



ADULT CARDIAC SURGERY:

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Surgery of Left Ventricular Aneurysm: A Meta-Analysis of Early Outcomes Following Different Reconstruction Techniques

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Background. The purpose of this study is to assess the effects of linear and geometric left ventricular aneurysm reconstruction on early postoperative outcomes.

Methods. A search of computerized databases supplemented with manual bibliographic review was performed for all peer-reviewed English language publications concerning randomized and nonrandomized studies reporting the results of left ventricular reconstruction after both linear and geometric reconstruction techniques. Meta-analyses of several short-term outcomes were performed.

Results. No randomized trial was identified. Eighteen nonrandomized trials were found with a total of 1,814 and 803 patients who underwent linear and geometric reconstruction, respectively. Meta-analysis of all studies ($n = 18$) revealed an increased risk of in-hospital death for patients undergoing linear reconstruction (relative risk = 1.59, 95% confidence interval: 1.12 to 2.26, $p = 0.01$). The subanalysis of studies in which linear reconstruction was adopted mainly in the first period of time, and

geometric reconstruction was adopted in a later phase, still showed a significant advantage in terms of in-hospital mortality for patients undergoing geometric reconstruction ($n = 11$ studies, relative risk = 1.89, 95% confidence interval: 1.22 to 2.93, $p = 0.004$). By contrast, when the two surgical approaches were carried out in the same time lag, there was no difference between linear and geometric reconstruction techniques ($n = 7$ studies, relative risk = 1.04, 95% confidence interval: 0.57 to 1.92, $p = 0.89$). No differences in the other outcomes of interest were observed.

Conclusions. The advantage for geometric reconstruction techniques in terms of in-hospital mortality shown in some studies can be an effect of learning curve or of improvement over time in management of these difficult patients. Further studies are required to clarify this issue.

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The surgical treatment of left ventricle (LV) aneurysms has been performed for nearly 50 years, but controversy still remains regarding the impact of different surgical techniques on postoperative results. Indeed, various surgical techniques were developed over the years with the aim of restoring LV function and of improving postoperative results. These techniques can be grossly classified into two different categories: linear reconstruction (plication and linear repairs) or geometric reconstruction (circular patch/endoventricular patch closure, direct LV recon-

struction using multiple concentric purse string sutures) techniques [1, 2]. Geometric reconstructions have the theoretical advantage of maintaining LV shape and geometry, thus possibly improving postoperative LV performance. That, however, did not consistently translate into improved outcomes, as no effect of surgical technique on operative or on long-term mortality was demonstrated [3, 4], or lower in-hospital and late mortality rates [5] and a possible functional improvement [6] were shown after LV reconstruction with geometric techniques.

There are no systematic reviews or meta-analyses comparing the results of linear versus geometric reconstruction techniques in LV aneurysm surgery; also, meta-analysis may provide additional statistical power that overcomes the limited sample size of most studies together with the low incidence of the major endpoints, for

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Table 1. Studies Included in Meta-Analysis in Which Both Techniques Were Used in Temporal Sequence

