Law Enforcement Officer Cardiac Screening Initiative (LEO-CSI)

A Clinical Study Activity

ABSTRACT

The leading cause of duty-related death among US police officers is myocardial infarction (MI). The number of law enforcement officers who die on the job is staggering. While guidelines for the medical screening of police officers do exist, the screening process is not mandated. As such, many departments do not provide medical screenings, while others may. It is conceivable that screenings are more frequently mandated at larger metropolitan police departments as opposed to smaller, more rural agencies. We also know, that despite the guidelines that exist, there is great variation in what the screening entails. With a population so vulnerable to coronary disease, we believe that appropriately screening this population for early detection of coronary artery disease is essential. We believe that the current screening techniques that are being employed (as variable as they may be), are not as good to accomplish the goal of early detection in such a vulnerable population. We further believe that new technologies are far superior to those currently being used, and that by eliminating the older tests, and adopting the newer tests, we will reduce the morbidity and mortality in police officers due to cardiovascular disease, and probably at a cost savings to law enforcement agencies and the tax-payer. Our proposed study is designed to collect those data from actual police officers.

PURPOSE

The leading cause of duty-related death among US police officers is myocardial infarction (MI). According to the International Association of Chiefs of Police data ¹, as well as data from the Officer Down Memorial Page ², *Line of Duty* death from MI is consistently the second or third leading cause of officer mortality. However, this data tracks only those officers who suffer their MI during duty hours. When extrapolated from a ten or twelve hour shift to a twenty-four hour day, death from cardiac disease easily becomes the number one killer of law enforcement officers.

Despite the high risk of heart disease, little has been done to detect coronary disease in its early and asymptomatic stage. Our goal is to examine current medical screening services employed by various law enforcement agencies, with "non-traditional" screening techniques in the hopes of reducing morbidity and mortality in police officers due to cardiovascular disease.

To support this goal, pro-active steps toward prevention can and should be done in the fight against atherosclerosis, the primary cause of cardiovascular disease. As with many diseases, early detection in asymptomatic individuals potentially increases benefits. These benefits can be realized through change in diet and lifestyle, or when indicated, via drug therapies or other medical treatments.

Conversely, if detection is not accomplished until the more advanced stages of cardiovascular disease, the negative consequences such as heart disease and stroke can be extremely severe, especially in public safety workers.

By changing the model of our health and medical screening techniques, we believe we can detect cardiovascular disease sooner and more efficiently in this high-risk profession, thus allowing for earlier, live saving, interventions.

In addition to identifying risk factors, we seek to determine whether two "new" screening tests can detect the presence of atherosclerosis in asymptomatic individuals better than our current methods.

Considerable research has been conducted and programs implemented addressing basic medical and wellness evaluations. While sub-maximal exercise stress tests are useful for estimating aerobic capacity, we contend that symptom limiting (maximal) exercise stress testing should NOT be routinely used for diagnostic and prognostic purposes. In place of conducting maximal stress tests, the use of advanced non-invasive screening for sub-clinical coronary heart disease (e.g. coronary artery calcium scoring), should be evaluated for integration in the police service and more-traditional evaluation tools need to be re-examined.

Continued research is needed to support occupational health and medical programs in law enforcement; to evaluate the cost-effectiveness and efficiency of investing in such programs; and to identify best practices. Further cost/benefit research is needed to address the economic impact by calculating program costs and identifying more sensitive and less costly options to determine a more accurate overall return on investment in health and wellness programs.

Wellness and screening programs have been shown to improve health outcomes. These programs should be implemented regardless of cost because of their positive impact on health. However, information about the cost-effectiveness of these traditional screening programs vs. newer methods is limited. This information is important to support in the sustainability, further development and refinement of these programs.

Novel biomarkers, being specifically lipoprotein-associated phospholipase A₂, and cardiac calcium score.

While there is a general understanding of the relationships between these biomarkers and the risk of cardiovascular events in the general public, very little is known about the specific relationship between these biomarkers and cardiovascular events in law enforcement. Police officers' strenuous activity and hostile work environments could alter the more general relationships.

Both modifiable and novel risk factors are known to be positively affected by diet and exercise, which suggests that greater knowledge of these factors and a commitment to health and wellness could lead to significant reductions in cardiovascular deaths and disabilities.

POTENTIAL IMPACT

There were estimated 12,000 police departments in 2013.

