Lipid profile outcome gaps of Arabs and South Asians receiving chronic Statin therapy

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ABSTRACT
Ethnicity is a variable in statin response, but the influence of it in Arabs and South Asians is not known. There is a possibility of under-treatment in the long-term management of dyslipidemia in the Arab population, ignoring post-initiation medication nonadherence and lifestyle. There could be potential genetic reasons also for the need for higher lipid-lowering therapy in Arabs. This study is to identify lipid profile outcome gaps of Arabs and South Asians who were receiving chronic statin therapy. A hypothesis generating retrospective cohort study was conducted to compare lipid profiles among patients treated with a statin for more than three months. The study compared two lipid profiles of Arab and South Asian patients on chronic management of dyslipidemia. T-test and Z-test were performed to compare the lipid profiles. The study participants included 42 Arabs and 28 South Asians. Arabs had a higher body mass index (P-value 0.05), and more of them were smokers compared to South Asians (P-value 0.04). Total cholesterol (P-value 0.03, 95%CI 1.08 to -21.29) and LDL cholesterol (P-value 0.03, 95% CI 0.51 to -17.51) reductions in 3 – 6 months were significant in South Asians, but not in Arabs. The lipid profiles in Arabs receiving chronic statin therapy might be poor compared to South Asians. Both populations need improvements in lipid-lowering therapy outcomes. This hypothesis should be studied further to prove inherent differences and poor therapy outcomes among Arab and South Asian population that might result in modifications in current healthcare management policies.

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INTRODUCTION
Race/ethnicity and environment factors are important factors in estimating atherosclerotic cardiovascular disease (ASCVD) risk and the effectiveness of lipid-lowering therapy (Naito et al., 2017). Statin therapy is the primary lipid-lowering therapy, along with lifestyle interventions, to treat dyslipidemia and reduce ASCVD risk (Hadjiphilippou and Ray, 2019). Percentage reduction and absolute reduction of low-density lipoprotein (LDL) cholesterol levels with statin therapy has been shown to vary in an individual due to numerous factors (Collins et al., 2016). It is essential to measure and interpret the lipid profiles of patients who are receiving...
statin therapy. Two major population groups in the United Arab Emirates are Arabs and South Asians. South Asians are mainly expatriates from India, Pakistan, and Bangladesh (The Media Lab, 2020). Many variables in lipid-lowering therapy might be different among these two population groups, and the treatment strategies need population-specific approaches (Lloyd-Jones et al., 2019). Genetic polymorphism is known to affect pharmacokinetics and pharmacodynamics of statin therapy (Maggo et al., 2011).

Racial differences exist in response to statins between Asians and Westerners (Naito et al., 2017). A study of Chinese patients could not find a higher risk of severe statin toxicity compared to non-Chinese (Li et al., 2016). Factors like this and differences in initial, post-initiation medication nonadherence and lifestyle shall result in potential under treatment (Aznar-Lou et al., 2017; Hutchins et al., 2015). Some patients who would not need statin therapy but have been recommended for lifestyle modifications are overtreated with statins (Mahmood et al., 2015).

Racial differences are not just genetic. Medication consumption behaviors and lifestyles are part of cultures. While considering individual aspects of patients, understanding population aspects are part of the patient-centred approach to care (McQuaid and Landier, 2018).

Potential differences among Arab and other populations in the UAE need to be studied to understand the effectiveness of lipid-lowering therapy in these populations. There are efforts to develop clinical recommendations for the management of lipid disorders in the Middle East region (Sayed et al., 2016). The creation of a familial hypercholesterolemia registry in the region shall result in a better understanding of different factors affecting lipid-lowering. Considering an increase in ASCVD-associated mortality in the middle east, it is essential to understand the treatment outcomes of patients taking chronic lipid-lowering therapy (Rasadi et al., 2016).

Large studies in middle eastern countries identified sub-optimal lipid-lowering therapy outcomes (Al-Hashmi et al., 2016; Sifri et al., 2014). Potential under treatment with a statin is suspected. As per our literature review, there are no studies comparing chronic statin therapy outcomes among Arabs and South Asians. Our study objective was to explore lipid profile outcome gaps among Arabs and South Asians receiving chronic statin therapy in the UAE.

MATERIALS AND METHODS

Study design

This was an exploratory retrospective cohort study of patients previously prescribed statin therapy who visited a private tertiary-level care hospital, Ajman, UAE, from January 2018 to December 2018. Lipid profiles of chronic statin users were compared in a real-world setting influenced by multiple factors, including post-initiation medication adherence and lifestyle. The study was to explore if there is a difference in lipid profiles exists between Arabs and South Asians in the UAE, not to conclude the difference. The difference could be attributed to ethnicity, lifestyle, and lipid lowering therapy in a future large study. These inherent differences could be part of the cultures of different patient communities.

