Predictors of Operative Time in Multicenter Port-Access Valve Registry: Institutional Differences in Learning

Dr. Glower

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ABSTRACT

Background: The predictors of operative time and the effects of learning in isolated valve operations using port-access techniques have not been defined.

Methods: Analysis of covariance was used to examine the determinants of procedure time, pump time, and aortic clamp time. In the largest prospective, registry of patients undergoing isolated aortic valve replacement (AVR, N=199), mitral repair (MVP, N=307), or mitral replacement (MVR, N=232) using port-access techniques 1997-1999 at 27 institutions.

Results: Institutional case volume ranged from one to 214 (median 6). Operative time was longer in redo procedures (5.3 ± 1.6 vs. 4.4 ± 1.3 hr, p = 0.0001), longer with MVP or MVR vs. AVR (4.8 ± 1.2 vs. 5.0 ± 1.5 vs. 3.8 ± 1.2 hr, p = 0.0001), and decreased with case number (mean decrease 1.00 + 0.19 min/case, p = 0.04). Operative time also varied between institutions (p = 0.001). Rate of learning (decrease in time per case) varied significantly between institutions only for MVP (p = 0.03). Similar analysis showed that pump time and clamp times did not significantly change over time (p > 0.17) but varied significantly between institutions. Institutional volume did not affect operative, pump, or clamp times or rate of learning (decrease in operative time/case).

Conclusions: These prospective registry data demonstrate that, for port-access valve procedures, procedure times continue to improve (learning) even after 100 cases. Procedure time and learning are affected by institutional differences and by the type of procedure, but are little affected by institutional volume. This data provides a model to understand learning of new surgical procedures, and this data suggests that port-access valve procedures can be mastered by a variety of institutions.

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INTRODUCTION

Higher institutional case volume and greater surgeon experience have been associated with decreased mortality in coronary bypass grafting (CBG) [Clark 1996] and decreased complication rates in laparoscopic abdominal surgery [Cagir 1994, Bennett 1997, Voitk 1999]. Yet few if any studies have documented the presence of a "learning curve" (improved outcome with initial experience over time) or the determinants of learning (improved outcome over time) for new cardiac surgical procedures [Pisano 1999]. Port-access is a new cardiac surgical technique introduced in 1996 to perform valvular operations using cardiopulmonary bypass (CPB) with combinations of either a small right thoracotomy and/or endovascular aortic occlusion [Pompili 1996]. While early results of port-access for mitral or aortic valve operation have been good, uncertainty persists whether factors such as institutional

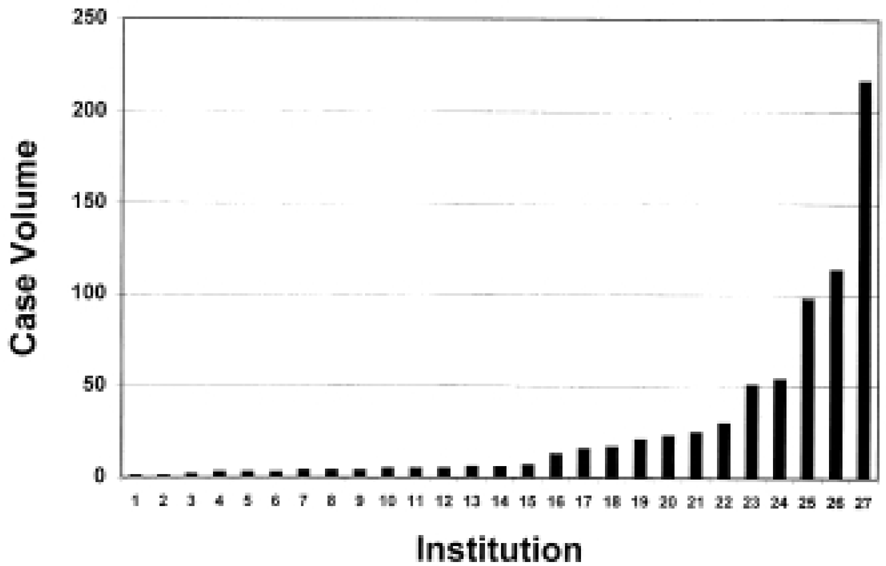

Figure 1. Distribution of volume of cases contributed by 27 institutions. Volume represents aortic and mitral cases combined. Data are sorted from least volume to greatest volume without respect to site identification number.

volume or learning curves influence the results of port-access procedures [Pisano 1999].