There were an estimated 900,000 police officers in the United States in 2013

There are between 100 and 200 Line of Duty Deaths each year

Last calendar year (2014) 133 officers were lost in the line of duty.

There have been 156 Line of Duty fatal heart attacks between 2004-2014

To date, 44 police officer fatalities have been reported in 2015, 11 from heart attack

Coronary heart disease is the leading cause of death among US police officers. The potential impact of this research on officer safety, health and wellness is enormous. Earlier detection of coronary heart disease and subsequent intervention will save lives.

PROJECT GOALS, OBJECTIVES, AND SPECIFIC AIMS

Coronary artery disease is the prevalent cause of cardiac death among police officers, and is due to a combination of personal and workplace factors. The personal factors are well known: age, gender, family history, diabetes mellitus, hypertension, smoking, high blood cholesterol, obesity, and lack of exercise, to name a few.

Workplace factors include sudden (and sometimes drastic) elevation in heart rate due to adrenaline rush (anticipatory, excitation or emotional), physical stress, or heat stress. Poor dietary or exercise habits in the workplace, poor sleep, restless sleep, sleep cycles and circadian rhythms, etc. Police officers also may have other exposures to workplace factors that are associated with adverse cardiovascular outcomes.

At the present time there is no universal protocol for the cardiac screening of law enforcement officers in the United States. We believe that great variations occur in the medical screening techniques among Police Departments. We also hypothesize that these variations may also be clustered by type of agency as well as by size of the Department, and by geographic location.

This is a preliminary clinical study to prove or disprove our hypotheses that; (1) Lp-PLA₂ markers and cardiac calcium scores are more predictive of cardiovascular disease in all types of law enforcement personnel, than traditional risk assessments. (2) That due to the validity, reliability, specificity, relative cost, and ease of access to these tests, more police officers will elect to have these tests. (3) Because these tests will identify a disease process sooner than similar (but inferior) tests, life-saving interventions can begin earlier, thus reducing line of duty, or premature deaths.

In addition, when our hypothesis is proven, we may feel that we need additional resources to promote the findings to a wider audience, and make strong efforts to encourage changes in procedure and influence a paradigm shift at the national and international levels.

If, we are unsuccessful in proving our hypothesis, we would still disseminate our "lessons learned", and report the data. In either case, we will disseminate our findings in order improve officer safety, health, or wellness.

From a session at the American College of Cardiology 2014 Scientific Sessions, a Houston Methodist Hospital study reported that testing of asymptomatic individuals really has worth. Nearly 1000 patients deemed low risk by the Framingham calculator and a plain treadmill exam were tracked for seven years. Coronary calcium proved a far better predictor of risk. It was stated; "Calcium scores are better predictors than routine exercise evaluation," and "If you've thought about doing a stress test on someone with no symptoms, do a calcium score first. There is no such thing as a false-positive calcium score. It is 100% accurate for coronary atherosclerosis." ¹³

The Los Angeles BioMed at Harbour UCLA Medical Center presented a 20-year study of nearly 5600 subjects. Mortality data was presented on no-, low-, moderate-, and high-calcium scores of those otherwise considered to be at low risk for heart disease. With an average follow-up period of 10 years, even patients with low calcium scores (1–99) were 50% more likely to die than patients with a calcium score of zero. Moderate scores (100–399) were associated with an 80% greater likelihood of dying, and high scores (above 400) were associated with a three-times-greater risk of dying as compared with patients with zero calcium. These patients had zero to one risk factor, including diabetes, hypertension, current smoking, family history, or diabetes. Ten percent of these "low-risk" patients had a severe burden of coronary artery calcium >400. 13

Data from researchers at Johns Hopkins presented information from the Multi-Ethnic Study of Atherosclerosis (MESA) group. Of the 1850 patients studied, a zero calcium score in "middle age" or older is a sign of healthy vascular aging and a good predictor of longevity. Younger participants and those without multiple traditional risk factors were more likely to maintain a score of zero during a second scan 10 years later. A healthy lifestyle was the best predictor of risk in those individuals.¹³

Finally, a research team from Mount Sinai St Luke's-Roosevelt Hospital Center in New York found some correlation between coronary calcium scores and single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), which produces a 3-D image of the heart. A negative calcium score generally indicated a normal perfusion status, but scores of \geq 400 were usually associated with ischemia. ¹³

Additionally, when cardiac calcium scores are coupled with Lp-LA₂ measurements, we believe the combined risk assessment for coronary artery disease may be superior to all other risk assessments combined (including; PAR-Q questionnaire, Framingham risk scores, health assessment questionnaire, resting EKG, submaximal graded exercise test with EKG, Triglycerides, Total Cholesterol, Low Density Lipoprotein (LDL-C) level, High Density Lipoprotein (HDL-C) level, and Total Cholesterol/HDL Ratio, biometric data such as girth or skinfold measurements to estimate body composition, social history, self-reported fitness level, etc.).