| Study (Year) | Time of Study | Patient Numbers | Age (Years) | Males | Urgent/ Emergent | Diabetes Mellitus | Hypertension | EF (%) -LV Function | 3VD-No. of Diseased Vessels | Number of Grafts | CPB Time (Minutes) |
|-----------------|-----------------|-----------------|-------------|----------|---------------------|-------------------|--------------|---------------------|-----------------------------|------------------|--------------------|
| Booloki (2003) | 1979–2000 | 65(L) | 62(L) | 87.6%(L) | 40%(L) | n.r. | n.r. | 32%(L) | n.r. | 3.0(L) | 159(L) |
| | | 22(G) | 63(G) | 86.4%(G) | 9%(G) | | | 23%(G) | | 3.0(G) | 168(G) |
| Coltharp (1994) | 11/1968–04/1993 | 439(L) 76(G) | 59 | 77.3% | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. |
| Jakob (1993) | 05/1985–12/1991 | 25(L) | 59(L) | 88.0%(L) | n.r. | 24.0%(L) | 44.0%(L) | 35%(L) | 54% 3VD(L) | 1.9(L) | 111(L) |
| | | 27(G) | 61(G) | 76.9%(G) | | 15.4%(G) | 46.2%(G) | 36%(G) | 62% 3VD(G) | 2.1(G) | 122(G) |
| Komeda (1992) | 01/1978–12/1989 | 281(L) 38(G) | 55.7 | 82.7% | n.r. | n.r. | n.r. | 85.9% with EF <35% | 63.3% 3VD | n.r. | n.r. |
| Lange (2005) | 05/1974–12/2000 | 200(L) | 55(L) | 87%(L) | n.r. | n.r. | n.r. | 35%(L) | 37% 3VD(L) | 1.4(L) | 82(L) |
| | | 105(G) | 62(G) | 76%(G) | | | | 33%(G) | 33% 3VD(G) | 1.6(G) | 124(G) |
| Lundblad (2004) | 01/1989–01/2003 | 74(L) | 61(L) | 81.1%(L) | n.r. | 6.8%(L) | n.r. | 34%(L) | 33% 3VD(L) | 2.2(L) | 91(L) |
| | | 85(G) | 62(G) | 74.1%(G) | | 10.6%(G) | | 35%(G) | 35% 3VD(G) | 2.3(G) | 114(G) |
| Mohajeri (1998) | 07/1984–06/1994 | 46(L) | 63(L) | 63.0%(L) | n.r. | n.r. | n.r. | n.r. | 53% 3VD(L) | 2.0(L) | 117(L) |
| | | 41(G) | 58(G) | 73.2%(G) | | | | | 56% 3VD(G) | 2.5(G) | 133(G) |
| Pasini (1998) | 1979–1993 | 99(L) 40(G) | 57 | 80.6% | n.r. | n.r. | n.r. | 27% with EF <30% | n.r. | n.r. | n.r. |
| Shapira (1997) | 07/1987–01/1995 | 20(L) | 63(L) | 60.0%(L) | 60.0%(L) | n.r. | n.r. | 30%(L) | n.r. | 2.5(L) | 116(L) |
| | | 27(G) | 64(G) | 77.8%(G) | 52.0%(G) | | | 25%(G) | | 2.2(G) | 130(G) |
| Sinatra (1997) | 04/1981–11/1994 | 87(L) | 57(L) | 89.7%(L) | n.r. | n.r. | n.r. | 34%(L) | 48% 3VD(L) | 1.9(L) | 154(L) |
| | | 31(L) | 57(G) | 77.4%(G) | | | | 36%(G) | 52% 3VD(G) | 2.6(G) | 161(G) |
| Soloman (2001) | 1988–2000 | 67(L) | 55(L) | 98.5%(L) | n.r. | 29.9%(L) | 37.3%(L) | 37.3%(L) | 60% 3VD(L) | 2.2(L) | 108(L) |
| | | 28(G) | 56(G) | 96.4%(G) | | 39.3%(G) | 46.4%(G) | 34.9%(G) | 64% 3VD(G) | 2.2(G) | 125(G) |

EF = ejection fraction; G = geometric reconstruction technique; L = linear reconstruction technique; n.r. = not reported; 3VD = three-vessel coronary artery disease.

example, in-hospital mortality. Thus, this study is designed to assess whether any difference between the two different LV reconstruction techniques occurs in the early postoperative outcomes of patients undergoing LV aneurysm surgery.

Material and Methods

The Meta-analysis Of Observational Studies in Epidemiology (MOOSE) guidelines for meta-analysis of observational studies were followed [7].

Search Strategy

Two reviewers searched Medline (1966 to May 2006), Embase (1980 to May 2006), and PubMed (up to May 31, 2006), including electronic links to related articles. All peer-reviewed studies published in the English language that dealt with trials comparing different techniques of LV reconstruction for LV aneurysms (both prospective randomized and retrospective observational studies were searched) were identified and reviewed. The text string employed (formatted for PubMed) was: ((left ventricular aneurysm OR left ventricle aneurysm OR left ventricular reconstruction OR left ventricle reconstruction OR left ventricular remodeling OR left ventricle remodelling OR left ventricular aneurysmectomy OR left ventricle aneurysmectomy) AND (plication OR linear closure OR endoaneurysmorrhaphy OR patch repair OR patch closure OR circular patch OR circular patch plasty OR endoventricular patch).

