THE ACCURACY OF REFERRAL FOR PORTABLE LIPID ANALYZERS IN AN OLD ORDER MENNONITE POPULATION

Maria Eve Main, MSN, ARNP[1]
Susan Jones, PhD, RN[2]
Cathy Abell, PhD, RN[3]

[1]Assistant Professor, School of Nursing, Western Kentucky University, eve.main@wku.edu
[2]Professor, School of Nursing, Western Kentucky University, susan.jones@wku.edu
[3]Associate Professor, School of Nursing, Western Kentucky University, cathy.abell@wku.edu

Key words: Cholesterol, Lipids, Mennonite, Portable Lipid Analyzers, Triglycerides

ABSTRACT

The primary purposes of this study were to: 1) examine the accuracy for referral of two portable lipid analyzers (PLAs) in an old order Mennonite population through a comparison to a national standardized reference laboratory, 2) examine the relationship of total cholesterol values with other known cardiovascular risk factors, and 3) foster the continued participatory model of health care service in this community. The self-selected sample was composed of 42 adult members of an old order Mennonite community residing in south central Kentucky. A descriptive correlational design was used in this study. There were clinically relevant variations in the total cholesterol and LDL-C in both of the analyzers. Additionally, there was a correlation between total cholesterol values and age. The study also facilitated the participatory model used with this community previously as the community members assisted in planning, implementing, and evaluating this project.

INTRODUCTION

Cardiovascular disease is responsible for 35.3% of all deaths in the United States (Lloyd-Jones et al., 2009). Epidemiological data clearly identify a relationship between elevated lipid levels and cardiovascular disease with a resultant emphasis on hyperlipidemia as a modifiable risk factor (Rosamond et al., 2008). The preventive health practices of screening and the early detection of hyperlipidemia are goals for health care providers to eliminate or modify the risks for cardiovascular disease. While venous blood samples analyzed in reference laboratories provide the most reliable measure of blood lipids, portable lipid analyzers (PLAs) have gained popularity in conducting baseline lipid screening in community type settings (Taylor & Lopez, 2004). In a lipid management program in rural Alabama the provision of lipid testing through a mobile health unit increased the access of community members to lipid screening and improved treatment for hyperlipidemia (Donaldson & Andrus, 2004). Rural residents often lack adequate transportation, financial resources, and a defined primary health care provider (Campo et al., 2008).

The Mennonites and Amish are collectively referred to as Anabaptists. They are descendents of a group of 100 founders who emigrated from Switzerland and Germany after persecution from the both Protestants and Catholics during the Protestant Reformation in the sixteenth century (Kraybill & Bowman, 2001). Members of these old order Anabaptist communities use horse and buggy for local transportation and do not have telephones or electricity. Additionally, most are only educated through the eighth grade (Wenger, 2003). The impetus for most adults in this community for seeking health care is the interference of a current illness with their ability to work (Armer & Radina 2006; Fisher, 2002).

Conservative Mennonite and Amish communities are among the most rapidly growing populations in the rural U.S. with the population doubling every 20 years (Young Center for Anabaptist & Pietist Studies, 2008). Their isolation by choice, rejection of technology, and a preference for illness care contribute to a low utilization of preventive screenings. Members from such communities are known to consume a high fat diet, have equivalent levels of obesity as the mainstream U.S. population, and avoid traditional health care (Fuchs, 1990; Glick, 1998; Rampersaud et al., 2008); therefore, they could benefit from cholesterol screening.

Portable lipid analyzers (PLAs) offer promise as one means to address this challenge of self-imposed isolation. However, it is of utmost importance that accurate information be obtained when using PLAs to measure lipid profiles in these isolated religious communities as well as any community setting. These devices provide a convenient and economical lipid panel with immediate results for the patient and health care provider. This will increase the patients' opportunity for faster referral and intervention. In recent years the availability of PLAs has increased (Taylor & Lopez, 2004), but the accuracy of the values obtained is inconsistent. Stein et al. (2002) found that portable measurements systematically overestimated triglycerides and high-density lipoprotein (HDL-C). Low-density lipoprotein-cholesterol (LDL-C) concentrations were underestimated and total cholesterol provided unbiased estimations. Bowden et al. (2004) found a false negative rate of 17.21% to 34.4 % in capillary cholesterol measurement as compared with venous measurement. When comparing the Cholestech LDX and the CardioChek PA to a laboratory gold standard, the Cholestech LDX demonstrated better reproducibility and was more accurate in categorizing the Framingham Risk Score (Dale, Jensen, & Krantz, 2008).

