Equipoise, Equipment and Site Selection

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Expertise randomization vs. Standard randomized trial

- **Expertise Randomization**: Patients randomized to high volume, expert radialists vs. high volume, expert femoralists
- Advantage is best procedure possible
- May be bias as high volume radialists may use different antithrombotic regimens (ie less bivalirudin, different heparin doses)
- Expertise randomization has been done in a number of surgical trials

Standard Randomization

- More feasible in centers with predominance in either access site
- Greater external validity
- In RIVAL, we chose a standard randomized trial methodology

Equipoise

- Centers with >90% radial access have difficulty randomizing due to lack of equipoise
- Even with physicians on board, nursing staff and patients often unwilling
- Request that closure devices be paid for in femoral group (not feasible in an academic trial)

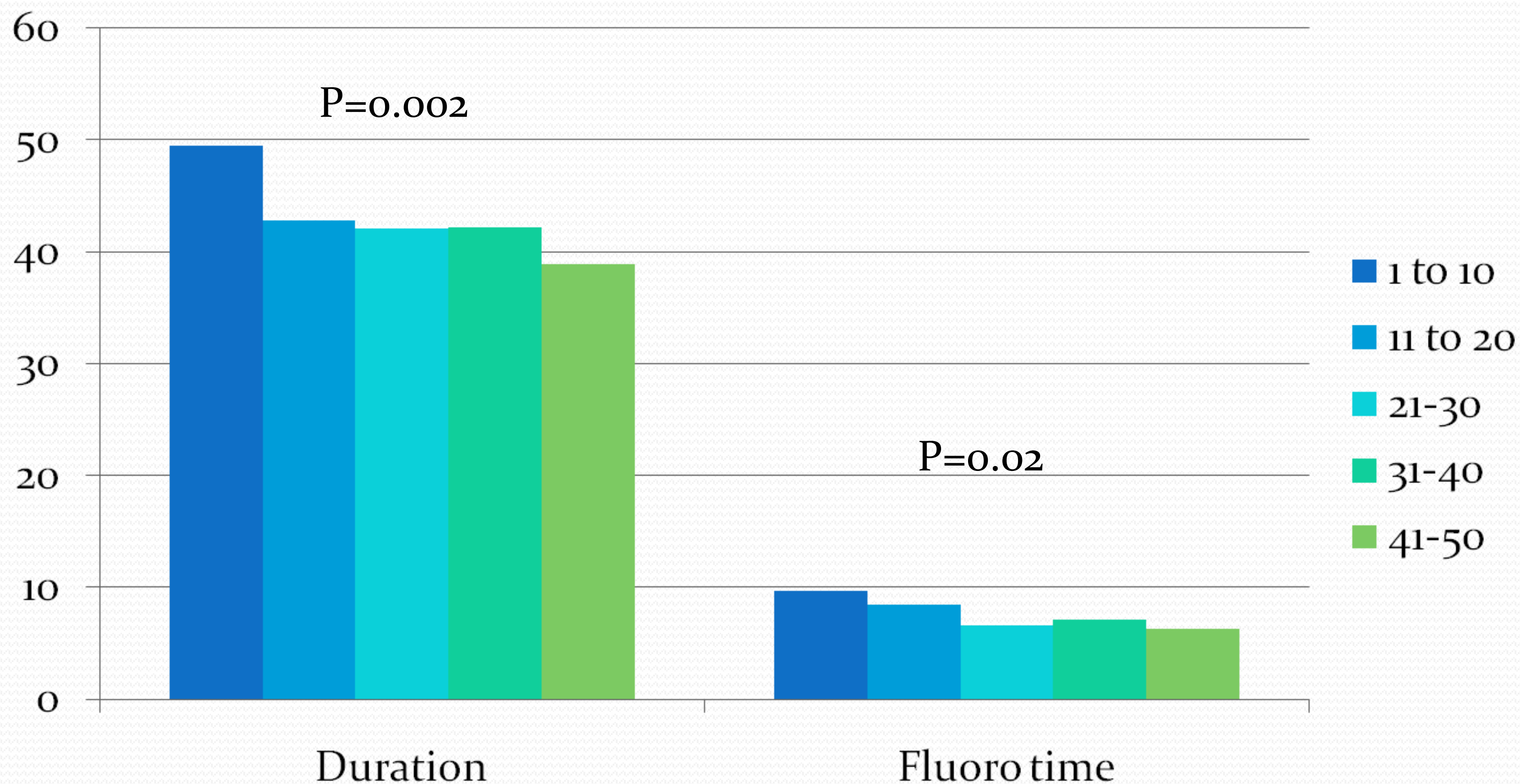
Equipoise

- Highest success for centers in transition
- Radial access between 20-70%
- Challenge is too avoid learning curve in the study

