



The Audit Of Using Of Statins Following A Diagnosis Of Acute Coronary Syndrome (ACS) In The Royal Alexandra Hospital

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1. Abstract:

Background

Statins are well-founded for the acute coronary syndrome as a secondary prevention therapy. Recent GGC guidelines recommend the use of maximum atorvastatin dose (80 mg).

Methodology

An audit was performed on all patients who had a clear diagnosis of ACS during admission at RAH within three weeks period(August 2019). Data collected from patient's medications chart, electronic system and medical note. IT included age, gender, statin before admission, statin during admission, lipid profiles, contraindication to statin use.

Results

72 patients were diagnosed with ACS through the audit period at an average age of 64 years. 61% (n=44) were men and 39% (n=28) were women. 60% (n=43) of the patients before admission on a statin. although of known ACS, 8% (n=6) of all patients had no lipid-lowering treatment. During admission, 33 per cent (n=24) of patients with ACS were measured the lipid profile. 61% (n=44) of cases received maximum atorvastatin dose. Only 22 % of those not licensed for the GGC guideline dose had clear side effects.

Conclusion

The current audit showed that 39 per cent of patients diagnosed with ACS did not receive a maximum dose of atorvastatin during admission, with only a 22 per cent of patients having side effects from using a statin. The results indicate non-compliance with GGC guidelines regarding the use of appropriate statin following a diagnosis of ACS during admission. future Plans will include applying new GGC guidance and medical team training sessions to emphasize evidence-based practices.

2. Background:

ACS is a medical emergency involving three kinds of cardiovascular disease associated with partial or completed coronary artery blockage. It includes unstable angina and myocardial infarction (STEMI or NSTEMI) (1). It is responsible for approximately one-third of mortality in the world, seven and a half million of which are caused by ischemic heart disease. Sudden death and ACS cause the majority of mortality, resulting in 1,7 million deaths every year. The rate of ACS usually rises with age, even though this occurs in males 7-10 years earlier than in females. The acute coronary syndrome tends to occur in men more than in women under the age of sixty, however, the majority of cases over 75 years of age seem to be female (2).

The diagnosis of ACS is based on patient clinical presentation as verified by abnormal Electrocardiogram (ECG) and the identification of particular biochemical markers. A 12-lead electrocardiogram (ECG) displaying an elevation of the ST segment which might imply a STEMI and The depressed ST segment indicates unstable angina or NSTEMI (3). Patients with ACS may have symptoms of nausea, chest pain, pain in the arms, sweating, discomfort, or swelling. The presence of ACS is indicated by a high sensitivity of troponin test that showing high troponin concentrations(3).

In preventing subsequent cardiovascular events, drug treatment is essential. In the NICE guidelines, a statin, ACE-inhibitor, DAPT (dual anti-platelet therapy) and a beta-blocker should be given to patients to control cardiovascular risk (4). Minimizing the low-density of cholesterol lipoprotein with statin treatment decreases the risk of cardiovascular occurrence in high-risk coronary heart disease patients(5). In addition to this, statins have also been utilized as secondary prevention for the reduction of cardiovascular deaths and stroke(6).

Statin are categorized according to their intensity, three of which could be defined by lower lipoprotein cholesterol (as a proportion) to low-intensity statin such as simvastatin 20mg that reduce LDL cholesterol by 20-30%, moderate-intensity statin such as rosuvastatin 5mg that reduce LDL cholesterol by 31-40% and high-intensity statin such as atorvastatin 80mg that reduce LDL cholesterol by approximately above 40% (7). Clinical studies such as the PROVE IT study proves that appropriate statin (atorvastatin 80 mg) is recommended in patients with ACS. Moreover, PROV IT trail has been shown to be the ideal therapy for atorvastatin 80 mg to avoid recurrence of an acute coronary event (8).

