



# Availability, Prices, and Affordability of Essential Cardiovascular Medicines in Tripoli, Libya: A Cross-Sectional Survey

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## Abstract

**Background** Cardiovascular diseases (CVDs) remain the leading cause of death worldwide. In many low-income and middle-income countries, these fatalities are exacerbated by poor accessibility and affordability of essential cardiovascular medications.

**Aim** This study was aimed to investigate the availability, prices, and affordability of essential CVD medications, and to determine the key factors influencing these outcomes in Tripoli, Libya.

**Methods** The World Health Organization/Health Action International method was employed to survey a convenience sample of 200 community pharmacies for 17 essential CVD medications in September 2023. Data on availability, presence of an import sticker, and prices of the originator brand (OB) and lowest-priced generic (LPG) for each medication were collected. The main measured variables were the percentage availability, the proportion of medications with an import sticker, the median price ratio (MPR), the price variation among pharmacies, the ratio of OB to LPG prices, and the affordability. The affordability was expressed in terms of the number of days a lowest-paid government employee would need to work to pay for a 1-month supply of medication. Descriptive statistics using Excel and R summarized availability, prices, and affordability. The Mann–Whitney U test compared metrics between originator and generic medicines. Spearman's rank correlation ( $\rho$ ) assessed variable relationships, and a mixed-effects linear regression model identified price determinants.

**Results** The mean availability of OBs was significantly lower than that of LPGs (25.6 vs. 55.9%,  $p < 0.007$ ). A total of 13% of OBs had an import sticker, whereas only 1% of LPGs did. Dispensing prices were higher than international reference prices for both OBs (MPR = 7.4) and LPGs (MPR = 3.7). Price variation across pharmacies exceeded a 4-fold difference for both OBs and LPGs. The OB/LPG price ratio was greater than 2. The cost of 1-month treatment courses exceeded 1-day wage on average for both OBs (2.9, 95% confidence interval [CI]: 1.7–4.1) and LPGs (1.5, 95% CI: 0.7–2.3). The availability level was negatively correlated with the days' wages ( $\rho = -0.42$ ,  $p < 0.04$ ) and positively correlated with the number of manufacturing countries and competing manufacturers ( $\rho = 0.5$ ,  $p < 0.01$ ). Conversely, the required number of days' wages was

## Keywords

- ▶ availability
- ▶ affordability
- ▶ price
- ▶ essential medicines
- ▶ cardiovascular diseases
- ▶ Libya

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positively correlated with the median unit price ( $\rho = 0.59$ ,  $p < 0.01$ ). Prices were significantly influenced by drug type (OB/LPG), drug class, and the region of manufacturer (Africa/ Asia).

**Conclusion** Essential CVD medications in Tripoli were found to have suboptimal availability and poor affordability. The price variation and the lack of importer information suggest systemic issues in the supply chain and distribution that require policy interventions.

### ملخص المقال باللغة العربية

التوافر، والأسعار، والقدرة على دفع سعر الأدوية الأساسية للأمراض القلبية في طرابلس، ليبيا: مسح مقطعي.

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**الخلفية:** لا تزال الأمراض القلبية الوعائية (CVDs) السبب الرئيسي للوفاة على مستوى العالم، وتتفاقم هذه الوفيات في العديد من البلدان المنخفضة والمتوسطة الدخل، بسبب ضعف توافر الأدوية القلبية الوعائية الأساسية وقدرة المرضى على تحمل تكلفتها.

**الهدف:** هدفت هذه الدراسة إلى تفصي مدى التوافر والأسعار والقدرة على تحمل تكلفة الأدوية الأساسية للأمراض القلبية الوعائية في طرابلس، ليبيا، وتحديد العوامل الرئيسية المؤثرة على هذه النتائج. **الطرق:** تم استخدام منهجية منظمة الصحة العالمية/التحالف الدولي للعمل الصحي (WHO/HAI) لمسح عينة متاحة من 200 صيدلية مجتمعية بطرابلس لـ 17 دواءً أساسياً للأمراض القلبية الوعائية في سبتمبر 2023. تم جمع بيانات عن التوافر، وجود ملصق الاستيراد، وأسعار الأدوية التجارية الأصلية (OB) وأدنى سعر لمكافئها الدوائي (الجنيس). كانت المتغيرات الرئيسية المقاسة هي: النسبة المئوية للتوافر، ونسبة الأدوية ذات ملصق الاستيراد، ونسبة السعر الوسيط (MPR)، وتفاوت الأسعار بين الصيدليات، ونسبة سعر الأدوية الأصلية إلى أدنى سعر للدواء الجنيس، وقدرة المواطن على دفع سعر الدواء، تم التعبير عن القدرة على الدفع من حيث عدد الأيام التي يحتاجها موظف حكومي منخفض الأجر للعمل لدفع ثمن تزويد شهر واحد من الدواء، تم تحليل البيانات وصفيًا واستدلاليًا باستخدام برنامجي Excel و R. قارن اختبار مان-ويتني يو بين هذه المقاييس للأدوية الأصلية والجنيسة، وقيم معامل ارتباط رتب سبيرمان ( $\rho$ ) العلاقات بين المتغيرات، وحدد نموذج الانحدار الخطي ذو المؤثرات المختلطة محدثات السعر.