Purposes of Study

Little is known about the accuracy for referral of PLAs in Amish and Mennonite old order communities. The primary purposes of this study were: 1) examine the accuracy for referral of two PLAs in an old order population through a comparison to a national standardized reference laboratory, 2) examine the relationship of total cholesterol values with other known cardiovascular risk factors and 3) foster the continued participatory model of health care service for this old order community.

METHODS

Research Design and Study Sample/Setting

A descriptive correlational design was used in this study. The self-selected sample included 42 adult members of an old order Mennonite community residing in south central

Kentucky. This project evolved from a previously established community and academic partnership. One of the investigators has worked with this community for 12 years establishing a monthly community health fair/clinic day with the residents of the community determining the topics for health teaching, preventive screenings, and other interventions. This collaboration has been successful in part due to the trust developed. Building trust among partners and obtaining commitment from community partners have been identified as facilitating factors for successful community projects (Lantz, et al., 2001).

Members of the community assisted with locating an appropriate site for the project and recruiting participants. A culturally sensitive flyer was distributed to potential participants through community gatherings one month prior to the date of data collection. The flyers were black and white with a rural image as a background. Data were collected during a one-day health fair at a country store on the periphery of the community. The participants were familiar with the store and felt comfortable in the location. This addressed the challenge of identifying a setting, which was convenient and acceptable for the residents of the community while offering the availability of electricity for the blood centrifuge.

The Institutional Review Board at Western Kentucky University approved the study. All participants provided informed consent before participation. Adult members of the community were eligible to participate in this study if they were at least 18 years of age and could read and write English. Participants were excluded if they were currently taking Coumadin, Warfarin, or Plavix, had a bleeding disorder, were pregnant or receiving chemotherapy treatment. Individuals were asked to fast for at least twelve hours before the laboratory tests were performed. As a benefit, participants received free lipid screening with the current recommendations for follow-up by a health care provider.

Portable Lipid Analyzers

The Accu-Chek Instant Plus was designated as PLA1. PLA1 yields total cholesterol (TC) results in three minutes from a drop of capillary blood with a range of 149 to 300 mg/dL. This monitor analyzes only the TC (Roche Laboratories, 2009). The Cardiochek PA was designated as PLA2 and can be used at home or in an office setting. Results are available within three minutes of completing the finger stick. The Cardiocheck PA monitor can perform a TC, HDL-C, calculated LDL-C and TRIG (Cardiochek, 2009). Both PLAs are designated as Clinical Laboratory Improvement Amendments (CLIA) waived tests. CLIA waived tests are defined as simple laboratory examinations that are cleared by the Food and Drug Administration for home or office use and employ simple methodologies that are accurate and are unlikely to render erroneous results (U. S. Food and Drug Administration, 2009).

Procedures

After acquiring consent, a researcher developed questionnaire was administered to collect desired data. The data collected included gender, age, early cardiac death in first-degree relatives, parity, and current intake of medications or herbals for lowering cholesterol, triglycerides or blood pressure. Individual participants had their weight and height measured to determine the most accurate body mass index (BMI). BMI was calculated as weight in kilograms divided by height in meters squared. Blood pressure was measured with an aneroid sphygmomanometer after the participant had rested for 5 minutes. All testing took place between 7:30 and 10:45 am. Prior to the capillary blood collection participant's fingers were cleansed with alcohol swabs and allowed to dry. Using lancets, capillary samples were collected and immediately applied to the appropriate test strips of two portable lipid analyzers. Following the collection of capillary samples venous samples were obtained by a certified medical technologist and dispensed into an evacuated red-top vacutainer. After the samples were centrifuged for 15 minutes, the tubes were stored at room temperature. Research personnel collecting blood samples were certified in Occupational Health and Safety Administration blood borne precaution education.