Greater Glasgow and Clyde (GGC) Guidelines indicated that it should be commenced atorvastatin 80 mg as secondary prevention with a patient who was diagnosed with the acute coronary syndrome (9). It is recommended that prescriber consider decreased the dose of atorvastatin 80mg or be started alternative statin in patients have serious side effects, substantial interactions with other medications or estimated glomerular filtration rate (eGFR) below 30ml/min. (9). Furthermore, the recommendations may not be suitable for all patients who on atorvastatin 80 mg as per the GGC guidance. In particular, it should decrease the high dose in people with enhanced danger of muscle toxicity, including myopathy or rhabdomyolysis(8). In addition, statins may be discontinued if the common side effects of flatulence, dizziness, gastrointestinal pain and myalgia become intolerable and impact patients ' quality of life. Prescribers should always follow GGC rules unless the patient has previously stated any of the co-morbidities(9).

GGC guidelines restricted the use of rosuvastatin 10-40mg and simvastatin 80mg in a patient subjected secondary prevention for ACS patients (9). It recommended that rosuvastatin only be used in patients who were not reached the target of lipid profile levels or who cannot tolerate atorvastatin 80mg or other statins, thus with doses of 40 mg or above being prescribed only on a specialist's recommendation (9). Whilst simvastatin 80mg, due to an increased risk of myopathy, it is not approved for ACS patients. In addition, there is evidence that a combination of statin and ezetimibe has a beneficial in lipid levels lowering and further therapy might be investigated in the event that these lipid levels lowering target are not reached or in patients of those who cannot tolerate statins (9).

The GGC guidance state that laboratory test the total lipid levels should be performed before lipid-reduction therapy started for ACS patients (10). This includes measurement of total cholesterol, triglycerides, lowdensity lipoprotein(LDL),

and high-density lipoprotein (HDL) cholesterol (10). The NICE guideline states that high-density lipoprotein cholesterol and total cholesterol should be measured in order to obtain the highest ACS risk assessment. Although lipid profile measurement is indicated after the admission for ACS patients, there is evidence showing that phasic modifications in serum lipid and lipoprotein concentrations following an ACS have been observed (11). However, since it considers that the alterations in the first 24 hours are minimal, it would seem reasonable to measure the lipid levels during that time(11).

The use of statin following ACS was audited at Newham University Hospital (London) in 2017 on 43 patients diagnosed with ACS ; results found that nearly 37 per cent of patients with ACS did not receive the maximum dose of atorvastatin, and 47 per cent of cases had a lipid profile during hospital admission (12). Based on these results, the decision was made to measure the use of appropriate statin following ACS at RAH and to investigate the compliance to implementation of the GGC guidelines.

2.1 Aims

To investigate whether prescribing of the appropriate statin (atorvastatin 80 mg) and measurement of lipid profile after an ACS diagnosis are in line with GGC guidelines.

2.2 Objectives

1. To quantify the extent to which patients diagnosed with ACS are prescribed atorvastatin 80mg daily for secondary prevention.
2. To quantify the extent to which patients had lipids measurements were performed prior to statin treatment initiation.

2.3 Standards

1. 90% of patients who had an ACS will have atorvastatin 80mg prescribed unless there is a documented contra-indication or interaction.
2. 90% of ACS patients should have a lipid profile performed prior to treatment

* The standards were based on GGC guidelines and the discussions with the clinical governance team and clinical lead pharmacists at the RAH.

3. Methods:

3.1 Patient selection

This was a cross-sectional observational audit carried out over a period of three weeks in cardiology wards of the RAH. Patients included in this study were admitted to the cardiology ward and coronary care unit (CCU) who had been diagnosed with acute coronary syndrome and were using statins and non-statin lipidlowering therapy. Patients who did not have a clear ACS diagnosis or who were initially diagnosed with ACS and altered the diagnosis during admission were excluded from the audit.

3.2 Patient Confidentiality

In the list identified in the ward list matching the number in the information collection form, all patients were provided with a number according to their ward. In the hospital pharmacy, the patient list containing the patient data was held in a separate folder.