Patient population and data collection

Arab and South Asian patients who were receiving a monthly prescription of a statin for more than three months and having at least two lipid profiles during a 3-6-month period were included in the study. For patients who were already being treated with statin therapy, the lipid profile was usually repeated in 3-6 months in the clinical setting, which is consistent with practice guideline recommendations on lipid monitoring. Patients receiving non-statin lipid-lowering agents and those who were hospitalized in 2018 were excluded. No matching between Arabs and South Asian groups were performed to capture inherent differences in their lifestyle and lipid lowering therapy.

Measuring two consecutive lipid profile follow-ups were helpful in comparing the effect of chronic statin therapy within Arab and South Asian groups. Initial lipid profiles were avoided as the study was not just trying to find the influence of genetic aspects or potentially higher levels of health care at the initiation of statin therapy. Once the patients were taking statins for more than three months, it would represent characteristics of chronic statin use. Thus, two consecutive lipid profiles follow-ups in 3-6 months of statin therapy provide a real-world assessment of lipid-lowering therapy in general to generate population-specific data.

The hospital electronic medical records were accessed of patients diagnosed with dyslipidemia, hyperlipidemia, or hypercholesterolemia. The patient profiles were accessed through one computer at an academic office inside the hospital. Data were collected from medical records and entered into a spreadsheet for analysis. The majority of the patients treated in the study setting were expatriate Arabs (from different Arab countries) and South Asians.
Asians (from India, Pakistan, and Bangladesh). Most of the patients treated in the study setting were covered with private insurance. Data collected include patient demographics, comorbidities, body mass index (BMI), statin use, and lipid profiles during the visits.

Data analysis

Two follow-up lipid profiles were analyzed to identify chronic statin treatment outcome gaps among Arabs and South Asians. SPSS software version 26 was used for t-test and Graphpad software for the Z-test.

RESULTS AND DISCUSSION

In the study period from medical records, 70 patient cases (42 Arabs and 28 South Asians) met eligibility criteria were selected for the study. Most of the patients were excluded due to a lack of monthly statin prescriptions and two lipid profiles in 3 – 6 months. Age, sex, and comorbidities were comparable between the two groups. A significant difference was observed for BMI and smoking status at the time of data collection (Shown in Table 1).

In addition to having a significantly higher BMI, extreme obesity was found to be higher among Arab patients. Table 2 shows the weight category distribution of Arabs and South Asians.

Table 3 shows the information on types of statins used and their intensity (dose) among the study population. Considering lower numbers in subgroups, no P-value was calculated.

Lipid profiles follow-ups of Arabs and South Asians were taken at 3 – 6 months interval shows some significant difference, as shown in Table 4. Total cholesterol and LDL cholesterol reductions were significant in South Asians, but not in Arabs. In both groups, HDL cholesterol decreased in 3-6 months instead of the expected increase. Though clinically not significant, the decrease in HDL cholesterol was more among Arabs. It shows a poor lipid profile among Arabs even if they are treated with statins.

Follow-up 1 was the first lipid profile collected in this study for patients receiving a statin for more than three months and the next lipid profile after 3-6 months was collected as follow-up 2.

Big or small, the majority of patients showed a decrease in total cholesterol, HDL cholesterol (HDL cholesterol is supposed to increase with statin therapy), and LDL cholesterol. Few patients show the opposite effect of an increase in total cholesterol, HDL cholesterol, and LDL cholesterol. Confidence interval reflects it with more range in decrease side.

The difference in lipid profile among Arabs and South Asians on the follow-up visits was provided in Figure 1.

Figure 1: The difference in lipid profile at the follow-up visit of Arabs and South Asians

LDL cholesterol is expected to reduce with statin therapy, but in 33% of Arabs and 25% of South Asian patients, had an increase over 100 mg/dL. While many patients had a reduction in their LDL cholesterol, others had an increase. It shows suboptimal therapeutic outcomes.

This is a real-world study comparing lipid profiles of Arabs and South Asians taking statins. Significant improvements were identified between two lipid profiles of South Asians on decreased total cholesterol and LDL cholesterol. The decrease in HDL cholesterol was statistically significant among Arabs. Differences in HDL cholesterol is not considered as a clinically significant outcome of lipid-lowering therapy. Higher obesity and smoking habit might have influenced relatively poor lipid profiles in Arabs.

Prognosis in lipid profile was unsatisfactory for many patients in both groups studied. Multiple factors might have influenced chronic statin therapy outcomes. The influence of ethnicity on statin response is probably not just genetic. Being Arab or South Asian in the UAE environment is not the same. UAE is a multi-cultural society. Differences in post-initiation medication adherence and lifestyle of Arabs and South Asians might have contributed to their lipid profiles. Higher Obesity among Arabs might be another reason why LDL cholesterol was higher in the Arab group. More data on a higher number of patients are required to conclude if there is a statistically significant difference exist between Arabs and South Asians on their differences in obesity patterns.

