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Audit and feedback to improve the management of dyslipidemia in primary care in Jamaica: A randomized controlled trial

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ABSTRACT

Background

Dyslipidemia is a major risk factor for cardiovascular disease. There is little documentation about dyslipidemia among patients attending public primary care clinics in Jamaica. This study reports on an intervention to improve the management of these patients.

Methods

500 records of patients with chronic diseases from six randomly selected health centers were audited in 2012. An intervention comprising feedback from audit, staff training in motivational interviewing, a reminder stamp in patients' records and patient education cards was conducted over 12 months at 3 intervention health centers. 250 patient charts were from 3 control health centers. All 500 patient records were re-audited one year later. Primary outcome was improved LDL control. Differences between intervention and control groups at baseline were tested using Pearson's χ^2 and student t tests. Within group differences at re-audit were tested using McNemar χ^2 and paired t-tests. Differences in lipid control were assessed using mixed effects logistic regression. Multi-level mixed effects analysis of variance models assessed for differential changes in lipid levels from baseline to re-audit.

Results

At baseline 21.7% of intervention and 14.2% of control patients achieved LDL targets (p = 0.143). Patients had a mean of 2.8 clinic visits during the intervention year. At re-audit, LDL increased by 0.34 mmol/L in the intervention group (p < 0.001), and by 0.15 mmol/L among the controls (p = 0.19).

Conclusions

There was no improvement in LDL control at re-audit. The study however provided useful information about lipid control among primary care patients in Jamaica.

Keywords: Dyslipidemia, Audit, Cardiovascular Disease, Jamaica

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INTRODUCTION

Cardiovascular diseases are a leading cause of death and disability in Jamaica.[1] Much of the cardiovascular diseases (CVD) are considered preventable. There are a number of risk factors for CVD which include non-modifiable factors such as age and sex, and modifiable factors such as hypertension, diabetes mellitus, smoking, sedentary lifestyle, poor dietary habits, dyslipidemia, and alcohol consumption. Dyslipidemia is estimated to

contribute to 50% of all myocardial infarction[2] and to 25% of strokes[3] worldwide.

The prevalence of high total cholesterol is 11.7% among Jamaicans aged 15-74 years[4] and it varies by age and sex; among males from 1% among 15 to 24 year olds to 17.7% in those 65 to 74 year old and in females from 7% among the 15 to 24 year olds to 32% among those 55 to 64 years of age.[4]

Failure to achieve lipid treatment goals is widespread in both developed and developing countries [5]. In the Dyslipidemia International Study (DYSIS), 63% of all patients and 55% of the high risk patients from Canada achieved their LDL goal.[5] In the Middle East, 44.5% of the total group and 30.5% of those at very-high risk achieved the LDL goal[6], while in the United Kingdom 63% of all the patients achieved the LDL goal.[7]

Proper control and management of dyslipidemia can reduce the burden of CVD and effective therapeutic agents are readily available. The health care services have an important role to play in providing quality care to persons at risk. The clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria.[8] The evidence about the effectiveness of audits and feedback as an intervention to improve quality is mixed. Some suggest that audit and feedback are effective in the short term and when combined with other approaches.[9] Others state that the effect is likely to be greater in settings where baseline adherence to recommended practice is low, and when feedback in delivered more intensively.[8, 10] Intensive feedback involves that which is given in a written format by a supervisor or senior colleague and is specific to the party involved.[8, 11]

The use of combined or multi-faceted interventions including provider reminders, incentives and educational training together with patient level interventions such as patient education materials, had mixed review with some authors reporting an increased effect. They however reported no increase in effectiveness of the audit and feedback alone.[9, 10, 12] Others reported that evidence for interventions to change provider behaviour in developing countries was limited or flawed due to poorly designed research and advocated for more stringent research in this area to be conducted.[8, 11]

The objective of the study was to assess the effectiveness of an audit and feedback intervention to improve the control of dyslipidemia among patients attending primary care clinics in the public health services in Jamaica.

