Evaluation of Utilisation and Concordance to Guideline-recommended Statin Therapy at Medical Outpatient Clinic, Hospital Kuala Krai

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Abstract

Introduction: Hyperlipidaemia is one of major risk factors for atherosclerotic cardiovascular diseases (ASCVD), so appropriate treatment is crucial to prevent morbidity and mortality.

Objective: The objective of this study was to evaluate the concordance of statin prescribing at medical outpatient clinic (MOPC), Hospital Kuala Krai to the 2013 ACC/AHA Guideline on the treatment of blood cholesterol, and to evaluate the therapeutic response of statin therapy.

Methods: A retrospective observational study was conducted from February to August 2017 at MOPC, Hospital Kuala Krai. Calculated 10-year ASCVD risk was estimated using pooled cohort equation for all patients. Patients were then grouped into one of the four treatment indication groups in descending order of ASCVD risk. Patients were assigned to high intensity statin therapy, moderate intensity or statin not beneficial categories according to the guideline. The prescribed statin intensities were compared to the guideline recommended statin intensities to determine the concordance rate. Therapeutic responses, defaulted rate and adverse drug reaction (ADR) were also evaluated.

Results: Overall, 106 patients were included in this study. The overall concordance rate was 43.4% with the highest in patient with clinical ASCVD (52.9%) and the lowest in patient with LDL-C \geq 4.9 mmol/L (22.2%). Moderate-intensity statin therapy was most frequently prescribed (63.2%) in which 50.7% of these patients should have been treated with high-intensity statin therapy. A total of 28.9% of patients achieve targeted reduction in LDL-C. The default rate was 16.0% and one ADR was reported. **Conclusion:** The concordant rate to the 2013 ACC/AHA Guideline on the treatment of blood cholesterol was below satisfactory. Although the default rate was acceptable, the treatment response based on the prescribed statin intensities needs a lot of improvement.

Keywords: hyperlipidaemia, cholesterol, ASCVD risks, statins, 2013 cholesterol guidelines

NMRR ID: NMRR-18-1132-42084

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Introduction

Over the decades, rapid urbanisation and modernisation along with changing lifestyles in Malaysia have left significant impacts on the general health of the population. While the nation experiences the reduction in communicable diseases, non-communicable diseases (NCD) such as cardiovascular diseases (CVD), diabetes mellitus and hypertension are on the rise. In Malaysia, NCD accounts for approximately 73% of total death¹. In addition, death caused by CVD, particularly ischemic heart disease and stroke has been topping the list for the last decade².

Among the major risk factors for NCD are dyslipidaemia, hypertension, diabetes and obesity³. According to the National Health and Morbidity Survey (NHMS) 2015, the prevalence of hypercholesterolemia in adults age more than 18 years old was 47.7%, and 38.6% of this belongs to undiagnosed hypercholesterolemia⁴. This data is in fact worrisome as major health burden is expected for years to come. Several strategies have been implemented to tackle this issue which includes primary and secondary prevention of CVD.

An observational study in Finland reported that reduction in major cardiovascular (CV) risk factors such as hypercholesterolemia, hypertension and smoking resulted in the reduction of observed CVD mortality⁵. Hence, this study aimed to focus on the usage of HMG-coA reductase inhibitor, or commonly known as statins, in the prevention of CVD. Numerous studies have shown that the usage of statins in primary and secondary prevention reduces CV events and CV mortality⁶. Unfortunately, inappropriate statin prescribing is still common in practice as it is often overprescribed or underutilised.

Several studies have concluded that the overall concordance to practice guidelines was suboptimal, ranging from 50 to 60%⁷⁻⁹. A study in Ireland demonstrated that although the usage of statin has increased over the years, the prescribing rate according to guideline was still low¹⁰. In addition, a study in Saudi Arabia concluded that almost one third of their patients received statin inappropriately¹¹. However, another study in the United States showed that overall concordance to the guideline was more than 50%¹².

We aimed to evaluate the utilisation of statins therapy among patients who followed up at the Medical Outpatient Clinic (MOPC) in Hospital Kuala Krai, Kelantan. The objectives of our study were: (1) to study the concordance of current statins prescribing to the 2013 American College of Cardiology / American Heart Association (ACC/AHA) Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults¹³, (2) to determine the prevalence of CV events after statins therapy and to evaluate the treatment success rate and safety of statins therapy.