To address these issues, a multi-institutional registry of port-access procedures, Port-Access International Registry (PAIR) (Heartport, Inc., Redwood City, CA) was initiated in 1997 and terminated in 1999 [Galloway 1999]. The current study examined the PAIR registry data to assess whether learning could be documented with port-access valve procedures and what if any factors influenced learning.

MATERIALS AND METHODS

Port-access cardiac surgery techniques have been reported extensively [Pompili 1996, Colvin 1998, Glower 1998, Mohr 1998, Galloway 1999, Gulielmos 1999, Reichenspurner 1999] and will not be described here. PAIR is a prospective observational consecutive cohort registry, initiated in June 1997, managed by an independent contract research organization, and sponsored by Heartport, Inc., Redwood City, CA) [Galloway 1999]. All institutions trained in port-access minimally invasive cardiac surgery were eligible to participate. One hundred four institutions elected to participate at one of three levels: brief case report form with in-hospital follow-up, brief case report form with 30-day follow-up, or comprehensive case report form with 30-day follow-up. The current study is limited to the 27 institutions choosing to contribute to PAIR using the comprehensive form.

The data incorporated a coding system to ensure that the patients and surgeons were not identified and that institutional identities remained confidential. Missing or inconsistent data were queried. Only patients with complete comprehensive forms were included in an analysis data set (738 patients).

Patient demographic data have been previously reported [Glower 2000]. The outcomes that were examined in the current study were aortic clamp time, CPB time, and operative time (defined as the time from skin incision to skin closure). The effect of institutional case volume was examined by dividing the reporting institutions into three groups based on the total volume of port-access cases reported in this series. Thus, three institutions had high volume ≥ 75 cases), six institutions had medium volume (20-74 cases), and 18 institutions had low volume (1-19 cases). In addition to institutional case volume, other independent variables that were examined were patient age, previous cardiac operation (yes/no), New York Heart Association heart failure class, and procedure (aortic valve replacement, mitral valve repair, or mitral valve replacement). To examine the effect of learning over time, patient case number was reported for each patient as the number of port-access cases (valve or coronary) previously done by that institution plus one.

Data analysis was performed using analysis of variance to detect independent effects of variables upon outcome times. Linear regression analysis was used to detect an effect of case number upon outcome time for all patients or groups of patients. Learning was defined to be present if a significant inverse linear relationship existed between case number and outcome time. Rate of learning was estimated as the slope of significant negative correlations between case number and outcome time (minutes decrease per case). Unless otherwise stated, data are presented as mean ± standard deviation of the mean.

RESULTS

A total of 738 isolated port-access aortic valve (AVR) replacement, mitral valve repair (MVP), and mitral valve

