Original Research

A community pharmacy-based cardiovascular risk screening service implemented in Iran

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INTRODUCTION

Cardiovascular disease (CVD) is the major cause of nearly 17 million deaths per year, which makes it one of concerns of health around the world. In Iran, a developing country with limited resources, CVD mortality rate continues to rise and is responsible for approximately half of all deaths. Reduction of CVD events and CVD-induced mortality is the primary goal of CVD prevention. Several studies have shown a significant rise in CVD risk factors in younger adults. Dyslipidemia, tobacco use, diabetes, hypertension, abdominal obesity, psychological factors, physical inactivity, frequent alcohol use, and diet account for approximately 90% of myocardial infarction risk in genders and all age groups around the world. However, serious outcomes can arise when patients are inappropriately monitored. It has been found that at least 25% of patients with CVD experience sudden death or non-fatal myocardial infarction without prior knowledge or symptoms of their pre-existing condition.

Screening programs have been shown to detect high risk patients with early disease development and guide them toward controlling modifiable risk factors. As a result, CVD morbidity and mortality can be reduced. In an Australian study from 1968 to 2000, an 80% decrease in CVD mortality rate was observed through reduction of three risk factors (blood pressure, cholesterol, and tobacco use).

Based on recommendations of many studies on CVD risk management, screening programs should include asymptomatic patients with risk factors such as smoking, obesity, high blood pressure, and cholesterol.

In general, screening is implemented for diseases with high prevalence and slow progress. Detection is highly dependent on the accessibility of diagnostic tests, behavioral management, and pharmacological interventions.
practice, but some patients rarely visit their primary care provider. Other strategies are needed to improve screening techniques. Community pharmacists are highly accessible health care professionals with knowledge and expertise in the management of CVD risk factors. Patients will often seek healthcare advice from pharmacists.

The role of community pharmacists in screening and health improvement programs have been investigated in developed countries. Community pharmacies are ideal sites for detection, education, and referral of high risk individuals with CVD. Mangum et al. highlighted the beneficial role of community pharmacies in screening for CVD and referral to physicians. It is also important to note that these pharmacy-based screening programs are not designed to replace the role of the physicians in primary cardiovascular care. Aim of the study

This study was designed to assess the feasibility of implementing a pharmacy-based CVD risk screening service in a referral pharmacy in Iran. The outcome of referring asymptomatic high risk population was also investigated.

METHODS

Study design

We designed a cross sectional study to explore the community pharmacist’s capacity for screening patients at risk for CVD. The protocol was approved by the Research Center for Rational Use of Drug, Tehran University of Medical Science.

Setting

This study was performed in 13-Aban Pharmacy, affiliated with the pharmacy faculty at the Tehran University of Medical Sciences. This site is one of the referral pharmacies in Tehran, the capital of Iran. The ‘Pharmacotherapy Consultation Clinic’ within the pharmacy area was used to provide a private space for CVD risk screening with minimal interference to routine pharmacy processes. Posters advertising free healthy lifestyle consultation and cardiovascular risk assessments were placed at the pharmacy entrance.

Population

Individuals could participate in study without an appointment every morning (9 AM to 2 PM on working weekdays) over four months of June to September 2014. The participants consented to enter the study and signed a consent form at first. The total daily requests were 6 and on average, three participants were eligible to enter the study daily.

Inclusion criteria

To be eligible for participation in this study, patients were required to be: 30-75 years old, without a prior diagnosis of diabetes or CVD, and without glucose or lipid test within three months. The investigator was a pharmacy student who had finished all pharmacy courses according to pharmacy curriculum except thesis.

Data collection and Risk factor assessment

The participants were asked about their age, sex, level of education, living region, current medications, medical and family history, smoking habit, physical activity, and consumption of herbal or dietary supplements.

The investigator, measured patient’s height, weight, waist circumference, blood pressure, random blood glucose level (RGL), total cholesterol (TC), and high density lipoprotein cholesterol (HDL) levels. (Table 1) HDL, total cholesterol levels, and BGL were obtained by capillary blood samples. Body mass index (BMI) and its classification was also calculated. Participants’ waist circumference was measured in a standing position after a normal exhalation using a flexible tape on the top of the iliac crest. The cut-offs for waist circumference in case of positive CVD risk was 102 cm for men and 88 cm for women. The accuracy and assurance of Cardiocheck and Accu-check devices has been previously confirmed.

Based on participants blood glucose values and fasting (last meal ≥ 8 hours) or non-fasting (last meal < 8 hours) status, they were classified into four different categories: normal blood glucose (<100 mg/dL for fasting and non-fasting), diabetes status indeterminate (100-200 mg/dL for non-fasting), impaired glucose tolerance (100-126 mg/dL for fasting), and diabetes (≥126 mg/dL for fasting; ≥200 mg/dL for non-fasting).