PROJECT METHODS

We propose to develop partnerships with several Police Departments across the country. We intend to solicit and recruit Police Department / partners / subjects with the following characteristics:

- Police Departments from several geographic areas of the Continental United States.
- Large Urban/Metropolitan Police Department(s)
- Small Rural Police Department(s)
- Officers of all ranks and positions.

Our goal is to compare whether our proposed two "new" screening tests can detect the presence of atherosclerosis in asymptomatic individuals better than the methods currently being employed in a variety of settings. We have designed this study to be inclusive. We want every type of police officer involved. We seek to obtain real clinical data (not generated for the purpose of this study) from a variety of subjects/and a variety of department types. We then wish to have the subjects complete our 2 screening tools, and compare them to their original (Department provided) results.

PROJECT MEASUREMENTS

PROCEDURES

Consented subjects will be asked to present themselves at a radiologic imaging facility, established by the research team. Prior arrangements and scheduling will be coordinated by the research team. When possible, every effort will be made to schedule subjects while they are on-duty (with the permission of the partner Department). All "patient paperwork" will be limited and/or completed prior to arrival. Once the subject arrives, he/she will escorted to a computed tomography (CT) scanner and have a non-invasive heart scan performed by a CT Technologist. The scan will be taken for 20-30 seconds, but from start to finish it takes approximately 10-15 minutes. The subject will then be asked to give a standard blood sample via venipuncture by a trained phlebotomist. The blood drawing procedure should take less than 5 minutes.

CARDIAC CALCIUM SCORE

The "heart scan" is done to obtain a cardiac calcium score. The cardiac calcium score is then used to calculate the risk of developing Coronary Artery Disease (CAD) by measuring the amount of calcified plaque in the coronary arteries. This procedure is performed to check for any plaque or calcium build up

in the coronary arteries which causes heart disease or can lead to a heart attack. Cardiac scoring is a better predictor of coronary events than cholesterol screening or other risk factors.

LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2

The blood draw is to evaluate the (Lp-PLA₂). Coronary artery disease is associated with the severity of atherosclerosis, which is an inflammatory disease. But although helpful for guiding treatment and improving prognosis, standard approaches for assessing a person's risk do not include inflammatory markers.¹⁴ So, individuals with a moderate risk, as determined by standard approaches, may actually be at greater risk of a myocardial infarction or stroke than predicted.¹⁵ High-sensitivity C-reactive protein (hs-CRP) is a marker of systemic inflammation that can improve risk stratification; however, it is not specific for cardiovascular disease. On the other hand, lipoprotein-associated phospholipase A₂ (Lp-PLA₂) is a specific marker of vascular inflammation associated with atherosclerosis.¹⁶ Following production by inflammatory cells, this enzyme cleaves oxidized phospholipids, generating pro-inflammatory molecules and oxidized fatty acids.

Increased blood levels of Lp-PLA₂ have been linked to increased risk for: 1) cerebral thrombosis, ¹⁷ 2) first ¹⁸ and recurrent ¹⁹ coronary events, 3) adverse prognosis after acute coronary syndrome, ²⁰ and 4) cardiovascular disease associated with metabolic syndrome. ²¹ A meta-analysis including more than 25 prospective studies found an approximate doubling of the risk for coronary artery disease and quadrupling of the risk for ischemic stroke when comparing Lp-PLA₂ values in the top quintile versus the bottom quintile. ²² The predictive value remained after adjustment for low-density lipoprotein (LDL)-cholesterol level and other established cardiovascular disease risk factors. ²²

