Randomised Comparison of Simultaneous Data from two Different Pressure Wires:

the COMET trial

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*on behalf of the COMET Investigators*
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Background & Aim

- The evidence base for the use of FFR in the diagnosis and management of patients with chest pain is robust.
- Despite this, the uptake of pressure wire (PW) for routine assessment of coronary lesions remains low.
- The most established PW systems available in clinical practice are the products of St Jude Medical (SJ) & Volcano Phillips.
- Recently, the Boston Scientific COMET™ wire received CE Mark and has entered routine clinical practice.
- There are, as yet, no suitably powered randomised trials using the PW systematically at the stage of diagnostic angiography and comparing outcome with management based upon angiography alone.
- This is the gap that will be filled by the 1100 patient RIPCORD2 UK trial, which is using the COMET™ wire.

The aim of the COMET trial was to assess, in a novel, randomised fashion, the diagnostic performance & drift for COMET™ (BS) & St Jude (SJ) PW in a study that allocates patients to simultaneous paired readings using 3 groups:

(a) BS-BS; (b) SJ-SJ; (c) BS-SJ*

*(Group C sub-randomisation for wire to be passed first)
Diameter: 0.14”
Primary Hypothesis

Is the magnitude of the difference observed in paired simultaneous recordings of coronary pressures any different with the use of BS & SJ PW when compared to 2 x SJ PW?

Statistical Considerations

100 patients – measuring FFR in 1.5 vessels per case = 150 vessels examined

In each vessel: Baseline Pd/Pa + FFR = 300 paired observations (ie 100 in each group)

For the primary outcome (Magnitude of delta SJ/SJ v Magnitude of delta BS/SJ):

assuming a control delta of 0.01 (SD 0.03) for 2 groups, each of 100 paired sets

we have 90% power to detect a difference of 0.0135

Precision Method:

For an observed mean difference of 0.01

Associated 95% CI for this point estimate would be (0.0041 - 0.016):

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Method

✓ Ethical approval granted for written informed consent in cases in whom FFR is clinically indicated
✓ Elective & NSTACS
✓ Web based randomisation after diagnostic angiography
✓ 2 centres (Southampton & Liverpool)
✓ Patients randomised to one of 3 paired wire options:
  ▪ BS - BS  n of Patients = 37  n of Paired Readings = 90
  ▪ SJ - SJ  n of Patients = 34  n of Paired Readings = 90
  ▪ BS - SJ  n of Patients = 35  n of Paired Readings = 108
  
(BS/SJ sub-randomised for wire to be passed first)

✓ For each vessel, 4 simultaneous pressure recordings were taken with the wires at exactly the same position...

1. Equalisation at the guide catheter tip
2. Baseline Pd/Pa at the target measurement site in the distal vessel
3. FFR at the target measurement site  (steady state maximum hyperaemia using iv adenosine)
4. Final Pd/Pa at the guide catheter tip (for estimation of “drift”)
   BS Drift estimation in 142 vessels;  SJ Drift estimation in 137 vessels
Results - between wire comparison

**Primary Outcome**

Observed absolute Δ
(irrespective of sign - Median and IQR)

BS-SJ  Median = 0.01  IQR (0.01 – 0.0225)
SJ-SJ  Median = 0.015  IQR (0.01 – 0.03)

(p = 0.61  Mann-Whitney test)
Results - Drift

**Primary Outcome**

Observed absolute $\Delta$ from Pd/Pa=1.0 at equalisation

(irrespective of sign - Median and IQR)

<table>
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<tr>
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<th>Boston</th>
<th>Median = 0.02</th>
<th>IQR (0.01 – 0.05)</th>
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<tr>
<td></td>
<td>St Jude</td>
<td>Median = 0.02</td>
<td>IQR (0.01 – 0.04)</td>
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($p = 0.14$ Mann-Whitney test)

**Boston Comet**

Mean = 0.02
SD = 0.039
N = 142

**St Jude**

Mean = 0.02
SD = 0.031
N = 137
SUMMARY

- We have used a novel method for comparison of 2 diagnostic devices
- The magnitude of the difference between BS & SJ wires is no greater than between a pair of SJ wires
- Both types of PW tested in this trial exhibit a small degree of drift, but there is no significant difference between the magnitude of this drift observed using either wire

CONCLUSION

There is no significant difference in performance between the COMET & SJM PW
How much drift is too much?

Should we routinely measure drift?

If so, what should we do about it?
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