Data Analysis

Data were analyzed using SPSS 16. Descriptive statistics were employed to analyze demographic data. T-tests were used to compare the means of cardiovascular risk factors between male and female. A Pearson product moment correlation (Pearson's *r*) was used to examine relationships between lipid values from the reference laboratory and known cardiovascular risk factors. Cross-tabulations were completed for TC (PLA1) and TC, HDL-C, LDL-C, and TRIG (PLA2) and the reference laboratory TC, HDL-C, LDL-C, and TRIG.

FINDINGS

Demographic data from the 42 participants indicated there was a nearly equal gender mix of men and women; however, one male participant's venous blood sample was lost in transit to the reference lab. The age of the participants ranged from 21 to 88 years with a mean age of 45.1 years for men and 51.4 years for women. None of the participants reported early cardiac death in a first-degree relative. The average number of children of the female participants was 6.5 children. Two of the forty-two participants noted taking prescription medicines for high cholesterol and two other participants noted taking prescription medicines for elevated blood pressure. Four participants noted taking herbs for elevated cholesterol, one participant noted taking herbs for elevated triglycerides, and one participant noted taking herbs for elevated blood pressure. The cardiovascular risk factors of the study participants are shown in Table 1.

The lipid values were categorized according to the National Cholesterol Education Program (NCEP) Adult Treatment Panel III guidelines (NCEP, 2001, see Table 3). Based on these predetermined values, the definition of each true positive, true negative, under-referral, and over-referral for TC, HDL-C, LDL-C, and triglycerides are shown in Table 3. Cross-tabulations of the values (see Table 4) revealed that the PLA1TC had an under referral rate of 33.3% and an over referral rate of 0%. The PLA2TC had an under referral rate of 0% and an over referral rate of 31.7%. For the remaining lipid values the PLA2 had an under referral rate of PLA2 HDL-C, (14.6%), PLA2 LDL-C (0%), PLA2 TRIG (0%) and over referral rates of PLA2 HDL-C (4.9%), PLA2 LDL-C (30.3%), and PLA2 TRIG (2.4%).

Table 1. Cardiovascular Risk Factors of a South Central Kentucky Old Order Mennonite Community By Sex

	Men (n=21) Mean (SD)	Women (n=20) Mean (SD)	t^a
Age, y	45.1 (15.4)	51.4 (18.0)	-1.20
RLTC	198.0 (38.8)	202.7 (32.8)	-0.42
RLHDL	50.6 (10.5)	58.4 (13.6)	-2.06
RLLDL	122.2 (35.6)	119.1 (33.2)	0.28
RL Triglycerides	126.5 (74.8)	125.3 (68.9)	0.05
PLA1 TC	183.8 (26.3)	184.0 (24.5)	-.029*
PLA2 TC	217.6 (60.0)	258.8 (43.1)	-2.56
PLA2 HDL-C	45.6 (15.1)	66.5 (19.2)	2.21
PLA2 LDL-C	159.4 (47.9)	172.7 (34.9)	0.08
Systolic blood pressure	132.5 (11.7)	136.8 (22.3)	-0.78
Diastolic blood pressure	77.9 (7.3)	75.3 (7.0)	1.17
Body mass index	25.7 (4.3)	28.7 (6.9)	-1.68

Note. The age range of participants was 21 to 88 years. [a]Men versus women
* $p < .05$

Table 2. Correlation of Reference Laboratory TC and BMI, Systolic BP, Diastolic BP, Age, and Children

	r^b		r^b
Body Mass Index	-0.01	Age	0.37*
Systolic Blood Pressure	0.25	Number of Children	0.19
Diastolic Blood Pressure	-0.02		

[b]Pearson's *r*
* $p < .05$

Table 3. ATP III Guidelines

	Total Cholesterol	HDL Cholesterol	LDL Cholesterol	Triglycerides
True Positive	RL $\geq$ 200 PLA $\geq$ 200	RL < 40 PLA < 40	RL $\geq$ 100 PLA $\geq$ 100	RL $\geq$ 150 PLA $\geq$ 150
True Negative	RL < 200 PLA < 200	RL $\geq$ 40 PLA $\geq$ 40	RL < 100 PLA < 100	RL < 150 PLA < 150
Under Referral	RL $\geq$ 200 PLA < 200	RL < 40 PLA $\geq$ 40	RL $\geq$ 100 PLA < 100	RL $\geq$ 150 PLA < 150
Over Referral	RL < 200 PLA $\geq$ 200	RL $\geq$ 40 PLA < 40	RL < 100 PLA $\geq$ 100	RL < 150 PLA $\geq$ 150

