CLINICAL EVALUATION OF A PIEZORESISTIVE-SENSOR-EQUIPPED RAPID-EXCHANGE PRESSURE MICROCATHETER SYSTEM FOR FRACTIONAL FLOW RESERVE MEASUREMENT

SUPREME STUDY

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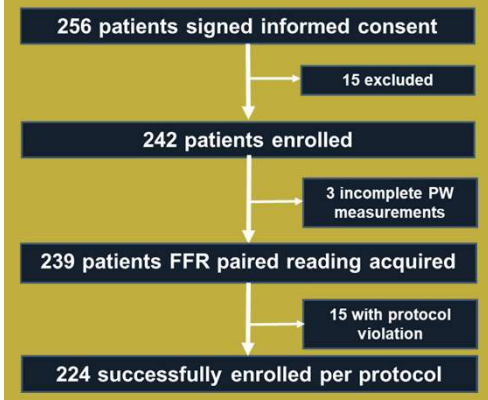
BACKGROUND

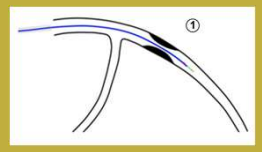
Major limitations for conventional FFR measurement using a pressure wire (PW) include the suboptimal handling characteristics and needs for occasional disconnecting and reconnecting of the PW. To address these limitations, a piezoresistive-sensor equipped pressure microcatheter (PMC), with a profile as small as 0.0205" and capable of accommodating any 0.014" guidewire, was developed

METHODS

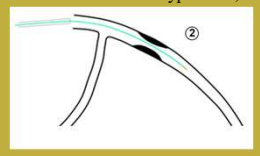
A total of 239 patients with intermediate (visually 30-70%) coronary stenoses were enrolled at four centers. FFR was measured first with the PMC over a PW, then with the PW alone. Stenoses with PW FFR≤0.80 were regarded as functionally significant. The primary endpoint was the Bland-Altman mean bias between the FFR of PMC and PW systems. Secondary endpoints included correlation, diagnostic accuracy, receiver operating characteristic (ROC), and drift.

STUDY FLOWCHART



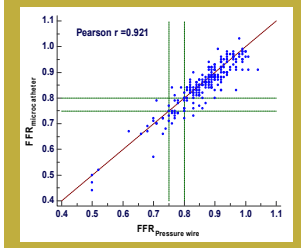


STEP 1: Use FFR microcatheter over the pressure wire for FFR at hyperemia;

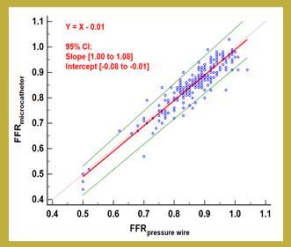


STEP 2: Withdraw FFR microcatheter after success and use pressure wire alone for FFR

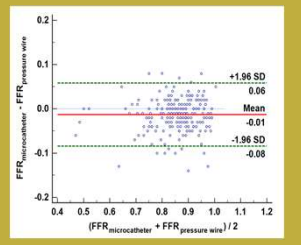
FIGURES AND CHARTS



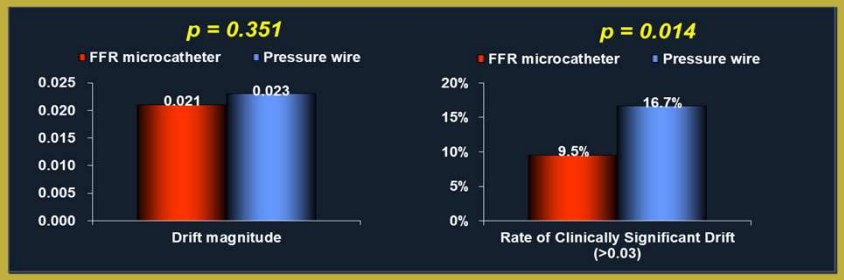
Correlation analysis of FFRPMC and FFRPW



Passing-Bablok regression analysis between FFRPMC and FFRPW

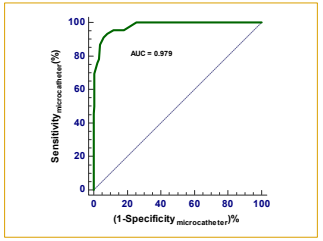


Bland-Altman plot of FFRPMC and FFRPW



Drift compared with those of pressure wire

ROC ANALYSIS



- AUC=0.979 ;
- Optimal cutoff for FFR microcatheter: 0.80
- Sensitivity: 91.3%
  95% CI :[79.2% to 97.6]
- Specificity: 94.0%
  95% CI: [89.5% to 97.0%]
- No serious adverse events occurred.

RESULTS

Results: From 239 patients, data of 224 patients (229 vessels) were approved by the core lab for per-protocol analysis. Quantitative coronary angiography showed that 17.9% vessels had diameters <2.5mm, and 55.9% vessels had stenoses >50%. The Bland-Altman bias between the two systems was -0.01 (p<0.0001) with [-0.08, 0.06] 95% limits of agreement. The Pearson correlation coefficient was 0.921 (p<0.0001). Using PW FFR≤0.80 as cutoff, the PMC per-vessel diagnostic accuracy was 93.4% [95% confidence interval: 89.4%-96.3%]; when considering the grey zone, there was no clinically meaningful diagnostic discordance in 99.6% of the cases, with both PW FFR and PMC FFR ≥0.75 or ≤0.80. The ROC curve showed the optimal cutoff is 0.80, with an area under the curve of 0.979 (p<0.0001). The PMC success rate was similar to PW (97.5% vs 96.3%, p=0.43) with no serious adverse event and had 51.6% less frequent clinically significant drift (CSD,defined as absolute drift >0.03) compared to PW (7.4% vs 15.3%, p=0.004).

CONCLUSION

Our study shows the novel PMC has minimal bias equal to the resolution of the current FFR systems (-0.01) and has high diagnostic accuracy (93.4%). This high accuracy, lower CSD frequency, and rapid-exchange nature make the PMC an attractive tool for coronary physiology assessment.

Disclosure INFORMATION

All authors have no personal relationships to disclose. This study is sponsored by Insight Liftech.

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