The whole screening time was about 30 minutes for each patient. All participants received a 10 to 15 minute recommendation about diet, weight management, physical activity, and tobacco cessation to reduce their modifiable risk factors. In addition, printed education materials (3 flyers about CVD, diabetes, and dyslipidemia) were also provided for the participants. The investigator provided a brief lifestyle advice to people who requested for the screening service and were not eligible to be recruited in the study.

Referral criteria and follow up

Participants were recommended to visit their physician if they had one of the following criteria: an estimated CVD Framingham risk factor above 20%, BP greater than 140/90 mmHg, TC equal to or greater than 200 mg/dL, HDL-C lower than 40 mg/dL, and BGL greater than 100 mg/dL for fasting or 200 mg/dL for non-fasting. A special referral letter

| Parameters | Referral criteria | How measured |
|------------|------------------|--------------|
| 10-year cardiovascular risk | High risk (score >20%) | Framingham Cardiovascular Risk Calculator* |
| Resting Blood pressure | BP > 140/90 mmHg | Measured twice through the right arm with a minimum interval of 10 minutes by OMRON DIGITAL MONITOR (M6 COMFORT). |
| Lipid Profile | HDL <40 mg/dL Total cholesterol ≥ 200 mg/dL | Analyzed with a lipid value analyzer (CARDIOCHEK PA, PTS DIAGNOSTICS). |
| Blood Glucose | BGL >100 mg/dL for fasting or BGL >200 mg/dL for non-fasting | Analyzed with a glucometer (ACCU-CHECK PERFORMA, ROCHE). |
signed by a clinical pharmacist was designed to provide a summary of the screening results.

After one month, the investigator telephoned all the individuals who received a referral letter. The following outcomes were assessed: 1) follow up with physician, 2) physician plan for further work-up and treatment, and 3) life style modifications. Two attempts were made to contact referred individuals.

Data analysis
We used descriptive statistics to investigate the demographic characteristics of the study population. Chi-squared, t-test and ANOVA were used to analyze possible associations between variables. Data were analyzed using SPSS. 22 and a p-value lower than 0.05 was considered as statistically significant.

RESULTS

Table 2. Cardiovascular risk screening results

| Parameter | Value |
|-----------|-------|
| Age (mean [SD]) years | 30–39 10 (36.5%) |
|                  | 40–49 10 (29.1%) |
|                  | 50–59 60 (20.9%) |
|                  | 60–75 50 (17.4%) |
| Education n (%) | academic education 125 (43.5%) |
|                  | under diploma 40 (13.9%) |
| Drug History n (%) | anti-hypertensive agents 40 (13.9%) |
|                  | lipid lowering drugs 63 (12.5%) |
| FBG (mean [SD]) | 103 (19) mg/dL |
| random BGL (mean [SD]) | 110 (20) mg/dL |
| SBP (mean [SD]) | 116.7 (5.7) mm Hg |
| DBP (mean [SD]) | 79 (10) mm Hg |
| TC (mean [SD]) | 164 (39) mg/dL |
| HDL-C (mean [SD]) | 41 (11) mg/dL |
| Framingham score (%) | 7.8 (9.7) |
| low risk (score ≤10) | 222 (77.5%) |
| moderate risk (10< score ≤20) | 39 (13.5%) |
| high risk (score ≥20) | 26 (9%) |
| BMI | overweight (BMI of 25–30) 130 (45%) |
|      | obese (BMI ≥30) 71 (24.7%) |
| Physical activity | moderate 71 (24.7%) |
|      | heavy 30 (10.5%) |

Two hundred and eighty-seven subjects were recruited in the study. The majority of participants were men (69.7%). Patients were screened from all 22 regions of Tehran, but most of them lived in region six where pharmacy was located. The demographic information and laboratory parameters have been summarized in Table 2.

A total of 146 individuals (50.8% of those screened) received a referral letter to seek advice from their physician. Among them, low HDL-C was the most common risk factor (76%) followed by high TC (34%), increased DBP (22%) and SBP (15%), high FBG (15%), and a 10-year risk factor greater than 20% (9%). The results of the cardiovascular risk factor screening have been demonstrated in Table 3. Among patients who were referred to a physician for a SBP >140 mm Hg or a DBP >90 mm Hg, 12 (30%) individuals had a previous diagnosis of hypertension and were already taking antihypertensive medications. In the study population, 2.4% had suspected diabetes and 5.2% had impaired glucose tolerance (IGT).

