Serum Cholesterol Auto-assay: Catalyst For Dietary Change?

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Abstract

An "over-the-counter," serum cholesterol assay was utilized to determine the motivational effectiveness of obtaining serial data on efforts to reduce dietary saturated fat intake. Assays of cholesterol did not appear to provide any significant ($p \leq 0.01$) motivational impact. Additional research needs to look at self-monitoring's impact on diet composition while addressing the following factors: the duration and reliability of self-reported food inventories and the accuracy of the self-monitoring assay system.

Introduction

Hypercholesterolemia continues to be recognized as a significant contributing factor in cardiovascular and cerebrovascular morbidity and mortality (National Institutes of Health, 1995). While numerous precursors contribute to the evolving etiology of these conditions, excessive dietary saturated fat intake has been recognized as a contributing factor in elevated levels of total serum cholesterol (Angotti and Levine, 1994). Prophylactic dietary interventions encourage the maintenance of a desirable body weight, consumption of dietary cholesterol of less than 300 milligrams per day, and a reduction of saturated fat intake to 8 to 10 percent of daily caloric requirements (The Expert Panel, 1993). Where clinical need is paramount, food consumption patterns can be favorably altered by consumer knowledge and attitudes, perception of success and self-monitoring (Haralson, Sargent and Schluchter, 1990; Barnes and Terry, 1991; Milas, et al., 1995) However, as with many interventions, extended compliance frequently is intermittent and results often short lived (Henkin, Garber, Osterland and Darnell, 1992).

The causes for non-compliance are numerous with insufficient knowledge of intervention outcomes and poor compliance motivation frequently contributors to a lack of long term success (Henkin, et al., 1992; Grundy, 1992). Sustained prophylactic or therapeutic modification of dietary saturated fat intake may be enhanced when opportunities for extended reinforcement and monitoring are available (Henkin, et al., 1992; The Expert Panel, 1988). As proactive cholesterol management efforts continue to be promoted, it may be advantageous to evaluate the motivational effectiveness of easily accessible, over-the-counter, self-analysis materials on efforts to reduce and maintain lower levels of dietary saturated fat. It is hypothesized, that in comparison to non-intervention controls, and subjects receiving only an interpreted two-day diet analysis, participants undergoing periodic self-analysis of total serum cholesterol and nutritional monitoring will elicit a significant ($p \leq 0.01$) reduction in dietary saturated fat intake.

Procedure

Volunteer, matriculating college (n=60) students undertook a 16 week investigation requiring periodic generation of self-reported, two day diet inventories and self-analyses of total serum cholesterol. The experimental design of the investigation required experimental group I to undergo a cholesterol assay and interpreted diet inventory during weeks 0, 4, 8, 12 and 16. Experimental group II received an interpreted food analysis during weeks zero and 16, and the control group completed a pre/post diet inventory but received no interpretation, of either record, until the conclusion of the investigation.

Exclusion criteria for this investigation included pregnant or lactating females; acknowledged cardiovascular, hepatic or gastrointestinal disease; acknowledged history of drug or alcohol abuse and use of medications that impact lipid levels. Participants, randomly divided into two experimental and one control group, provided "socio-demographic" information and completed two day diet inventories that were evaluated for saturated fat content. With the exception of frame size determination, all variables were self-reported. Determination of frame size was based on the mean of two dominant wrist circumference measurements utilizing a technique previously reported (Dennison and Dennison, 1990). Assessment of the self-reported diet records utilized the computerized, nutritional analysis program, The Dine System, and yielded a variety of nutritional data including total

daily calories, percent of daily calories derived from all types of fat as well as percent of calories attributed to saturated fat sources. Mean consumption of saturated fats, for each evaluated period of time, was computed from the percentage of total daily calories attributed to these fats found on each of the two self-reported diet records. At the initial and each subsequent interval when diet inventories were requested and analyzed, all participants, excluding the control group, received a detailed individual consultation that reviewed the results of the analysis, identified evolving trends in serial analyses, addressed desirable percent of daily calories derived from saturated fat and provided multiple strategies for enhancing food selection choices that could reduce dietary saturated fat consumption. Participants in the control group completed a two day diet inventory with results not interpreted until the conclusion of the investigation. In an attempt to reduce qualitative and quantitative variation in weekly food selection, participants were encouraged to consistently generate food records, over the course of the study, from the same chronological period.

