

Drug utilization studies and pharmacoeconomic analysis of statins used in prevention of coronary artery disease patients

Estudios de utilización de fármacos y análisis farmacoeconómico de estatinas utilizadas en la prevención de pacientes con enfermedad arterial coronaria

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Abstract

Aim or Objective: Statins are the most effective class of drugs for lowering serum low density lipoproteins (LDL). The use of low dose statins from previous studies demonstrated prevention of cardiovascular disease events and mortality. Current evidence is insufficient to assess the balance of beneficial effects and adverse events pertaining to initiation of statins in different age groups. The current study is focused on drug utilization pattern of statin and its economic impact among coronary artery disease (CAD) patients. **Background:** A retrospective cross-sectional study was conducted at the out-patients lipid and cardiology section of Fujairah Hospital, Fujairah, United Arab Emirates. About 206 patients prescribed with statins took part in this study. It showed that males (65%) were treated more on statins compared to females (35%). Whereas predominate age group in these patients were geriatrics (> 65 years old). Among all classes of statins, Atorvastatin 40mg was prescribed highest (36.41%) followed by Rosuvastatin 20mg (25.24%). Atorvastatin 10mg was found to produce maximum lipid reduction among all statins. In addition, the current study revealed that age and systolic blood pressure play a pivotal role (P-value < 0.05) in adversely affecting CAD risk factors. **Results:** It was re-

vealed from our investigation patients with high systolic blood pressure (SBP) had a greater mean LDL value (2.3042 mmolN) and patient with low SBP had the least mean LDL value (1.5758 mmolN). Similarly, it was observed that patients <35 years had the greater mean LDL value which is (3.1525 mmolN), followed by patients between (36-45) years (mean LDL was 2.5761 mmolN), and patients >65 years found to be having least mean LDL value (1.7635 mmolN). Another interesting finding through pharmacoeconomic analysis that atorvastatin 10mg had a benefit over other doses in reducing LDL levels. **Conclusion:** Patients age and medical history related to prior treatments received, play a very critical role in understanding CAD pathogenesis and disease progression. Further, the study revealed that Atorvastatin 10mg had safe and beneficial effects over other doses and other treatment alternatives for prevention and progression of CAD and reducing the LDL levels cost-effectively.

Keywords: Pharmacoeconomic, retrospective, cross-sectional, Atorvastatin, Cardio Vascular Disease, Low Density Lipoprotein, Cost-effective statin, Systolic Blood Pressure.

Finalidad u objetivo: Las estatinas son la clase de fármacos más eficaz para reducir las lipoproteínas de baja densidad (LDL) séricas. El uso de estatinas en dosis bajas de estudios previos demostró la prevención de eventos de enfermedades cardiovasculares y mortalidad. La evidencia actual es insuficiente para evaluar el equilibrio entre los efectos beneficiosos y los eventos adversos relacionados con el inicio de estatinas en diferentes grupos de edad. El estudio actual se centra en el patrón de utilización de estatinas y su impacto económico entre los pacientes con enfermedad de las arterias coronarias (EAC). **Antecedentes:** se realizó un estudio transversal retrospectivo en la sección de lípidos y cardiología para pacientes ambulatorios del Hospital Fujairah, Fujairah, Emiratos Árabes Unidos. En este estudio participaron alrededor de 206 pacientes a los que se les prescribieron estatinas. Mostró que los hombres (65%) fueron tratados más con estatinas en comparación con las mujeres (35%). Mientras que el grupo etario predominante en estos pacientes fue el geriátrico (>65 años). Entre todas las clases de estatinas, la atorvastatina 40 mg fue la que más se prescribió (36,41%), seguida de la rosuvastatina 20 mg (25,24%). Se descubrió que 10 mg de atorvastatina produce la máxima reducción de lípidos entre todas las estatinas. Además, el estudio actual reveló que la edad y la presión arterial sistólica desempeñan un papel fundamental (valor de $p < 0,05$) a la hora de afectar negativamente a los factores de riesgo de enfermedad coronaria. **Resultados:** Nuestra investigación reveló que los pacientes con presión arterial sistólica (PAS) alta tenían un valor medio de LDL mayor (2,3042 mmol/l) y los pacientes con PAS baja tenían el valor medio de LDL más bajo (1,5758 mmol/l). De manera similar, se observó que los pacientes <35 años tuvieron el mayor valor medio de LDL que es (3,1525 mmol/l), seguido de los pacientes entre (36-45) años (la media de LDL fue 2,5761 mmol/l) y los pacientes >65 años. Se encontró que tenía el valor de LDL medio más bajo (1,7635 mmol/l). Otro hallazgo interesante a través del análisis farmacoeconómico fue que 10 mg de atorvastatina tuvo un beneficio sobre otras dosis para reducir los niveles de LDL. **Conclusión:** La edad de los pacientes y el historial médico relacionado con los tratamientos anteriores recibidos desempeñan un papel muy importante en la comprensión de la patogénesis de la EAC y la progresión de la enfermedad. Además, el estudio reveló que 10 mg de atorvastatina tenía efectos seguros y beneficiosos sobre otras dosis y otras alternativas de tratamiento para la prevención y progresión de la enfermedad coronaria y la reducción de los niveles de LDL de forma rentable.