METHODS

This was a cluster randomized controlled trial with the health center as the unit of randomization. This study was conducted within the South East Regional Health Authority (SERHA) one of four Regional Health Authorities that are responsible for the delivery of health care in the public sector in Jamaica. Health centers were included if they had at least 2 weekly chronic disease clinics and a full time medical records clerk assigned. Health centers located more than 60 minutes by road from the Kingston metropolitan area or those with an ongoing diabetes intervention were excluded. Of the 89 health centers within SERHA, 20 met the eligibility criteria. Six health centers were randomly selected and three assigned to be either an intervention or control site. Each eligible health center was assigned a number in sequence and the numbers randomly chosen from a bag of numbers.

The sample size calculations were based on an estimated 40% control level among patients with diabetes attending primary care clinics in Jamaica.[13] Assuming that lipid control in the population is marginally higher than the level of control of diabetes, lipid control is estimated to be 45% at the time of the first audit. In keeping with the hypothesis it was expected that by the end of the study 55% of patients in the intervention group and 47% of patients in the control group will have their total cholesterol controlled. Assuming that the correlation between the repeated cholesterol measurements is 0.3 for all measurements and 8% is the smallest meaningful difference between control proportions for groups A (intervention) and B (control) the number of participants needed for each group is 120. This calculation is based on formula provided by

Diggle et al 2002,[14] for binary outcomes and used a type 1 error probability of 0.05, power equal to 0.8, and 2 measurements per participant. Since the health center was used as the cluster and to compensate for the effect of clustering, the sample size was adjusted using a design effect of 1.06. An item non-response effect of 20% was applied to the sample size calculation in anticipation of information missing from some medical records. The sample size was calculated to be 120 for each group but this was increased to 250 participants each from group in order to facilitate sub-group analyses.

Medical records from each clinic were selected for audit with numbers being proportional to the number of patients that were seen annually. Records of patients 18 years or older who attended the clinic for at least 18 months were eligible to be audited. Three research nurses were trained to collect the audit data using the audit instrument. The medical records officer identified the clinical records of the patients seen on the day of the audit and the research nurse included every second clinical record if that patient met the inclusion criteria. The baseline audit was conducted between October and December of 2012. There was no blinding of the researcher or the data collection team.

The audit criteria were derived from the Ministry of Health MOH 2007 guidelines for the management of hypertension and diabetes. The cut points used to assess for lipid control were for total cholesterol < 5.2 mmol/L; LDL < 2.6 mmol/L; HDL > 1.1 mmol/L in men and HDL >1.3 mmol/L in women and triglycerides <1.7mmol/L. There were process of care measures recommended to be done at the initial visit, at each visit or annually. This paper will only report on the achievement of lipid targets.

The intervention comprised of feedback of the findings of the baseline audit, training of practitioners in motivational interviewing, a reminder stamp in the patient records, and distribution of patient education cards. Monthly visits by the researcher to the intervention clinics were planned. The re-audit was conducted on the same patient dockets between November and December of 2013. The primary outcome was improved LDL control.

The data were analyzed using Stata 13 statistical software. Patient characteristics, outcomes and process of care measures at baseline for intervention and control groups were tested for differences using Pearson's χ^2 and student t tests. Within group differences at re-audit were tested using McNemar χ^2 and paired t tests. Differences in lipid control were assessed using mixed effects logistic regression. Multilevel mixed effects analysis of variance models assessed for differential changes in the continuous biomedical indices from baseline to re-audit.

Ethical approval to conduct this study was received from the UWI Ethical review board Ref. Number ECP 218, 11/12. The study was registered at Clinicaltrials.gov with Identifier: NCT02438943

RESULTS

A total of 500 patient dockets were screened at baseline, 250 from the intervention and control groups respectively. The patients' ages ranged from 24 to 98 years and the median age was 65.2 years for the intervention group and 66.2 years the control group. (Table 1)

There were no significant differences in baseline characteristics of the patients in the intervention and control groups except with respect to the use of aspirin (61.6% vs 48.8%, p < 0.005). Dyslipidemia was diagnosed in 48.0 % and 44.4% of the patients while more than 90% had hypertension and 52% and 45.2 % of the intervention and control groups respectively had diabetes. Heart disease, stroke and peripheral vascular disease were diagnosed in smaller proportions of these patients. Smoking and alcohol used were reported in less than 10 % of the patients. Statins were prescribed for 46% of these patients, while over 90% were given oral antihypertensive medications and 45% and 40% of the intervention and control patients were prescribed oral diabetic medications.