Contributing factors to a poor lipid profile include statin nonadherence, statin non-response, diet, lifestyle, and comorbidities (Halava et al., 2014). In a natural patient care environment, physicians, pharmacists, and other healthcare professionals advise
Table 1: Patient demographics of Arabs and South Asians receiving statins

| Characteristic                | Arab (n=42, 60%) | South Asians (n=28, 40%) | Combined (n=70) | P-value |
|------------------------------|-----------------|---------------------------|-----------------|---------|
| Age (years), Mean (±SD)      | 53.0 ±7.5       | 52.7±8.1                  | 52.8±7.7        | 0.8851  |
| Age range                    | 36-70           | 37-68                     | 36-70           | -       |
| Male, No. (%)                | 31 (74%)        | 20 (71%)                  | 51 (73%)        | 0.82588 |
| Female, No. (%)              | 11 (26%)        | 8 (29%)                   | 19 (27%)        | 0.82588 |
| Body mass index, Mean (±SD)  | 32.1 ±5.7       | 29.7 ±3.4                 | 31.1 ±5.1       | 0.0521  |
| Current Smoker, n (%)        | 9 (21%)         | 1 (4%)                    | 10 (14%)        | 0.03662 |
| Hypertension, n (%)          | 31 (74%)        | 22 (79%)                  | 53 (76%)        | 0.64552 |
| Type-2 diabetes mellitus, n (%) | 28 (67%)     | 23 (82%)                  | 51 (73%)        | 0.15272 |
| Previous Stroke, n (%)       | 2 (5%)          | 1 (4%)                    | 3 (4%)          | 0.81034 |
| Previous acute coronary syn- drome, n (%) | 9 (21%) | 7 (25%)                   | 16 (23%)        | 0.72634 |
| Previous percutaneous coronary intervention, n (%) | 6 (14%) | 6 (21%)                   | 12 (17%)        | 0.4354  |

Table 2: Body mass index pattern for Arab and South Asian patients taking statins

| Nutritional status   | BMI          | Arabic (n=42) | South Asians (n=28) | Total (n=70) |
|----------------------|--------------|--------------|---------------------|--------------|
|                      | n            | n            | n                   | n            |
| Underweight          | Below 18.5   | 0            | 0                   | 0            |
| Normal weight        | 18.5-24.9    | 2            | 5%                  | 2            |
| Pre-obesity          | 25.0-29.9    | 17           | 40%                 | 13           |
| Obesity class I      | 30.0-34.9    | 10           | 24%                 | 10           |
| Obesity class II     | 35.0-39.9    | 8            | 19%                 | 3            |
| Obesity class III    | Above 40     | 5            | 12%                 | 0            |

Table 3: Type and intensity of statins used in the study population

|                  | Arab (n=42) | South Asians (n=28) | Total (n=70) |
|------------------|-------------|---------------------|--------------|
| Atorvastatin     | 32 (76%)    | 19 (68%)            | 51 (73%)     |
| Rosuvastatin     | 9 (21%)     | 8 (29%)             | 17 (24%)     |
| Pitavastatin     | 1 (2%)      | 1 (4%)              | 2 (3%)       |
| High intensity   | 7 (17%)     | 2 (7%)              | 9 (13%)      |
| Medium intensity | 35 (83%)    | 25 (89%)            | 60 (86%)     |
| Low intensity    | 0 (0%)      | 1 (4%)              | 1 (1%)       |

patients on improving therapy outcomes. Patients who have problems with adherence to medication and lifestyle are supported/counseled by health professionals. Patient and healthcare professional communication regarding statin therapy might be inadequate (Brinton, 2018).

Patient-related factors account for the highest reasons for predicting medication adherence (Catapano, 2012). Patients’ understanding of their coronary risk profile was found to improve lipid-lowering therapy outcomes, though small (Grover, 2007). In addition to that, the level of self-care naturally varies among patients. Ignorance from patients might even result in dyslipidemia being largely untreated (Petrella et al., 2007).