The outcomes searched were the following: in-hospital mortality, stroke, myocardial infarction, acute renal failure, reoperation for bleeding, low output syndrome/postoperative inotropes requirement, and postoperative intra-aortic balloon pump need. The outcome definitions used by the original researchers were accepted. Bibliographies of included articles were also searched.

Several strategies were employed to avoid duplicate publications. If the same institution produced multiple studies, only studies reporting recruitment time periods were considered. If there was sample overlap between studies, only the largest study was included. To minimize temporal bias, as well as interinstitutional variability, studies were included in the meta-analysis only if they contained both linear and geometric reconstruction patient cohorts, with a minimum of 10 patients treated with either technique; also, separate analyses were performed for studies reporting the results of simultaneous use of both techniques and for studies where a temporal trend (eg, linear reconstruction techniques were used mainly or totally in the early years whereas geometric reconstruction techniques were used mainly or totally later on) in the use of linear and geometric reconstruction techniques was clearly identified. Data abstraction and analysis of temporal trends in the adoption of either technique of each study was performed by two reviewers (A.P. and P.D.), and disagreements were solved by consensus.

Table 2. Studies Included in Meta-Analysis in Which Both Techniques Were Used Simultaneously

| Study (Year) | Time of Study | Patient Numbers | Age (Years) | Males | Urgent/Emergent | Diabetes Mellitus | Hypertension | EF (%)-LV Function | 3VD No. of Diseased Vessels | Number of Grafts | CPB Time (Minute) |
|-----------------|-----------------|------------------|----------------|----------------------|---------------------|----------------------|----------------------|-----------------------------------|-----------------------------|------------------|-------------------|
| Antunes (2005) | 05/1998–12/2001 | 76(L) 34(G) | 60(L) 59(G) | 89.5%(L) 73.5%(G) | 9.2%(L) 8.2%(G) | 18.4%(L) 8.8%(G) | 57.9%(L) 52.9%(G) | 61.8%(L) 65.5%(G) with EF <40% | 75% 3VD(L) 76.5% 3VD(G) | 2.8(L) 2.7(G) | 80(L) 88(G) |
| Doss (2001) | 1989–1996 | 32(L) 20(G) | 62 | 76.9% | n.r. | n.r. | n.r. | 37.5% | n.r. | n.r. | n.r. |
| Kesler (1992) | 01/1984–12/1989 | 40(L) 22(G) | 58(L) 60(G) | 70.5%(L) 49.1%(G) | n.r. | 20.0%(L) 22.7%(G) | 40.0%(L) 54.5%(G) | 36%(L) 28%(G) | 2.6(L) 2.5(G) | 2.5(L) 2.5(G) | 145(L) 152(G) |
| Tavakoli (2002) | 01/1989–12/1998 | 61(L) 34(G) | 61(L) 62(G) | 86.9%(L) 76.5%(G) | 11.5%(L) 8.8%(G) | n.r. | n.r. | 35%(L) 29%(G) | n.r. | 2.3(L) 2.2(G) | 86(L) 105(G) |
| Turkay (1997) | 01/1989–12/1998 | 36(L) 36(G) | 47(L) 50(G) | 88.9%(L) 94.4%(G) | n.r. | n.r. | n.r. | 43%(L) 44%(G) | 17% 3VD(L) 11% 3VD(G) | n.r. | n.r. |
| Vicol (1998) | 1985–1995 | 51(L) 10(G) | n.r. | n.r. | n.r. | n.r. | n.r. | 70%(G) with EF <30% | 53% 3VD(L) 60% 3VD(G) | 2.6(L) 2.8(G) | 130(L) 152(G) |
| Vural (1998) | 01/1991–11/1996 | 121(L) 127(G) | 52(L) 54(G) | 89.2%(L) 89.8%(G) | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. |

EF = ejection fraction; G = geometric reconstruction technique; L = linear reconstruction technique; n.r. = not reported; 3VD = three-vessel coronary artery disease.