Site Selection

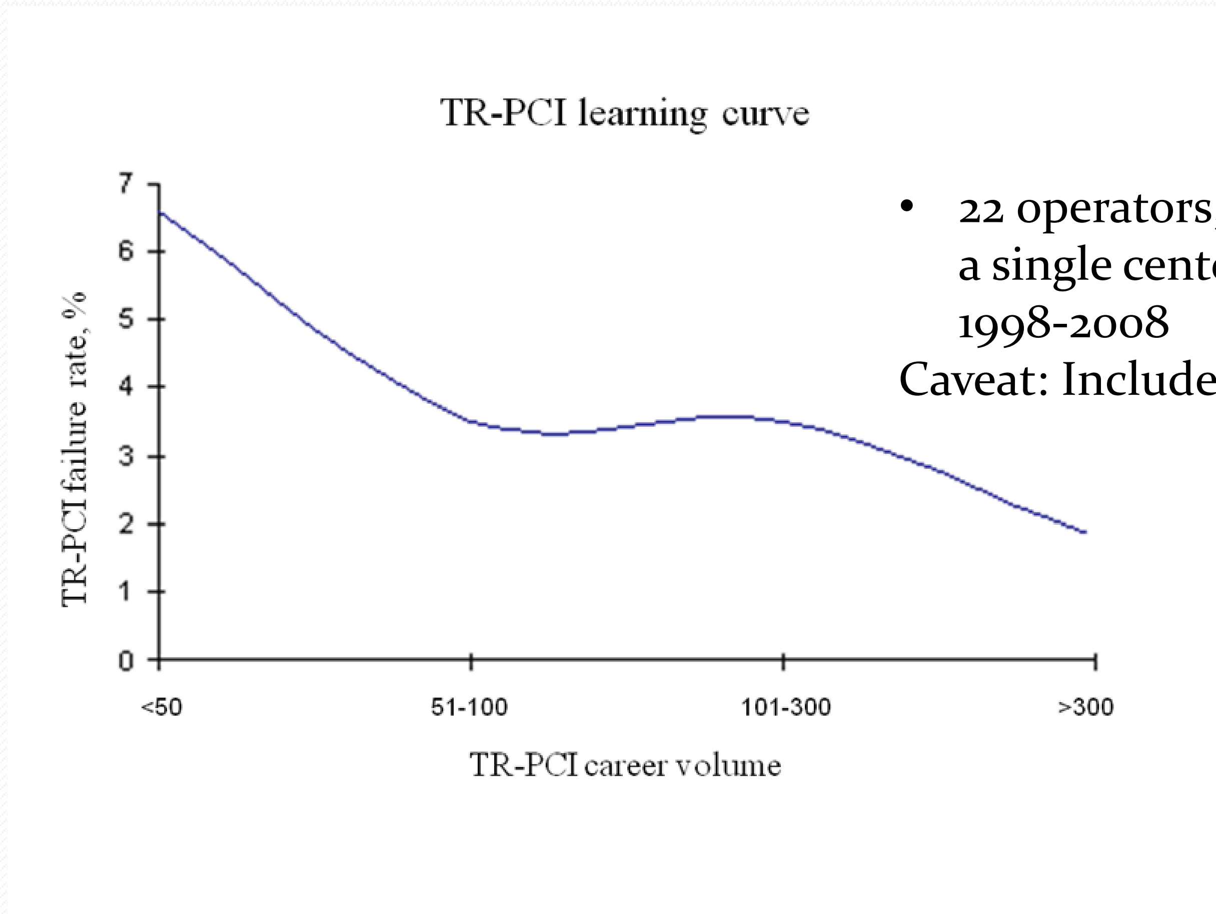
- RIVAL used a minimum annual Radial access volume of 50 procedures in last year
- Based on data from a few small studies showing that high volume femoral operators can pick up radial access fairly quickly
- RIVAL had high volume operators 300 PCI/year with 40% procedures radial

Learning Curve: Diagnostic



Hildick-Smith DJR, et al. Int J Cardiol 1998

What is the Radial Learning Curve



- 22 operators, 12,312 PCI at a single center between 1998-2008

Caveat: Included PCI fellows

Ball WT, et al. Can J Card. Abstract 2010.

Learning Curve

- Likely a threshold effect and it may vary by individual
- The threshold is unknown
- The less experience the higher the cross-over less study power
- Optimal to chose as experienced operators as feasible

Equipment

- RIVAL, we did not mandate specific radial sheaths and diagnostic catheters
- Closure devices were left at discretion of interventional cardiologist
- The appropriate equipment is likely linked to centers' radial PCI volume
- Suggest recommending patent hemostasis technique to prevent radial occlusion

Conclusion

- Suggest recruit high volume radial operators and centers
- Consider using a higher cutpoint of 200 radial procedures ever (with 50 radial PCI in last year)
- Feasibility forms can determine what cut point is practical in advance of the trial starting