**النتائج:** كان متوسط توافر الأدوية ذات العلامة التجارية الأصلية أقل بشكل ذي دلالة إحصائية من نظيره للأدوية الجنيسة (25.6% مقابل 55.9%،  $p < 0.007$ ). حمل 13% فقط من منتجات العلامات الأصلية ملصق استيراد، مقارنة بـ 1% فقط من الأدوية الجنيسة. تجاوزت الأسعار المحلية الأسعار المرجعية الدولية لكل من العلامات الأصلية (نسبة السعر الوسيط  $MPR = 7.4$ ) والأدوية الجنيسة ( $MPR = 3.7$ ). بلغ تفاوت الأسعار بين الصيدليات أكثر من أربعة أضعاف لكلا النوعين، وكان متوسط سعر العلامات الأصلية يزيد عن ضعف سعر الأدوية الجنيسة. تجاوزت تكلفة العلاج الشهري أجر يوم واحد لكلا الفئتين (العلامات الأصلية: 2.9 يوم، فاصل ثقة 95%: 1.7-4.1؛ الأدوية الجنيسة: 1.5 يوم، فاصل ثقة 95%: 0.7-2.3). أظهر التحليل ارتباطاً سلبياً بين مستوى التوافر وأيام الأجر المطلوبة ( $\rho = -0.42$ ,  $p < 0.04$ ) وارتباطاً إيجابياً مع عدد الدول المصنعة والشركات المتنافسة ( $\rho = 0.5$ ,  $p < 0.01$ ). كما ارتبطت أيام الأجر إيجابياً بالسعر الوسيط للوحدة ( $\rho = 0.59$ ,  $p < 0.01$ ). تأثر السعر بشكل ملحوظ بنوع الدواء (أصلي/جنيس)، وفتته الدوائية، ومنطقة تصنيعه (أفريقيا/آسيا).

**الاستنتاج** توصلت الدراسة إلى أن توافر الأدوية الأساسية للأمراض القلبية الوعائية في طرابلس دون المستوى الأمثل، وتشكل تكلفتها عبئاً مالياً على المرضى، ويعكس التفاوت الكبير في الأسعار وغياب معلومات الاستيراد خلالاً ميكلياً في سلسلة التوريد، مما يستدعي تدخلاً عاجلاً من صانعي السياسات لتنظيم السوق وضمان الوصول العادل إلى العلاج.

**الكلمات المفتاحية:** التوافر، القدرة على القدرة على الدفع، السعر، الأدوية الأساسية، الأمراض القلبية الوعائية، ليبيا.

## Introduction

Cardiovascular diseases (CVDs), a group of conditions affecting the heart and blood vessels, remain the leading cause of premature death globally.<sup>1</sup> In 2022, CVDs accounted for approximately 32% of global deaths, with more than 75% were reported in low- and middle-income countries (LMICs).<sup>2,3</sup> At the national level, CVDs caused around 14,048 deaths in 2021.<sup>4</sup> Beyond physical disability, these diseases also influence mental health and impose a heavy financial burden on individuals, families, and health care systems worldwide.<sup>1</sup> Global expenditure on cardiovascular care is expected to exceed \$1,044 billion by 2030.<sup>5</sup>

The effective management of CVDs often requires a combination of medication and lifestyle modification. Medications play a central role in managing symptoms, halting

disease progression, and reducing the risk of complications, including heart attacks and strokes.<sup>1</sup> Patients with CVDs must have access to the appropriate medications and diagnostic technologies. According to the World Health Organization (WHO), the following essential CVD medications should be accessible: statins, diuretics,  $\beta$ -blockers, angiotensin-converting enzyme inhibitors, calcium channel blockers, and aspirin.<sup>2</sup> These medications are considered to be cost-effective for both primary and secondary prevention.<sup>6</sup>

