Randomization as a Concept to Improve Follow-Up and Reduce Cost in Long-Term Health Related Quality of Life Studies Addressing Cardiac Surgery

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Why Full QOL Assessment Can be Problematic

- Assume following CV Sx: QOL is assessed at baseline, 6-mth, and annual thereafter until pt is lost, presumed lost or dead.
- Our program: 16 CV Sx/wk (≈ 800 /yr)
- Assume 100% baseline compliance, 90% 6-mth and 12-mth compliance
- Start program in 2004

Daily QOL Assessment Schematic

	1st Yr of QOL Program		2nd Yr of QOL Program		3rd Yr of QOL Program		4th Yr of QOL Program	
QOL Schedule	1st 6-mth Cohort	2nd 6-mth Cohort	3rd 6-mth Cohort	4th 6-mth Cohort	5th 6-mth Cohort	6th 6-Mth Cohort	7th 6-Mth Cohort	8th 6-Mth Cohort
Baseline	1-4 B	1-4 B	1-4 B	1-4 B	1-4 B	1-4 B	1-4 B	1-4 B
6-mth		6-mth	6-mth	6-mth	6-mth	6-mth	6-mth	6-mth
1-year			12-mth	12-mth	12-mth	12-mth	12-mth	12-mth
2-yr					24-mth	24-mth	24-mth	24-mth
3-yr							36-mth	36-mth
QOL / Day	1-4	1-4 + 90%(1-4)	1-4 + 90%(1-4) + 90%(1-4)	1-4 + 90%(1-4) + 90%(1-4)	1-4 + 90%(1-4) + 90%(1-4) + 90%(1-4)	1-4 + 90%(1-4) + 90%(1-4) + 90%(1-4)	1-4 + 90%(1-4) + 90%(1-4) + 90%(1-4) + 90%(1-4)	1-4 + 90%(1-4) + 90%(1-4) + 90%(1-4) + 90%(1-4)
Total	1-4	2-8	3-12	3-12	4-16	4-16	5-20	5-20

Why Not Randomize?

- How much time, effort and $$$$ for QOL assessment is too much?
- Does a theoretical QOL value exist?
- How few patients can we assess to get statistically significant and representative results?

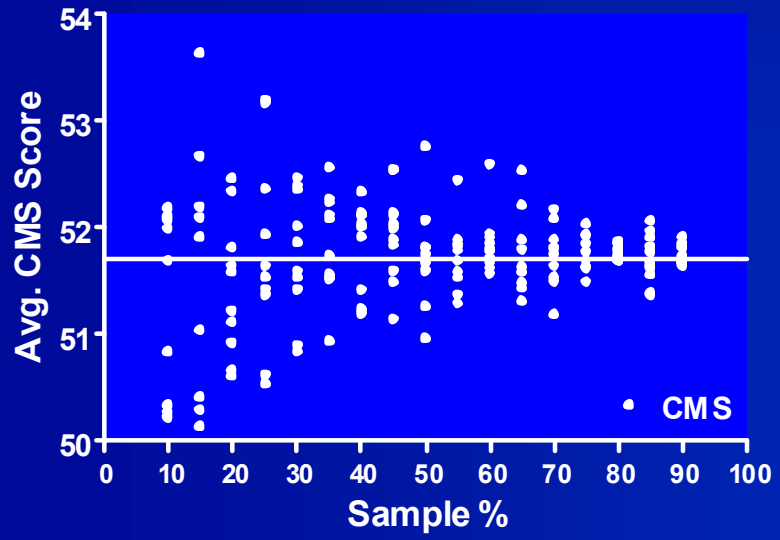
Methods

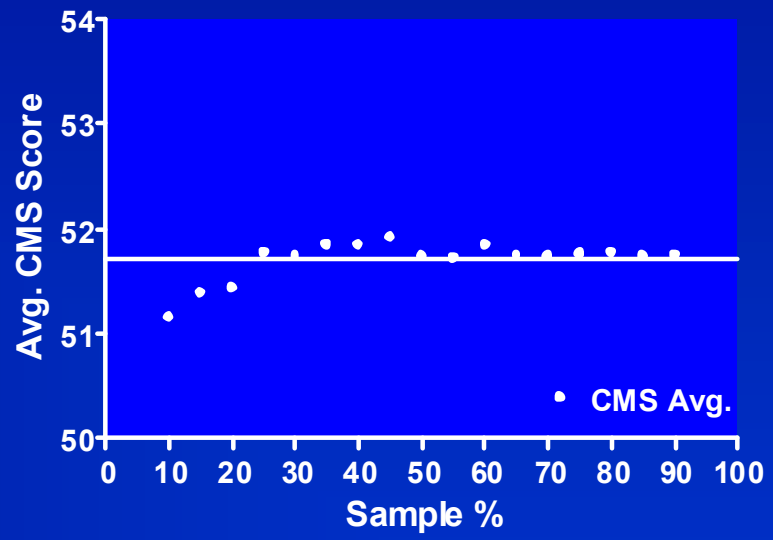
- **Subjects:** 492 current participants in our prospective HRQL program CV Sx.
- **QOL:** SF-12
- **Statistical Plan:** Identify baseline pt subgroups and ultimately generate a randomization sample to maximize information collected and minimize HRQL variance.