3.3Data Collection Form

A form of data collection based on a particular inquiry was intended to meet all the target requirements for this audit (see Appendix 1). The initial data collection form was piloted and modified as it lacked some question to complete the investigation. This was resolved by adding a question about 'the starting time of initiated statin' was added to the original data collection. A further question about 'exact time for measurement of lipid profile' was also added to the data collection. A final question about 'reasons of prescribing inappropriate statin for ACS' was added to complete the data collection form. The new data collection form was piloted and debated with pharmacists in order to ensure the validity and to recognize any other unclear data (see Appendix 2).

The form of data collection depended on specific identifiers and information relating to the use of statins during the diagnosis of ACS. This information included the date of data collection; the ward number; the demographic properties of the patient such as age and gender on admission; type and dose of statins whether, was not prescribed before admission and/or during admission; time of initiated of statin during admission; lipid profile during admission; and finally, the reasons of prescribing inappropriate statin for ACS and if the patients had intolerance, side effects, Interaction or allergy form using statin.

3.4 Data Collection

The data was collected for 72 patients admitted between 05.08.2019 and 23.08.2019 (3 weeks) on patients who were admitted to the RAH.

□ Using Trakcare and Clinical Portal, the electronic system for the recognized wards was obtained.

- Patients who were on a statin was recorded on their ECS as a repeat medication; the patient's file number, the patient's name and the name of the statin and dose were noticed.
- The wards were visited and the chart of medication and case notes were checked to ensure that the patient was given a clear diagnosis of ACS. Once verified, the specifically designed data collection form was completed without recording patient-recognizable information.
- The number of ACS patients whose statins were appropriately prescribed (atorvastatin 80mg) during admission was recorded.
- The number of ACS patients whose had a lipid profile performed was recorded.
- When the patient was discharged from the hospital, the IDL was checked to identify whether the statin was changed or not.

3.5 Data analysis

All the data obtained were structured into a table using Microsoft Excel to analyse the data. The information were then analysed in a spread sheet according to factors. In addition, the fundamental Excel coding including proportion, AND, IF and COUNTIF, was used to convey to what extent the guidelines were applied properly. We created a lot of graphics after that to represent the result.

4. Results:

All patients on the cardiology ward and the coronary care unit (CCU) of were screened daily (except at weekends) throughout the 3 weeks of data collection. 108 patients were initially investigated to determine if the patients had a clear diagnosis of ACS. However, 36 patients of 108 cases were excluded from the data analysis because the patients had no clear diagnosis of the acute coronary syndrome (Type 1 MI); some of those excluded had raised troponin, ECG changes or myocardial infarctions in the absence of a coronary artery process (Type 2 MI). The 7 patients screened in the pilot were included in the final data collection process. Overall, 72 patients were included in the data interpretation.

Table 1: Characteristics of patients (n=72)

Characteristic	Value (%)
Hospital ward	
CCU	51 (70.1)
Ward 8	21 (29.9)
Gender	
Female	28 (38.9)
Male	44 (61.1)
Age	
≥75	31 (43.1)
<75	41 (56.9)

Table 1 summarises the baseline demographics for 72 patients included in the audit. The main wards were ward 8 (cardiology), where 21 patients were screened (30%), while in the coronary care unit (CCU), 70% (n=51) of the cases were screened. According to the gender in this audit, males diagnosed with ACS (61%, n=44) were more than females (39%, n=28). In terms of age, the median was 62, the mean was 65 and the range was between 29-96 years old

4.1 The use of statins before and during admission:

Table 2: The use of statins pre-admission and during admission, and the changes in type and dose after diagnosis of ACS

Statins	Number of patients and (%)
Statin pre and after admission	
Patients on statins pre-admission	43 (59.7)
Patients commenced new statins during admission	23 (32)
Patients not prescribed statins	6 (8.3)
The changes after admission (after diagnosis of ACS)	Total patients (43)
Change in type and/or dose of statins	26 (60.5)
No change and continue on same statin at same dose	17 (39.5)

The table 2 illustrates the patients who were on a statin before admission and shows the change in statin prescribing following diagnosis of ACS during admission. Out of 72 patients on statins, 43 (60%) were on statins prior to admission, 17 (61%) cases of these continued on the same statin at the same dose after admission and another 23 patients (39%) had an increase in the dose of statin, or were changed to another statin. However, 32 patients (40%) of total cases were commenced a new statin after diagnosis of ACS during admission.