During the follow up, 132 participants out of 146 high-risk individuals were contacted via telephone. The reasons for unsuccessful follow up in the remaining 14 people were because of missing telephone numbers or missed calls after two attempts. Among those contacted, 71 participants (54%) discussed their health screening results with physician. Of the visited patients, 21 (15.9%) were recommended to change their lifestyle, and 21 (15.9%) individuals received underwent drug therapy (Table 4).

Further analysis revealed a significant difference between gender and physician visit rates (p=0.009, 59.4% of men versus 30.8% of women). More than half of the individuals (62.2%, 90 patients out of 132) reported that they had one or more lifestyle changes. The most common alteration was dietary modification (Table 5). Comparison of parameters based on gender has been illustrated in Table 6. In regard to smoking, systolic and diastolic blood pressure, mean Framingham score, and fasting blood glucose, there were significant differences between two groups (p<0.001) and

Table 3. Cardiovascular risk screening results

| Risk parameters | Num. (%) |
|----------------|---------|
| 10 year risk factor ≥ 20% | 26 (9%) |
| Systolic blood pressure ≥ 140 mmHg | 32 (11.1%) |
| Diastolic blood pressure ≥ 90 mmHg | 22 (7.6%) |
| Total cholesterol ≥ 200 mg/dL | 50 (17.4%) |
| HDL-cholesterol ≤ 40 mg/dL | 108 (36.7%) |
| Blood glucose level (randomly) ≥ 200 mg/dL | 7 (2.4%) |
| Blood glucose level (fasting) ≥ 100 mg/dL | 15 (5.2%) |
| Smoker (current) | 52 (18%) |
| Body mass index ≥ 25 kg/m2 | 201 (72%) |
| Raised waist circumference of | 74 (37%) |
| Men (≥ 102 cm) | 66 (75.8%) |
| Women (≥ 88 cm) | |
| Total | 140 (48.7%) |
| Family history of CVD | 134 (46.7%) |

Table 4. Report of 132 subjects referred to physician after one month

| Did not discuss results with the physician | Num. (%) |
|------------------------------------------|---------|
| Discussed with doctor and were doing their laboratory test | 10 (7.6%) |
| Discussed with doctor and were given life style change advice | 21 (15.9%) |
| Discussed with doctor and drug therapy was started/change | 21 (15.9%) |
| Discussed with doctor and no action was done by the physician | 4 (3%) |
| Were in waiting list for visits to the physician | 15 (11.4%) |

Table 5. Change in lifestyle after one month follow up of high risk group

| Risk factors | Number (%) |
|--------------|------------|
| Started a regular exercise program | 50 (37.8%) |
| Started on a weight loss program and went on diet | 44 (33.3%) |
| Changes in dietary habits | 79 (59.8%) |
| Reduced salt intake | 23 (17.4%) |
| Reduced saturated fats | 63 (47.7%) |
| Reduced consumption of sugar | 20 (15.2%) |
| Increased consumption of fruit and vegetables | 18 (13.6%) |
women had lower measures than men. However, the HDL was considerably higher in female group (p<0.001).

**DISCUSSION**

Screening programs are implemented for prevalent disease states with silent progression such as cardiovascular disease and have been shown to successfully identify high risk populations in order to prevent subsequent complications. To our knowledge, this is the first study to evaluate a community pharmacy-based CVD screening service in Iran. Our study focused on pharmacy clients without previously diagnosed CVD or diabetes. This study intended to examine the CVD risk profile of participants and the number of referrals by pharmacist in order to provide further insight into the effectiveness of these services.

About half of the participants (50.8%) had at least one risk factor for CVD and were referred to a physician. Considering the exclusion criteria in this study (diagnosis of diabetes, hypertension, or recent glucose or lipid test), the majority of elderly population were not eligible to participate. Additionally, because there was no high risk Framingham score in the age category 30-39 years old, the Framingham total score (9%) was less than similar studies reporting a range of 17.8%–35%. Particularly Hunt et al. used the Framingham score to identify 18% of the study populations as high-risk in their screening in the UK.

Our study reported a high prevalence of impaired HDL and total cholesterol level. More than one-third of participants had dyslipidemia. Azizi et al. and Hosseini et al. have warned about lipid abnormalities especially low HDL compared to other risk factors in an Iranian population. Abundance of low HDL in Iranian population might be due to several elements including genetics, obesity, minimal physical activity, and high-carbohydrate diets.

Moreover, our results showed that screening services can identify individuals who may require hypertension therapy changes. Our study proposes a 32% prevalence of uncontrolled pre-diagnosed hypertension among all treated hypertension patients. Zillich et al. in HOME study proved the effectiveness of a community pharmacist-based blood pressure monitoring program in patients with uncontrolled blood pressure. Similar studies found that blood pressure control is improved when community pharmacists intervene through patient education, blood pressure monitoring, drug therapy management, and medication adherence.