Sampling Strategy

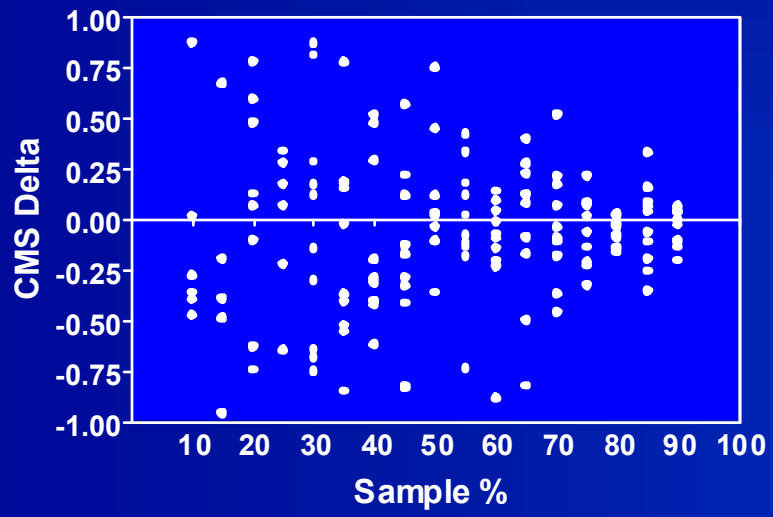
1. Composite scores only.
2. Assign each pt at random number,
3. Beginning at 10%, sample 17 groups in incremental 5% increases
4. Calculate an average CMS and CPS score (all pts)
5. Calculate an average CMS and CPS score for each incremental sample group
6. Calculate a delta CMS and CPS score as the difference between each sampled value and the overall aggregate average CMS or CPS score
7. Repeat until 10 sampled groups of 17 were achieved