Table 4. Portable Lipid Analyzer Results by True Positive, True Negative, Under-referral, and Over-referral as Compared to the Reference Laboratory

	PLA1 TC (n = 33)	PLA2 TC (n = 41)	PLA2 HDL (n = 41)	PLA2 LDL (n = 33)	PLA2 TRIG (n= 41)
True Positive	27.3%	48.8%	70.7%	66.7%	22.0%
True Negative	39.4%	19.5%	9.8%	3.0%	75.6%
Under Referral	33.3%	0%	14.6%	0%	0%
Over Referral	0%	31.7%	4.9%	30.3%	2.4%

DISCUSSION

The primary purpose of this study was to examine the accuracy of PLAs for referral in an old order Mennonite community. There were clinically relevant variations in the total cholesterol and LDL-C in both of the analyzers. PLA1 systematically underestimated the TC and PLA2 systematically overestimated the TC as compared to the reference lab. Additionally, thePLA2 systematically overestimated the LDL as compared to the reference lab. The NCEP in the Adult Treatment Panel III has focused on primary prevention in persons with multiple risk factors, specifically aiming to lower the LDL (NCEP, 2001). This recommendation supports the use of PLA2, which provides a complete lipid panel. However, PLA2 is significantly more expensive to purchase and operate. The cost of PLA1 is $217.94 for the monitor and $81.52 for 25 strips (Roche, 2009). The cost of PLA2 is $668.47 for the monitor and $150.00 for 15 strips (Cardiochek, 2009). This economic consideration is most important when providing preventive health services to populations with limited resources such as the old order Mennonites.

A secondary purpose of the study was to examine the relationship of total cholesterol values with other known cardiovascular risk factors. Many large studies have indicated strong association of abnormal lipids with hypertension and elevated BMIs (Brown, et al., 2000; Lloyd-Jones et al., 2009). In this sample, the correlation between the reference laboratory (RL) TC and age (r =.37, p =.009) was the only significant correlation.

In 2006, among the overall US adult population aged 20 years or older the mean age adjusted serum total cholesterol level was 195 mg/dL for men and 201 mg/dL for women (Kilmer et al., 2008). In a study of lipid levels in an old order Amish, Pollin et al. (2004) found that the mean serum TC was 211.9 mg/dL for men and 212.6 for women. In an old order Mennonite community Glick et al (1998) found the mean serum cholesterol for men was 174.3 mg/dL and for women was190.8 mg/dL. In this study, the mean RLTC for men was 198 mg/dL and the mean RLTC for women was 202.7 mg/dL. The prevalence of serum cholesterol values greater than 240 in US Caucasians between the ages of 30 to 50 years ranges from 14 percent to 38 percent (Pencina et al., 2007). In this sample, the prevalence of the RLTC greater than 240 in participants from 30 to 50 years ranged from 3 to 10 percent.

In 2006 the National Health and Nutrition Examination Survey (NHANES) survey identified the prevalence of hypertension (BP ≥ 140 or diastolic BP ≥ 90) in US adults as 29%

(Ostchega et al., 2007) which was equivalent to this population's hypertension prevalence of 28.5%. The NHANES also identified the prevalence of obesity (BMI > 30) in the US population 20 years and older in men as 33.3%, and in women 35.3% (Centers for Disease Control and Prevention , 2009). In this sample the prevalence of obesity in adults 20 years or older is 24%, in men 9.5 %, and in women 38%. Fuchs (1990) found that Amish women have higher rates of obesity in comparison to non-Amish women.

The guiding principles incorporated in this project included the promotion of active collaboration and participation from all partners, the fostering of co-learning, the dissemination of the project results in useful terms, and the use of culturally appropriate interventions (O'Fallon & Dearry, 2002). Initially, during the established community activities, some of the residents posed questions regarding the accuracy of the cholesterol readings obtained from a PLA. The researcher involved in working with the community pursued this. Again, following-up on concerns/request is one way the researcher established trust and acceptance by the community members.