4.2 Types of statin and doses being administered during admission:

Table 3: A breakdown of the types of statins the patients were using and the doses being administered during admission

The type of statins after diagnosis of ACS	Number of patients and (%)
High intensity statin	57(79.2)
Atorvastatin 20mg	2 (2.8)
Atorvastatin 40mg	8 (11.1)
*Atorvastatin 80mg	44 (61.1)
Simvastatin 80mg	1 (1.4)
Rosuvastatin 20mg	2 (2.8)
Moderate intensity statin	7 (9.7)
Atorvastatin 10mg	2 (2.8)
Simvastatin 40mg	4 (5.6)
Rosuvastatin 5mg	1 (1.4)
Low intensity statin	2 (2.8)
Pravastatin 40mg	2 (2.8)
Patients not prescribed statin during admission	6 (8.3)
Non-statin (ezetimibe 10mg)	3 (4.2)
Patients not prescribe any lipid lowering agent	3 (4.2)

*Red denotes formulary statin

Table 3 shows the types of statins the patients were using and the doses being administered, there were 4 types of statin and different doses after the diagnosis of ACS (atorvastatin, simvastatin, rosuvastatin and pravastatin). More than half (61%, n=44) of patients were prescribed atorvastatin 80mg for ACS patients and only 2 cases out of the 72 cases were prescribed low-intensity statin (pravastatin 40mg). However, 8.3% (n=6) of the sample did not receive statin and 4.2% (n=3) of patients were received non-statin therapy (ezetimibe 10mg).

4.3 The initiation of statins according to intensity:

Figure 1: The proportion of patients prescribed a statin according to the intensity following a diagnosis of ACS