Palabras clave: Farmacoeconómico, retrospectivo, transversal, Atorvastatina, Enfermedad Cardio Vascular, Lipoproteínas de Baja Densidad, Estatinas Costo-efectivas, Presión Arterial Sistólica.

Background

Coronary artery disease (CAD) is one of the most predominant cardiovascular disease that affect the heart. CAD is mostly associated with the rupture of an atherosclerotic plaque resulting in partial or complete thrombosis of the artery. Recently, there is a noticeable increase in the cardiovascular disease (CVD), the leading cause of death in many countries. The use of statins also spiked owing to its benefits in protecting the diseased from cardiovascular events. According to Adult Treatment Panel (ATP III) guide lines, the optimal target of LDL-C is less than 100 mg/dl, if the LDL-C is 130-159 mg/dl it will be considered as borderline high, and if it is between 160-189 mg/dl it will be considered as high. If its more than 190 mg/dl it is considered as very high LDL-C¹³.

Drug utilization was defined by WHO in 1977 as the marketing, distribution, prescription and use of drugs in society with resulting medical and socio-economic consequences. The standard measurement of drug utilization and drug exposure in a population called "defined daily dose" which is defined by WHO as the assumed average maintenance dose per day for a drug for its main indication in adults^{2,14}. Given the multiple therapeutic options available in the market, the health care provider must carefully consider not only the efficacy and safety of the drug but also in terms of total treatment cost. Pharmacoeconomics is a branch of pharmaceutical science that guides us to make an informed decisions about the use of cost-effective medicines. The benefit of cost-effective analysis is to improve patient care quality at affordable price for the health care provider thereby reducing total treatment cost with an emphasis in decreasing the incidence of adverse drug reaction and to improve outcome related to drug therapy¹².

Atorvastatin and Rosuvastatin are the statins which are widely used as lipid lowering agents prescribed in the hospital for prevention of coronary artery disease (CAD). The chief objective of the study is to decipher the effectiveness of statins in managing and treating the elevated cholesterol level thereby preventing cardiovascular (CV) events. Further, the study also examines the clinical as well as cost effectiveness of Atorvastatin compared to Rosuvastatin. The present observational study was conducted with a view to preliminarily investigate the use of defined daily dose as a unit to measure study utilization for statin therapy. In this study, the reflection model assessed cost-effectiveness for a healthcare providers and patient's perspective through the direct medical cost for the year of 2018. The clinical outcome was evaluated by reduction of LDL-C level⁴.

This study was conducted at the out-patient's lipid and cardiology section of Fujairah Hospital, UAE. It is also the only referral center for all complicated cases. The retrospective data was collected from the patient records using standard and validated questionnaire for the duration of one year (January – December 2018) at tertiary referral hospital. Information such as patient demographics, current medical condition, comorbidity, lipid profile, liver profile, renal profile, creatine kinase, obesity, alcohol intake, smoking and medication has been collected for the purpose of this study. The clinical outcome was then evaluated by using reduction in LDL-C levels as criteria. The outcome was considered reject when the outcome of the patients obtained be unknown. Then the drug utilization study analysis was carried out by calculating "Defined Daily Dose" which provided a rough estimate of the quantity of drug that was used in a proportion of specific population by the following equation:

$$\text{DDD}\backslash 1000 \text{ patients} \backslash \text{day} = \frac{(\text{amount of drug "mg"})}{1000} \times$$

$$(\text{DDD} * 365 \text{ day} * \text{sample size})$$

Analysis

Statistical analysis was performed using IBM Statistical Package for the Social Sciences (SPSS) Software version 25. All the data expressed as the mean and standard deviation. Parametric and Nonparametric tests were used to find out significant outcome. Markov decision analysis was used to assess Pharmacoeconomic investigation. $P \leq 0.05$ was considered as the significant while $P \geq 0.05$ as not significant.

