Restoring ventricular restoration: A call to re-evaluate a surgical therapy considered ineffective

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Abstract
The technique of surgical restoration of postischemically dilated left ventricles (SVR) has almost disappeared from operating theaters after the Surgical Treatment of IsChemic Heart failure (STICH) Trial demonstrated no treatment effect in patients with CAD and ejection fraction below 35%. Criticism on the trial was expressed stating that surgical expertise and patient selection (i.e., almost no aneurysm patients included) may have been inadequate to test the procedure’s potential. Gaudino and colleagues now propose to conduct an analysis comparing the STICH patient population to a group of comparable SVR patients treated by a center with documented specific expertise for this technique. We here address the background of the trial and the following controversy and suggest a rationale why the suggested analysis has the potential to add valuable information to the field.

KEYWORDS
aneurysm, cardiac surgery, heart failure, surgical ventricular reconstruction

1 INTRODUCTION

Surgical ventricular restoration, also known as surgical ventricular reconstruction (SVR), and classic aneurysmectomy are similar surgical procedures that used to be routinely performed in patients with dilated and dyskinetic ventricles for decades up to the beginning of the new millennium.1-3 There appeared to be consensus that large aneurysms require resection for its risk of rupture and its negative impact on functional performance of the remaining contracting muscle. The resection of an aneurysm with or without additionally required bypass grafting (CABG or coronary artery bypass grafting) was usually rewarded by an increase in left ventricular ejection fraction, a decrease in ventricular volume, and a perceived improvement in patient prognosis.1-4

The 1990s and early 2000s were then filled with the development of surgical modifications that suggested benefits not only for patients with ventricular aneurysms (i.e., dyskinetic myocardium bulging out during systole) but also for patients with akinetic myocardium (i.e., dilated, regionally dysfunctional, and not-aneurysmatic ventricles).5-10 Nowadays, any kind of ventricular surgery for these reasons has almost completely disappeared from the operating rooms worldwide mainly for two reasons. First, classic aneurysms no longer develop at the same frequency due to better and faster medical and interventional therapy.11,12 Second and most importantly, the STICH trial (Surgical Treatment of IsChemic Heart failure) assessed the clinical efficacy of SVR in its second hypothesis comparing SVR plus CABG to CABG alone in patients deemed appropriate candidates for SVR.13 The trial demonstrated a completely neutral outcome with respect to mortality and quality of life but reported increased cost.13,14

As a result, cardiologists stopped referring patients despite reputable surgeons continuing to argue for SVR’s potential benefit.4,15-17 Several experts expressed heavy criticism regarding the STICH trial for significant shortcomings regarding patient selection, surgical experience, and the actual performance of SVR.15,18 Irrespective of this academic struggle,15,11 the trial practically buried the technique.

Now, 12 years later, Gaudino et al.20 propose to address this question again, but not by a new prospective randomized trial, but by...
The STICH trial was criticized for selecting the “wrong patients.” The vast majority of patients in the trial were those with enlarged but akinetic ventricles. Classic aneurysms were hardly included. Previous experiences from the world’s leading experts in this field suggested that patients with akinetic myocardium fared worst if compared to those with classic aneurysm. Thus, it appears that the trial failed to show a benefit for SVR in dilated akinetic ventricles. It did not actually test the effect of SVR on mainly dyskinetic ventricles (i.e., classic aneurysms).

However, with the exception of STICH, there is no randomized trial that compared the efficacy of SVR or any other modification of ventricular surgery to a control group that did not receive ventricular surgery. We had reviewed these questions in detail before. A summary of 36 reports of 5-year outcomes after ventricular surgery from 1980 to 2010 showed an astounding survival rate of around 70% without a trend to better survival in most recent years. While these data can be interpreted in many different ways, including arguments in favor of SVR, surgeons may have to accept that SVR’s clinical efficacy has still not been demonstrated. On the contrary, as it currently stands, STICH has shown that SVR’s clinical efficacy has still not been demonstrated. On the contrary, as it currently stands, STICH has shown that SVR is not effective. Additionally, medical therapies for heart failure with reduced ejection fraction patients have evolved since the conduct of STICH H2 which would serve to potentially reduce the absolute effect of any surgical approach in similarly medically-treated patients.