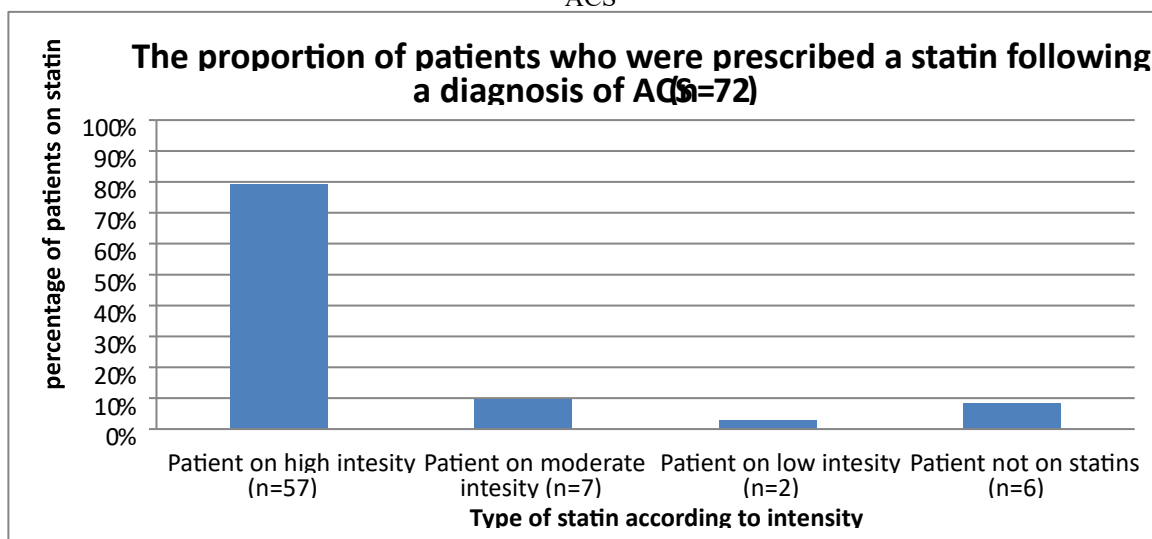


Figure 1 demonstrates the proportion of patients who have prescribed a statin on admission following a diagnosis of ACS. Overall, 79% (n=57) of the sample was prescribed a high-intensity statin (Atorvastatin 20-40-80mg, simvastatin 80mg and rosuvastatin 20mg); and 10% (n=7) of patients were prescribed moderate-intensity statin (Atorvastatin 10 mg, simvastatin 40mg and rosuvastatin 5mg). A smaller proportion (8%, n=6) was prescribed non-statin therapy. The

remaining 2 of the 72 patients were prescribed low-intensity statins (pravastatin 40mg). In general, approximately 82% (n=66) of the cases were prescribed statins during admission after the diagnosis of ACS.

4.4 Appropriateness and accuracy of prescribing of statins:

Figure 2: The proportion of statins correctly prescribed according to the GGC Guideline

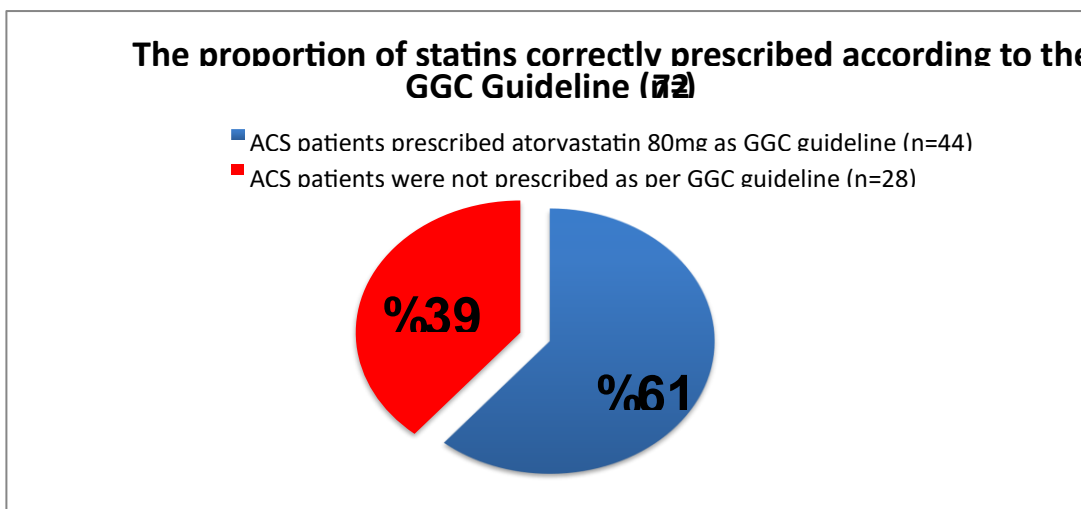


Figure 2 compares the percentage of patients who were appropriately prescribed atorvastatin 80mg according to GGC guidelines with those cases where the guidelines were not adhered to. The number of patients whose atorvastatin 80mg was prescribed appropriately was 44 out of 72 (61%) as per GGC NHS guidelines. However, there were 39% (n=28) of patients not were prescribed the maximal dose of atorvastatin after ACS diagnosis.

4.5 Possible reasons why Atorvastatin 80mg not prescribed as per GGC guidelines:

Figure 3: Breakdown of why atorvastatin 80mg was not prescribed for all ACS patients as per GGC guidelines