Methods

Study design and subjects

This retrospective study was conducted at the Medical Outpatient Clinic (MOPC), Hospital Kuala Krai, Kelantan, Malaysia from March 2017 to August 2017. The patients' medical records from the date the first statin prescription was written to at least 3 months later were reviewed. The research was registered with the National Medical Registry Research Registry (NMRR) and approval to conduct the research was obtained from the Medical Research and Ethics Committee (MREC). Patients who were initiated with statin monotherapy from year 2014 to 2016 were reviewed for study inclusion. Patients were randomly selected from the patient record centre at MOPC. The recorded systolic blood pressure (SBP) to the date as near as possible to the date of starting statin therapy was retrieved.

Patients without baseline lipid profile tested before starting statin treatment were excluded from the study. Any patients whose statin therapy were started before year 2014 were excluded from this study because the ACC/AHA guideline on hyperlipidaemia treatment published on 2013 ¹³ was used as a reference to determine the guideline concordance of statin prescribing pattern in MOPC. Due to the lack of statin intensity recommendation for patients younger than 40 years or older than 75 years, they were excluded from the study unless they have clinical atherosclerotic cardiovascular disease

(ASCVD) or measured low-density lipoprotein cholesterol (LDL-C) level of \geq 4.9mmol/L. In addition, patients with LDL-C concentration less than 1.8mmol/L without any clinical ASCVD were also excluded from the study. Also, any patient whose 10-years ASCVD risk could not be calculated (i.e. patients younger than 40 years or older than 79 years, with a high-density lipoprotein cholesterol (HDL-C) of < 0.5 mmol/L or > 2.6 mmol/L, with total cholesterol (TC) level of < 3.4 mmol/L or > 8.3 mmol/L or SBP < 90 mm Hg or > 200 mm Hg) were excluded from further evaluation. Any contraindication of statin therapy was assumed to have been reviewed by the prescriber before initiating statin treatment.

ASCVD risk estimation

Estimation of 10-year ASCVD risk was calculated based on the pooled cohort equation for all patients using the ASCVD Risk Estimator¹⁴. This calculation was intended to aid healthcare providers in estimating the 10-year and life time risks of ASCVD. This calculation made use of patients' age, gender, race, TC, HDL-C, SBP, use of blood pressure-lowering therapy, status of diabetes mellitus and smoking status to estimate the risk of developing ASCVD. Although initiation of statin therapy in patients for secondary prevention of ASCVD and LDL-C > 4.9 mmol/L was not required, the 10-year ASCVD risk was still calculated for all included patients in this study.

Patient categorisation

After detailed evaluation of patients' medical records, all included patients were divided into 4 groups, in descending order of ASCVD risk. Patients who required secondary prevention of ASCVD, i.e. those with documented history of acute coronary syndrome (ACS), coronary or other arterial revascularization, cerebral vascular disease (CVD) or peripheral artery disease, were placed in Group 1. Patients with LDL-C concentration > 4.9mmol/L were grouped in Group 2. Group 3 consisted patients who aged between 40 and 75 years with diabetes but without any previous history of ASCVD and had LDL-C concentration ranged between 1.8-4.8 mmol/L. Patients who aged from 40 to 75 years without history of ASCVD or diabetes with an LDL-C level of 1.8-4.8 mmol/L and calculated 10-years ASCVD risk \geq 5% were assigned to Group 4.

Statin intensity and therapeutic goal

After the 10-year ASCVD risk calculation and assignment to statin treatment benefit groups, the recommended intensity of statin therapy and therapeutic response were determined for each patient. The therapeutic response, expressed by percentage reduction from the baseline LDL-C concentration over at least 3 months of statin therapy was defined based on the recommended statin intensity. The patients were assigned to moderate intensity, moderate-high intensity, or high intensity based on the recommendation of the guideline¹³. These guideline-recommended statin intensities were then compared with the prescribed statin intensities received by the patients to assess guideline concordance.

Outcomes assessment

The primary objective of this study was to evaluate the concordance of statin therapy to the ACC/AHA Guideline on the treatment of blood cholesterol. In order to assess the guideline concordance, the prescribed statin therapies in the included patients were classified as high, moderate or low intensity and then compared with the suggested intensity in the guideline. The secondary objective was to assess the therapeutic response of statin therapy after at least 3 months of treatment. The therapeutic responses were achieved if the percentage reduction of LDL-C concentration from baseline were < 30%, 30-50%, > 50% in patients receiving low, moderate and high intensity statin therapy respectively. In addition, any adverse drug reactions due to statin therapy, defined as three times increases in

baseline AST/ALT level, complained of muscle pain at biceps / triceps, thorax or thigh muscles, were recorded. Any ASCVD or CVD that occurred after statin therapy and patient concordance to statin therapy were also assessed in this study.

