Caries management by risk assessment: The CaMBRA randomized clinical trial

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Background: The Caries Balance

Pathological Factors
- Acid-producing bacteria
- Frequent eating/drinking fermentable carbohydrates
- Sub-normal saliva flow & function

Protective Factors
- Saliva flow & components
- Fluoride - remineralization
- Antibacterials: chlorhexidine, xylitol, new?

Caries

No Caries

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chinowa
Kyoto, Japan
June 2001
Overall Aim of the Study

The overall objective of the study was:
To provide clinical evidence that caries risk assessment with aggressive preventive and therapeutic measures can restore the balance between caries pathological and protective factors, thereby reducing new caries formation over 2 years.
Caries Management Study

Visit 1
DMFS
Radiographs

Randomization

Control

Visit: 2 → 3 → 4-6 → 7

Final DMFS
Radiographs

Conventional
Tx Plan
Restorations

All
Restorations
Complete

Intervention

Visit: 2 → 3 → 4-6 → 7

Final DMFS
Radiographs

Restorations,
Antibacterial
+/-Fluoride Rinses

All
Restorations
Complete

Salivary MS, LB, F every visit

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Methods – Study Enrollment

• 3 yr randomized clinical trial: 231 adults (18+ yrs)
• Eligibility: 16+ teeth, 1-7 cavities, no root caries

• Restorations completed (RC) in average of 12 mo
• Saliva samples (paraffin stimulated) every 6 mo:
  ❖ selective microbiology (MS & LB, CFU/ml saliva)
  ❖ fluoride (F, ppm)
Methods – Tx Grps

**Preventive Intervention (PI) Group (n=116)**
- Chlorhexidine gluconate (0.12%) rinse, 1/day for 2 weeks every 3 months (or 1 week / month) based on salivary MS and LB levels
- Fluoride mouthrinse daily (0.05% NaF) based on salivary F level

**Control (C) Group - conventional care (n=115)**
- No fluoride or chlorhexidine rinse supplied
- Providers unaware of salivary assay results

- 2 year follow-up after RC to final examination
- Final examination (1 calibrated examiner - JAW)
<table>
<thead>
<tr>
<th>Overall Caries Risk</th>
<th>( \log_{10} \text{(Mutans Strep + 1)} ) (CFU/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>( F &gt; 0.08 \text{ ppm} )</td>
<td>Low ( \leq 4.0 )</td>
</tr>
<tr>
<td>( \log_{10} \text{(LB +1)} ) (CFU/ml)</td>
<td>Low ( &lt; 1.3 )</td>
</tr>
<tr>
<td>Medium ( 1.3 - &lt;3.0 )</td>
<td>Medium</td>
</tr>
<tr>
<td>High ( \geq 3.0 )</td>
<td>Medium</td>
</tr>
</tbody>
</table>
Decayed Surfaces vs. log MS and log LB

Baseline Bacterial Levels vs Decay

High Bacterial Challenge
Log MS Control

Log MS Intervention (CHX +/- F)

Visit # - 6 month intervals

Restorations

Log MS vs Time Mean (SE)

Log(CFU/ml)
Log LB vs Time
Mean (SE)

Restorations

Log LB Control
Log LB Intervention
(CHX +/- F)

Visit # - 6 month intervals
Final Caries Status Related to Baseline Bacterial Levels
CaMRA Randomized Clinical Trial
Final Caries Status Related to Baseline Bacterial Levels
Caused by a Random Clinical Trial
Final Caries Status Related to Bacterial Levels 6 Months Prior
CaMRA Randomized Clinical Trial
Final Caries Status Related to Bacterial Levels 6 Months Prior
CaMRA Randomized Clinical Trial
Mean (SE) $\Delta$DMFS, $\Delta$DFS

$p = 0.106$

$p = 0.097$

$n=52$

$n=57$

$n=52$

$n=57$
Limitations

• Lower enrollment than (231 not 296), but better retention than planned
  → slightly smaller sample size (109 not 122)

• Compliance
Overall Conclusions

• Oral MS challenge stays essentially the same even after restoring all teeth with cavities

• Chlorhexidine gluconate (0.12%) +/- F (0.05% NaF) intervention is valuable during and after treatment to reduce caries risk status

• Caries risk status can be determined from MS, LB counts and F concentration in saliva

• Favorably altering the Caries Balance somewhat reduces subsequent caries levels
Did We Prove Our Hypothesis?

This randomized clinical trial:
provided clinical evidence that
caries risk assessment with
aggressive preventive and therapeutic
measures can beneficially alter the
balance between caries pathological and
protective factors somewhat reducing
new caries formation over 2 years
Reflections? Questions?