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Cost impact and percentage of Native American patients with Type 2 DM and Cardiovascular Disease with the ATP III recommendation of an LDL <70.

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Abstract

Objective: The main objective of the study was to obtain the average LDL cholesterol level in Native Americans patients with Type II DM and cardiovascular disease who are receiving their healthcare at the Albuquerque Indian Health Service. Specifically, the study determined the percentage of patients meeting the Adult Treatment Panel III recommendations of an LDL <70 for high risk patients and the cost impact to lower the LDL in those not currently at this level. High risk being defined as having coronary heart disease.

Design: The study design is a combination of a chart review and review of the Resource Patient Management Systems (RPMS) of patients receiving their healthcare at Albuquerque's Indian Health Services hospital/clinics.

Setting/population: The population is the Native American patients receiving their healthcare at the Albuquerque Indian Health Services and includes patients with both cardiovascular disease and Type II diabetes. The sample size consisted of 14 patients with Type II diabetes; age >18y/o; had seen the PCP at least once in the last three years; had at least 1 LDL value recorded in the past year, did not have abnormal liver enzymes/liver failure; did not have abnormal kidney function tests outside of normal limits; and did not have baseline LDL > 150mg/dl.

Main outcome measures: The main outcome was to determine the average LDL levels of those who are considered "high risk" and to determine what proportion were treated to LDL <70 mg/dl. A secondary outcome assessed involved the average financial impact based upon projected attempts through lipid lowering agents to reach an LDL <70 mg/dl.

Results: Twenty eight (28) percent of Albuquerque's Indian Health Service "high risk" population is being treated to goal LDL levels. For those not currently achieving this level, Simvastatin ranging in dose from 2.5-80 mg Q PM could be utilized to bring these patient to goal levels. Simvastatin is the first line agent utilized by the Albuquerque Indian Health Services. Based on the unit pricing of this particular statin, patients can be brought to goal at an average of \$10 per year/per patient.

Conclusion: The conclusions of this particular research project are two fold. First in performing this research, it was found that only 28% Albuquerque's Native American population who receive their care at the Albuquerque

Indian Health Service were being treated to goal. Second, the additional cost to bring these patients to recommended LDL levels is not very large.

Introduction

Much research has been done in the areas of cardiovascular disease and diabetes and preventative measures that have been taken to combat these diseases. Recent data has shown that the mortality rate associated with cardiovascular disease has been declining since the 1970s in the many western countries. (2) Despite this decline in westernized countries, United States' Native American populations are experiencing a gradual increase in mortality associated with cardiovascular disease.(1) Although many factors contribute to this discrepancy, including smoking, diet, and genetics a potential approach to this issue is stricter control of cholesterol levels. Recent recommendations by the National Cholesterol Education Program Report states that treating high risk patients to LDL levels to < 70 mg/dL is indeed beneficial. (3) Benefits to these patients being measured in terms the decrease of major cardiovascular events. The goal of this particular research was to attempt to find out what percentage of Albuquerque's Indian Health Service cardiovascular disease and diabetic population were being treated to the recommended goal of < 70 mg/dl. After finding the percentage of patients that were actually being treated to goal, the next step would be to find out the additional cost needed to bring those patients to goal LDL levels.

Methods

Design: The design is a combination of chart review of patients who seek services at the Albuquerque Indian Health Services and utilization of the data collection software used at the Albuquerque Indian Health Center, called the Resource Patient Management Systems (RPMS).

Sample size: The initial patient review consisted of 1000 patients to determine those who met the inclusion and exclusion criteria of the study. The end sample size was 14.

Inclusion criteria: diagnosis of Type II diabetes, 18 years or older; active patient (seen primary care provider at least once in the last three years) within the DMS database, a history of cardiovascular disease (having a documented myocardial infarction).

Exclusion Criteria: abnormal liver enzymes (AST, ALT outside of normal Limits); abnormal kidney function tests (GFR and creatinine levels outside of normal limits); baseline LDL > 150mg/dl.