Table 3. Summary of Meta-Analytic Results and Effect of Type of Studies

| Outcome | No. of Studies | Ref. | All Studies | | RR (95% CI) | p Value |
|--------------------------|----------------|--------------------|-----------------|----------------|------------------|---------|
| | | | No. of Patients | | | |
| | | | Linear Rec. | Geometric Rec. | | |
| In-hospital mortality | 18 | 3-6,9-22 | 1,814 | 803 | 1.59 (1.12-2.26) | 0.01 |
| Myocardial infarction | 3 | 5,12,15 | 145 | 153 | n.c. | n.c. |
| Stroke | 3 | 4,12,13 | 141 | 83 | n.c. | n.c. |
| Renal failure | 3 | 12,13,15 | 111 | 90 | n.c. | n.c. |
| Reoperation for bleeding | 5 | 4,5,13,15,18 | 323 | 213 | 1.49 (0.83-2.68) | 0.18 |
| Low output inotropes | 8 | 4-6,12,13,15,17,18 | 404 | 303 | 1.05 (0.77-1.43) | 0.76 |
| IABP | 8 | 3-6,9,13,15,17 | 557 | 372 | 1.41 (0.77-2.56) | 0.26 |

CI = confidence interval; IABP = intra-aortic balloon pump; n.c. = not computed; Rec. = reconstruction; Ref. = reference; RR = relative risk.

Analyses

Data abstracted were analyzed by means of RevMan 4.2.8 (Cochrane Collaboration, Oxford, United Kingdom). Effects on dichotomous outcomes were expressed as relative risk (RR) with 95% confidence intervals (CI). Heterogeneity was assessed with the Q statistic. In the absence of significant heterogeneity, treatment effects were

pooled with the fixed-effects model. If there was significant heterogeneity ($p \leq 0.1$), the random-effects model was used; in addition, each outcome was assessed first on all studies selected for meta-analysis, then separately on studies where both techniques were used simultaneously, and on studies where a temporal trend was clearly detectable (techniques used in sequence). For