The STICH trial was further criticized for the lack of appropriate experience of the surgeons and the resulting inferior quality of the procedure, specifically inadequate volume reduction. This aspect has brought about a discussion on the interpretation of SVR’s effect on hemodynamics and the best way to assess it. The impact of surgical expertise on outcomes has been documented in several areas of cardiac surgery. The fact that surgeons performed SVR without having performed it before in relevant numbers is, therefore, a problem. However, the STICH surgical leadership committee supported training sessions for SVR surgeons, which were led by the expert surgeon at the same center from which the non-randomized comparator cohort comes. Thus, the efforts were made, but the expertise in selecting the “right patients” and “expertly perform” surgical procedures do not come overnight. From a different perspective, the lack of a potential treatment effect may have been camouflaged by a learning curve of surgeons in performing trials. However, the proper or improper performance of such a procedure should be measurable with today’s imaging tools. In reality, there is uncertainty about how to interpret the changes brought about by SVR, specifically regarding myocardial performance.

Incising a dilated, dys- or akinetic ventricle, placing purse-string sutures, possibly resecting endocardium and/or ventricular muscle, and closing the incision with or without a circular or oval-shaped patch has several documented and several speculated effects on the ventricle and its function.

First, the ventricular volume is reduced by SVR. Inappropriate performance should therefore be detectable. Indeed, the reported average volume reductions by the trial were lower (19%) than that reported by experts (up to 40%). However, the volumes reported by the STICH trial were obtained before surgery and during the 4 months postoperative visit, while the greater values from other reports were obtained immediately after surgery. Since post-SVR redilatation is a realistic and also already reported scenario, it is conceivable that the reported volume reduction in STICH is less than what was actually achieved with the operation.

Second, a scar is formed along the incision, which may affect systolic but more importantly diastolic function, which is more difficult to assess and was not a specific part of the STICH investigations. The Batista operation was probably the most dramatic surgery with respect to volume reduction. Hemodynamic assessment after a Batista procedure demonstrated the desired reduction in wall stress and improvement in systolic function by pressure-volume loops but also found a significant increase in diastolic dysfunction. Practically, this is easily envisioned if one imagines a large stiff scar running through a previously unscarred myocardium. However, in the case of SVR for an aneurysm, the ventricle is incised in an already scarred area and sutures and patches are placed at the border zone to the contracting muscle. Thus, it is conceivable that the reduction in volume with an SVR procedure performed in a patient with classic dyskinesia may translate into hemodynamic benefit without causing diastolic dysfunction.

While wall tension cannot be directly measured by echo or other imaging tools of daily practice, the effect of volume reduction on the ejection fraction is visible and has repeatedly been reported as a marker for the success of the operation. Reduction in wall tension reduces oxygen consumption, thus, facilitating ventricular pump function. However, considering that SVR reduces end-diastolic volume (i.e., the denominator of the ejection fraction) and expecting that stroke volume remains in the range from before surgery, the reported increase in ejection fraction may just be a mathematical consequence.

Third, patients with dilated ventricles often present with certain degrees of mitral valve regurgitation. SVR may affect mitral valve function per se, or the valve is addressed additionally during SVR surgery, which in addition adds complexity to the volumetric and contractile assessment of surgical effects.

Fourth, investigations have addressed the shape of the ventricle. Sphericity indices were proposed and speculations on myofiber-alignment
and a possible reorientation through SVR were made. In reality, the plethora of the different suggested SVR modifications and the above-described difficulties in interpreting the functional impact of SVR make it impossible to adequately judge these propositions.

Considering the potential mechanisms of SVR and the above-described problems in its effect-interpretation, only one conclusion can be fully supported: The effect of surgical ventricular reconstruction for clinical practice can only be evaluated based on a clinically visible outcome. That was the ultimate goal of STICH. The outcome of Hypothesis 2 was neutral with a negative impact on the conduct of SVR. If the expressed concerns regarding SVR in STICH hold true, the suggested analysis by Gaudino et al. has the potential to shed light on it. In other words, the comparison of the STICH SVR patients to a population of patients selected for SVR and operated on by one of the world’s leading experts on surgical ventricular reconstruction should either reject the criticism (i.e., reconfirm STICH outcomes) or accept them in the population operated and demonstrate that SVR still has therapeutic value among similar patients. In the latter case, if the analysis suggests that outcomes differed substantially among the non-randomized cohorts, this may spur the need for a randomized trial following-up to STICH H2 in such patients.

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