Table 1 Baseline Characteristics of the Patients by Intervention Group

Characteristic	Intervention		Control	
Age (years)				
Median (IQR)	65.2 (54.3-72.6)		66.2(55.5- 73.2)	
Sex	**no.**	**%**	**no.**	**%**
Females	155	62	162	64
Medical history				
Hypertension	227	90.8	236	94.4
Diabetes Mellitus	130	52.0	113	45.2
Dyslipidaemia	120	48.0	111	44.4
Heart disease	16	6.4	15	6.0
Stroke	16	6.4	13	5.2
PVD	51	20.4	40	16.0
Hypertension and DM	110	44.0	99	39.6
Prescribed Medications				
Antihypertensives	225	90.4	234	93.6
Insulin	27	10.8	25	10.0
Oral hypoglycaemic	113	45.2	100	40.0
Statins	115	46.0	114	45.6
Aspirin	154	61.6	122	48.8**
Other characteristics				
Current smoker	13	5.2	16	6.4
Alcohol use	13	5.2	15	6.0

Lipid control:

Only 221 patients (115 patients in the intervention group and 106 in the control group) had one fasting lipid test done within twelve months of their most recent clinic visit and these were the tests included in the analyses (Figure 1). LDL targets were achieved among 21.7% of the intervention and 14.2% of the control group, total cholesterol (TC) target was achieved in 51.3% of the intervention patients and in 55.7% in the control group while most patients were at goal for HDL (75.7% and 76.4%) and triglycerides (87% and 82.1%). The mean LDL values were above goal in both groups while the mean values were within normal range for total cholesterol and triglycerides (Table 2). There were no significant differences among patients in the control and intervention groups.

There was no harm or unintended effects to the participants from either of the two research groups. Feedback on the baseline audit and training in motivational interviewing for all of the health care providers at the intervention sites was done. Reminder stamps were placed in the patient charts and patient education cards were distributed. Patients in the intervention group had a mean of 2.8 visits to the health center during the intervention period. Most had 2 or 3 visits but number of repeat visits ranged from none among 27 (5%) of patients, to 10 visits by one patient. There were 94 sets of paired data (48 from the intervention and 46 from the control patients) available for analysis after the re-audit (Figure 1). There were no improvements in the level of control of the various lipids fractions among patients in the intervention or control groups (Table 3). The mean LDL increased by 0.34 mmol/L among the patients in the intervention group while the mean HDL increased by 0.23 mmol/L in the control group (Table 4).

Using the mixed effect logistic model and reporting the effect as odds ratios, it was predicted that patients in the intervention group were 84% less likely to achieve their LDL target at the time of the re-audit than those in the control group (Table 5).

