Periodontal Disease Influencing Acute Coronary Syndrome

K. Pflimlin, DO1, A. Singh, MD1, D. McElroy, PhD2, S. Banga, PhD2, M. Kazimuddin, MD3, M. Joyce, PharmD4, J. Storck, OMS-IV5, D. Chaney1, P. Jones, DO1, T. Donley, DDS3

1The Medical Center, Bowling Green, KY
2Western Kentucky University, Bowling Green, KY
3Research Foundation & Educational Trust

Introduction

The PD-ACS trial is designed to test the hypothesis that oral health is a contributing factor in influencing ACS. The emerging literature suggests that increased oral inflammation plays a role in the development of CAD given the increased systemic levels of inflammation as a result of periodontal disease. Prior studies have pointed out the need for carefully-designed, targeted studies to appropriate test this hypothesis. High sensitivity c-reactive protein, IL-6, and IL-1b have been the most extensively studied to date.

Study Design

- Enrollment with 1:1 randomization:
- Randomized controlled trial, non-blinded
- All ACS patients will undergo oral inflammation screening protocol.
- All patients receive baseline laboratory levels during their presentation with ACS
- The patients randomized into the treatment group receive a comprehensive oral examination as well as periodontal treatment. The non-treatment group will be encouraged to continue good oral hygiene practices and continue their oral hygiene regimen as well as provided with a list of dentists in the area.
- All patients will be followed at their regularly scheduled cardiology appointments as well as by the periodontist for monitoring their levels of oral inflammation in the intensive treatment group.
- Both groups in the treatment group and the patients to continue their current course of oral hygiene will also obtain laboratory testing again at 12 months.
- All patients in the study will be monitored for repeat admissions for ACS.

Outcomes/Analysis

Primary Outcome: Repeat ACS events (Unstable angina, Non-STEMI, STEM) and/or death
Secondary Analysis: Biochemical profile systemic inflammatory burden, oral inflammation levels

Statistical Analysis:
- Fisher’s Exact Test for primary outcome
- If duplicate analysis is to be performed at a later date → Cochran-Mantel-Haenszel Test
- Paired T-test will be implemented to analyze the oral inflammation before and after treatment for subgroup analysis
- If the data is found to be non-normal distribution: a Wilcoxon sign-rank test will be used instead of the paired T-test.
- ANCOVA will be utilized for each biochemical marker levels plotted against oral inflammation levels
- A hazard ratio and relative risk ratio will also be calculated to evaluate the probability of events in the treatment group compared to the probability of an event in the control group (both instantaneously and cumulative, respectively).

Alpha = 95; Beta = 80%; Projected P value deemed statistically significant: 0.05
All initial labs will be run once the assay wells have been utilized. All repeat labs will be obtained @ 1 year for patients.

Biochemical Analysis

Quintessential Laboratory Studies:
- hs-CRP – ELISA
- IL-1b – ELISA
- IL-6 – ELISA
- TNF-alpha – ELISA
- LDL – In-house MCBG
- HgbA1c – In-house MCBG

Investigative Laboratory Studies:
- IL-1a – ELISA
- IL-8 – ELISA
- GM-CSF – ELISA
- INF-g – ELISA
- MCAF – ELISA

* All ELISA – MyBioSource, Inc.

References

Available upon request