

## The need for a new tricuspid regurgitation grading scheme

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The adverse effects of severe tricuspid regurgitation (TR) on longterm outcomes has now been reported in a number of natural history studies.<sup>1,2</sup> Current treatment for TR is primarily with optimal medical therapy involving diuretics, or surgery.<sup>3</sup> Surgical mortality for isolated tricuspid valve interventions however, remains higher than for any other single valve surgery.<sup>4,5</sup> Despite the low risk of added tricuspid repair at the time of the left-sided disease surgery,<sup>6</sup> and the current guideline recommendation to intervene with annular dilation even in the absence of severe TR,<sup>3,7</sup> combined left and right heart valve surgery remains underutilized. In addition, as more left-sided valve disease is treated with transcatheter therapies, the negative impact of TR on survival in these patients has underscored the importance of developing transcatheter solutions to this disease.<sup>8,9</sup>

Echocardiography remains the primary imaging modality to diagnose the aetiology and severity of the disease once patients are referred.<sup>3,10</sup> A vena contracta  $\geq$ 0.7 cm, effective regurgitant orifice area (EROA) of  $\geq$ 0.40 cm<sup>2</sup>, and regurgitant volume  $\geq$ 45 mL, qualify as severe.<sup>11</sup> Despite guidelines advocating a multi-parametric and semiquantitative or quantitative approach,<sup>11,12</sup> most clinicians continue to use qualitative parameters, contributing to the significant underdiagnosis of severe disease. Late in the natural history of the disease, patients fail to respond to diuretics and present with signs of severe right heart failure and low flow. These end-stage patients may have what has been referred to as 'massive' TR,<sup>12</sup> however even this term fails to capture the severity of regurgitation in patients currently being treated in early feasibility trials of transcatheter devices.<sup>13</sup> The SCOUT (Percutaneous Tricuspid Valve Annuloplasty System for Symptomatic Chronic Functional Tricuspid Regurgitation) trial found on average, a reduction in quantitative effective regurgitant orifice area (EROA) of  $-0.22 \pm 0.29$  mm<sup>2</sup> (the equivalent of a full grade). However the baseline quantitative EROA was  $0.85 \pm 0.22 \text{ mm}^2$  and the resulting EROA was  $0.63 \pm 0.29 \text{ mm}^2$ . The current grading schemes for TR thus fail to take into account the 'torrential' nature of TR in the patients currently enrolling in these trials. Despite reducing the TR severity from 'severe TR' to 'severe TR', the SCOUT trial showed that the equivalent quantitative reduction of a 'grade' of TR was associated with an increase in forward stroke volume, and resulted in significant improvements in quality of life measures. Although long-term outcomes related to transcatheter reductions in TR are not yet available, natural history studies would suggest that any reduction in TR severity may be associated with a decrease in mortality. It thus seems reasonable to think that not all 'severe' grades of TR will have the same in prognosis and defining these grades will be important in determining outcomes in future trials.

To better characterize the severity of TR currently being treated with various transcatheter devices,<sup>14</sup> we propose increasing the grades to include very severe (or massive), as well as torrential (*Table 1*). The cut-offs for these grades are based on the ranges of values for the current grades of mild or moderate. The SCOUT trial also showed that traditional proximal isovelocity surface area (PISA) method underestimates the quantitative method for assessing effective regurgitant orifice area (EROA) and different cut-offs should be

Table I Proposed expansion of the 'Severe' grade					
Variable	Mild	Moderate	Severe	Massive	Torrential
VC (biplane)	<3 mm	3-6.9 mm	7–13 mm	14–20 mm	≥21 mm
EROA (PISA)	<20 mm <sup>2</sup>	20–39 mm <sup>2</sup>	40–59 mm <sup>2</sup>	60–79 mm <sup>2</sup>	≥80 mm <sup>2</sup>
3D VCA or quantitative EROA <sup>a</sup>			75–94 mm <sup>2</sup>	95–114 mm <sup>2</sup>	≥115 mm <sup>2</sup>

VC, vena contracta; EROA, effective regurgitant orifice area; 3D VCA, three-dimensional vena contracta area. <sup>a</sup>3D VCA and quantitative Doppler EROA cut-offs may be larger than PISA EROA.

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considered. Using this new grading scheme the majority of the 12 As-Treated SCOUT early feasibility trial patients would have seen a 1-2 grade reduction in TR.

As new devices are being tested in clinical trials, the assessment of procedural success may be based in part on reduction in TR severity similar to trials for mitral regurgitation.<sup>15</sup> The new grading scheme incorporates our current knowledge about the baseline severity of disease and the clinically relevant reduction in TR severity with transcatheter intervention. The new grading scheme will have a significant impact on the design of future device trials and determine outcomes using quantitative echocardiographic parameters.

**Conflict of interest:** Rebecca Hahn declares the following possible conflicts of interest: National PI for the SCOUT trial for which she receives no compensation and Echo Core Lab Director for multiple tricuspid device trials for which she receives no direct compensation.

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