Ethical Clearance

Ethical approval was obtained from the institute as well as from the research ethics committee (REC) of Ministry of Health and Prevention (MOHAP).

Demographic description of the participants

The data of the present study was collected from 206 coronary artery disease patients, out of which 65% (134) were male, and 35% (72) were female (Table 1). Patients with age group 65 years old were the most predominantly affected 39.81% (82), and age group less than 35 years old were the least affected 1.0% (2). About 80.6 % (166) of the patients were not in the smoking category and 96.1% (198) were non alcoholic. As far as the statin utilization, we found that 75% (36.4) of the study population were prescribed Atorvastatin 40mg whereas Rosuvastatin 20mg was prescribed to 52% (25.2). Majority of the patients enrolled in the study 67% (32.5) had comorbid condition such as hypertension, dyslipidemia, and diabetes. It is noticed that 38.3 % (79) of the study population were obese and 37.9 % (78) were overweight. A total of (33.5) patients (69%) were having un-controlled BP and 23.3% (48) had a high BP.

Table 1. Patient Demographics

Variables	N= 206 N (%)
Gender	
Male	134 (65)
Female	72 (35)
Age Groups	
<35	2 (1.0)
36-45	17 (8.3)
46-55	38 (18.4)
56-65	67 (32.5)
>65	82 (39.8)
Smoking	
Yes	40 (19.4)
No	166 (80.6)
Alcohol	
Yes	8 (3.9)
No	198 (96.1)
Statins	
Atorvastatin 10mg	12 (5.8)
Atorvastatin 20mg	32 (15.5)
Atorvastatin 40mg	75 (36.4)
Atorvastatin 80mg	6 (2.9)
Rosuvastatin 10mg	29 (14.1)
Rosuvastatin 20mg	52 (25.2)
Co-morbidities	
DL	12 (5.8)
DM	9 (4.4)
DM + DL	7 (3.4)
HTN	23 (11.2)
HTN + DL	15 (7.3)
HTN + DL +DM	67 (32.5)
HTN + DM	47 (22.8)
NO	26 (12.6)
Blood Pressure Systolic	
LOW BP	61 (29.6)
NORMAL BP	27 (13.1)
HIGH BP	48 (23.3)
UN-CONTROLLED BP	69 (33.5)
BMI category	
Under weight	5 (2.4)
Normal weight	29 (14.1)
Over weight	78 (37.9)
Obese	79 (38.3)

Efficacy of Atorvastatin and Rosuvastatin on the reduction of LDL between different groups based on different factors

This analysis considered the reduction of LDL-C based on different groups, here the results in table-2 displayed that there is a relationship between the mean levels of LDL reduction and different age groups (P value <0.05). There exists another relationship worth considering between the reduction of LDL levels to arterial blood pressure value in patients with CAD (P value <0.05)

Table 2. Effect of statins on the reduction of serum levels of LDL between different age groups and arterial blood pressure

Variables (N)	N	LDL (mean \pm SD)	LDLC (mean \pm SD)
Age Groups			
<35	2	3.15 \pm 0.64	3.30 \pm 0.84
36-45	17	2.57 \pm 1.04	2.39 \pm 1.09
46-55	36	1.94 \pm 0.67	1.86 \pm 0.87
56-65	65	2.29 \pm 1.14*	2.12 \pm 1.14*
>65	79	1.76 \pm 0.84	1.72 \pm 0.84
Blood Pressure Systolic (mmHg)			
Low BP (<100)	4	1.57 \pm 0.26	1.46 \pm 0.28
Normal BP (120-130)	109	1.99 \pm 0.91*	1.88 \pm 1.01*
High BP (140-159)	65	2.30 \pm 1.03	2.20 \pm 1.08
Un-controlled BP (\geq 180)	20	1.64 \pm 0.67	1.60 \pm 0.53
Statins			
Atorvastatin 10mg	12	1.82 \pm 0.78	1.77 \pm 0.85
Atorvastatin 20mg	32	2.12 \pm 0.82	2.05 \pm 0.95
Atorvastatin 40mg	75	1.99 \pm 0.92	1.81 \pm 0.93
Atorvastatin 80mg	6	2.29 \pm 1.06	2.59 \pm 1.38
Rosuvastatin 10mg	29	2.12 \pm 1.23	1.92 \pm 0.92
Rosuvastatin 20mg	52	2.07 \pm 0.90	2.06 \pm 1.14
ANOVA test - *P value <0.05 , Post hoc analysis			