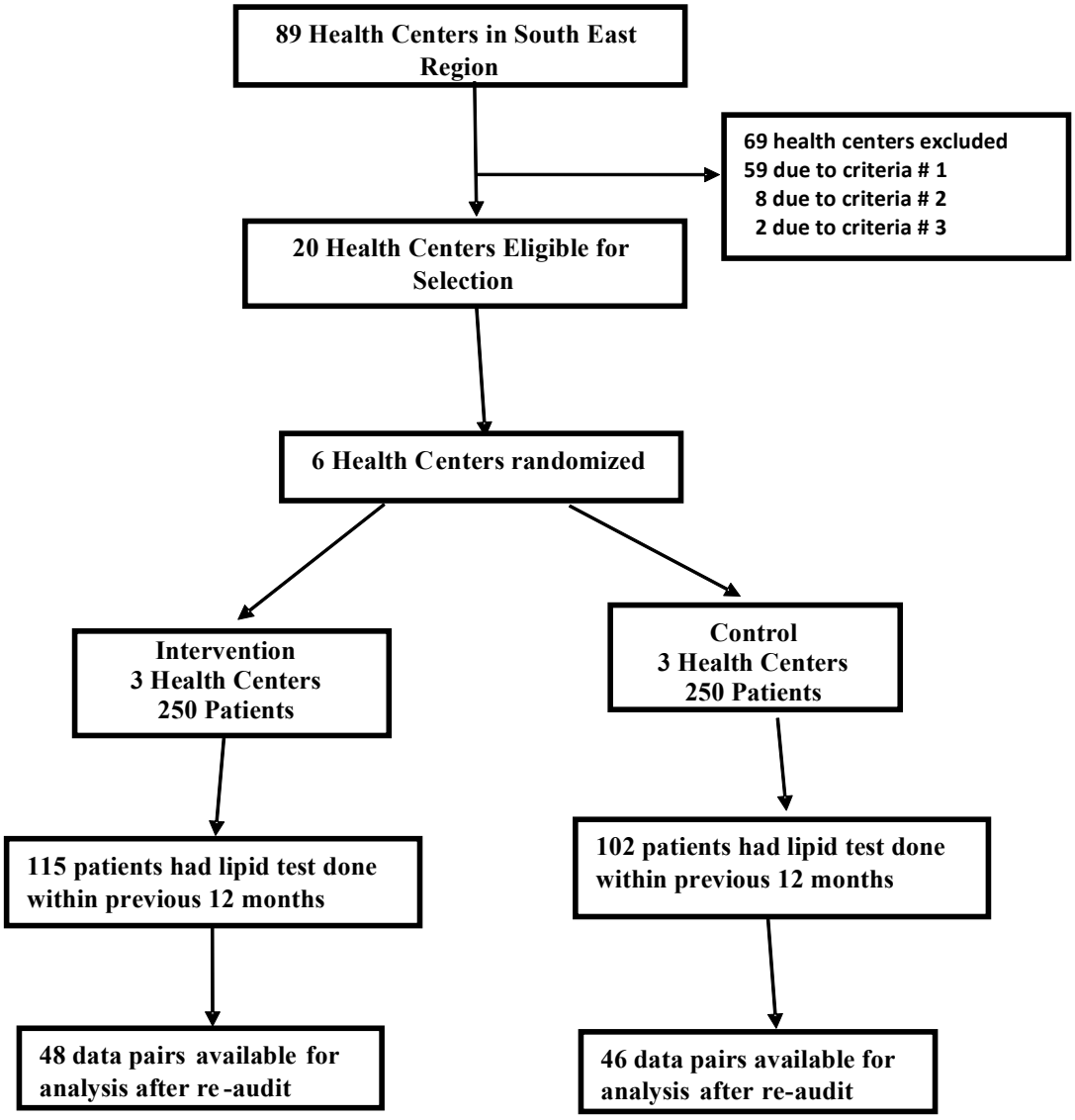

Figure 1 Flow Diagram Showing the Selection of Patient Records for Auditing

Table 2 Baseline Levels of Control and Mean Values of Lipids Fractions

Outcome	Intervention			Control		
Levels of control	**n**	**%**	**95% CI**	**n**	**%**	**95% CI**
TC	59/115	51.3	42.2, 60.4	59/106	55.7	46.2,65.1
LDL	25/115	21.7	14.2, 29.3	15/106	14.2	7.5, 20.8
HDL	87/115	75.7	67.8, 83.5	81/106	76.4	68.3, 84.5
TG	100/115	87.0	80.8, 93.1	87/106	82.1	74.8, 89.4
Mean Values	**n**	**mean**	**95% CI**	**n**	**mean**	**95% CI**
TC	114	5.14	4.95, 5.33	106	5.03	4.84, 5.22
LDL	105	3.29	3.06, 3.53	90	3.38	3.19, 3.57
HDL	104	1.65	1.48, 1.81	91	1.48	1.31,1.65
TG	114	1.16	1.07, 1.24	105	1.19	1.07,1.32

Units for TC (total cholesterol), LDL (low density lipoproteins), HDL (high density lipoproteins) &TG (triglycerides) are mmol/L

Table 3 Change in Control Levels and Mean Values of Lipids from Baseline to Re-audit

	Intervention		Control	
	Change in levels of control			
	% change	95% CI of change	% Change	95% CI of change
TC	-6.3	-18.6,5.9	7.1	-8.5,22.8
LDL	-11.1	-24.4,2.2	-3.6	-16.4,9.2
HDL	-1.6	-12.5, 9.3	-1.8	-16.2,12.6
TG	-6.3	-18.6,5.9	3.6	-8.1,15.2
	Change in mean values			
	mmol/L	95% CI	mmol/L	95% CI
TC	0.00	-0.13,0.13	-0.02	-0.15, 0.11
LDL	0.18	0.00,0.36	0.08	-0.08, 0.25
HDL	-0.13	-0.29,0.04	-0.15	-0.28,-0.02
TG	-0.00	-0.06, 0.05	-0.03	-0.10,0.04