Statistical analysis

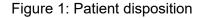
Statistical analysis for this study was conducted using Statistical Package for the Social Sciences (SPSS) software version 20. Normally distributed and skewed data were analysed using Student *t*-test and the Wilcoxon rank sum test respectively. Pearson's chi-square test and Fisher's exact test were used to analyse categorical data. For comparison of multiple groups of data, ANOVA test was used. A priori level of significance was set at < 0.05.

Results

A total of 955 patients were treated with statins from year 2014 to 2016 at MOPC in Hospital Kuala Krai. Of these patients, 778 were excluded from the study because these patients were initiated with statin treatment before the publication of the ACC/AHA Guideline on the treatment of blood cholesterol in 2013. Then, 71 patients were also excluded from the final analysis because baseline profile lipid profiles were not recorded when they were started with statin therapy (Figure 1). Therefore, a total of 106 patients were included in this study.

Cohort Characteristic

The majority of patients in this cohort were Malay (92.5%), and female patients made up almost half of the total patient population (Table 1). Over 50% of the patients in this study were also treated for diabetes (51.9%) or hypertension (54.7%). In addition, the overall mean baseline TC and LDL-C were 5.72 mmol/L (standard deviation (SD) 1.58) and 3.48 mmol/L (SD 1.29) respectively, which were higher than the recommended upper normal limit of TC < 5.2 mmol/L and LDL-C < 2.6 mmol/L. Furthermore, the mean baseline SBP was also higher than the normal SBP of 120mm Hg. About one-third of the studied patient population were smokers while they were treated with lipid lowering agents.



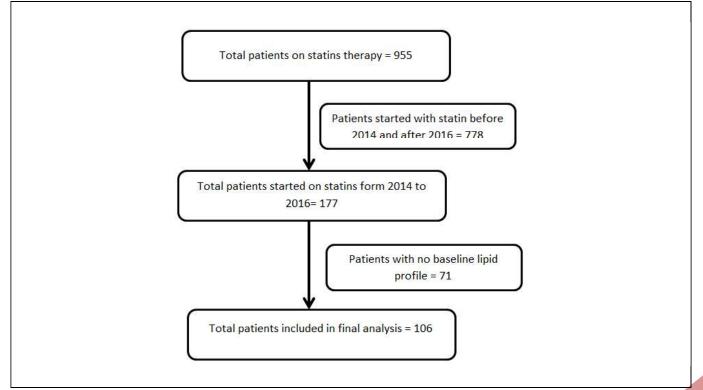


Table 1: Baseline characteristics of s	study population
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Characteristic	All, n=106	Guideline concordant prescribing, n=46	Guideline discordant prescribing, n=60	P-value
Age, mean (SD)	57.6 (13.0)	59.9 (12.8)	54.5 (12.7)	0.192 [*]
Gender, n (%)				0.147 [#]
Female	50 (47.2)	18 (39.1)	32 (53.3)	
Male	56 (52.8)	28 (60.9)	28 (46.7)	
Race, n (%)				0.317 [#]
Malay	98 (92.5)	41 (89.1)	57 (95.0)	
Chinese	7 (6.6)	4 (8.7)	3 (5.0)	
Indian	1 (0.9)	1 (2.2)	0	
Weight, kg, mean (SD)	66.2 (12.9)	64.4 (13.2)	67.9 (12.8)	0.266*
TC, mmol/L, mean (SD)	5.72 (1.58)	5.60 (1.34)	5.79 (1.78)	0.200*
LDL-C, mmol/L, mean (SD)	3.48 (1.29)	3.31 (1.09)	3.58 (1.42)	0.120 [*]
HDL-C, mmol/L, mean (SD)	1.39 (0.45)	1.43 (0.43)	1.40 (0.48)	0.657 [*]
SBP, mm Hg, mean (SD)	141 (24.5)	143 (23.5)	138 (24.9)	0.754 [*]
Diabetes, n (%)	55 (51.9)	22 (47.8)	33 (55.0)	0.464#
Hypertension, n (%)	58 (54.7)	25 (54.3)	33 (57.6)	0.947 [#]
Smoking, n (%)	32 (30.2)	18 (39.1)	14 (23.3)	0.079 [#]