Sub-optimal LDL cholesterol reduction and no increase in HDL cholesterol in our study are similar to many observational studies (Colantonio et al., 2007; Akyea et al., 2019). Statin-associated adverse events are one of the leading reasons for nonadherence to statin therapy (Maningat et al., 2013). Adherence to therapy is not usually consistent over time. Many factors affect medication and lifestyle adherence (Colantonio et al., 2007). The beneficial cardiovascular outcomes with statin therapy require long-term management of dyslipi-
Table 4: Two follow up lipid profiles of patients on chronic statin use

|                                      | Arab (n=42) | South Asians (n=28) | P-value** |
|--------------------------------------|-------------|---------------------|-----------|
|                                      | Mean        | SD                  |           |
| Follow-up 1 total cholesterol (mg/dL)| 169.2       | 31.9                |           |
| Follow-up 2 total cholesterol (mg/dL)| 164.3       | 35.2                |           |
| Change in total cholesterol (mg/dL)  | -4.8        | 44.2                | 0.24      |
|                                      |             |                     |           |
| P-value**                            |             |                     | 0.03 (95% CI 1.08 to -21.29) |
| Follow-up 1 HDL cholesterol (mg/dL)  | 44.5        | 13.9                |           |
| Follow-up 2 HDL cholesterol (mg/dL)  | 42.7        | 10.9                |           |
| Change in HDL cholesterol (mg/dL)    | -1.8        | 7.0                 | 0.05 (95% CI 0.37 to -3.99) |
|                                      |             |                     |           |
| P-value**                            |             |                     | 0.33      |
| Follow-up 1 LDL cholesterol (mg/dL)  | 93.4        | 27.9                |           |
| Follow-up 2 LDL cholesterol (mg/dL)  | 90.6        | 34.4                |           |
| Change in LDL cholesterol            | -2.7        | 35.9                | 0.31      |
|                                      |             |                     |           |
| P-value**                            |             |                     | 0.03 (95% CI 0.51 to -17.51) |
| Follow-up 1 triglycerides (mg/dL)    | 147.5       | 81.2                |           |
| Follow-up 2 triglycerides (mg/dL)    | 155.8       | 69.0                |           |
| Change in triglycerides (mg/dL)      | 7.7         | 59.3                | 0.20      |
|                                      |             |                     | 0.30      |

*Unpaired t-test was used to find differences between Arabs and South Asians.
**Paired t-test was used to find the difference between the two lipid profiles of the same group.

demia (Collins et al., 2016). Cardiovascular risks are high among Arabs. In the Middle East, the rate of increase in cardiovascular disease (CVD)-associated mortalities is one of the highest in the world (Ramahi, 2010). Management of dyslipidemia is suboptimal in Arabian Gulf countries (Rasadi et al., 2016). An epidemiologic, observational, cross-sectional, multicenter study conducted in the UAE, Saudi Arabia, Lebanon and Jordan demonstrated that despite statin therapy, a high proportion of patients failed to meet lipid targets and many had a very high risk of CVD (Sifri et al., 2014).

A prospective 12-week study in 70 patients with newly diagnosed dyslipidemia in UAE showed the effectiveness of atorvastatin, simvastatin and rosuvastatin after 12 weeks of treatment (John et al., 2014). A cross-sectional study in Kuwait showed lower adherence to statin compared to the study reports from Canada and the US (Al-Foraih and Somerset, 2017).

In Qatar, a study on 1542 diabetes patients with dyslipidemia and prescribed with statins showed that rosuvastatin therapy was the most effective statin to LDL cholesterol goal achievement (Bener et al., 2014). Atorvastatin 10–80 mg reduce LDL cholesterol by a mean (SD) of 35.7% (16.0) to 49.2% (17.3). Rosuvastatin 5–40 mg reduced LDL cholesterol by a mean (SD) of 41.4% (12.8) to 55.5% (14.8) (Trompet et al., 2016).

Optimal lipid-lowering therapy is required considering many factors (Al-Rasadi and Al-Sabti, 2015). An integrated approach might be needed to produce better therapeutic outcomes (Lansberg et al., 2018). Measures to be taken to improve medication adherence and lifestyle interventions. Dose titration of statins based on lipid profile is required (Grundy et al., 2018). The approach shall be tailored by dose titration, the addition of another lipid-lowering agent, or PCSK9 inhibitors to Arabs or South Asians based on their differences in population-specific needs.

**Limitations of the study**

A retrospective study design is a limitation, but most of the similar studies are retrospective considering feasibility issues. Some of the patients with any missing data might have been responded well to statin therapy. Patient adherence was not measured, so it is not clear which patients were more or less adherent to their statin therapy. These limitations are acceptable as the study is exploring the differences in outcomes, not the factors contributing to it. Future studies are recommended to study the influence of factors contributing to the outcomes.
CONCLUSIONS

A significant difference is observed in lipid profiles outcomes of South Asians and Arabs on statin lipid-lowering therapy. The difference cannot be attributed entirely to statin response in these ethnic groups. Obese and smoking differences might have contributed to poor lipid profiles. Cultural differences influence lifestyle differences. Considering these factors are pivotal in blood lipid management as the therapy outcomes need improvements. Further research is required in a larger study population to conclude lipid profile outcomes in Arabs and South Asian in the UAE, considering higher cardiovascular disease risk in the region. Clinical guidelines need to be updated, representing currently underrepresented Arab population.

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Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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