Relationship between mean LDL and group of age

The data analysis of this study showed that, there is a statistically significant relationship between the LDL reduction and age group (P value <0.05). The most effected group was, patients <35 years having greater mean LDL which was (3.1525 mmolN), and patients >65 years found to be having the least mean LDL value (1.7635 mmolN). These results are similar to that finding of another cross-sectional study which conducted in Al-Ain between March-2004 to February-2005, which revealed that the lipid profile tend to be worst in early ages and better at older ages (>60 years old). Also, its clear that younger males had a higher number of risk factors than females or older males³. This can be explained by adverse lifestyle choices of the patients less than 35 years old. This could be ascribed to the sedentary life style.

Relationship between mean LDL and systolic BP

A prospective 15-year cohort study of two independent cross-sectional random samples of subjects exhibited that coronary heart disease, stroke, cardiovascular disease and all-cause mortality among men and women aged 45-64 years increased with the increasing systolic blood pressure. Among women aged 45-64 years, systolic hypertension increased the relative risk of these fa-

tal events. Among men aged 45-64 years, only coronary heart disease mortality was significantly associated with systolic hypertension.

A double blind, placebo controlled parallel group study designed to determine the lipid lowering agent efficacy on a blood pressure showed that statin therapy remained efficacious in the presence of antihypertensive therapy but did not enhance the blood pressure lowering action of those drugs. Therefore, it is unlikely that blood pressure reduction is the mechanism by which statin mediates its reported short-term effects on cardiovascular morbidity¹⁰.

On the other hand, there is another randomized, double blind, cross sectional study, revealed that the intensive lipid lowering agents reduced total cholesterol, LDL-C and triglyceride ($p<0.001$), ($p<0.001$), ($p<0.003$) respectively, and also it demonstrated that the systolic blood pressure lessened after the intensive statin therapy ($p=0.04$)⁶. Further, a randomized, double-blind, placebo-controlled trial reported that statins lower both SBP and DBP relative to placebo; that the effect extends to persons with "pre-hypertension"¹⁸. Furthermore, other studies reported that the statin therapy led to a greater reduction in systolic blood pressure^{5,9}.

In addition, the study revealed that there exists a significant relationship between the reduction in mean LDL value with a systolic BP (P value <0.05). It can be noticed that patients with high systolic BP had a greater mean LDL value (2.3042 mmolN), followed by patients with normal systolic BP (1.9978 mmolN) and patient with low systolic BP had the least mean LDL value (1.5758 mmolN) (Table 2).

This could be due to the effect of statins on blood pressure fairly by the vasodilatory effect that follows their capacity to improve endothelium-dependent vasorelaxation. Additional mechanisms could involve the up-regulation of nitric oxide synthase. It was identified that statins increase the availability of nitric oxide through an increase in endothelial nitric oxide synthase activity and expression and also inhibit endothelin-1 production^{9,19}. Impairment in peripheral arterial compliance has been observed in patients with high serum cholesterol levels and could contribute to increased blood pressure. The treatment with statins, by reducing serum cholesterol levels, can increase arterial compliance, thereby improving the vasodilator capacity of the large arteries. This could have contributed to the overall blood pressure-lowering effect observed in the study^{7,11}.

Defined daily dose (DDD) and the cost of statin utilization

In current study DDD\1000 patients\day was calculated according to the drug therapeutic committee with reference to the WHO recommended method (ATC) classification and its found to be (20.24) for Rosuvastatin followed by (13.5) for Atorvastatin.