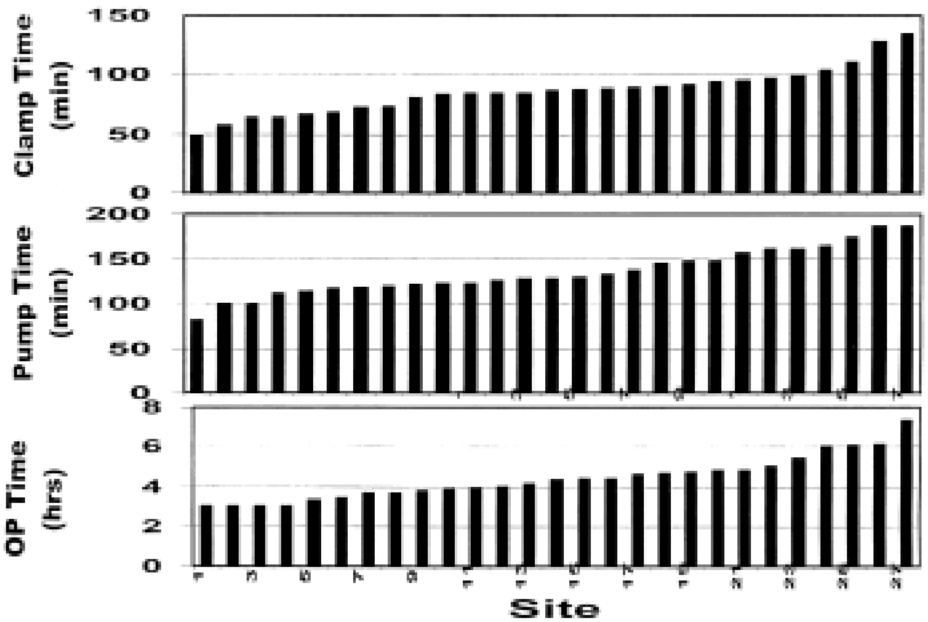

Figure 2. Distribution of mean aortic clamp times (top panel), cardiopulmonary bypass (pump) times (middle panel), or operative (OP) times (bottom panel) for 27 institutions. Data are sorted from least volume to greatest volume without respect to site identification number.

replacement (MVR) cases reported between July 1997 and August 1999 were analyzed. This report includes cases from 27 institutions with a distribution of aortic or mitral cases contributed per institution seen in Figure 1 (◎). Reported institutional volume ranged from 1 to 214 cases (median 6). Of these 738 cases, 199 (27%) were AVR, 307 (42%) were MVP, and 232 (31%) were MVR.

Mean aortic clamp time was 88 ± 38 minutes. By analysis of variance, the determinants of aortic clamp time were institution (p = 0.008) (Figure 2, ◎), redo (redo 78 ± 48 vs. nonredo 90 + 36 min., p = 0.006), procedure (AVR 77 ± 26 vs. MVP 92 ± 39 vs. MVR 91 ± 44 min., p = 0.006), and NYHA class (p = 0.04). Institution volume category (high, medium, or low) did not affect aortic clamp time (p = 0.08), and experience (case number) also failed to affect aortic clamp time (p = 0.17). By linear regression analysis, aortic clamp time did not decrease significantly with experience (case number) (p = 0.2) (Figure 3, ◎).

Mean CPB time was 107 ± 40. By analysis of variance, the determinants of CPB time were institution (p = 0.001) (Figure 2, ◎) and procedure (AVR 107 ± 40 vs. MVP 137 ± 45 vs. MVR 155 ± 83 min., p = 0.001). Institution volume category did not affect CPB time (p = 0.5), and experience (case number) also failed to affect CPB time (p = 0.23). However, by linear regression analysis, CPB time did decrease significantly with experience (case number) at a mean rate of 0.13 ± 0.03 min per case (p = 0.001) (Figure 3, ◎).

Mean operative time was 4.6 ± 1.4 hours. By analysis of variance, the independent determinants of operative time were institution (p = 0.001) (Figure 2, ◎), procedure (p = 0.001), redo (p = 0.001), and case number (p = 0.04). Mean operative time varied significantly between institutions (p = 0.001) (Figure 2, ◎). Institution volume category did not affect operative time (p = 0.3). Operative time was longer in redo procedures (5.3 ± 1.6 vs. 4.4 ± 1.3 hr, p = 0.001) and was longer with MVP or MVR vs. AVR (4.8 ± 1.2 vs. 5.0 ± 1.5 vs. 3.8 ± 1.2 hr, p = 0.001). Operative time decreased with case number (mean decrease 1.00 ± 0.19 min/case, p = 0.01, Figure 3, ◎).

