. Right ventricular stroke volume was compared with 3-dimensional pulmonary artery flow to quantitate tricuspid valve regurgitant fraction(14). Annular area was measured by planimetry on short axis cine images and septolateral dimension from long axis cine images in mid-diastole. T1 and T2 parametric reconstructions assessed acute edema, and late gadolinium enhancement imaging was performed at 30 days to assess fibrosis. Non-contrast 4-

dimensional flow was acquired over the whole heart (4D Flow 2.4, Siemens), and reconstructed after seeding voxels within the right atrium, right ventricle, and pulmonary artery. Volumetric CT (Aquilion One, Toshiba) was performed in a subset after PASTA.

Data are represented as mean $\pm$ standard deviation. Statistical analysis comparing pull-through forces was performed using two-tailed two-sample equal variance t-tests. No further statistical comparisons were performed because of small sample sizes.

RESULTS

Pledgets and exchange knots

The maximum outer diameter of the suture-exchange knot was 0.032" at the guidewire shaft and 0.024" at the tip [SUPPLEMENT FIGURE S1A]. The connection was secure, with no loss of suture after 88 *in vivo* annular suture exchanges in 22 animals.

The force required for pull-through failure in freshly explanted naïve swine hearts with a single *ex vivo* needle directed puncture was 8.0 ± 2.6 N. This was significantly lower than the pull-through force in non-survival (40.6 ± 11.7 N, $p < 0.01$, $n = 8$) and 30-day (41.1 ± 11.5 , $p < 0.01$, $n = 8$) PASTA explants. In non-survival PASTA explants, the pledgets technically did not pull-through at all but rather the myocardium was torn at these extreme forces. Septal and free-wall pull-through forces were comparable.

Procedure outcomes

The procedure was conceived and developed in 23 pigs that are not further described.

PASTA was performed in six consecutive non-survival naïve pigs; 10 naïve pigs that were survived to 30 days; and six pigs with iatrogenic functional tricuspid regurgitation and annular dilatation, survived to 30 days [SUPPLEMENT FIGURE S2].

All 22 pigs (44–69 kg) had technically successful procedures with percutaneous trans-apical or percutaneous trans-jugular delivery of a pledgeted suture bridge across the tricuspid annulus to create a double orifice valve. Tension was applied variably to accomplish complete ($n = 11$) or partial ($n = 11$) apposition of the annular edges. Doppler interrogation showed no regurgitant jets through the suture sites.

Complications

Four animals had apical access related complications (pneumothorax ($n = 3$), hemothorax ($n = 3$), and pericardial effusion ($n = 2$)) that were expected after knowingly traversing lung tissue and after closing without pericardial drainage. One animal had iatrogenic volume overload. Four had PASTA-related complications, including leaflet tearing ($n = 2$) from out-of-plane imaging, chord entrapment ($n = 3$) and leaflet entrapment ($n = 1$) from loss of catheter position, transient AV node block ($n = 1$), and ventricular fibrillation during wire electrification ($n = 1$). One naïve pig had severe tricuspid stenosis from over-aggressive annular apposition.

Geometric and hemodynamic impact of PASTA

The procedure created a tricuspid valve pressure gradient of 1.7 ± 1.5 mmHg in naïve pigs and 0.7 ± 0.8 mmHg in pig models of tricuspid regurgitation. Hemodynamics at baseline, post procedure and 30 days are shown in TABLE 1.

Immediately post procedure there was a sizeable reduction in tricuspid dimensions (TABLE 1; SUPPLEMENT FIGURE S3). Annular area reduced from 10.1 ± 0.8 cm² to 3.8 ± 1.5 cm² in naïve animals and from 13.1 ± 1.5 cm² to 6.2 ± 1.0 cm² in diseased animals. Septal-lateral diameter, measured at the target sites, reduced from 3.9 ± 0.3 mm to 1.4 ± 0.6 mm in naïve animals and 4.4 ± 0.4 mm to 1.7 ± 1.0 mm in diseased animals.

Right ventricular end-diastolic volume reduced from 94 ± 13 ml to 85 ± 14 ml in naïve animals and 157 ± 25 ml to 143 ± 20 ml in diseased animals.

Results were sustained at 30 days apart from in one animal where there was a significant leaflet tear from a poorly selected crossing target, which released suture tension. One animal with tricuspid regurgitation had leaflet entrapment from PASTA, and continued to have progressive right ventricular dilatation.

The results were not adjusted for the 21–30% increase in weight in between measurements.