TC: total cholesterol; LDL-C: low density lipoprotein cholesterol; HDL-C: high density lipoprotein cholesterol; SBP: systolic blood pressure; SD: standard deviation

* Student *t*-test, [#] Pearson's chi-square test

Concordance with 2013 ACC/AHA Guideline on the treatment of blood cholesterol

The overall rate of concordance with the 2013 ACC/AHA Guideline on the treatment of blood cholesterol was 43.4% as demonstrated in Table 2. The most commonly prescribed statin intensity in this study was moderate intensity (63.2%). The common indication of initiating statin treatment in patients of this cohort was clinical ASCVD (48.1%), followed by diabetes (26.4%), ASCVD risk of at least 5% (17.0%) and baseline LDL-C of \geq 4.9 mmol/L (8.5%).

Among patients who received guideline concordant statin therapy, 58.7% of them had history of clinical ASCVD, who required statin therapy for secondary prevention of ASCVD. However, patients with clinical ASCVD recorded the highest proportion (40.0%) among patients whom were not treated with guideline concordant statin therapy. Patients with baseline LDL-C of 4.9 mmol/L or higher, who had the second highest risk of developing ASCD, had the lowest rate of being treated with guideline suggested intensity statin therapy (4.3%).

Although high intensity statin therapy was the most commonly suggested regimen (61.3%), a higher percentage of patient population of this study were started with moderate intensity statin treatment (63.2%) instead. Moderate intensity statin therapy was the most frequent wrongly-prescribed treatment regimen (76.7%) when compared to high (3.3%) and low intensity statin regimen (20.0%) respectively. Of all the patients who received guideline discordant treatment, 73.3% of them received a lower statin intensity than what they were supposed to receive according to the guideline.

When high intensity statin was prescribed, this regimen was used correctly in 92.6% of the occasions (Table 3). However, while moderate intensity statin therapy was the most commonly started treatment, only 31.3% of the patients (21 out of 67) were appropriately treated according to the guideline. Of patients who received moderate intensity statin therapy, half of them should have received high intensity statin treatment. Furthermore, of all the patients treated with low intensity statin, 75% should have received higher intensity therapy.

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		Guideline	Guideline	
Characteristic, n (%)	All	concordant	discordant	P-value
		prescribing	prescribing	
Overall	106	46 (43.4)	60 (56.6)	
Indication for statin therapy				0.215
Clinical ASCVD	51 (48.1)	27 (58.7)	24 (40.0)	
Baseline LDL-C \ge 4.9 mmol/L	9 (8.5)	2 (4.30)	7 (11.7)	
Diabetes	28 (26.4)	11 (23.9)	17 (28.3)	
ASCVD risk $\ge 5\%$	18 (17.0)	6 (13.0)	12 (20.0)	
Guideline recommended statin intensity				<0.001
High	65 (61.3)	25 (54.3)	40 (66.7)	
Moderate	26 (24.5)	21 (45.7)	5 (8.3)	
Statin not beneficial	15 (14.2)	0	15 (25.0)	
Prescribed statin intensity				<0.001
High	27 (25.5)	25 (54.3)	2 (3.3)	
Moderate	67 (63.2)	21 (45.7)	46 (76.7)	
Low	12 (11.3)	0	12 (20.0)	
Reason for guideline discordance				
Dose lower than recommended	-	-	44 (73.3)	
Dose higher than recommended	-	-	16 (26.7)	
ASCVD: atherosclerotic cardiovascular dis	02000			

Table 2: Characteristics of statin treatment among study population

ASCVD: atherosclerotic cardiovascular diseases

Table 3. Concordance of prescribed statin therapy to the 2013 ACC/ATIA guideline				
Prescribed statin	Guideline suggested statin intensity therapy, n (%)			
intensity	intensity No benefit Moderate intensity	High intensity	Total	
High Intensity	1 (3.7%)	1 (3.7%)	25 (92.6)	27 (100)
Moderate Intensity	12 (17.9%)	21 (31.3%)	34 (50.7)	67 (100)
Low Intensity	3 (25.0%)	4 (33.3)	5 (41.7)	12 (100)
Total	16	26	64	106