By analysis of covariance, the rate of learning (decrease in operative time per case) was independently affected by the procedure (p = 0.001), and redo (p = 0.001). Significant learning (decrease in operative time per case) was present for AVR (p = 0.03) but not for MVP (p = 0.5) or MVR (p = 0.9) (Figure 4, ◎). Learning rate was significant for both nonredo cases (0.08 ± 0.0.01 min/case, p = 0.04) and for redo procedures (0.25 ± 0.01 min/case, p = 0.03) (Figure 5, ◎). Rate of learning was not affected by institutional volume (p = 0.9), and rate of learning was significant only for high volume institutions (Figure 6, ◎). Rate of learning varied significantly between institutions only for MVP (p = 0.03) (Figure 7, ◎).

In summary, institutions differed significantly in aortic clamp time, CPB time, and operative time in port-access valve cases. Evidence of learning (significant decrease in time per case) was present for operative time and CPB time but not for aortic clamp time. For operative time, evidence of learning was present for port-access valve cases even over 100 cases of institutional experience. The rate of learning (decrease in operative time per case) was greatest in redo procedures, in aortic valve replacement, and high volume centers. Rate of learning varied significantly between institutions only for mitral valve repair. Institutional volume did not affect operative, pump, or clamp times.

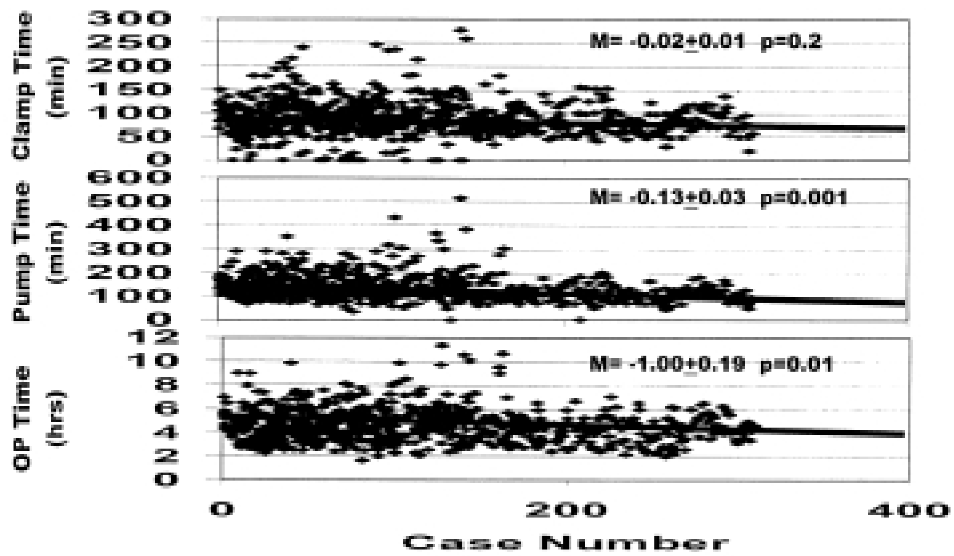

Figure 3. Reported aortic clamp times (top panel), cardiopulmonary bypass (pump) times (middle panel), or operative (OP) times (bottom panel) as a function of case number. Shown are mean regression lines of time versus case number along with regression line slope (m, min/case) and p value.

DISCUSSION

Like any new technique that is evolving rapidly, port-access has been observed to be associated with a learning curve [Pisano 1999, Vanermen 1999], both at individual institutions and across institutions during the evolution of the surgical procedure. Through improved surgical techniques and methods, better patient screening, and increased use of aortic versus femoral arterial cannulation, complications of aortic dissection, stroke, and inadequate valve repair have become much less frequent [Glower 1999] than initially reported [Mohr 1998]. One would therefore expect that patient outcome and facility of performing port-access operations should improve with experience and might be influenced by the volume of port-access cases performed by the operating team. These issues have only been partially addressed for port-access coronary bypass grafting (CBG) by one study which found that procedure time decreased with experience, but at different rates at different institutions [Pisano 1999].