PASTA in functional tricuspid regurgitation

Iatrogenic tricuspid regurgitation increased annular area from 9.3 ± 2.0 cm² to 13.2 ± 1.5 cm², predominantly in the septal-lateral dimension. The mean MRI regurgitant fraction was $32 \pm 12\%$. Tricuspid regurgitation fraction measured by MRI was severe in one, moderate-severe in four, and mild in one pig. Tricuspid regurgitation fraction was $4 \pm 5\%$ in the six pigs immediately after PASTA with no regurgitant color flow by echocardiography or MRI 4D flow [FIGURE 4]. At 30 days, one of these animals had unintended suture traction on the anterior leaflet causing residual moderate tricuspid regurgitation (regurgitant fraction 24%). The remaining four had a regurgitation fraction of $3 \pm 4\%$ and no regurgitant doppler color flow.

Right coronary artery

Post-procedure angiography demonstrated an intact right coronary artery in all cases. Two out of 22 pigs developed a kink in the right coronary artery at the site of suture tension, with pressure wire Pd/Pa >0.98 in both and no angiographic flow obstruction.

Tissue characterization by MRI, Necropsy and Histopathology

No acute injury was identified on MRI imaging of myocardial edema immediately post-procedure. There was no MRI late gadolinium enhancement evidence of scar at 30 days.

Necropsy after all experiments demonstrated a suture bridge from septum to free wall creating a complete or partial double orifice tricuspid valve, maintained to 30 days. The anterior leaflet was restricted in two animals with leaflet tear and entrapment respectively. In the other 20 animals, all leaflets were mobile with good coaptation as demonstrated on CT and by 'water test' [FIGURE 5A+B; SUPPLEMENT VIDEO 1]. Focal endocardial abrasion

was typically evident acutely where the suture exited on the atrial side. The suture and pledgets completely endothelialized by 30 days [FIGURE 5C].

Microscopy with hematoxylin and eosin and Trichome stains revealed linear myocardial necrosis with mineralization of fibers and neutrophilic infiltrates, likely because of focal heat injury in non-survival animals (n=4), and replacement fibrosis around the pledget site in 30-day animals (n=5). There also was localized chronic inflammatory foreign body response around the pledget.

DISCUSSION

We demonstrate that pledget-assisted suture tricuspid annuloplasty can create a double-orifice valve and abolish tricuspid regurgitation in an animal model. PASTA was performed using commercially-available equipment in what we believe to be the first transcatheter cardiac surgical suturing procedure. Despite guidance by 2-dimensional ultrasound and X-ray instead of direct surgical visualization, we are able to place all sutures accurately at the intended site in 20 of 22 cases. Commercial catheter-based suture systems have been developed, but these typically implant fixation devices rather than knots (such as *Sutura Inc*, Defunct (15)), or are open surgical adjuncts (such as *Neochord Inc*, St. Louis Park, MN, (16)).

PASTA is enabled by several novelties. First, we implanted trans-annular double bite suture pledgets to create a broad anchor area with limited tissue perforation. The double-puncture pledget technique resulted in a five-fold higher pull-through force compared with a single-puncture alternative, a strategy used in some investigational technologies (e.g. Mitralign/Trialign (17), Tewksbury, MA). Our technique compares favorably to surgical (“partial thickness”) sutures in ovine tricuspid annulus, with a reported pull-through force of 6.5 ± 2.2 N (18). Second, we exchange a traversing guidewire for a permanent suture, by crimping a simple low-profile knot to connect the two. We expect this suture delivery technique to be widely applicable. Third, because the tricuspid septal annulus is not anatomically delineated, we developed a technique to employ a muscular septal “bite” extending into the coronary sinus ostium to establish a pledgeted septal anchor.

The procedure is inspired by Hetzer’s surgical technique of double-orifice tricuspid annular repair (8). They report durable repair in 91 patients, most of whom had functional tricuspid regurgitation, Ebstein’s anomaly, or endocarditis, and massive annular dilation up to 6.2mm. No patients required reoperation, though ‘freedom from reoperation’ likely underestimates rates of residual or recurrent tricuspid regurgitation(19).

This technique can narrow the septal-lateral tricuspid annular dimension to any desired extent, including complete apposition to create a double-orifice tricuspid valve. By narrowing basal diameter, PASTA reduces RV volume immediately, but the longer-term impact is not yet clear. Delivering each individual suture pair is more cumbersome in PASTA than surgery. However, the ability interactively to titrate tension while the heart beats, and to avoid the morbidity of open surgical exposure, may ultimately outweigh the comparative ease of surgery.