Total serum cholesterol was assayed via the use of the Johnson & Johnson' Advanced Care Cholesterol Testing Kit and followed the experimental sequence previously identified. This whole blood, self-assessment technique utilized a self-contained "cassette" that included a blood separation device, a sample measurement system and a mechanism for release of reagents (Allen, DeLizza, Ramel, Jeong and Singh, 1990). The assay was easy to administer requiring only a "finger lance," had a low cost, and was considered accurate with results demonstrating a 0.97 correlation to established clinical methodology (Allen, et al., 1990). Additionally, this technique demonstrated excellent serial reliability yielding a variance in analytical precision of 4.2% (Allen, et al., 1990). Participants received explanations of appropriate collection, analysis and disposal protocols, in both written and verbal form, prior to the completion of each auto-assay of total serum cholesterol, were required to have fasted for at least eight hours prior to assessment and to have been chronologically consistent in their collection protocols. Uniformity of raw data entry was addressed through the use of a single operator for all data management tasks. Statistical analyses utilized measures of central tendency for description of the group as a whole and subsets of data based on experimental design. Analysis of variance methodology identified any significant between group variation and provided the basis for inferential conclusions.

Results

Of the 60 subjects originally recruited for the investigation, only 38, 63 percent of the original sample, completed the 16 week protocol. This high rate of attrition resulted from numerous factors that included 55 percent (n = 12) withdrawing due to an unwillingness to repeat the "finger lance" necessary to acquire a blood specimen, 32 percent (n = 7) withdrawing as a result of concerns over the accuracy of the cholesterol assay results, 9 percent (n = 2) ceasing participation for unknown reasons and 4 percent (n =1) withdrawing due to data submission non-compliance. Future investigations requiring cholesterol self-analysis might address potential attrition by having participants undergo the assays collectively where peer influence might "bolster the courage" of participants reluctant to initiate the collection of a blood specimen and/or by requiring participants to initiate and complete the "finger lance" and assay under the direct supervision and/or with the assistance of a clinician. Additionally, comparing self-analysis cholesterol data with results obtained from "traditional" clinical methodology would serve to address accuracy concerns. Both steps might have a favorable impact on attrition and need to be strongly considered in future investigations utilizing this "over-the- counter" material.

Though conventional practice frequently accepts an experimental cell of 20 (Bruning and Kintz, 1997), diminished numbers will affect the power of statistical tests to a degree that differences may not be detected (Bruning and Kintz, 1997). A post hoc evaluation of sample size utilizing a desired power of 0.95 and both a moderate (0.50) and conservative (0.80) estimation of the "standard effect size" (Cohen, 1977; Bruning and Kintz, 1997) suggested the power of these statistical tests had been weakened and interpretation of and inferences based on these data needs to be viewed very cautiously. Experimental group I, undergoing multiple cholesterol assays and diet analyses, was comprised of 13 individuals, 7 females and 6 males. Ages varied from 18 to 28 years with 92 percent of this sample equal to or younger than 22 years. Fifty-four percent identified their frame size as "medium" and forty- six percent reported their activity patterns as "moderately active," that is, "participating in 10 to 20 minutes of continuous running or 20 to 45

minutes of brisk walking at least three times per week" (Dennison and Dennison, 1990). Group II, composed of 11 females and 2 males, also totaled 13 participants. Exhibiting ages ranging from 18 to 41 years, 69 percent were 22 years or younger. Fifty-four percent identified their frame size as "small," with 69 percent self-reporting activity patterns as "moderately active." The control group, comprised of 5 females and 7 males, totaled 12 subjects. Ages ranged from 18 to 31 years with 75 percent of this group 22 years and younger. A "medium" frame was exhibited by 50 percent of this group and 42 percent reported activity patterns as "moderately active." Additional descriptive data for all groups are found in Table 1.