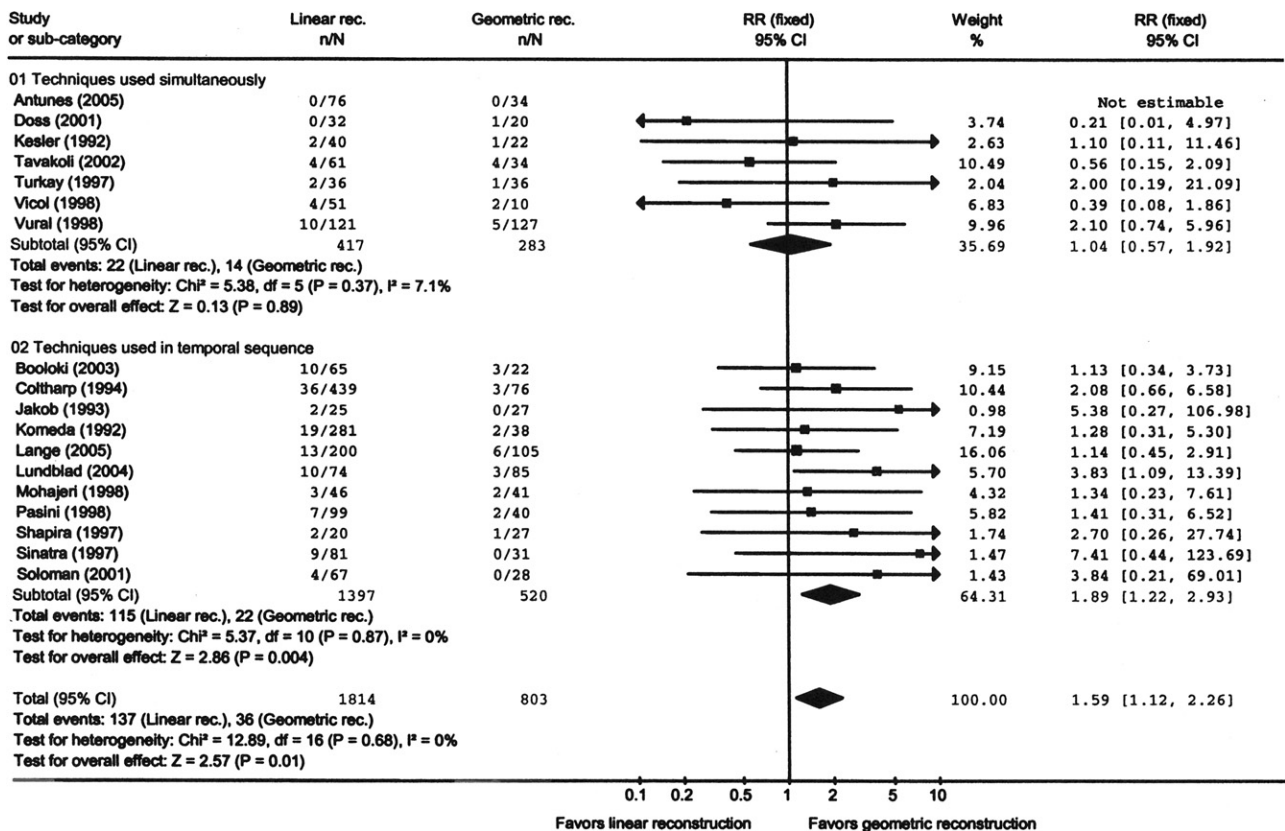


Fig 1. Meta-analysis of studies, denoted by first author and publication year, that evaluated in-hospital mortality after linear reconstruction (rec.) and geometric reconstruction techniques. The relative risk (RR) and 95% confidence intervals (95% CI) for each study are displayed on a logarithmic scale. Squares indicating individual trial differences are scaled according to weighting in the meta-analysis. The width of the diamond for pooled data denotes the lower and upper 95% confidence intervals. Note that the x-axis is logarithmic.

Table 3. Continued

| Studies Using Both Techniques in Temporal Sequence | | | | | | Studies Using Both Techniques Simultaneously | | | | | |
|--|-------------------|-----------------|----------------|------------------|---------|--|-----------------|-----------------|----------------|------------------|---------|
| No. of Studies | Ref. | No. of Patients | | RR (95% CI) | p Value | No. of Studies | Ref. | No. of Patients | | RR (95% CI) | p Value |
| | | Linear Rec. | Geometric Rec. | | | | | Linear Rec. | Geometric Rec. | | |
| 11 | 3,5,9,10,12,14–19 | 1,397 | 520 | 1.89 (1.22–2.93) | 0.004 | 7 | 4,6,11,13,20–22 | 417 | 283 | 1.04 (0.57–1.92) | 0.89 |
| n.c. | | n.c. | n.c. | n.c. | n.c. | n.c. | | n.c. | n.c. | n.c. | n.c. |
| n.c. | | n.c. | n.c. | n.c. | n.c. | n.c. | | n.c. | n.c. | n.c. | n.c. |
| n.c. | | n.c. | n.c. | n.c. | n.c. | n.c. | | n.c. | n.c. | n.c. | n.c. |
| 3 | 5,15,18 | 207 | 157 | n.c. | n.c. | 2 | 4,13 | 116 | 56 | n.c. | n.c. |
| 5 | 5,12,15,17,18 | 252 | 211 | 1.27 (0.86–1.88) | 0.23 | 3 | 4,6,13 | 152 | 92 | n.c. | n.c. |
| 5 | 3,5,9,15,17 | 405 | 280 | 1.30 (0.82–2.05) | 0.26 | 3 | 4,6,13 | 152 | 92 | n.c. | n.c. |

each endpoint, meta-analysis was carried out only when a minimum of 200 patients could be pooled in each treatment arm.