Participants received a copy of their reference laboratory TC, LDLC, HDLC and triglycerides by mail. Those participants with abnormal results also received a recommendation to visit their local health care providers. The results of this study in aggregate were presented to the members of the community prior to any publication. There were many questions from the community and they voted to continue to use PLA1. This model has increased collaboration with community members and providers of services in rural areas. PLAs offer a method to meet the challenges in many rural populations regarding access, cost, and the lack of a defined primary health care provider however; at present, there are limitations to their use. Additionally, the project offered learning opportunities for undergraduate and graduate students. The students were engaged in the process of collecting data and were exposed to the health care beliefs and practices of members of an old order Mennonite community.

Limitations

All participants were Caucasians from an old order Mennonite community in south central Kentucky. This limits the generalizability of these results to a larger population. Additionally, much of the demographic data were self-reported and may have been inaccurate. All finger stick samples were obtained before the phlebotomy for venous samples, which may have introduced a systematic bias. The small sample size also limits generalization to the larger population.

CONCLUSION

More research is needed to understand the variances between portable lipid analyzer measurement and venous samples. The recommendations for practice and education include increasing the health care providers' and students' awareness concerning the rising use of PLAs and their potential of inaccuracy for referral. The venous samples avoid both false positives and false negatives that may be obtained with the use of portable lipid analyzers. In summary, accurately measuring lipid values in hard to access populations is important and PLAs provide an easy to use and rapid determination of lipid values. However, PLAs should not be used to make clinical decisions for diagnosis and management of patients.

AUTHOR NOTE

The authors have no conflict of interest to declare. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

ACKNOWLEDGEMENTS

This study was supported by a grant from the South Central Kentucky Area Health Education Center, which is appreciated. The authors would like to thank those who participated in the study.

REFERENCES

Armer, J.M. & Radina, M.E. (2006). Definition of health and health promotion behaviors among Midwestern old order Amish families. Journal of Multicultural Nursing & Health, 12(3), 44-53.

Bowden, R.G., Kingery, P.M., & Rust, D.M. (2004). Assessing risk using different cholesterol-screening methods. Public Health, 118(3), 225-229. [MEDLINE]

Brown, C.D., Higgins, M., Donato, K.A., Rohde, F.C., Garrison, R., Obarzanek, E., et al. (2000). Body mass index and the prevalence of hypertension and dyslipidemia. Obesity Research, 8(9), 605-619. [MEDLINE]

Campo, S., Askelson, N.M., Routsong, T., Graaf, L.J., Losch, M., & Smith, H. (2008). The green acres effect: the need for a new colorectal cancer screening campaign tailored to rural audiences. Health Education Behavior, 35(6), 749-762. [MEDLINE]

Cardiochek (2009). Products listing. Retrieved June 30, 2009, from http://www.cardiochek.com/products

Centers for Disease Control and Prevention (2009, April). Obesity and overweight. Retrieved June 30, 2009, from http://www.cdc.gov/nchs/fastats/overwt.htm

Dale, R.A., Jensen, L.H., & Krantz, M.J. (2008). Comparison of two point-of-care lipid analyzers for use in global cardiovascular risk assessments. Annals of Pharmacotherapy 42(5), 633-639. [MEDLINE]

Donaldson, A.R., & Andrus, M.R. (2004). Pharmacist-run lipid management program in rural Alabama. American Journal of Health System Pharmacist, 61(5), 493-497. [MEDLINE]

Fisher, K. (2002). Lessons learned while conducting research within an Amish community. Journal of Multicultural Nursing and Health, 8(3), 21-28.