Table 4 Change in Mean Outcomes from Baseline to Re-audit, Adjusted for Age, Sex, BMI and Baseline BP Value

	Intervention group		Control group	
	Change (mmol/L)	95% CI	Change (mmol/L)	95% CI
TC	0.03	-0.13,0.18	-0.03	-0.19,0.12
LDL	0.34	0.14,0.54***	0.15	-0.06,0.36
HDL	-0.15	-0.34,0.04	-0.23	-0.42,-0.03*
TG	0.03	-0.04,0.1	-0.07	-0.14,0.00

*p< 0.05 *** p < 0.001

Table 5 The Predictor of Control of the Lipid Fractions: Re-audit vs. Baseline

	Intervention		Control	
	OR	95% CI	OR	95% CI
TC	0.46	0.15, 1.44	3.05	0.91, 10.25
LDL	0.16	0.04,0.62*	0.53	0.12,2.35
HDL	0.78	0.22,2.72	0.83	0.22,3.17
TG	0.32	0.09,1.18	2.32	0.51,10.50

* $p < 0.05$

DISCUSSION

At the time of the re-audit there were no significant changes in the proportions of patients from either intervention or control group that achieved their lipid goals. There was a marginal but not statistically significant increase in the number of patients from the control group that achieved their total cholesterol and triglyceride goals. This seems to indicate that there was no effect of the intervention but that any changes observed were probably due to chance.

With the reduced sets of paired data available for analysis the power of the study to show an effect was compromised. Other factors also contributed to the negative findings. The feedback given was not specific, but general to all of the members of staff. The feedback was also not intensive as the supervisors were not present at 2 of the three feedback sessions and with limited supervision and accountability some staffs were not prepared to make the changes that could improve patient outcomes. There were also patient factors such as non-adherence to the recommendations of the staff as well as inadequate resources to enable both the staff and the patients to fulfil their responsibilities such that a demonstrated effect would be evident.

The low level of LDL control observed among the patients in this study was so even though of the 239 patients who were diagnosed with dyslipidemia, 224 (93.7%) were prescribed an oral medication which was usually a statin. In other studies it was the LDL lipid fraction for which the majority of patients had achieved control.[15]

The DYSIS studies have demonstrated that the proportion of persons achieving their lipid goals was related to their level of CVD risk[6, 16] with the high risk patient being less likely to achieve their lipid goals. The proportions of patients that achieved their LDL goal in this present study was even less than among patients who are considered to be of high or very high risk in these other locations. The risk profile of patient is not routinely conducted but this seems to suggest that many of the patients seeking care in the primary care setting could be considered to be of high CVD risk.

Poor attainment of lipid control has been attributed to the under diagnosis of dyslipidemia and suboptimal use of lipid lowering therapies in other studies[5, 17] and these may have been also played a role here. However patient adherence with medications and lifestyle modifications were not ascertained in this study. This low level of lipid goal achievement is a matter that should be addressed in the short term if we are to reduce the burden of cardiovascular diseases in Jamaica. It would be useful to conduct a prospective study to investigate this further.

As dyslipidemia is an important risk factor for CVD, primary care patients should be monitored routinely in the same way that hypertension and diabetes are monitored. National guidelines on the management of dyslipidemia should be developed, disseminated and implemented. An adequate mix of staff and the resources needed to deliver the appropriate level of care to the patients must be made available. The staff should then be held accountable to deliver the time and quality of service that they are contracted to offer. Any similar study that is done in the future should include the commitment of the staff and their supervisors to make the necessary changes after the feedback is given as well as an assessment of the patient adherence.

LIMITATIONS

The power of the study and its ability to observe an effect of the intervention was reduced as only 44% of the lipid tests were done within twelve months of the patients' most recent clinic visit could be included in the baseline analysis. Also only paired data could be used to assess for changes at re-audit. Finally as the repeat blood tests that were used to evaluate the benefit of the intervention were done a mean of 5 months after the start of the intervention, the study effectively reported on the results after approximately five months of intervention.

CONCLUSIONS

The intervention did not show an effect. This could be due mainly to the reduced pairs of data available for the analysis that reduced the power of the study. The study however provided baseline information on the levels of lipid control among patients in the primary care setting in Jamaica and useful insight into the organizational and human resource issues that affect the level of care being offered to these patients.

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