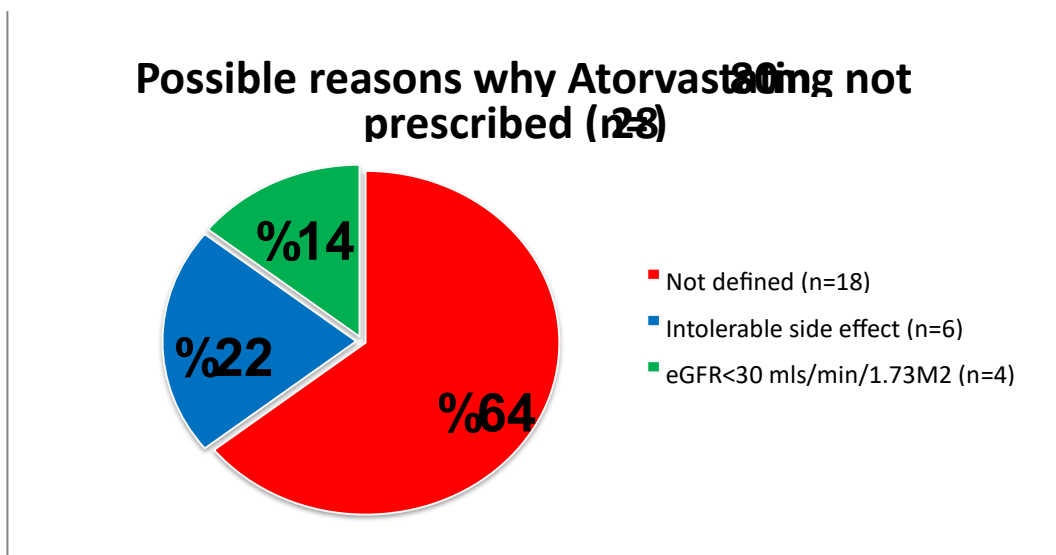


Figure 3 summarises the possible reasons for ACS patients were not prescribed atorvastatin 80mg during admission (n=28). According to data gathered on ECS, 22%(n=6) of patients who had documented adverse effects after using the statin. In the 14% (n=4) of patients where chronic kidney disease and eGFR<30 mls/min/1.73M2 were documented in the medical notes and confirmed by biochemistry laboratory results, a low dose of atorvastatin was prescribed. Overall, in more than half of the cases where GGC guidelines were not adhered to (64%, n=18) there were no documented reasons as to why atorvastatin 80mg was not prescribed.

4.6 The measuring of lipid profile during using of statins for ACS patients:

Figure 4: The proportion of patients who had a lipid profile carried out.

