FFR Cost Effectiveness In Multivessel Disease



The FAME Study

- The <u>Fractional Flow Reserve</u> (FFR) vs. <u>Angiography for <u>Multivessel</u> <u>Evaluation</u> (FAME) Study demonstrated significantly improved health outcomes at one year in patients randomized to multivessel percutaneous coronary intervention (PCI) guided by FFR compared to those patients guided by angiography alone.</u>
- In the FAME Study, 1005 patients with multivessel CAD were randomly assigned to FFR-guided PCI or angiography-guided PCI with DES and followed for one year.
- The FAME Study shows that routine FFR measurements significantly improves procedural outcomes and saves cost without prolonging the procedure.
- FAME's primary endpoint was met and confirmed patients assessed with FFR had an overall reduction in MACE (Major Adverse Cardiac Events) rates to 28% at one year.



Cost Effectiveness Data Collection and Analysis Method

- As a secondary endpoint, a cost utility analysis comparing costs vs. quality-adjusted life years (QALY) was performed with a time horizon of one year. QALYs were calculated using utilities determined by the EQ-5D with U.S. weights.
- Direct medical costs (in U.S. \$) included direct costs from the procedure and hospitalization, as well as follow-up events related to major adverse cardiac events (MACE). Initial procedure costs were calculated from actual resource consumption; costs for MACE-events were estimated from the published literature.
- Confidence intervals for both QALYs and costs were estimated by a statistical bootstrap percentile method (1000 replications). Direct costs were collected throughout the clinical trial at implant, one month, and one year.



Key Economic Findings

- Significant reduction in number of stents required per patient
- Significant reduction of cost for materials used at procedure
- Significant reduction of total cost over one year
- Significant reduction in amount of contrast used
- No significant difference in procedure time



Supporting Data on Key Economic Findings

Economic Outcomes	FFR guided (n=496)	Angio guided (n=509)	Difference
Significant reduction in stents required per patient (p<0.001)	1.9	2.7	0.8
Significant reduction of cost for materials used at procedure (11%) (p<0.001)	\$5332	\$6007	\$675
Significant reduction of total cost over one-year (14%)	\$12,291	\$14,357	\$2,066
Significant reduction in amount of contrast used (p<0.001)	272 ml	302 ml	30 ml
No significant difference in procedure time (p=0.51)	71 min	70 min	1 min

Total cost reduction at one-year was \$2,066, of which \$675 was directly related to direct material cost.

FAME Study Economic Outcomes

Improved Outcomes at Lower Costs



Bootstrap simulation indicated that the FFR-guided strategy was cost-saving in 99.8% and cost-effective in all 1,000 scenarios.



Conclusions

- The FAME Study confirms that routine FFR measurements significantly improves procedure outcomes and reduces cost without prolonging the procedures.
- Routine FFR measurement reduces MACE by 28%
- Total average cost savings after one year was \$2,066
 (14%) including \$675 associated with direct material costs