PASTA may compare favorably with other transcatheter devices under development. Perimeter narrowing techniques such as Trialalign(13) (Mitralign) are inherently inefficient, because large circumferential changes induce modest area reductions. Tricinch(20) (4Tech Inc, Galway, Ireland) apposes the anterior tricuspid annulus to an extracardiac structure (IVC) subject to respiratory motion, while PASTA remains wholly intracardiac. FORMA (Edwards Lifesciences, Irvine, CA) reduces regurgitation by imposing an intravalvular mass(21). Leaflet — versus annular — apposition procedures (such as Mitraclip(22)) (Abbott Vascular, Abbott Park, IL) are best applied near commissures even while most regurgitation occurs in the center of the multileaflet tricuspid valve. Annuloplasty implants (such as Cardioband(23), Edwards Lifesciences) are promising but require extensive multifocal fixation. None of these techniques appear suitable in enormous annuli and often reduce tricuspid regurgitation severity from torrential to severe (24), which would be considered a failure in surgically repaired tricuspid valves(19).

Limitations

We developed the PASTA technique despite knowingly traversing lung tissue in animals, which we would not tolerate in humans. Accordingly, serious complications were common. Procedure mortality was related to percutaneous right ventricular apical access (lung traversal causing pneumothorax and hemothorax) and closure (pericardial effusion). In humans the expected transapical trajectory would avoid lung traversal, and is amenable to surgical or percutaneous access. These complications were avoided in the trans-jugular iteration of PASTA.

In two animals, we inadvertently traversed the basal anterior leaflet rather than annulus. This caused leaflet tears. Thereafter we learned better intracardiac echocardiography techniques that avoid out-of-plane catheters to assure adequate annular traversal. In patients, we would not attempt PASTA if there were insufficient (<4mm) annular tissue rims between the right coronary artery and the anterior leaflet, and we would add three-dimensional echocardiography guidance, which is not available in our animals. Right coronary artery kinking may not be tolerated in patients with diseased coronary arteries and may require rescue stent implantation. Ventricular fibrillation is common and expected during cardiac electrosurgery in our swine; there is human experience crossing the interventricular septum using radiofrequency ablation without complication (25,26). In naïve animals without annular dilation, PASTA may create functional tricuspid stenosis. This may explain the mild transvalvular gradients we observed after PASTA. In humans, we do not expect tricuspid stenosis to occur, but overcorrecting tricuspid regurgitation and leaving mild stenosis is often well tolerated (27).

The long-term durability of this technique is untested. It is possible that the annulus would continue to dilate around the tension points of the suture. Moderate degrees of dilation would likely be well tolerated without recurrence of tricuspid regurgitation given the large reduction in annular area with PASTA. We did not see pledget pull-through at 30 days, by which time endothelialization was complete. However, even optimally secured pledgets may pull through in patients with fragile tricuspid annuli. Worse, the annulus could tear

away from the myocardium if excessive tension is applied. Alternatively, the ventricle may remodel favorably, reducing tension.

There is no good animal model of torrential tricuspid regurgitation with preserved leaflets. The animal models in this study developed only modest annular dilatation so the efficacy of this technique in massively enlarged annuli, or in patients with chronic tricuspid regurgitation, is untested.

Conclusions

Percutaneous pledget-assisted suture tricuspid annuloplasty (PASTA) is feasible, reduces annular area, and eliminates tricuspid regurgitation in an animal model. Serious complications were common in this technical development study, but were mostly related to apical access and not likely to be visited upon patients. The technique may be applied cautiously in selected patients who have no clinical or investigational option.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

FUNDING

Supported by Z01-HL006040 and Z01-HL006039 from the Division of Intramural Research, NHLBI, NIH

We thank Erina He for illustrations, Katherine Lucas and Joni Taylor for animal care, Jonathan Mazal and Kendall O'Brian for MRI, Merdim Sonmez for stent manufacture, and Michael Eckhaus for pathology assistance.

ABBREVIATIONS

PASTA Pledget assisted suture tricuspid annuloplasty

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PERSPECTIVES

What is known?

Functional tricuspid regurgitation is caused by annular dilation and leaflet traction and can be highly symptomatic. Double-orifice surgical apposition of the septal and lateral annular walls durably reduces tricuspid regurgitation.

What is new?