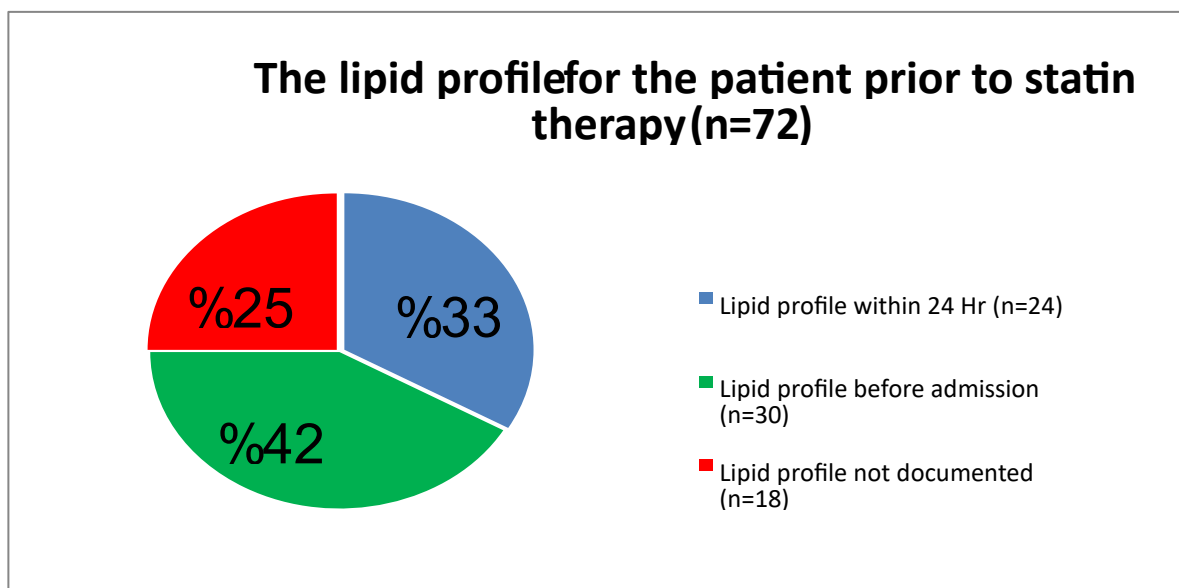


Figure 4 compares the proportions of lipid profiles carried out around the time of acute coronary syndrome, 42% (n=30) of patients had a lipid profile measured before admission to the hospital and before diagnosed as ACS. In 25% (n=18) of cases where the statin was prescribed, there was no record of a lipid profile being measured. Overall 33% (n=24) of patients had a lipid profile screen within 24 hours of admission for ACS which is considered the appropriate time frame for measuring a lipid profile, in line with NHSGGC guidelines.

5. Discussion

5.1 The use of statin following a diagnosis of ACS during admission

One of the audit's original goals was to determine the proportion of the appropriate statin was prescribed during admission after the diagnosis of ACS. The results of this audit (Figure 1) indicate that more than 79% (n=57) of patients were commenced high-intensity statin following a diagnosis of ACS more than a moderate or low-intensity statin. This is consistent with the findings of the PROVE IT study, which showed that high-intensity statin was superior to a low or moderate-intensity statin in a reduction of cardiovascular reoccurrence (8). The GGC guidelines recommend the use of atorvastatin 80mg (high-intensity statin) as the most appropriate statin for secondary prevention of ACS (4). However, according to the results in figure 2, only 61% (n=44) of patients were prescribed atorvastatin 80mg following a diagnosis of ACS during admission which is significantly below the standard set for this audit (90%). It was expected that more than 90% of patients would be prescribed atorvastatin 80mg. Thus, the evidence of this audit infers the noncompliance of the prescribers with GGC guidelines when initiating secondary prevention medication in onethird of ACS patients.

Despite the importance of compliance with GGC guidelines, 39% (n=28) of patients were discharged not on the maximal dose of atorvastatin. This digression from the guidelines may be caused by a number of precipitating factors. It may partly be due to prescribers who were not aware of the content of the GGC guidance. In addition, in 4 patients out of the 28 patients not prescribed maximal dose atorvastatin, chronic kidney disease was present and an eGFR < 30 ml/min/1.73M² was documented in the medical notes and confirmed by biochemistry laboratory results (figure 3). The Renal Drug Database (RDD) does not recommend considering a reduction in the dose of atorvastatin 80mg unless the creatinine clearance is less than 10ml/min, which did not apply to any of the patients in the current audit (14). Moreover, patients who had a side effect of using atorvastatin 80mg was documented, was expected to receive another type of statins or another lipid-lowering therapy such as (ezetimibe 10mg) because of the side effects of statins. As a result, 8.1% (n=6) of patients (see figure 3) who were intolerant to atorvastatin 80 mg were considered compliant with GGC guidelines for their therapy.

5.2 The lipid profile performing for ACS patients during admission:

Although lipid profile measurement is recommended after patients with ACS are admitted, the levels of serum lipid during admission were observed in less than a third of the patients (n=24). According to GGC guidelines, it is recommended to measure a lipid profile as a baseline before initiation of statin therapy with a goal of achieving a target total cholesterol level < 4.0mmol/L (10). This is particularly important after admission with ACS where an atherosclerotic event has occurred. As can be seen in figure 4, 42% (n=30) of patients had a lipid profile measured before admission to the hospital and before diagnosed as ACS. This may indicate that the physicians were satisfied with the previous lipid profile of patients despite the patients needing to have a new lipid profile after ACS.