The results of a one-way analysis of variance indicated no statistically significant between group differences ($p \leq 0.01$). Additionally, an ANOVA with repeated measures, was undertaken to assess the significance of observable, serial change in total cholesterol and saturated fat values. Though modest variation was observed, none proved to be statistically significant ($p \leq 0.01$).

Discussion

A lack of statistically significant change might be attributed to several factors. Insufficient or inaccurate inventory reporting may have contributed to these results. It has been suggested that collection of a two-day food inventory is inadequate to accurately evaluate consumption patterns and nutritional components (Basiotis, Welsh, Cronin, Kelsay and Mertz, 1987). Generation of true group mean data would require three day records for caloric content, six days for total fat and an eight day record for saturated fat consumption (Basiotis, et al., 1987). With the difficulty in acquiring short duration food consumption data with college age subjects (McGowan, et al., 1994), longitudinal collection, without significant incentives, could be a challenge. Also, it can not be discounted that numerous participants were already making food selection choices low in saturated fats, an occurrence that would have an effect on potential magnitude of change. However, mean baseline percent of daily calories derived from fat as well as saturated fat consumption percentages, while close to recommended quantities in the two experimental groups, suggested this did not occur. Further, a lack of meaningful change in body weight, caloric and total fat consumption suggested poor reduced saturated fat dietary adherence.

Additionally, the majority of participants relied on an institutional food service where limited control over selection and preparation was available. While cafeteria food selection includes low-fat products there are frequently an abundance of high-fat and/or "fast-food" style items (McGowan, Joffe, Duggan and McCay, 1994). This coupled with the frequent inclusion of "snacks" in the college-age diet (National Cholesterol Education Program, 1991) may have compromised intervention efforts. Further, Henkin, et al. (1992) have reported that acquiring follow-up diet inventories may result in an effect where subjects temporarily follow a desirably prudent diet. Not only would this compromise the legitimacy of saturated fat data, but could confound cholesterol assay results. Additionally, well documented problems with the accuracy of self-reported data (Bingham, 1987; Black, et al., 1993) might also have contributed to a lack of statistically significant change.

Of major concern to this investigation was the attrition associated with perceived cholesterol data inaccuracy. Thirty-two percent of the 60 original subjects acknowledged concerns over the validity of the self-administered assay results and chose to withdraw. Anecdotally, they related having had clinically evaluated, fasting serum cholesterol assays in their recent, pre- participation medical history, were familiar with those results and noted a substantial variation between self-administered data and those derived from clinical evaluation. Self-perception of success (Milas, et al., 1995) and participant attitude (Barnes and Terry, 1991; Terry, Oakland and Ankeny, 1991) have been identified as key elements in diet modification compliance. If subjects perceived their cholesterol data to be erroneous, though unacknowledged by participants continuing with the investigation, it could have compromised the motivational effectiveness of the self-assay and affected their willingness to initiate or continue dietary fat reduction strategies. Additionally, improper "collection" procedures along with degraded assay materials might also have contributed to these results. Though lucid instructions were provided and only assay materials with acceptable shelf-life were utilized, sample collection and assay administration errors and/or degradation of reagents might account

Table 1. Group Descriptive Data (Mean ± S.E.M.)