Several studies have approximated the awareness and treatment of hypertension in an Iranian population around 50% and 35%, respectively, while the rate of hypertension is lower than 16% due to accessibility of pharmacies, the short screening process, and increased attention to drug histories, launching a screening service in pharmacies could improve hypertension awareness and control.

According to the Diabetes Federation, 1.5 million of Iranian adults suffer from diabetes. This corresponds to a prevalence of 7-17% in several adult urban populations and nearly 50% of patients with diabetes are unaware of their condition. In our study, the rate of suspected patients to Diabetes was 2.4% while a number of studies have reported detection of undiagnosed diabetes up to 15-21% through other methods such as high risk group-based screening or glycosylated hemoglobin measurement. A greater contribution of younger age groups and random blood glucose testing may be the main reasons for a low percentage of people with diabetes in this study. Therefore, fasting blood glucose or hemoglobin A1c rapid tests are highly recommended in future studies. In regards to the uptake of service, people mainly from 6th and 7th regions of Tehran primarily participated in the study, indicating the importance of proximity to the screening site. In regards to the age of the study subjects, one-third were 30-39 years old (36.5%), perhaps due to the prevalence of annual tests in elderly patients. This led to the exclusion of older ages from the screening. Among studies, the pattern of attendance in pharmacy-based screening programs in both genders is different and females usually accounts for the majority of the population. In the present study, a majority of the participants were male (69.7%). This observation could be due to the characteristics of the study setting as the referral pharmacy in the country.

Furthermore, the comparison of smoking, systolic and diastolic blood pressure, HDL, mean Framingham score, and fasting blood glucose demonstrated a significant difference between genders (p<0.001). Similarly, Tonstad et al. indicated better outcomes for females considering Framingham score and HDL.

Of the 132 participants contacted in follow-up phase, 15.9% were visited by a physician and were recommended to change their lifestyle, and 15.9% underwent drug therapy. Adherence to the recommended physician follow up for participants with CVD risk was 46% in our study. Other screenings for cardiovascular disease have demonstrated follow up rates up to 83%. Utilization of support services such as reminder telephone calls, appointment reminder letters, collaboration with local physicians, and assistance with transportation have been demonstrated to increase the rate of follow-up.

### Table 6. Comparison of measured parameters according to gender

| Variable                      | Female (n=87) mean (SD) | Male (n=200) mean (SD) | p-value |
|-------------------------------|-------------------------|------------------------|---------|
| Age                           | 47 (11.6)               | 45.7 (12.2)            | 0.4     |
| Smoking (%)                   | 5.7%                    | 23.5%                  | <0.001  |
| Systolic blood pressure       | 110 (14.8)              | 119.5 (15.3)           | <0.001  |
| Diastolic blood pressure      | 75.83 (10)              | 80.77 (9.3)            | <0.001  |
| Fasting blood glucose         | 104.13 (15.66)          | 111.16 (30.28)         | 0.042   |
| Total cholesterol             | 165 (35.2)              | 163 (40.1)             | 0.727   |
| HDL                           | 47.21 (12.5)            | 38.41 (9.3)            | <0.001  |
| Framingham score              | 3.38 (2.6)              | 9.86 (10.94)           | <0.001  |

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A further positive aspect of community pharmacies as screening location is that both ill and healthy individuals visit the pharmacy. Community pharmacies allow for the extension of clinical interventions to a larger percentage of the population who may not visit the physician.\(^\text{40}\)

However, to generalize the results of this study to the country, we should address the barriers of the screening services. In our previous study on pharmacist' attitude and perceived barriers about CVD screening services, we demonstrated the lack of regulatory authority, compensation mechanism, limited pharmacy space, and lack of health care facilities, socio-cultural issues, and delay in referral of patients for treatment.\(^\text{24}\)

**Limitations**

A key limitation in the design of this study was that it was conducted at one center. Further studies are required to examine the effect of multimeter screening services on participants' characteristics, CVD risks prevalence, referral, and follow up rates. In addition, the level of satisfaction and willingness to pay for pharmacy-based screening service should be evaluated in future studies.

**CONCLUSIONS**

In our study which was the first CVD risk screening in Iran, community pharmacist was successful in identifying patients with CVD risks. This demonstrates an opportunity for an extended role of pharmacist beyond the traditional dispensing of medicines.

**CONFLICT OF INTEREST**

The manuscript is reviewed and approved by all the authors and no conflicts of interests have been declared.

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