The initiatives focused on modifiable risk factors require substantial system and infrastructural changes, supportive environments, and individual behavioral adjustments. These are difficult and time-consuming endeavors, especially in low-resource countries.<sup>5</sup> As a result, millions of people with CVDs still have no viable alternatives other than relying on long-term pharmacotherapy to control the disease.<sup>5</sup> Given

that most people with CVDs require long-term treatment, continuous and affordable access to essential medications is critical for their survival, disease control, and improved quality of life.<sup>3,5,7</sup> However, people in LMICs have poor access to efficient health care services. Consequently, treatment is started late, and many people die prematurely during their most productive years.<sup>2</sup> A recent study revealed that more than 50% of eligible patients were not taking any of the basic CVD medications,<sup>6</sup> with high cost and limited availability among the major contributing factors.<sup>7,8</sup>

In Libya, the health system comprises both public and private sectors, with the public sector being the primary provider of health services. This sector provides free health care, including preventative, curative, and rehabilitative treatment to all citizens. Medicines are procured based on the national essential medicines list issued in 2019.<sup>9</sup> This list includes antianginal medicines, antiarrhythmic medicines, antihypertensive medicines, medicines used in heart failure, antithrombotic medicines, and lipid-lowering agents. Although almost all Libyan hospitals, polyclinics, and public health care facilities are capable of performing provisional diagnoses of CVDs, the magnitude and quality of these services are affected by the severe shortages of qualified personnel, essential medications, diagnostic equipment and supplies.<sup>10,11</sup> These issues were exacerbated by the political conflicts leading to partial or complete shutdown of many public health care facilities. As a result, approximately 55% of CVD patients being referred to the major hospitals or to the private sector.<sup>10</sup> The private sector has expanded significantly, offering a wide range of cardiac services.<sup>11</sup> In this sector, the health services are paid either by insurance companies or out-of-pocket<sup>11</sup> (the major path). Currently, most Libyans with CVDs purchase their necessary medications out-of-pocket from the private sector due to the public sector's inadequate supply.

It is crucial to examine the availability and affordability of essential medications for CVDs and the difficulties posed for health care systems to develop strategies that ensure appropriate access to these medications.<sup>3,5</sup> To date, no previous published studies have examined these issues in Libya. Therefore, this study aims to investigate the availability, prices, and affordability of essential medications for CVDs offered by community pharmacies in Tripoli, Libya, and to identify the factors associated with these outcomes.

## Methods

### Selection of Medicines

Essential CVD medications were first identified through the Libyan Essential Medicines List.<sup>9</sup> The national list contains 55 cardiovascular drugs, a few of which had either only one dosage form or one dosage strength. From this list, 17 medications suitable for outpatient use without direct hospital supervision were selected. This criterion was confirmed by reviewing the monograph of each medication in the British National Formulary 83. The selected drug list was reviewed by three community pharmacists with over 5 years of professional experience. The pharmacists were consulted to refine the drug list, specify the most commonly used

strengths or dosage forms for medications with multiple formulations, and verifying the preidentified originator brand names (OB). The term OB describes a pharmaceutical product that is marketed by the original manufacturer, who is also the owner of its intellectual property. As a result, some targeted strengths and dosage forms were adjusted. The final list is provided in **Supplementary Table S1** (available in online version only).

A pilot study was conducted in 25 community pharmacies to train two senior pharmacy students. The training covered pharmacists interviewing, obtaining, and documenting the required data in a special proforma and data analyses based on the determined study variables. The data from the pilot study were excluded from the main study's analysis because of the 1-month time gap between the two stages, which could affect the stability of the market's prices.

An ethical approval for conducting this study was obtained from the Scientific Research and Ethics Committee at the University of Tripoli (SREC-UOT); Ref No: SREC-UOT 10-2022.

### Data Collection

This is a descriptive cross-sectional study using the WHO/Health Action International (HAI) standard methodology.<sup>12</sup> The main study was conducted in Tripoli from September 4 to 25, 2023. The target sample size was estimated to be 193, based on the total number of 384 community pharmacies in Tripoli (Libyan Pharmacist Syndicate, July 2023). Under these assumptions, the level of drug availability is 50% with an accepted margin of error of 5%. A convenience sample of 200 private retail pharmacies distributed in 12 regions of four municipalities in the city was surveyed. The data collectors visited each pharmacy and interviewed the pharmacist on duty. For every medication on the list, the following information was recorded: availability, source, presence of an import sticker (the sticker serves as the study's operational indicator of legally recorded importation), price of the preidentified OB, and price for the lowest-priced generic (LPG). LPG refers to the lowest-priced generic product that is offered at the pharmacy. If a pharmacy offered multiple generics, only the formulation with the lowest unit price was recorded (price per tablet, to account for the variation in package quantities).