Fuchs, J.A., Levinson, R.M, Stoddard, R.R., Mullet, M.E., & Jones, D.H. (1990). Health risk factors among the Amish: Results of a survey. Health Education Quarterly, 17, 197-211. [MEDLINE]

Glick, M., Michel, A.C., Dorn, J., Horwitz, M., Rosenthal, T., & Trevisan, M. (1998). Dietary cardiovascular risk factors and serum cholesterol in an old order Mennonite community. American Journal of Public Health, 88(8), 1202-1205. [MEDLINE]

Kilmer, G., Roberts, H., Hughes, E., Li, Y., Valluru, B., Fan, A., et al. (2008). Surveillance of certain health behaviors and conditions among states and selected local areas--Behavioral Risk Factor Surveillance System (BRFSS), United States, 2006. MMWR Surveillance Summer, 57(7), 1-188. [MEDLINE]

Kraybill D.B., & Bowman C.F. (2001). On the back roads of heaven: Old Order Hutterites, Mennonites, Amish, and Brethren. Baltimore, MD: Johns Hopkins University Press.

Lantz, P.M., Viruell-Fuentes, E., Israel, B.A., Softyley, D., & Guzman, R. (2001). Can communities and academia work together on public health research? Evaluation results from a community-based participatory research partnership in Detroit. Journal of Urban Health, 78(3), 495-507. [MEDLINE]

Lloyd-Jones, D., Adams, R., Carnethon, M., De Simone, G., Ferguson, T.B., Flegal, K., et al. (2009). Heart disease and stroke statistics--2009 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation, 119(3), 480-486. [MEDLINE]

National Cholesterol Education Program (2001). Third report of the national cholesterol education program expert panel on detection, evaluation, and treatment of high blood cholesterol in adults. Retrieved June 30, 2009, from http://www.nhlbi.nih.gov/guidelines/cholesterol/atp

O'Fallon, L.R., & Dearry, A. (2002). Community-based participatory research as a tool to advance environmental health sciences. Environmental Health Perspectives, 110 Suppl 2, 155-159. [MEDLINE]

Ostchega, Y., Yoon, S.S., Hughes, J., & Louis, T. (2008). Hypertension awareness, treatment, and control-continued disparities in adults: United States, 2005-2006. NCHS Data Brief 3, 1-8. [MEDLINE]

Pencina, M.J., D'Agostino, R.B., Beiser, A.S., Cobain, M.R., & Vasan, R.S. (2007). Estimating lifetime risk of developing high serum total cholesterol: Adjustment for baseline prevalence and single-occasion measurements. American Journal of Epidemiology 165(4), 464-472. [MEDLINE]

Pollin, T.I., Hsueh, W.C., Steinle, N.I., Snitker, S., Shuldiner, A.R., & Mitchell, B.D. (2004). A genome-wide scan of serum lipid levels in the old order Amish. Atherosclerosis, 173(1), 89-96. [MEDLINE]

Rampersaud, E., Mitchell, B.D., Pollin, T.I., Fu, M., Shen, H., O'Connell, J.R., et al. (2008). Physical activity and the association of common FTO gene variants with body mass index and obesity. Archives of Internal Medicine, 168(16), 1791-1797. [MEDLINE]

Roche Laboratories (2009). Product listing. Retrieved June 30, 2009, from http://www.roche.com/products/product-list.htm

Rosamond, W., Flegal, K., Furie, K., Go, A., Greenlund, K., Haase, N., et al. (2008). Heart disease and stroke statistics--2008 update: A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation, 117(4), e25-146. [MEDLINE]

Stein, J.H., Carlsson, C.M., Papcke-Benson, K., Einerson, J.A., McBride, P.E., & Wiebe, D. (2002). Inaccuracy of lipid measurements with the portable Cholestech L.D.X analyzer in patients with hypercholesterolemia. Clinical Chemist, 48(2), 284-290. [MEDLINE]

Taylor, J.R., & Lopez, L.M. (2004). Cholesterol: Point-of-care testing. Annals of Pharmacotherapy, 38(7-8), 1252-1257. [MEDLINE]

U.S. Food and Drug Administration (2009, June 8). Tests waived by FDA from January 2000 to present. Retrieved June 16, 2009, from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/

Wenger, L.M. (2003). Unser satt leit: Our sort of people health understandings in the old order Mennonite and Amish community (Unpublished master's thesis). University of Waterloo, Waterloo, Ontario, Canada.

Young Center for Anabaptist and Pietist Studies, Elizabethtown College (2008). Amish population growth 1992-2008. Retrieved November 1, 2008, from http://www2.etown.edu/amishstudies/