


Discussion

Dr Frank Hanley (Stanford, Calif). Dr Vida and his colleagues have addressed an important issue, that is, maximizing maintenance of pulmonary valve annular integrity during tetralogy of Fallot repair. There is a long history focusing on maintenance of pulmonary valve annular integrity in tetralogy of Fallot dating back to the early work of John Kirklin, who primarily focused on Z scores alone.

Over the years many technical maneuvers have been suggested to improve the percentage of patients in whom the annulus is preserved. In recent years, the introduction of intraoperative balloon dilation of the annulus has been introduced as one of these options, somewhat parallel to Hegar dilation or other forms of dilation of the valve. Several publications since 2007 have retrospectively assessed the potential benefit of this technique.

This study by Dr Vida and his colleagues is the first to incorporate at least some degree of prospective design. The authors prospectively assigned cohorts of patients either to receive or not to receive an intraoperative balloon procedure versus the standard treatment. And they used a predefined anatomic characteristic, the size of the pulmonary annulus preoperatively, to determine which group the patients would belong.

The results are encouraging that this may be a useful technique and the study is an important contribution. There are, however, uncertainties and significant limitations with respect to drawing definitive conclusions based on the results. I have a few questions that address those potential limitations.

The first relates to study design. It seems unfortunate that you did not match the patients based on their pulmonary valve annular size. So as it turns out, you have picked a favorable anatomic group who get the preservation and a more unfavorable anatomic group that received the standard technique, so you can see where a potential bias would be present in the long-term results. Why did you not decide to do a matched control of the pulmonary valve annular size and just randomize matched patients into those 2 groups? It would have been easy to do.

Dr Vida. We started to apply this technique a few years ago. At the beginning, we decided to start with milder forms of tetralogy of Fallot with less severe pulmonary valve Z scores. As we have gained more experience with this new technique, we have been treating even more severe forms of tetralogy of Fallot.

Our initial limit for choosing the balloon dilation technique was a pulmonary valve Z score equal to or more than ~3, and this, at the beginning, was surgeon dependent. In the last couple of years, with the advent of more aggressive additional pulmonary valve plastic techniques, such as leaflet delamination, we decided to be more aggressive, applying this technique in patients with a Z score as low as ~4.

Initially, we had a tendency to oversize our balloon catheters during the pulmonary valve dilation phase, based on the...
experience from the catheter laboratory, where our cardiologist colleagues usually go up to 120% to 150% of the initial pulmonary valve diameter. However, we have learned that, to avoid unexpected tears of the pulmonary valve leaflet or annulus during the dilation, it is better to dilate the annulus up to the expected normal value for the patient’s body surface area by using high-pressure noncompliant balloons.

As you pointed out, 1 of the major limitations of this study is that it is not a prospective randomized clinical trial. We analyzed our patient population in a retrospective fashion, comparing patients who underwent pulmonary valve preservation with patients who underwent a standard transatrial/transpulmonary repair technique.

Looking back at our results, we were able to preserve almost half of the pulmonary valves in our patients with tetralogy of Fallot. However, we can speculate, considering the latest achievements with this technique, that we could have saved more valves during the early stages of our experience, potentially saving the pulmonary valve in up to the 75% of our patients.

**Dr Hanley.** So I mean clearly this was more learn-as-you-go than prospectively designing. The read of the paper, in all fairness, sounds a little bit more like it was prospectively set up that way. But we have all been there, and learning as we go is a good technique, I am not criticizing that at all.

Another question relates to the follow-up. There is a discrepancy in the median follow-up periods for the 2 groups, and it is large: 433 days for the balloon group and 712 for the other group. And importantly, over the 433 days of follow-up for the preservation group, the percentage of patients who developed significant regurgitation almost doubled from 11.8% to 20%. A skeptic I guess could argue that if the preservation group was allowed to go out to 712 days, almost another 300 days, if there was another point on the curve, there was probably going to be a significant increase further, because it has already been demonstrated there has been some, a further increase in the amount of regurgitation, and would it be different than the control group?

**Dr Vida.** Yes, the follow-up time is different between our study groups. In fact, as we became more familiar with the pulmonary valve preservation technique, we were able to preserve most pulmonary valves during early repair of tetralogy of Fallot, especially in the last few years; this contributed to the shorter follow-up time in the preservation group.

