

Supplementary Materials

Real-Time Monitoring and Step-by-Step Guidance for Transcatheter Tricuspid Annuloplasty Using Transesophageal Echocardiography

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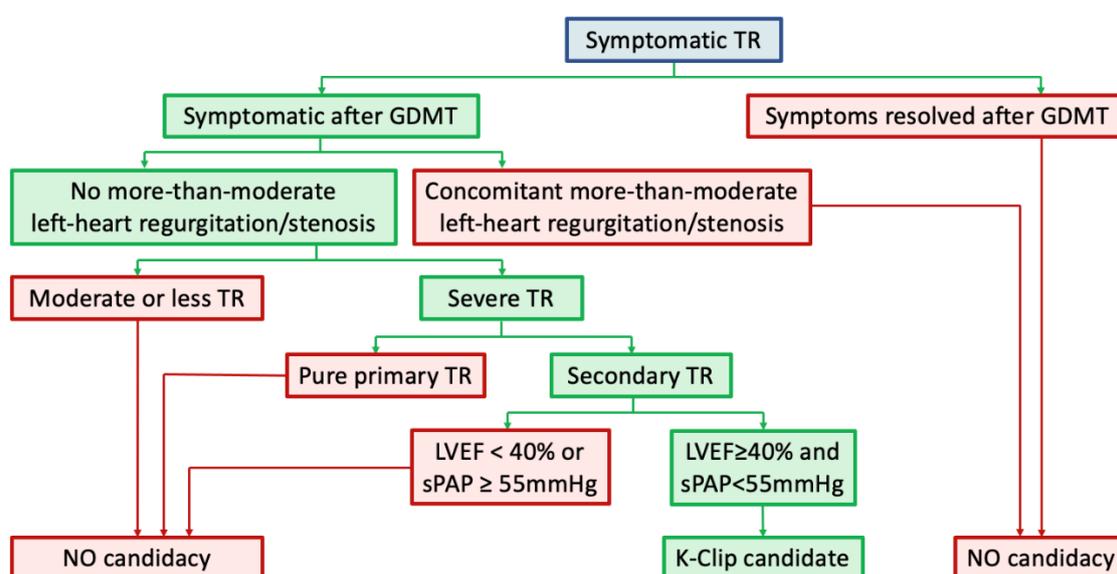


Figure S1. Patient screening protocol for the First-in-human study of K-Clip™ system. TR, tricuspid regurgitation; GDMT, guideline-directed medical therapy; LVEF, left ventricular ejection fraction; sPAP, systolic pulmonary arterial pressure.

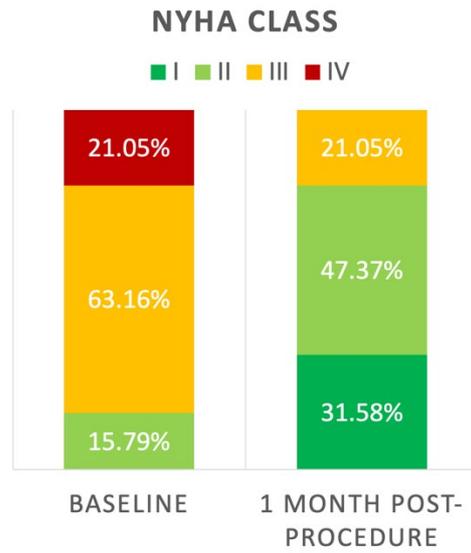


Figure S2. NYHA functional status was improved after implantation of the K-Clip™ system. NYHA, New York Heart Association.

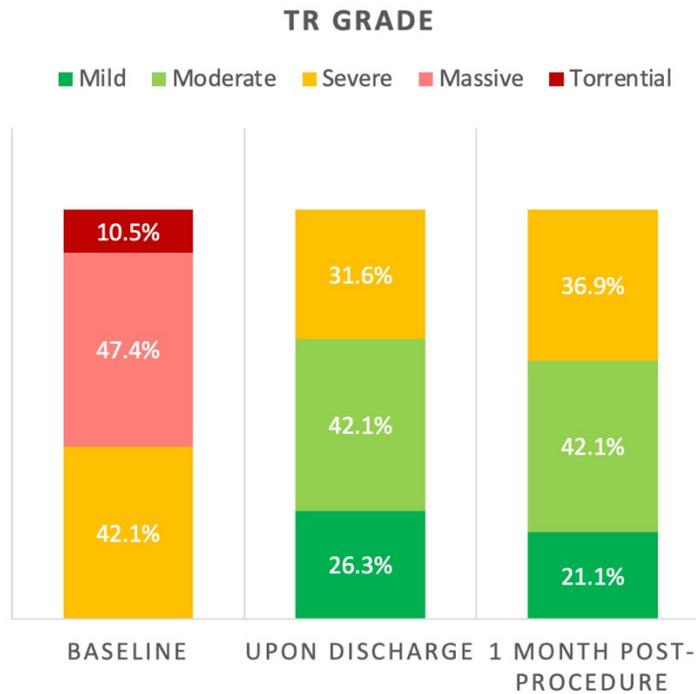


Figure S3. TR was reduced immediately and 1-month post-procedure. TR, tricuspid regurgitation.

Table S1. Baseline demographics of patients received K-Clip implantation.

Variable	N=19
Age	73.4±8.7
Gender (Male)	63.2%
NYHA Class	
I	0
II	3(15.8%)
III	12(63.2%)
IV	4(21.1%)
Hypertension	9(47.3%)
Diabetes	4(21.1%)
Atrial fibrillation (AF)	15(78.9%)
Previous mitral valve surgery	4(21.1%)
I-II degree atrioventricular block	0
Myocardial infarction	0
Stroke	0
Percutaneous cardiac intervention	1(5.2%)
ICD	2(10.5%)
Renal failure	0
Previous annulus intervention	0
STS score, %	7.9±3.1

NYHA, New York Heart Association; ICD, intra-cardiac defibrillator; STS, society of thoracic surgeons.

Table S2. Baseline characteristics of tricuspid regurgitation by echocardiography.

Variable	N=19
TR grade	
Severe	8(42.1%)
Massive	9(47.3%)
Torrential	2(10.5%)
TR etiology	
Functional	15(78.9%)
Secondary to AF	11(57.8%)
Secondary to left heart disease	4(21.1%)
ICD-lead related	0
Degenerative	0
Mixed etiology	4(21.1%)
Right atrium (major*minor axis), mm	(72±10.8)*(43.8±7.3)
Right ventricle (basal diameter), mm	48±9
Tricuspid annulus diameter (major*minor axis), mm	(47.2±5.0)*(43.8±7.3)
Vena contracta width (major*minor axis), mm	(15.3±5.9)*(14.8±5.4)

TR, tricuspid regurgitation; AF, atrial fibrillation; ICD, intra-cardiac defibrillator. *, means "times".

Table S3. Summary of the procedural safety of K-Clip implantation.

Adverse Events	N=19	
	Event counts	Subject counts (%)
All adverse events (AE)	3	2 (10.53)
AE during screening	0	0
AE during treatment	3	2 (10.53)
Relation to test device		
Related	1	1(5.26)
Not related	2	1(5.26)
Severity of AE		
Mild	3	2 (10.53)
Moderate	0	0
Severe	0	0
All severe adverse events (SAE)		
SAE during screening	0	0
SAE during treatment	1	1(5.26)
Relation to test device		
Related	0	0
Not related	1	1(5.26)
SAE leading to death	0	0