Evaluation of the cost of statin utilization for patients with CAD

A comparison of the costs between different doses of Atorvastatin, shows that Atorvastatin 40mg was the most widely used quantity per year, it costs 5.93 AED per tablet, 162,333.75 AED per year and 2,16,445AED per 100 patients. The second abundantly used dose was Atorvastatin 20mg, costs 4.05AED per tablet, 11,680AED per year and 147,825 AED per 100 patients and Atorvastatin 10mg and 80mg which had the equivalent amount issued per year. The cost for Atorvastatin 80mg was 11.86 AED per tablet, 51,946.8 AED per year and 8,65,780 AED per 100 patients, whereas Atorvastatin 10mg costed 2.57AED per tablet, 11,256.6 AED per year and 93805 AED per 100 patients. Among Rosuvastatin group, high dose (20 mg) was widely pre-scribed and compared to its low dose 10mg (Table 3).

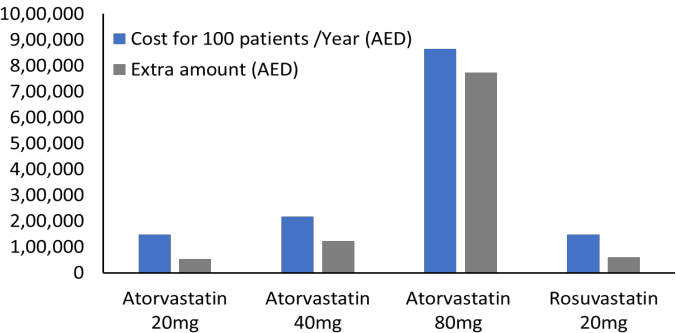
Statins	N	Cost per tab. (AED)	Amount of drug issued/ year (mg)	Cost for 1 year (AED)	Cost for 100 patients /Year (AED)
Atorvastatin 10mg	12	2.57	4,380	11,256.6	93805
Atorvastatin 20mg	32	4.05	11,680	47,304	147,825
Atorvastatin 40mg	75	5.93	27,375	162,333.75	216,445
Atorvastatin 80mg	6	11.86	4,380	51,946.8	865,780
Rosuvastatin 10mg	29	2.37	10,585	25,086.45	86,505
Rosuvastatin 20mg	52	4.01	18,980	76,109.8	146,365

Cost evaluation of the additional amount spent on statins

From the previous analysis it is observed that, Atorvastatin 10mg has lowest cost with greater mean LDL reduction among studied group. Thus, we calculated the extra amount that we could have saved if Atorvastatin 10mg was used instead of Atorvastatin 20mg. The amount saved would be 54,020 AED, 122,640 AED and 771,975 AED, for Atorvastatin 40mg, the saved amount would have been and Atorvastatin 80mg, the saved amount would have been. As a whole, the whopping amount that can be saved if Atorvastatin 10mg was used instead of other Atorvastatin doses was (948,635 AED) (Figure 1).

According to the analysis, Rosuvastatin 10mg and Rosuvastatin 20mg had approximately the same mean LDL reduction with different costs. Thus, we calculated the additional amount that could be saved if 10mg dosage of Rosuvastatin was used instead of 20mg., In such scenario 59,860 AED could have been saved. Pharmacoeconomic analysis showed that a total of 1,05,15,795 AED could have been saved if Atorvastatin 10mg was used due of its because of its affordability as well as efficacy in the reducing the serum LDL levels.

Figure 1: The additional amount spent on Atorvastatin & Rosuvastatin higher doses



The dose-to-dose comparisons between Rosuvastatin and Atorvastatin revealed that Atorvastatin 10mg reduced LDL cholesterol better than Rosuvastatin 10mg. Similarly, Rosuvastatin 20mg lowered LDL cholesterol higher than Atorvastatin 20mg, whereas Atorvastatin 40mg reduced LDL cholesterol better than Rosuvastatin 20mg. The best LDL-C reductions with both types of statins were obtained at dose of 10mg (Table-2). A comparative analysis at all statins included in the current study revealed a substantial money could have been saved if Atorvastatin 10mg was used due its affordability.

From the results of the study, it can be said atorvastatin 10mg was the cost-effective statin in patients with coronary artery disease for one year. Although we didn't find a significant statistically difference in the LDL-C reduction between Atorvastatin and Rosuvastatin with different doses. However, further studies are necessary to compare the effects of different statins on lipid parameters.