Table 3: Concordance of prescribed statin therapy to the 2013 ACC/AHA guideline

Therapeutic response of statin therapy

Thirty patients did not have their fasting lipid tested after the initiation of statin therapy, so their treatment outcomes were not be assessed. In the remaining 76 patients, the overall success rate of achieving suggested percentage reduction in baseline LDL-C level was only 28.9% (Table 4). The achievement of targeted LDL-C reduction in patients treated with guideline concordant statin therapy did not differ significantly from those who received guideline discordant statin therapy [odd ratio = 0.457 (95% confidence interval 0.165-1.259, p=0.129)]. Patient with clinical ASCVD had the lowest rate of achieving the recommended reduction in baseline LDL-C level (15.6%) when compared to the other 3 groups of patients. The highest success rate of achieving targeted percentage reduction in LDL-C concentration belonged to the group of patients with baseline LDL-C 4.9 mmol/L and higher (55.6%). There was a significantly higher percentage of patients started with low intensity statin therapy (75%) that achieved targeted reduction from baseline LDL-C level when compared to patient receiving high intensity (4.5%) and moderate intensity statin therapy (36%) (p=0.010).

In contrast, the highest treatment failure rate of statin therapy was observed in group of patients whom were treated with high intensity statin therapy (95.5%). Nevertheless, a sub-analysis

found that there was a significantly higher percentage of patients with clinical ASCVD that were treated with high intensity statin therapy (77.8%) when compared to patients with baseline LDL-C \geq 4.9 mmol/L (7.4%), diabetes (11.1%) and ASCVD risk \geq 5% (3.7%) respectively (p=0.020). Additionally, patients who had achieved targeted percentage reduction from baseline LDL-C were found to have higher baseline TC level (6.52 versus 5.65 mmol/L, p=0.033) and had higher baseline LDL-C level (4.23 versus 3.38 mmol/L, p=0.008).

Among the 106 included patients, 17 (16.0%) patients did not come for follow up monitoring after being started with statin therapy. There was no statistically significant difference in the default rate across all four indication groups of patients (p=0.104). Similar finding was observed in patient being started with different intensities of statin treatment. There was no significant different in defaulted rate across these groups (p=0.059). There were no ACS events or adverse drug reactions documented on the patients' clinical progress folder since patients were started on statin therapy. Only one patient reported to have at least three times increased in liver enzymes from baseline within three months period of starting statin therapy. The enzyme levels decreased to normal range after statin therapy was withheld.

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Characteristic	All	Success, n (%)	Fail, n (%)	P-value
Overall	76	22 (28.9)	54 (71.1)	
Indication for statin therapy, (%)				0.057
Clinical ASCVD	32	5 (15.6)	27 (84.4)	
Baseline LDL-C \geq 4.9 mmol/L	9	5 (55.6)	4 (44.4)	
Diabetes	19	5 (26.3)	14 (73.7)	
ASCVD risk ≥5%	16	7 (43.8)	9 (56.2)	
Prescribed statin intensity, (%)				0.010
High	22	1 (4.5)	21 (95.5)	
Moderate	50	18 (36.0)	32 (64.0)	
Low	4	3 (75.0)	1 (25.0)	

Table 4: Treatment outcomes of statin therapy among study population

Discussion

This observation study evaluated the overall concordance of statin prescribing at Hospital Kuala Krai with the 2013 ACC/AHA Guideline on the treatment of blood cholesterol. We found that the overall concordance rate to the guideline was 43.4% and this was lower compared to other published studies. A study conducted in the United States by Christina Ng *et.al.* reported an overall concordance to the guideline of 65.8%¹⁵. In addition, another study carried out in Saudi Arabia also reported relatively high overall concordance rate of 72.4%¹⁶. Almost all the patients with 10-years ASCVD risk \geq 7.5% in the US study received the correct intensity of statin therapy¹⁵, and about 80% of the patient with clinical ASCVD in the Saudi Arabia study were treated with the appropriate intensity of statin therapy¹⁶. Our study reported that the highest concordance rate was observed in patient with clinical ASCVD at only 52.9%. The overall concordance rate to the guideline needs to be improved, because when compared to other published studies, majority of our patients has higher systolic blood pressure, higher baseline LDL-C level and higher 10-years ASCVD risk^{15, 16}.

The study conducted in Saudi Arabia reported that their most common indication to start statin therapy was clinical ASCVD (54.7%)¹⁶. Similar finding was also observed in this study whereby almost half of the patients who received statin treatments were patients with clinical ASCVD (48.1%). However, in the United States, patients with diabetes mellitus were found to be the group that most frequently received statin therapy as primary prevention of ASCVD¹⁵. Although the majority of our

patients received statin for secondary prevention of ASCVD, but moderate-intensity statin was the most commonly prescribed intensity. This could indicate that our patients with clinical ASCVD, whom have the highest risk to develop fatal cardiovascular diseases, were possibly being under-treated.