Sensitivity analyses on meta-analyses were performed by removing studies in which the largest (or smallest) effect was found; the study that enrolled the highest number of patients; and studies not reporting any event. Additionally, we performed random-effects meta-analysis on the outcomes of interest.

Publication bias was explored through visual inspection of funnel plots in which the inverse of the estimated variance of the natural logarithm of the adjusted relative risk was plotted against the natural logarithm of the adjusted relative risk for each outcome [8]. Statistical significance was defined by *p* value of 0.05 or less.

Results

The search yielded 23 observational nonrandomized candidate studies [3–6, 9–27]; no randomized study was found. Among them, 18 trials [3–6, 9–27] were identified and included in the analysis with a total of 1,814 and 803 patients who underwent linear and geometric reconstruction, respectively. The remaining five studies were excluded for uncertainty on reporting of perioperative

results based on group assignment to linear or to geometric repair [23–25], for duplicate publication [26], or because the number of patients was lower than 10 in one of the treatment arms [27].

Meta-analysis of all the studies (*n* = 18) showed a significantly increased risk of in-hospital death for patients undergoing linear reconstruction (RR = 1.59, 95% CI: 1.12 to 2.26, *p* = 0.01).

The temporal sequence of surgical procedure was found of particular relevance, when separate analyses were performed on studies where both techniques were used in temporal sequence (see Table 1 for clinical features) and on studies where both techniques were used simultaneously (see Table 2 for clinical features). The subanalysis of studies in which linear reconstruction was adopted mainly in the first period of time, and geometric reconstruction was adopted in a later phase still showed a significant advantage in terms of in-hospital mortality for patients undergoing geometric reconstruction (*n* = 11 studies, RR = 1.89, 95% CI: 1.22 to 2.93, *p* = 0.004; Table 3 and Fig 1). By contrast, when the two surgical approaches were carried out in the same time lag, there was no difference between linear and geometric reconstruction techniques in terms of in-

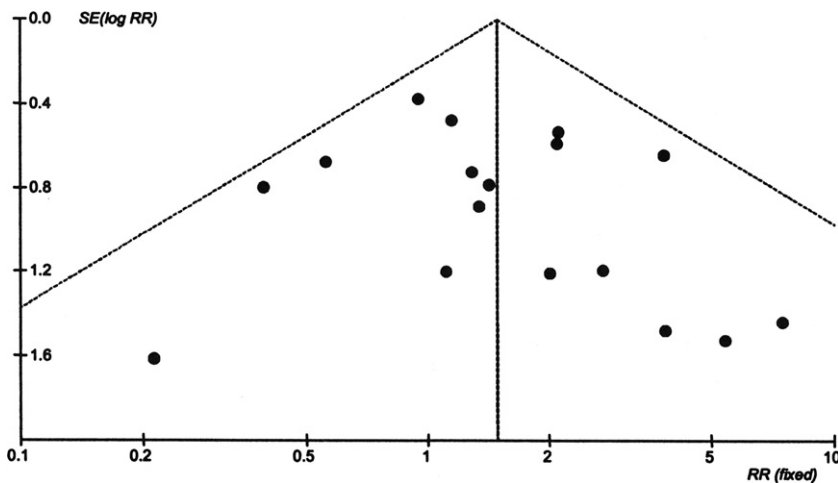


Fig 2. Funnel plot with 95% confidence interval for in-hospital mortality in studies comparing linear and geometric reconstruction techniques for left ventricular aneurysm surgery. Each circle represents a study. The shape of the funnel plot is symmetrical, indicating lack of publication bias. (RR = relative risk; SE = standard error.)

hospital mortality ($n = 7$ studies, $RR = 1.04$, 95% CI: 0.57 to 1.92, $p = 0.89$; Table 3 and Fig 1).

The assessment of the effect of different reconstruction techniques was not carried out owing to low number of patients (fewer than 200) in at least one of the treatment arms for myocardial infarction, stroke, and renal failure when all studies were evaluated together, and for some of the subanalyses performed based on the temporal trend documented in the studies (Table 3). When computable, no differences in the other outcomes of interest were observed (Table 3).

