Salivary Diagnostics

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Original Presentations by:
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Salivary Diagnostics

- Preliminary Information
  - Not yet ready for Prime Time
- Three Major Concepts
  - Salivary Diagnostics
  - Point of Care Testing
  - Lab on a Chip
Salivary Diagnostics

- Is it comparable to blood?
- Biological fluid that contains many analytes
- Non-invasive collection
  - Easily done at multiple outpatient settings
Salivary Diagnostics

- Utilized in other disease processes
  - Cancer
  - Infectious disease
  - Diabetes mellitus
  - Potential for virtually any disease
Point of Care Testing

• Gurney/bedside vs. Centralized lab
• Cost of equipment greatly reduced
• Results in 10-15 minutes vs 1-6 hours
Point of Care Testing

- Samples placed on individual card for the appropriate test
- Card placed in common analyzer where result is reported
Lab on a Chip
Lab on a Chip

- Sample placed on card
- Card placed in analyzer
Cardiac Diagnostics

Acute Coronary Syndrome
(IMA, D-dimer, Troponin I, Troponin T, CKMB, Myoglobin and Digoxin)

At Risk Testing
(CRP, TNF Alpha, IL1-data, WBC)

Congestive Heart Failure Prognosis
(BNP, Pro BNP, Urotensin)
Time Course of Established AMI Biomarkers in Serum

[Graph showing the time course of biomarkers (Myoglobin, Total CK, CK-MB, LDH, and Troponin I) normalized to the upper limit of normal versus hours from onset of infarction.]
Biomarkers of ACS

Ratio of median concentration for the ACS (NSTEMI & STEMI) over median concentration for the controls
ROC Curves for 21 and Top-5 Biomarkers for AMI Diagnosis

**SALIVA (UK & UL)**

**SERUM (UK & UL)**

43 Controls, 23 NSTEMI, 25 STEMI
ROC Curves for Combination EKG and Saliva Biomarker Panel

**SERUM (UK & UL)**

**SALIVA (UK & UL)**

43 Controls, 23 NSTEMI, 25 STEMI
Dose Response Curves

<table>
<thead>
<tr>
<th>CRP</th>
<th>IL1b</th>
<th>MPO</th>
<th>MYO</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2 ng/mL</td>
<td>0.2 ng/mL</td>
<td>2 ng/mL</td>
<td>2 ng/mL</td>
</tr>
<tr>
<td>2 ng/mL</td>
<td>5 ng/mL</td>
<td>50 ng/mL</td>
<td>500 ng/mL</td>
</tr>
</tbody>
</table>

Signal Intensity

Log Relative Concentration

CRP, IL1b, MPO, MYO
Healthy Donor – UT002

CRP  IL1b  MPO  MYO

Ambulance Patient - EMS2

CRP  IL1b  MPO  MYO

Ambulance Patient - EMS3

CRP  IL1b  MPO  MYO

q15/off0/0.25
EMS Study

- Is there a role for salivary markers in the pre-hospital setting?
- Can they replace blood tests for definitive diagnosis by reducing time from diagnosis to treatment?
EMS Study

- Collect saliva samples from patients with ACS symptoms
- Evaluate for markers found in University of Kentucky MI study
- Correlate with diagnosis of STEMI/NSTEMI
EMS Study

- Faculty from UTHSCSA School of Health Professions Coordinate:
  - patient recruitment
  - patient history
  - collection of samples
  - Geoff Smith, LP
  - David Wampler, PhD, LP
SAFD Paramedics

- Danny Zamora
- Timothy Worley
- Christopher Velasquez
- Trenton Thames
- Greg Tetsch
- Hank Schott
- Robert Payne
- Mark Olson
- James Murray
- Michael Mumme
- Juan Morin
- Donald Merecka
- Jeremy McElroy
- Ray Mays
- Terrence D Lowe
- Mark Lerma
- Jonathan Hosek
- Alberto Garcia
- Joel Fox
- Marti Flores
- Robert Dugie
- Kenneth Dugger
- Michael Dixon
- Eli Dierkhising
- Kevin Cryus
- Kristy Crenshaw
- Kelvin Broadnax
- Peter Baron
Requirements for Study Enrollment

- IRB Training 1 Hour
- Study Training 1 Hour
- Review/Updates 1 hour, Group mtg
- Research Assistant – Bi-Weekly phone reminder

- Cooler issued
- Swab obtained
- Sampled delivered to VA

- Verbal consent by paramedic followed by formal consent post-event
EMS Study

- Cardiologist will confirm patient diagnosis
- Salivary diagnostics lab will process samples for delivery to Rice University
EMS Study

- Markers will be analyzed using lab on a chip technology
EMS Study

• Potential Findings:
  – Increase accuracy of diagnosis in combination with ECG
  – Reduce diagnosis time
  – Alter treatment
Saliva ACS biomarker testing in ambulance

User: paramedics, highly trained
Environment: EMS vehicle, battery power, significant vibrations, compact
Accessories: used in connection with EKG, radio communications with hospital

12 lead EKG used by paramedics to transmit initial findings to emergency room physicians. EKG does not diagnose NSTEMI cases.

Saliva testing allows for identification of NSTEMI patients
Results

- Acute Coronary Syndrome/ Chest Pain
- Recruited 29/ 120 patients
- 7 Confirmed STEMI/NSTEMI
- 3 Heart Failure
• Is this important?
• Will it alter therapy?
• Does it improve outcomes?
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• Alan Lin
• Terry Baucher
• John McDevitt

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Salivary Diagnostics Projects

• Four funded Groups
  – UT Austin-UTHSCSA-UK-UL
    • Cardiac disease
  – NYU
    • Tuberculosis
  – UCLA
    • Oral cancer
  – Tufts
Future