The utilisation of high-intensity statin therapy in our setting was appropriate with 92.6% concordance rate. Similar finding was observed in the US study which reported that the 92.5% of the total high intensity statin prescription abide by the guideline recommendation¹⁵. On the other hand, the study conducted in Saudi Arabia recorded a slightly lower high intensity statin concordance rate at 72.2%¹⁶. Although the usage of high intensity statin therapy in our setting was highly concordant to the guideline recommendation, but only 41.2% of patient with clinical ASCVD actually received high intensity statin treatment, which was significantly lower when compared to the Saudi Arabia study of 83.3%¹⁶. In addition, moderate intensity statin therapy was found to be most frequently prescribed for our patients (63.2%) in which half of these patients should have received high-intensity statin therapy. A clinical trial showed that high intensity statin therapy with atorvastatin was able to reduce the risk of all-cause mortality after acute coronary syndromes (ACS) by 12%¹⁷. In addition, clinical trials such as ALLIANCE (Aggressive Lipid-Lowering Initiation Abates New Cardiac Events) and GREACE (GREek Atorvastatin and Coronary-heart-disease Evaluation) trials had highlighted the benefits of atorvastatin in reducing the risk of non-fatal myocardial infarction by 47-59%¹⁸.

About 15% of total patients in this study were over treated with higher intensity statin, which was comparable to the Saudi Arabia's study that recorded about 13.3%¹⁶. On the other hand, underutilisation of statin therapy were observed in more than one-third of the patients studied, which was similar with the US study¹⁵. The Arab study recorded a much lower underutilisation of statin therapy when compared to our study (21.0% versus 41.5%). This study was not able to identify the causes of inappropriate use of statin in our facility but other study had shown that the prescribing of statin seldom fully abide by the suggestions in the clinical practice guidelines¹⁹. A study conducted in Ireland that evaluated the influence of guideline on statin prescribing showed that although the overall prescribing rate of high intensity statin may increase in response to the guideline recommendations, it was still common to observe that physicians prescribed lower doses of statin therapy than those suggested in the clinical practice guideline²⁰. Inaccurate estimation of ASCVD risk was found to be another factor contributed to non-concordance in the prescribing of statin treatment²¹.

Our study found that around seventy percent of the patients failed to achieve the targeted treatment goal after three months of statin therapy and only 15.6% of patients with clinical ASCVD were able to achieve targeted percentage of LDL-C reduction. Four hallmark trials, which studied the benefits of the high-intensity statin therapy against moderate intensity statin therapy in patients with post-acute coronary syndrome or coronary artery disease, also showed that, patients were not able to achieve at least 50% reduction in serum LDL-C concentration at the end of the trials ²²⁻²⁵. However, in these trials, average LDL-C concentration was less than 1.8mmol/L at the end of the studies. The ACC/AHA 2013 guideline did not recommend the LDL-C treatment target as there was insufficient evidence to support such a recommendation¹³. Even though patient had been treated with guideline-concordant statin therapy, the percentage reduction in the LDL-C concentration can be affected by other factors such as patients' compliance to medication and inter-patient metabolic variability in the response to statin treatment. These factors were not assessed in this study.

This study had several limitations. First of all, this is a retrospective study, hence there were many instances that documentation was incomplete or patients' data was missing. In addition to statin therapy, the guideline also suggested concordance to diet modification, healthy lifestyle and medication compliance, which were not included in this study for analysis. Additionally, the shared-decision making and clinician-risk discussion in starting statin therapy could not be captured in this study, thus its effect on the concordance rate was not able to be determined. Finally, this study was done in a single facility with limited sample size, thus the results could not be generalised and provide a true indication on the overall concordance rate at the national level.

Conclusion

In conclusion, only about 40% of our patients received appropriate intensity statin therapy as per guideline recommendation, which needs to be improved. Our study provided an overview on the utilisation of statin therapy in our facility. We hope that, with the introduction of the latest Malaysia clinical practice guideline on the management of hyperlipidaemia 2017, the overall guideline-concordant statin prescribing rate can be improved and the prescribing of statin therapy can be optimised.

Acknowledgement

We would like to thank the Director General of Health Malaysia for his permission to publish this article.

Conflict of Interest Statement

No external funding was received and the authors declared no conflict of interest.

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