Neither our sensitivity analyses nor the test for publication bias modified data, and meta-analyses conclusions remained robust to methodologic changes; also, no publication bias was detected, as tested using the Egger method [8]. As an example, Figure 2 shows the analysis of publication bias for in-hospital mortality of all studies: the shape of the funnel plot was symmetrical.

Comment

The repair of LV aneurysm dates back more than 50 years; in fact, in 1954 Bailey and Likoff [28] performed the first LV aneurysmectomy on the beating heart with the use of a side-biting clamp through a thoracotomy, whereas the first successful repair of this pathology with the use of cardiopulmonary bypass was performed by Cooley and associates [29] by plication and linear closure in 1958. Linear reconstruction technique then became the gold standard until the mid 1970s and 1980s when the concept of LV aneurysm repair with preservation of LV geometry gained increasing popularity, and several techniques were then described to restore an elliptical shape of the LV [30–33]. The concept that cardiac fibers need proper orientation was also recently highlighted again by the work of Torrent-Guasp and colleagues [34], who theorized that ventricular myocardium consists of a continuous band of muscle oriented as an helix, and the contractile wave that preferentially runs through this band can induce a coil-like twisting and a reciprocal twisting in the opposite direction of the LV and of the septum determining LV ejection in systole and suction in diastole.

From a theoretical standpoint, and also from an intuitive one, geometric LV reconstruction techniques aimed at restoring and maintaining a more physiologic elliptical LV cavity offer several advantages with respect to linear reconstruction: among them, the chance to exclude the akinesis of the septum, the possible tension decrease in the transitional area, an easier revascularization of the left anterior descending artery, and—especially—an improved muscle fiber alignment that might result in a more efficient contraction and, as a consequence, better postoperative LV performance that might warrant improved early outcomes.

For these reasons, the concept of restoring the elliptical LV shape and of excluding the noncontractile areas of the LV linked to the geometric reconstruction has been widely accepted by the CT surgical community, and in recent years, this approach has found a potentially much

wider target population of patients who are affected by heart failure due to ischemic cardiomyopathy that does not show clearly dyskinetic but only akinetic LV areas [35], patients who may theoretically benefit from geometric left ventricular reconstruction/remodeling. As a consequence, the question of the results that can be achieved with different LV reconstruction strategies has become of great interest.

The results of this meta-analysis highlight some issues of the current surgical therapy of the LV aneurysms. First of all, the possible advantage in terms of in-hospital mortality for patients undergoing surgery following geometric principles of LV reconstruction is likely an effect of the improvement over time of management of these patients and of the learning curve, and this possible advantage needs further evidence from well-designed prospective randomized multicenter studies.

In fact, although the meta-analysis of all the papers pooled together shows that there is a potential protective effect of geometric reconstruction techniques, this evidence is dramatically weakened by the majority of the studies included in the analysis reporting the results of surgical series covering several years of practice, when linear reconstruction techniques were totally or mainly adopted earlier and geometric reconstruction strategies were implemented later, when both management strategies and technical skills of the surgeons might have substantially improved over time. In fact, when examining the effect of the two surgical strategies on the studies that reported the results of surgical series in which both techniques were used at the same time, the effect on mortality was no more evident at all ($RR 1.04$, 95% CI: 0.57 to 1.92), and there was a substantial equivalence of these two techniques. The same equivalence was also documented for some of the outcomes of interest, namely, reoperation for bleeding, the postoperative need of inotropes or the occurrence of low output syndrome, and the need of aortic counterpulsation; in all these three cases, there was no clear advantage of either approach.

Interestingly, our analysis showed that, with current literature evidence, it is not possible to document differences between these two strategies for three of the major complications occurring after cardiac surgical procedures: perioperative myocardial infarction, stroke, and renal failure. The number of patients who could be pooled for the analysis was in all these three cases quite low and did not reach the criteria that were settled a priori for meta-analysis.