A 2008 consensus panel recommended testing Lp-PLA₂ as an adjunct to traditional risk factor assessment in individuals with moderate or high risk of cardiovascular disease as defined by Framingham risk scores. The panel found that an Lp-PLA₂ level >200 ng/mL indicates an individual's risk is actually higher than that determined using Framingham risk scores, and more intensive therapy is appropriate. For example, an individual with a moderate Framingham risk score and an elevated Lp-PLA₂ may be reclassified as being at high risk. The LDL-cholesterol goal would then be reduced from <130 mg/dL to <100 mg/dL, and more intensive life-style changes would be recommended. Similarly, in individuals with an elevated Lp-PLA₂ and high Framingham risk score, the LDL-cholesterol goal would be reduced from <100 mg/dL to <70 mg/dL. Though the consensus panel only recommended Lp-PLA₂ measurement in moderate- or high-risk individuals, studies have shown that elevated Lp-PLA₂ also predicts coronary artery disease and ischemic stroke in the general population. ^{23,24}

Subsequent to the 2008 consensus panel recommendations, other studies have shown that elevated Lp-PLA₂ levels are predictive of cardiovascular events including myocardial infarction and ischemic stroke. Furthermore, a 2010 meta analysis of 32 prospective studies showed a log-linear association between Lp-PLA₂ level and risk of coronary artery disease and total vascular mortality. Lastly, studies have shown that the predictive value of Lp-PLA₂ is independent of, and additive to, that of hs-CRP. 17,18,22

EXERCISE TREADMILL TEST

Traditionally, many agencies have employed treadmill testing to identify provocable ischemia by ECG criteria. Although, this makes some degree of intuitive sense, however, pragmatically it is of limited utility as an ECG stress test will only detect hemodynamically significant stenosis that are restrictive to coronary flow. Because it is important to identify coronary lesions before they become hemodynamically significant, stress testing is less effective at identifying pre clinical plaque.

INDIVIDUALS WHOM WE BELIEVE ARE SUITABLE FOR TESTING:

- Individuals with moderate risk of cardiovascular disease (≥2 risk factors and Framingham 10-year risk score ≤20%).
- Individuals with high risk of cardiovascular disease (Framingham 10-year risk score >20%).
- Individuals with coronary artery disease or risk equivalents (i.e., symptomatic carotid artery disease, peripheral artery disease, abdominal aortic aneurysm, diabetes mellitus).
- Individuals with moderate risk of stroke.
- Individuals employed in Public Safety.

INTERPRETIVE INFORMATION

Increased Lp-PLA₂ levels are associated with increased risk of cardiovascular disease and stroke. The preponderance of evidence suggests that a concentration <200 ng/mL is optimal, a concentration from 200-235 ng/mL is associated with a moderate risk of cardiovascular disease and stroke, and a concentration >235 ng/mL is associated with a high risk of cardiovascular disease and stroke. ^{15,24,25,28} Risk is independent of age and gender. Patients with elevated levels may benefit from intensified lipid-lowering therapy and lifestyle changes. ¹⁵

All testing and interpretation will be carried out with strict adherence to equipment, instruments, standards, and procedures.

More detailed information on Lp-PLA₂ testing, case studies, clinical information, technical information, literature, and references can be found at: http://www.plactest.com/index.html.

PROJECT ANALYSIS

We intend to compare the subjects' risk of coronary artery disease via the combined risk determined by the cardiac calcium score, and the lipoprotein-associated phospholipase A_2 score versus the subjects other (previously obtained) evaluations (with whatever indicators were evaluated). A detailed battery of statistical tests will be conducted in consultation with our biostatistician, including factor analysis,

ANOVA, MANOVA, and correlation coefficients. Particular attention will be paid to the specificity of Lp-PLA₂ and cardiac calcium scores in these occupationally high-risk subjects who are less than 35 years old.

The Principal Investigator (PI) and research team do have the expertise to perform the planned analysis and defend the results in a peer review process. A brief introduction into the capabilities of the research team is provided below, as are biosketches in the appropriate area.

DISSEMINATION AND IMPLEMENTATION

The researchers will work closely with, and frequently update their findings via status reports, to the Federal Emergency Management Agency (FEMA), the International Association of Chiefs of Police, and many others. We anticipate using these organizations' existing resources (websites, magazines, and conferences) to support dissemination and implementation throughout the la enforcement community to improve officer safety, health, or wellness. A final report will be generated and provided to the aforementioned Agencies. In addition, the results will be presented by the researchers at appropriate conferences (both police and medical related). The investigators will also work closely with the national organizations in an effort to disseminate any findings that may result in procedural changes.

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