On the other hand, in 25% (n=18) of cases where the statin was prescribed, there was no record of a lipid profile being measured. It was expected to the measurement of lipid profile in more than half patients especially that more than 56% (n=41) of patients below 75 years old and no document of lipid levels for most of those patients following a diagnosis of ACS during admission. The majority of patients (77% n=48) did not have a lipid profile measured prior to commencing statin therapy. This means that there was poor adherence to GGC guidelines related to lipid profile measurements practices in the treatment plan of ACS.

A possible reason for failing to meet the standard (90%) is that some physicians have the concept that levels of serum lipids and lipoproteins may vary after ACS diagnosis, and thus have the notion that these measurements are not accurate. After an acute coronary syndrome, phasic modifications were observed in serum lipid and lipoprotein concentrations according to the previous study that proven some changes in the lipid profile after diagnosis of ACS, although this study also stressed the importance of checking lipid levels as soon possible before initiating lipid-lowering therapy(11). In addition, one of the possible explanations, some prescribers are unaware of the importance of the lipid profile performing or the risk of total cholesterol if the target levels not met for patients with ACS during admission. A future study could, however, be conducted to gain insight into the doctors ' reasoning behind non-compliance with GGC guidance regarding the measurement of lipid levels in patients with ACS. A future study could, however, be conducted to gain insight into the doctors ' reasoning behind non-compliance with GGC guidance regarding the measurement of lipid levels in patients with ACS.

5.3 The comparison of the audit results :

A similar audit was carried out in 2017at Newham University Hospital in London, collecting information on statin prescribing, and the proportion of patients with lipid profile during an ACS diagnosis(12). The investigators concluded that atorvastatin 80 mg was received by more than 63 % of patients while only 57 % of patients had a lipid profile. These findings were broadly similar to those of this current audit. The NICE guideline recommend that the findings of previous audits should be used to improve the quality of healthcare in order to avoid the same outcomes from recurring(15). For the future, prescribers should be encouraged to comply more closely with protocols if indicated. Such practices will also enhance the outcomes of patients.

5.4 Limitations

5.4.1 Small sample size

The collection of data was restricted to 72 patients, due to the small sample in this audit and the lack of time to collect more data. It will further enhance the results ' reliability if there were a large number of patients.

5.4.2 Diagnosis of ACS

A clear diagnosis of ACS had to be confirmed before the patient could be enrolled in the audit. If the doctor wasn't sure about the diagnosis, laboratory results and ECG had to be repeated and the patient followed-up the next day to make sure the patient had a clear diagnosis of ACS, all of which was a painstaking process.

5.5 Conclusion and Future plan:

This audit identified the need for further work to enhance the knowledge of the prescribers responsible for statin prescribing; the physicians need to be informed of the latest changes to the GGC guidance. Overall, atorvastatin 80 mg was not adequately prescribed, and results related to lipid profile measurements for ACS patients during admission (33%, n=24) were clearly not coming near the audit performance standards of 90%. Therefore, to decrease the poor adherence to the GGC guidelines, it is suggested that health workers, particularly prescribers, be trained and motivated to be up-to-date with the updated GGC guidelines. In addition, as part of quality improvement, this audit could be repeated and a training session based on the results of this audit presented to improve the quality of prescribing of healthcare providers.

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Data collection form SAMPLE EXTENDED DATA COLLECTION

No:
Age: _____
Gender: Male Female

1. Was the patient on Statins before admission? Yes No Unknown
If yes, which Statins and which dose :

2. On admission, which Statins are prescribed, dose and when started? Statin :
 Dose :

3. Did the patient have a lipid profile during admission? Yes No Unknown

Appendix 1

Data collection form

Patient No:
Age: _____
Gender: Male Female

1. Was the patient on Statins before admission? Yes No Unknown
If yes, which Statins and which dose :

2. On admission, which Statins are prescribed, dose and when started? Statin :
 Dose :
 starting time:

3. Does patient had lipid profile at 24h of admission? Yes No Unknown
If No, what is the date of the last lipid profile? ____

4. Was any reasons of prescribing inappropriate statin for ACS? Yes No Unknown
If yes, what is the reason? Contraindication Interaction Intolerance Allergy Other

Appendix 2