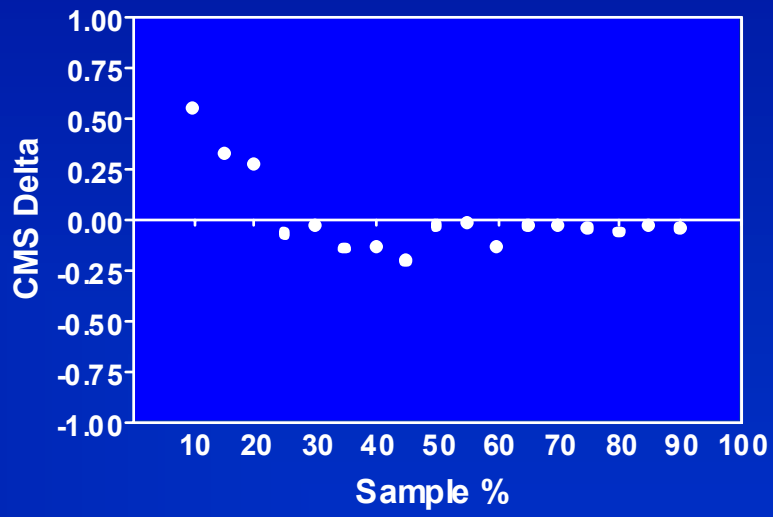
Distribution of Sampled CMS Averages



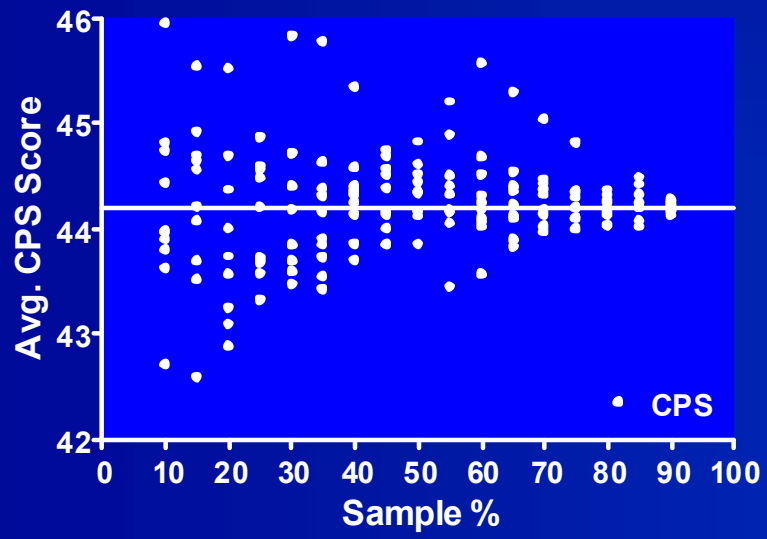


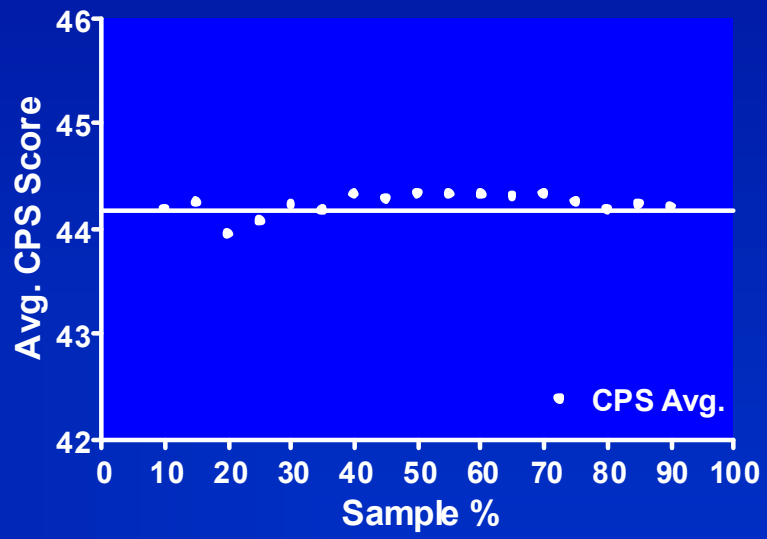
Distribution of Sampled CMS Deltas



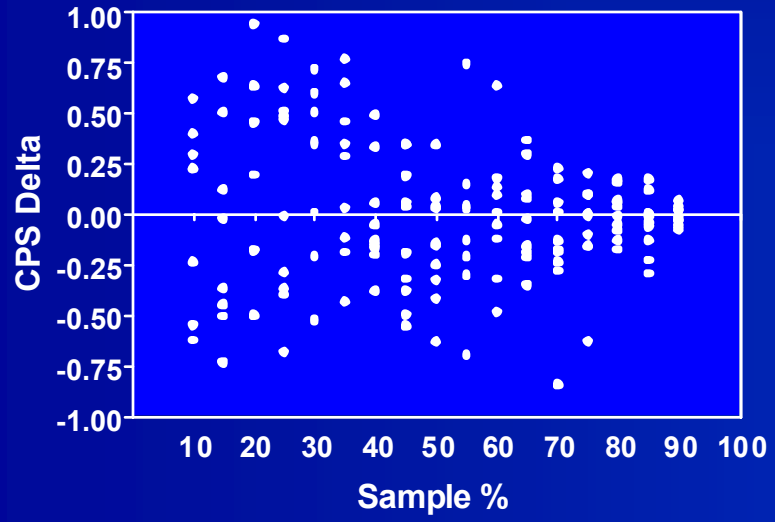


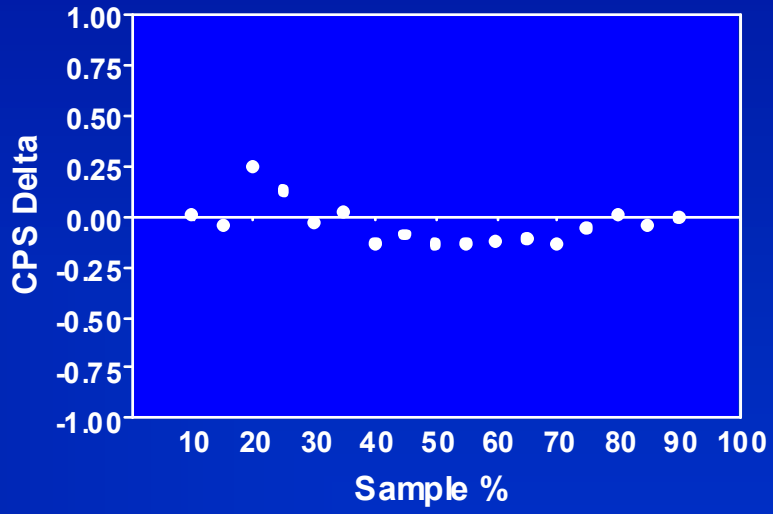
Distribution of Sampled CPS Averages





Distribution of Sampled CPS Deltas

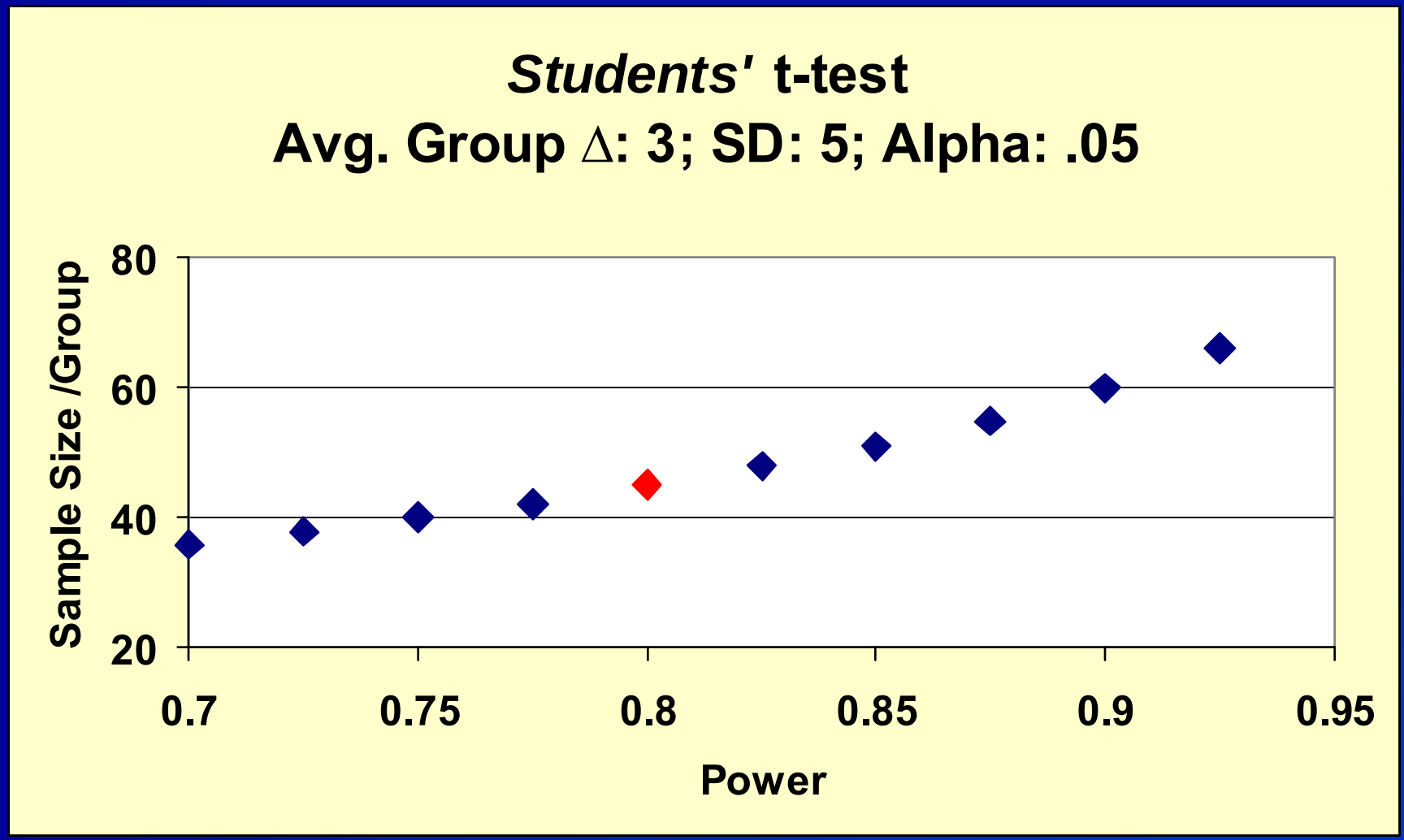




Reverse Power Analysis

- All Pt scores = normal theoretical value
- How many pts would be required to achieve 95% power for a 2-sample t-test assuming maximum conditions
- Alpha=0.05; Avg. Group Δ=3; SD=5

Per Group Estimates



Conclusions

- We currently achieve 300-400 /6-mths
- Using *Students*' t-test as a default test
- A min. of 45 pts per group is required for 80% power
- Based on all pt data, a sample of 40%-60% would achieve this or..
- 140-240 pts /6-mths

Conclusions

- Annual ≈ Program Cost: $100k with a 3%-5% annual increase in cost
- Based on a reduction of pts ≈ 40%-60%:
- Anticipated Cost Savings $40k-$60k

Thank You