Using percutaneous catheters and off-the-shelf equipment, we delivered pledgeted sutures to appose the annulus of the tricuspid valve between the middle of the anterior leaflet and the posterior septal leaflet. This markedly reduced tricuspid annular area and tricuspid regurgitation in an animal model.

What is next?

The PASTA procedure will cautiously be applied to patients without other good options to treat severe tricuspid regurgitation. Transcatheter pledgeted cardiac suture repair may have numerous applications in structural heart disease.

FIGURE 1.

PASTA overview, viewed from the ventricles. A) A dilated tricuspid valve annulus, and B) a double orifice valve created by PASTA pledgeted sutures between the postero-septal and mid-anterior annulus. MRI images before (C) and after (D) PASTA demonstrating reduced annular dimension from 10.4cm² to 2.9cm². (E) Necropsy 30 days after PASTA, viewed from the atrium. S=septum; A=anterior annulus; P=posterior leaflet.

FIGURE 2.

PASTA procedure steps. A) In the transapical approach, two guidewire perforate the septal annulus and are snared and externalized through a jugular sheath. B) The guidewires are connected to a pledgeted suture, which is then pulled into the annulus. A second pair of guidewire perforations are made at the anterior annulus. C) The tips of these guidewires are connected to the suture previously externalized through the jugular sheath and are pulled back through the apex. D) A knot pusher delivers a pledget and applies tension to appose the annular targets. E) In the trans-jugular approach, a deflectable catheter delivers guidewires to anterior and septal (F) targets on the tricuspid annulus. G) These are exchanged for pledgeted sutures. H) A Cor-Knot ties opposing sutures, apposing annular targets.

FIGURE 3.

Intracardiac echocardiography and X-ray fluoroscopy of septal (A, B, D, E) and free wall (C +F) guidewire traversal. A loop snare is positioned from a jugular sheath and a catheter and guidewire mark the right coronary artery. A red circle marks the right coronary artery. G) Severe TR pre-procedure. H) No TR seen after the procedure. A=atrium; V=ventricle.

FIGURE 4.

MRI 4-D flow analysis on a swine with functional TR before (A–C) and after (D–F) PASTA during diastole (A,D) and systole (B,E). PASTA causes diastolic flow acceleration across the tricuspid valve (D) and abolishes regurgitation (E) leaving only caval flow in the atrium. PASTA abolishes tricuspid regurgitation (C, F). RA=atrium; RV=ventricle; PA=pulmonary artery.

FIGURE 5.

CT and necropsy at 30 days after intentional partial annular apposition. Pledgets are evident on short-axis (A) and long-axis (B) views of the tricuspid annulus. Enhanced leaflet apposition is evident (B, arrow). Despite incomplete apposition, the suture and pledgets are endothelialized (C).

Catheter hemodynamics and MRI-derived chamber volumes and flows before, immediately after, and 30-days after PASTA in naïve and TR model swine.

TABLE 1

	Naïve (n=16)			TR Model (n=6)		
	Baseline	Immediate post	30d	Baseline	Immediate post	30d
HR bpm	67±12	73±16	87±7	79±14	80±12	87±4
MAP mmHg	56±8	49±10	69±3	50±8	50±5	64±3
mPAP mmHg	12±4	13±3	12±3	14±6	15±6	9±2
RVDP mmHg	5±3	5±3	3±1	10±4	7±1	3±1
RA mean mmHg	4±3	6±2	3±1	6±3	7±1	4±2
TV gradient mmHg	0	2±2	0±1	0	1±1	0±1
TV annulus area cm ²	10.1±0.8	3.8±1.5	6.4±2.9	13.1±1.5	6.2±1.0	6.3±1.0
Septal-lateral distance mm	3.9±0.3	1.4±0.6	1.2±1.2	4.4±0.4	1.7±1.0	1.3±0.2
RVEDV ml	94±13	85±14	97±19	157±25	143±20	154±55
RVESV ml	47±9	48±7	53±15	83±28	87±20	97±46
RV SV ml	46±11	38±8	44±11	71±10	55±10	68±13
RV EF %	49±8	42±5	45±8	47±9	39±8	44±8
RA area cm ²	11±2	11±2	12±3	13±4	12±3	13±3
IVC diameter mm	1.5±0.1	1.6±0.1	1.7±0.2	1.4±0.2	1.6±0.2	1.6±0.1
Pulmonary forward flow ml/beat				48±11	53±9	63±6
Regurgitation fraction %				32±12	4±5	9±11