A systematic review and meta-analysis on the therapeutic equivalence of statins found that Atorvastatin 10mg reduced the LDL level by (30-40%) whereas Rosuvastatin ≥ 10mg and Atorvastatin ≥ 20mg reduced the LDL levels more than 40%. It was also observed that among all types of statins, the only two statins that could reduce LDL-C more than 40% were Rosuvastatin and Atorvastatin at a daily dose of 20 mg or higher (Weng et al., 2010). A systematic review and meta-analysis conducted to determine by how much statin reduce LDL-C and incidence of IHD events and stroke, found that the reduction in the LDL-C according to statin dose reduced IHD events and stroke. also, it showed that the greater reduction in LDL-C with Rosuvastatin 80mg (58%) followed by Atorvastatin 80mg (55%), and according to dose-dose comparison we found that Rosuvastatin has a greater reduction in LDL-C than Atorvastatin in equivalent doses¹. In another systematic review it was reported that Rosuvastatin was more efficacious in reducing the LDL-C than Atorvastatin ^{15-17,21}.

According to non-invasive prospective study conducted in Rajah Muthiah Medical College Hospital from Novem-

ber –2015 to April 2016, reported that Atorvastatin 80mg produce maximum lipid reduction (34.62%) followed by Atorvastatin 40mg (26.23%), next Rosuvastatin 20mg (25.10%), then Atorvastatin 20mg (24.16%) and the least lipid reduction produced by atorvastatin 10mg. These findings indicate that atorvastatin and Rosuvastatin exhibited a mean lipid reduction of 26.23% and 25.10% at doses like 40mg and 20mg respectively⁸. Furthermore, there is another prospective observational study which was conducted at cardiology department of Cosmopolitan Hospital, showed that in the pairwise, dose-to-dose comparisons with Atorvastatin, Rosuvastatin 10mg reduced LDL cholesterol significantly more than Atorvastatin 10mg. Rosuvastatin 20mg reduced LDL cholesterol significantly better than Atorvastatin 20mg, and Rosuvastatin 40mg reduced LDL cholesterol significantly comparative to Atorvastatin 40mg. The best LDL-C reductions were obtained with Rosuvastatin at dose of 40mg (Dr. V. V. Padmavathi et. al., 2014). Furthermore, according to the percentage LDL reduction (table -2), it shows that Rosuvastatin (5mg-10mg) with cost of 4.05 dirhams per tablet and Atorvastatin (20mg) with cost of 2.57 dirhams per tablet have the same LDL reduction which is (30-40%). Also it demonstrates that Rosuvastatin (20 mg) with cost of 4.01 dirhams per tablet is equivalent to Atorvastatin (80mg) with cost of (11.86 dirhams per tablet), reduce the LDL by (50-55%)¹⁰.

This study clearly indicate that statins were extensively prescribed and used for patients with coronary artery disease. The study also reveals that Rosuvastatin was the most used class of statins according to defined daily dose. This study also sheds light that, age and systolic blood pressure play a major role in adversely affecting CAD risk factors. In conclusion, analysis of the study data demonstrated that Rosuvastatin 10mg had a benefit in prevention of coronary artery disease and reducing the LDL with the least cost. A large monetary benefit can be achieved if Rosuvastatin 10mg when used due to its efficacy in the reduction of LDL, instead of other statins which would cost around 1,05,15,795 AED for 100 patients per year. Hence, it can be suggested as the cost-effective statin in patients with coronary artery disease.

Study limitation

This is a retrospective study, thus all the limitations related to retrospective study design were observed, namely incomplete records and lack of detail information. This study being a cross-sectional one, represents only survivor patients. The study is that treatment with HTN drugs among CAD group could have resulted in lower blood pressure with CAD.

Recommendations

An awareness campaign to educate the public about the heart disease and importance of their health. Also, we can advise and encourage the public to take the 'National Periodic Health Screening', at the health centers of UAE. To get a detailed insight about the statin utilization in emirate of Al-Fujairah, a prospective study with a large sample representing the whole emirate is recommended. Awareness campaign, workshops and continuous medical education (CME) to educate the health care providers especially the physicians, pharmacists and postgraduate medical students to balance both cost and quality of treatment when prescribing the medicine for the patient.

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List of abbreviations

AED: Arab Emirates Dirham. ATP: Adult Treatment Panel. CAD: Coronary Artery Disease. CME: Continuing Medical Education. CVD: Cardiovascular Disease. DBP: Diastolic Blood Pressure. HTN: Hypertension. IHD: Ischemic Heart Disease. LDL: Low Density Lipoprotein. NPHS: National Periodic Health Screening. SBP: Systolic Blood Pressure. UAE: United Arab Emirates

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