Methodology: 1000 patients were randomly selected from the above database. The charts were then randomly assigned values ranging from 1-1000. The remaining charts were then subjected to the inclusion/exclusion criteria as described above. . The 14 remaining patient charts were then utilized to determine the data obtained in the results section. The patients' LDL values, LDL values from goal and the percentage of LDL needed to be decreased in order to reach goal were obtained. Once the percentage of LDL needed to be decreased to reach goal LDL levels was obtained, the amount and cost of statin was obtained using the 2008-2009 Lexi-Comp's Drug Reference Handbook. (5) Pricing per unit of drug was based on information obtain from the McKesson website. (6) The amount of medication to reach recommended LDL levels were then calculated for 1 day, 7 days, 30 days, and 365 days. (Ex. If a patient required an additional decrease in LDL of 33%, the additional amount of simvastatin to reach goal as recommended was 20 mg based upon information obtained using the Drug Reference Handbook. The amount per unit was found to be \$.02, which was based on the price per unit as found on the McKesson website. This amount was multiplied by 1, 7, 30, 365 days to the total cost to bring the patient to goal LDL level. Once this level was obtained for each individual, the values were averaged for the study individuals.)

Statistical/Data Analysis: Confidence intervals obtained were based on information obtained from *Scientific Calculations*. (7)

Results

The final sample size of participants included in the final portion of the study was 14. Only 28 percent (95% CI 2-42) of the patients who met the study criteria were being treated to a goal LDL of less than 70 mg/dl. See

Figure 1.

The percentage of LDL required to reach the recommend goal of <70 mg/dl was calculated for each patient. The average LDL percentage needed to reach goal levels ranged between 13-50%. The LDL percentages were then utilized to determine which medications would be best suited to lower the patients LDL to the recommend level based on the info obtained from the Drug Information Handbook. Based on the information obtained from the Drug Information Handbook, it was found that simvastatin ranging from 2.5 to 80 mg could be utilized to bring this particular subset of patient to goal levels. Based on the amount of drug needed to bring this subset of patients to recommended level, the average cost of additional drug to bring patients to goal level was calculated for 1 day, 1 week, 1 month and 1 year. Based on the percentage LDL reduction to reach goal levels and the per unit pricing the average additional cost to bring these diabetic patients to goal averages \$10 a year per patient. These results can be seen on Figure 1.

Discussion

1) In performing this research it was found that only 28% of the diabetic patients who receive their care at the Albuquerque Indian Health Service were being treated to recommend goal LDL levels. This percentage is very surprising considering that diabetes and cardiovascular disease is on the rise among the Native American Community. What is even more surprising is that the additional cost, based on unit pricing, could be as low as \$10 person per year based on McKesson pricing which is utilized by the Indian Health Service.

2) Despite being at a higher risk of for developing diabetes and the subsequent complications, a lower percentage of the Albuquerque Native American population is being treated to LDL recommendation as compared to the rest of the United States. According to Kennedy et al, 42% of United States' general diabetic population is being treated to goal LDL level.(4) Although the complications of diabetes are due to multiple variables, perhaps it would be justifiable to attempt to treat these high risk patients to levels comparable LDL levels of the national average. By simply reducing the LDL

level to reach the national level, one is likely to see a reduction in mortality of the Native American Populations.

3) In performing this particular research attempt it is important to reiterate that diabetes and its complications are multi-factorial. It would also be important to note that many factors that affect the mortality of diabetic patients were not controlled for in this particular study. Factors that were not controlled that are worthy for consideration include genetics, smoking, diet, weight, previous medical problems, etc, all factors that could affect the mortality of diabetic patients.

4) Based on searches of the Native Health, Pub Med, Medline plus, and Cochrane databases research related to the area of diabetes, Indian Health Service, LDL goal levels, and mortality, no research has been performed specific to this area. Further research should be performed in order to determine if the obtained LDL percentage remains consistent. Further research should include a larger scale study with a greater number of patients. Further studies including other Indian Health Service Units might add further insight into the issue at hand. In addition, greater care should be taken to control for factors including smoking, genetics, other medical problems, etc, all factors that could complicate study outcomes.

Strengths and limitations

Strengths of this particular study include that it was the first chart review at the Albuquerque Indian Health Services that served to evaluate treatment goals of LDL levels.

Limitations of this particular study includes the total number of participates, after inclusion and exclusion criteria, resulting in a rather wide confidence interval. Other potential limitations of this study are since the study was done using patients who sought treatment at the Albuquerque Indian Health Services the results can not be generalized to the non Native American populations. In addition, the data obtained were of patients who visited Albuquerque's Indian Health Service so the results can not be generalized to include other Indian Health Service facilities. This particular research attempt was a very good pilot study with much room for additional research. Additional research should include a much larger chart review that will lead to more data for analysis.

Average LDL (mg/dl)	Ave. % LDL Decrease	Ave Unit cost	Ave cost (1 day)	Ave Cost (1 week)	Ave Cost (1 Month)	Ave cost (1 year)
90.34	20.42%	\$0.03	\$0.03	\$0.21	\$0.87	\$10.70

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