Taken together, these data underscore the scantiness of evidence concerning the efficacy of different surgical approaches aimed at treating LV aneurysms, and highlight the compelling need for additional evidence to support the extension of the geometric reconstruction technique concept to ischemic cardiomyopathy patients who show akinetic areas who may theoretically benefit from LV reconstruction surgery. Even if the vast majority of surgeons (and we are among them) strongly believe that a geometric LV reconstruction strategy is the most appropriate approach even in these cases, our study

shows that, unfortunately, definitive evidence about the superiority of this approach is still lacking.

Limitations of the Study

The findings of this meta-analysis must be interpreted with some caution. First, the design of the study may lack the experimental element of a random allocation to the linear or to the geometric reconstruction techniques, and very few studies included in the meta-analysis reported the criteria considered by the individual surgeons to allocate patients to either group. Second, the two groups were not comparable for all the factors that can alter the outcome of interest, and confounding factors cannot be excluded.

It is worth mentioning that most of the studies included in our meta-analysis showed higher mean values of cardiopulmonary bypass time in case of geometric reconstruction technique, whereas the number of grafts performed in both groups was similar. It was not possible in our study to evaluate the clinical importance of this observation in the early outcome, and we may only hypothesize that patients who underwent geometric LV reconstruction might be affected by a relatively more severe disease or disarrangement of the left ventricle requiring a more complex repair, or that geometric reconstruction is a more time-consuming procedure.

Finally, as already stated, it is well known that meta-analysis is most effective when analyzing randomized studies [36], but in this case only observational studies were available. It is obvious that this meta-analysis does not substitute for a randomized trial, and perhaps one is called for. Based on the results of this meta-analysis, it is not clear if such a trial should be designed as a superiority trial or an equivalence trial. In either event, the trial size might be very large; and regardless of its mathematical attractiveness, such a trial might not be clinically realistic.

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INVITED COMMENTARY

The clinical issue studied in the paper by Parolari and colleagues [1] presents interesting statistical challenges. The gold standard for comparing two clinical methodologies (linear and geometric reconstruction techniques in this instance) is an adequately powered randomized trial. Quite often there are not randomized trials of sufficient size, and the techniques of meta-analysis allow for combination of the results of smaller trials; the meta-analysis also allows for inclusion of results from multiple centers. Unfortunately, no combination of trial results can improve on the quality of the included trials; for this reason selection of trials to use in a meta-analysis is generally limited to randomized trials.

The literature on reconstruction techniques contains results on over 2500 patients in 18 studies. Since none of these studies were randomized, it would be easy to dismiss the possibility of a meta-analysis on such a basis alone. But the important clinical question of comparing the reconstruction techniques would remain, and surely these data are sufficient to throw some light on the clinical issue.

What can be done is to combine some or all of the 18 observational studies using standard meta-analysis techniques, and recommendations for use of such meta-analyses in epidemiology are given by Stroup and colleagues [2].

The major problem with analysis of an observational study is assignment bias. Any observational study should take steps to account for the bias, and one important step is to isolate and compare the sources of bias. Temporal trends were a clear potential source of bias in the reconstruction studies, and the meta-analysis identified studies where the temporal effect could be analyzed. The standard method for overcoming assignment bias would be matching based on propensity scoring [3]. Since that was not done in the underlying studies there was no opportunity to do so in the meta-analysis.

Another important problem is publication bias, since studies that produce statistical significance seem to have

greater acceptability. The standard method for analyzing publication bias is the funnel plot, and that was done in the Parolari paper.

When the meta-analysis has been performed, with as much accounting as possible for assignment and publication bias, one still has an observational study. The resulting study is larger than the studies that were combined; to the extent that the studies are consistent the meta-analysis will have a smaller error than the individual included studies. As discussed by Egger et al, there remains the possibility of over interpreting the results [4].

In spite of the problems of observational studies, the meta-analysis accomplishes two important goals. First it allows a systematic use of the many studies on reconstruction techniques. Second, the meta-analysis furnishes valuable information for use in designing a randomized trial; such a trial may or may not be feasible, but the meta-analysis will help the clinical community make an informed decision.

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