This study demonstrates for the first time that for port-access valve procedures, procedure times continue to

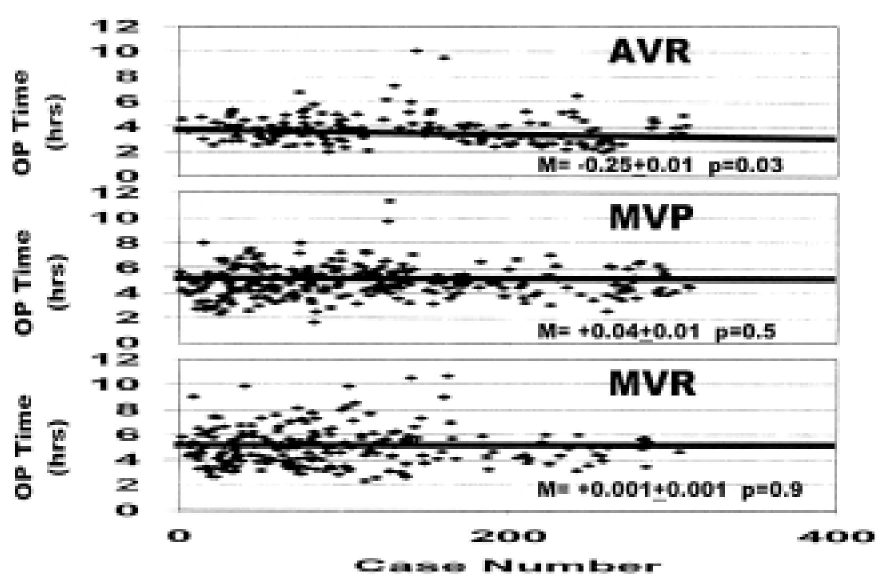

Figure 4. Operative (OP) times as a function of case number for AVR (top panel), MVP (middle panel), and MVR (bottom panel). Shown are mean regression lines of time versus case number along with regression line slope (m, min/case) and p value.

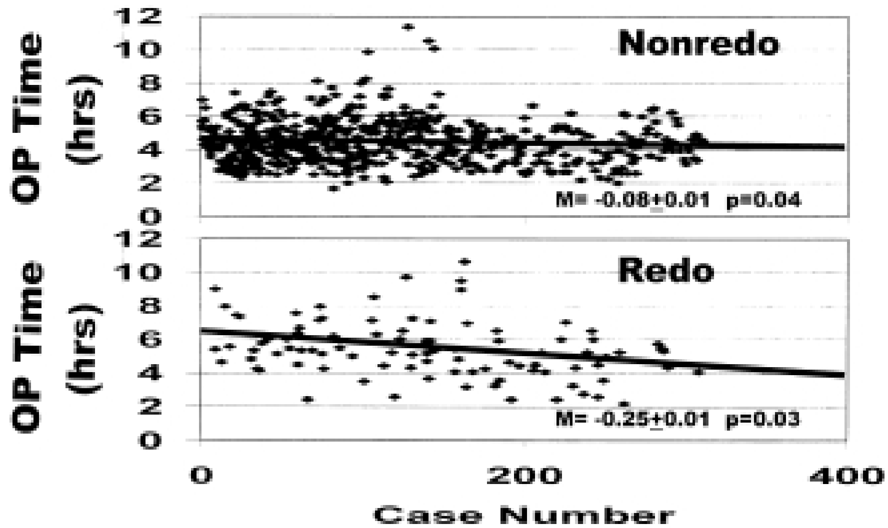

Figure 5. Operative (OP) times as a function of case number redo procedures (top panel), and nonredo procedures (bottom panel). Shown are mean regression lines of time versus case number along with regression line slope (m, min/case) and p value.