Nonetheless, the shorter postoperative follow-up time, and because we are still in a learning phase with this new technique, our results are encouraging. In fact, most patients in the preservation group, almost 90%, were discharged home with none to trivial pulmonary valve regurgitation. Only a few of them, all with severe forms of tetralogy of Fallot, had a moderate degree of pulmonary valve regurgitation.

On the contrary, when we used an artificial cusp to achieve pulmonary valve competence during transannular patch repair, we have since the beginning had a higher frequency of more severe forms of valve regurgitation, which progressed over time in most patients.

**Dr Hanley.** Absolutely. You have clearly shown that short term you come up with less regurgitation. I guess the concern is way further out.

One last brief question. For what percentage of the patients in the preservation group did you use artificial material on the patch? Because I would say, and I will not respond after, but my concern there is the more you use artificial material on a young infant, pulmonary valve or any valve, the more likely you are going to have failure later.

**Dr Vida.** We needed to use biological material in 4 patients during pulmonary valve preservation. All these patients had more severe forms of tetralogy of Fallot, with an initial Z score less than −3.5. These patches were used to further extend the pulmonary valve leaflet coaptation area after balloon dilation and leaflet delamination, in order to achieve optimal valve competence.

**Dr Christopher A. Caldarone (Toronto, Ontario, Canada).** You bring up a novel concept, this concept of the delamination to extend the size of the pulmonary valve leaflets, and I think that would warrant some more discussion in terms of what the limits are to that technique and there may be a few tips that you may have in that regard. Can you just give us the briefest of comments on that.

**Dr Vida.** The pulmonary valve in patients with tetralogy of Fallot is usually thick and dysplastic and in most cases bicuspid. Following balloon dilation, a gap in the valvular tissue is usually present at 1 commissure level. In order to fill this gap and to make that valve competent, we extend the pulmonary leaflets by delaminating them at the hinge point level down to the right ventricular myocardium.

After delamination, a good coaptation between leaflets is usually achieved, however leaflets are usually prolapsing and need to be resuspended recreating a new commissure. If the leaflet is too short after delamination, the risk is a decrease in its motion after resuspension. To avoid the creation of a still, immobile leaflet, we decided to extend 1 leaflet end by means of a prosthetic patch. An initial concern deriving from the delamination process was possible right ventricular muscle blood infiltration. However, it did not happen in our patients, possibly because the delaminated site is exposed to the pressure of the pulmonary district, which is usually low in patients with tetralogy of Fallot.

**Dr Caldarone.** It is very interesting.

**Dr Emile Bacha (New York, NY).** Nice work. As you know, I am a proponent of the technique, but I have given it up for the severe end of the spectrum of tetralogy of Fallot. I do not use it anymore for very low Z scores or severely stenotic valves. I use it for the moderate range of Z scores up to −2.5, −3. I do not really like to use Z score either because it does not take into account the morphology of the pulmonary valve, and only measures the annular size with no accounting for the effective orifice and the cusp morphology.

However, it seems to me what you are doing is using a balloon as only 1 of the steps in your management of your severe tetralogy of Fallot spectrum. You are using patches, you are putting stitches in the valve. And so I would agree with Dr Hanley’s comment that probably what you are going to see long term is more pulmonary regurgitation developing because you have instrumented this valve so much by necessity. And in my view, I would rather do a controlled surgical intervention on a severely stenotic valve, such as dividing it where I want to, as opposed to having a balloon...
with a somewhat nondiscriminate tear of the valve, and then reconstruct this valve.

**Dr Vida.** Well, I agree with you. This treatment is appealing for milder forms of tetralogy of Fallot with a pulmonary valve Z score of −3 or higher. With the advent of a more aggressive approach, we were able to treat more severe forms, and, so far, have achieved good mid-term results. These results are significantly superior to the results from our standard transatrial/transpulmonary approach. However, a longer follow-up is certainly mandatory to prove the efficacy of this technique.

**Dr Bacha.** I do not disagree with plasty for the valve and working on the valve trying to preserve it. But I am saying that, at the severe end of the spectrum, you probably have more control over what you do with this valve if you divide it where you want it, as opposed to introducing a balloon. The valve may tear in a place that you do not want it to tear.

**Dr Vida.** Because of its high success rate, our current policy is to attempt the preservation of the pulmonary valve in every single patient during repair of tetralogy of Fallot. This technique guarantees superior results in terms of pulmonary valve competence at discharge compared with our standard repair. In cases where the pulmonary valve cannot be preserved, these patients can be easily converted to the standard approach without additional risk.