Variable	I	II	Control
n	13	13	12
Age (yrs.)	20.77 ± 0.67	24.31 ± 2.09	21.50 ± 1.09
Height (ins.)	67.69 ± 1.08	65.15 ± 0.95	67.83 ± 1.24
Frame Size[a]	2.15 ± 0.19	1.69 ± 0.24	2.00 ± 0.21
Weight - pre (lbs.)	157.18 ± 6.92	133.00 ± 5.10	153.92 ± 8.44
Weight - post (lbs.)	157.00 ± 6.92	133.33 ± 5.37	153.58 ± 8.16
Weight Change (lbs.)	-0.18 ± 0.35	0.33 ± 0.51	-0.33 ± 0.84
Activity Patterns - pre[b]	2.92 ± 0.21	3.00 ± 0.16	3.42 ± 0.29
Activity Patterns - post[b]	2.92 ± 0.21	3.00 ± 0.16	3.42 ± 0.29
Total Calories - pre[c] (kcals.)	2235.69 ± 197.18	1892.39 ± 134.88	2128.67 ± 223.34
Total Calories - post[c] (kcals.)	1345.00 ± 267.71	2196.92 ± 221.66	1907.50 ± 256.23
Mean Total Calories Change (kcals.)	-525.77 ± 211.13	161.62 ± 181.88	-63.83 ± 199.89
Total Fat - pre[c] (%)	34.23 ± 2.18	35.08 ± 2.71	25.42 ± 2.60
Total Fat - post[c] (%)	30.69 ± 4.11	32.31 ± 2.93	28.08 ± 2.09
Mean Total Fat Change (%)	-0.15 ± 3.22	-2.92 ± 2.56	1.67 ± 2.14
Total Saturated Fat[c] - pre (%)	13.85 ± 1.41	14.00 ± 1.06	10.92 ± 0.63
Total Saturated Fat[c] - post (%)	12.69 ± 1.81	12.85 ± 1.25	10.58 ± 1.08
Mean Total Saturated Fat Change (%)	0.85 ± 1.67	-1.15 ± 1.23	-0.33 ± 1.01
Total Cholesterol - pre (mg/dL)	134.62 ± 13.31	---	---
Total Cholesterol - post (mg/dL)	157.31 ± 6.60	---	---
Mean Total Cholesterol Change (mg/dL)	11.08 ± 7.95	---	—

[A]1 = small, 2 = medium, 3 = large

b 1 = very sedentary, 2 = sedentary, 3 = moderately active, 4 = active, 5 = very active

c Developed from mean data from individual 2 day food record analyses.

for perceived data errors. While fiscal limitations precluded a comparison of self-administered results with those obtained via clinical assay or a test-retest evaluation of reliability, the validity and reliability of self-administered serum cholesterol data needs to be addressed in a non-clinical, non-laboratory environment before inherent inaccuracies in these auto-assessment materials can be discounted.

Several additional factors, not addressed in the experimental design, might have presented confounding influences. Though self-reported activity data remained unchanged over the duration of the investigation, 52% of all participants labeled themselves as "moderately active," that is, participating in 10 to 20 minutes of continuous running or 20 to 45 minutes of brisk walking at least three times per week. This categorization, while addressing duration of effort, does not account for intensity of effort which may have had an impact on lipid utilization (Saltin and Karlsson, 1971; Sink, Thomas, Araujo and Hill, 1989). Also unaccounted for were the influences of "occupational" stress (Muldoon, et al., 1992; Siegrist, Peter, Cremer and Seidel, 1997) and water-soluble dietary fiber (Jensen, Haskell and Whittam, 1997) both of which can affect serum cholesterol.

Conclusions

Although limited by a small sample and a high rate of participant attrition, the following conclusion appears justified. Serial assays of serum cholesterol utilizing easily accessible, "over-the-counter," self-analysis materials do not appear to provide any significant motivational impact on efforts to reduce and maintain low levels of dietary saturated fat. While these results suggest no linkage between knowledge of serum cholesterol levels and management of dietary saturated fat intake, these findings need to be viewed as preliminary until addressed in subsequent inquiries. The focus of additional research might, again, look at self-analysis cholesterol monitoring' impact on diet composition while addressing the following factors: participant retention, the duration and reliability of self-reported food inventories and the accuracy of the self-monitoring assay system. Most critical to subsequent investigations is the confirmation of cholesterol assay validity.

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