improve (learning) even after 100 cases. Procedure time and learning are affected by institutional differences, by the type of procedure, and to some extent by institutional volume. The fact that rate of learning was most different between institutions for MVP may have resulted from the greater technical difficulty, longer procedure time, and greater variation in MVP techniques relative to AVR and MVR. The fact that institutions differed significantly in clamp time, CPB time, and operative times suggests that institutions with longer times might be able to achieve shorter times by overcoming institutional differences or by adopting surgical procedures used in faster institutions. The significant learning in operative time but not in clamp or cardiopulmonary bypass time suggests that the improvements in time come largely from decreasing time spent off pump, such as preparation for CPB, surgical exposure, and wound closure. The fact that total institutional volume did not affect times and/or improved rate of learning only in high volume centers suggests that port-access can be mastered by a variety of institutions even with lower case volumes. Yet experience beyond 100 cases may augment the rate of learning. Whether there is a lower case volume limit where results may suffer could not be detected by this study.

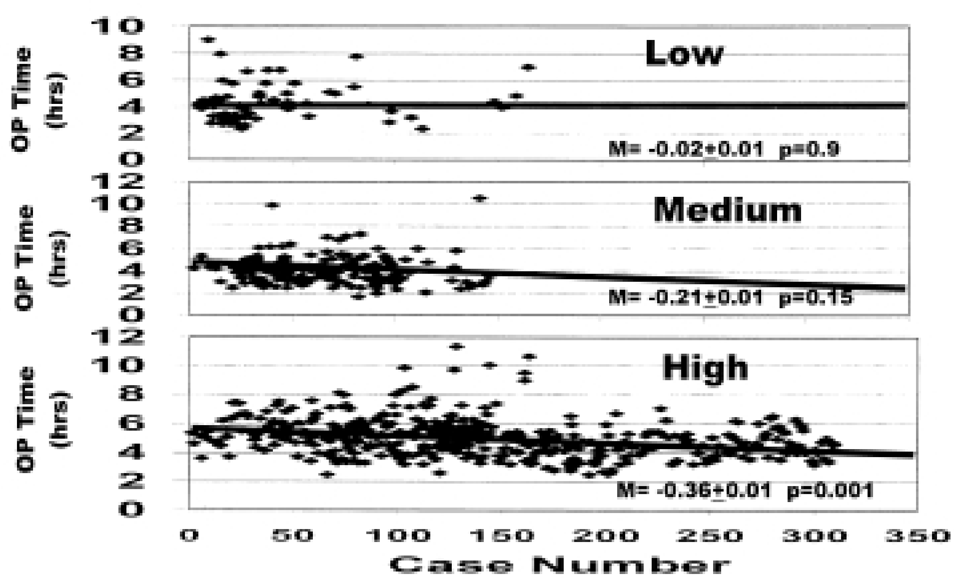

Figure 6. Operative times as a function of case number for low volume institutions (top panel), medium volume institutions (middle panel), and high volume institutions (bottom panel). Shown are mean regression lines of time versus case number along with regression line slope (m, min/case) and p value.

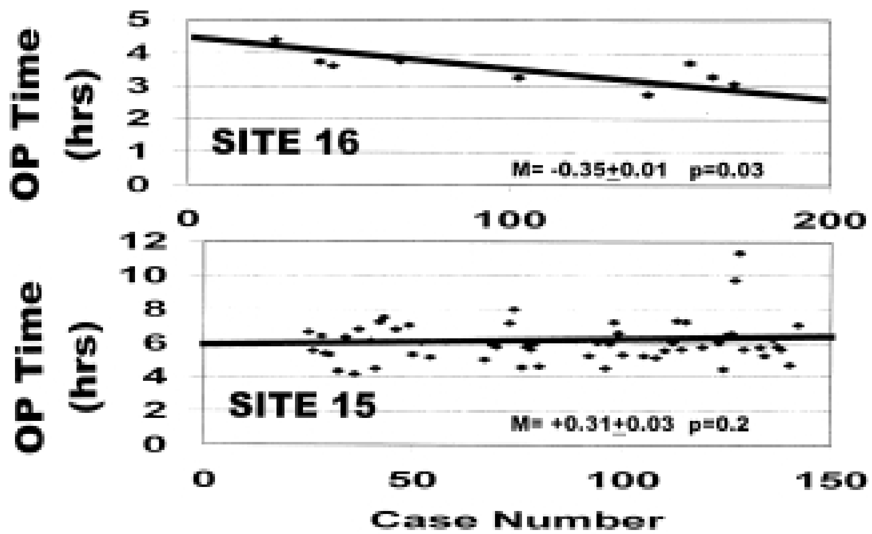

Figure 7. Operative times as a function of case number for MVP in two institutions, one with improved operative time with experience (top panel, #16) and one without improved operative time with experience (bottom panel, #15). Shown are mean regression lines of time versus case number along with regression line slope (m, min/case) and p value.

This study has several limitations. First, the results reported herein tended not to include the initial 10 to 15 cases (initial learning curve) at the participating institutions. At Duke University, the procedure time did fall significantly over the first 15 cases, yet these early cases were prior to initiation of the PAIR registry. Thus, this study cannot exclude the possibility that learning might be more significant in the initial learning curve at each institution (first 15 cases) [Pisano 1999].

Secondly, many of the differences attributed to institutional differences might actually reflect differences in patient mix between institutions rather than differences between the institutions themselves. This analysis examined only a limited number of patient related variables. Thirdly, patients' outcomes such as morbidity and mortality were not examined in this study and may not behave as did procedure times. The report from Glower et al. [Glower 2000] from the same PAIR registry found that institutional case volume did not affect mortality, stroke, or re-operation for bleeding after port-access mitral of aortic valve operation. End points such as mortality, stroke, or bleeding have a sufficiently low incidence that detecting a learning curve over the first 10 to 20 cases would require a much larger series than reported here.

Finally, this data reflects the relatively early experiences of many institutions with a technology that is rapidly evolving (port-access). Thus the importance of institutional differences and the presence of learning might be more or less prominent as a surgical technique such as port-access evolves and matures.

CONCLUSION

This study serves as a model to understand learning of new surgical procedures. This study suggests that new surgical techniques such as port-access valve procedures can be mastered by a variety of institutions, that learning (improved results with experience) can occur in new procedures, and that learning is influenced by institutional differences and by differences between procedures.

REFERENCES

1. Bennett CL, Stryker SJ, Ferriera MR, Adams J, Beart RW Jr. The learning curve for laparoscopic colorectal surgery. Preliminary results from a prospective analysis of 1194 laparoscopic-assited colectomies. Arch Surg 132:41–4, 1997.
2. Cagir B, Rangraj M, Maffuci L, Herz BL. The learning curve for laparoscopic cholecystectomy. J Lap Surg 4:419–27, 1994.
3. Clark RE. Outcome as a function of annual coronary artery bypass graft volume. The Ad Hoc Committee on Cardiac Surgery Credentialing of the Society of Thoracic Surgeons. Ann Thorac Surg 61:21–6, 1996.
4. Colvin SB, Galloway AC, Ribakove G, Grossi EA, Zakow P, Buttenheim PM, Baumann FG. Port-access mitral valve surgery: summary of results. J Card Surg 13:286–9, 1998.
5. Galloway AC, Shemin RJ, Glower DD, Boyer JH Jr, Groh MA, Kuntz RE, Burdon TA, Ribakove GH, Reitz BA, Colvin SB. First report of the Port-Access International Registry. Ann Thorac Surg 67:51–8, 1999.
6. Glower DD, Landolfo KP, Clements F, Debruijn NP, Stafford-Smith M, Smith PK, Duhaylongsod F. Mitral valve operation via port-access versus median sternotomy. Eur J Cardio Thorac Surg 14:S143–7, 1998.
7. Glower DD, Komtebedde J, Clements FM, Debruijn NP, Stafford-Smith M, Newman MF. Direct aortic cannulation for Port-Access mitral or coronary bypass operations. Ann Thorac Surg 68:1529–31, 1999.
8. Glower DD, Siegel LC, Frischmeyer KJ, Galloway AC, Rib-

akove G, Grossi E, Robinson N, Ryan WH, Colvin S. Predictors of outcome in a multicenter port-access valve registry. Ann Thorac Surg 70:1054–9, 2000.
9. Gulielmos V, Wagner F, Waetzig B, Solowjowa N, Tugtekin SM, Schroeder C, Schuler S. Clinical experience with minimally invasive coronary artery and mitral valve surgery with the advantage of cardiopulmonary bypass and cardioplegic arrest using the port-access technique. World J Surg 23:480–5, 1999.
10. Mohr FW, Falk V, Diegeler A, Walther T, van Son JAM, Autschbach R. Minimally invasive port-access mitral valve surgery. J Thorac Cardiovasc Surg 115:567–76, 1998.
11. Pisano GP, Bohmer RMJ, Edmondson AC. Experience versus learning: Evidence from the adoption of minimally invasive cardiac surgery [working paper 00-036]. Harvard Business School 1999.
12. Pompili MF, Stevens JH, Burdon TA, Siegel LC, Peters WS, Ribakove GH, Reitz BA. Port-access mitral valve replacement in dogs. J Thorac Cardiovasc Surg 112:1268–74, 1996.
13. Reichenspurner H, Weltz A, Gulielmos V, Boehm DH, Reichart B. Port-Access cardiac surgery using endovascular cardiopulmonary bypass: Theory, practice, and results. J Card Surg 14:275–80, 1999.
14. Vanermen H, Wellens F, DeGeest R, Degrieck I, VanPraet F. Video-assisted port-access mitral valve surgery: From debut to routine surgery. Will trocar-port-access cardiac surgery ultimately lead to robotic cardiac surgery? Sem Thorac Cardiovasc Surg. 11:223–34, 1999.
15. Voitk A, Joffe J, Alvarez C, Rosenthal G. Factors contributing to laparoscopic failure during the learning curve for laparoscopic nissen fundoplication in a community hospital. J Lapendo Adv Surg Tech 9:243–8, 1999.

APPENDIX

Centers contributing data to this study

Abbott Northwestern Hospital	Minneapolis	MN
Baptist Medical Center	Oklahoma City	OK
Bellvue Hospital	New York	NY
Boston Medical Center	Boston	MA
Brigham and Women's Hospital	Boston	MA
Bryn Mawr Hospital	Bryn Mawr	PA
Carilion Roanoke Memorial Hospital	Roanoke	VA
Carolinas Medical Center	Charlotte	NC
Chippenham Medical Center	Richmond	VA
Cleveland Clinic Foundation	Cleveland	OH
Duke University Medical Center	Durham	NC
Hopital Broussais	Paris	France
Inova Fairfax Hospital	Fairfax	VA
Loyola University Medical Center	Maywood	IL
Massachusetts General Hospital	Boston	MA
Mission St. Joseph's Health System	Asheville	NC
New York University Medical Center	New York	NY
Onze Lieve Vrow Clinic	Aalst	Belgium
Orlando Regional Medical Center	Orlando	FL
Presbyterian Hospital	Dallas	TX
St. Francis Hospital	Roslyn	NY
St. Francis Hospital Center and Health Centers	Beech Grove	IN
St. Luke's Medical Center	Milwaukee	WI
Stanford University Medical Center	Stanford	CA
Universitatsklinikum	Frankfurt	Germany
Willis-Knighton Medical Center	Shreveport	LA
Winthrop University Medical Center	Mineola	NY