### Data Analyses

The data were entered into an Excel sheet, checked for errors, and then analyzed. Medication availability was determined by calculating the percentage of the 200 pharmacies stocking each medication on the day of data collection,<sup>8,12</sup> with the outcome placed in one of five categories: not available at all (0%), extremely low (< 30%), low (30–49%), fairly high (50–80%), and high (> 80%).

Prices were recorded in the local currency (Libyan dinar). We determined whether there were price variations among the pharmacies by calculating the highest-to-lowest price ratio of OBs and LPGs, separately. Through this ratio, it was possible to determine how many times the highest unit price in a collection of product unit prices was higher than the lowest price. Moreover, the prices of OB were compared with the LPGs' prices through the median price ratio (MPR).

The median prices for medications available in more than four pharmacies were calculated and converted to U.S. dollars (1 USD = 5.195 LD). These were compared with the international reference prices (IRPs), which represent the most recent procurement price list released in 2016 by the Management Sciences for Health.<sup>13</sup> These reference prices were issued to support drug procurement agencies in developing countries and provide a useful benchmark for price comparisons across countries. The worldwide annual consumer inflation rate was used to adjust the IRPs to current prices (year 2023). The MPR was calculated by dividing the local median prices by the adjusted IRP. An MPR greater than 2.5 was interpreted as an excessively high local dispensing price.

Affordability of a medication used for chronic condition was expressed as the number of workdays a lowest-paid unskilled government worker would have to work to earn the cost of a 1-month supply.<sup>8,12</sup> According to the most recent government wage table, the lowest daily wage is 25 LD (US \$4.8/day). The affordability was calculated by dividing the cost of treatment for a 30-day supply by the lowest daily wage of an unskilled government employee. The cost of a monthly treatment was estimated by first determining the quantity required for a 30-day supply through the defined daily dose (DDD). For Example, the DDD of acetylsalicylic acid 75mg is one tablet per day, a one-month treatment requires 30 tablets. This quantity was then multiplied by the median price of single dosage form unit. The single-unit price was used to avoid the variation in the package quantity across different manufacturers. The cost of a monthly treatment was considered affordable if it did not exceed a 1-day wage.

The Mann-Whitney U test was used to compare the non-normally distributed availability, affordability, and MPR metrics between OBs and LPGs. Spearman's rank correlation ( $\rho$ ) was employed to assess the relationship between availability/affordability and their continuous associated factors (e.g., number of competing manufacturers). Finally, a mixed-effects linear regression model was constructed to identify factors significantly affecting the median unit price while accounting for the nonindependence of price observations nested within the surveyed drug formulations. The lowest price category was set as the reference category for each variable in the model. All statistical analyses were performed using R software (version 4.4.1), and a  $p$ -value of  $<0.05$  was considered statistically significant.

## Results

Across all medicines, the mean availabilities of OBs and LPGs were 25.6% (95% confidence interval [CI]: 8–43) and 55.9% (95% CI: 37.6–75.5), respectively (**Table 1**). Among the available medications, only 13% of OBs and 1% of LPGs carried an import sticker. As shown in **Fig. 1**, a high availability level ( $>80\%$ ) was observed for two OB drug classes (beta-blockers and P2Y12 inhibitor) and five LPG drug classes (beta-blockers, P2Y12 inhibitor, angiotensin-converting enzyme inhibitors, statins, and nonsteroidal anti-inflammatory drugs [NSAIDs]). Individual drug availability analysis

(**Table 1**) showed that five OBs (acetylsalicylic acid, digoxin, enalapril, furosemide, and hydralazine hydrochloride) were completely unavailable in all surveyed pharmacies. Six OBs were available at only an extremely low level, whereas two OBs were available at a high level. In contrast, all LPGs were available in varying proportions, with seven medications showing a high availability. Further details are presented in **Table 1**.

**Table 1** shows that the mean MPR of OBs was numerically higher than that for LPGs, but this difference was not statistically significant ( $p > 0.05$ ). Among the eight OBs for which data were available, five had an MPR larger than 2.5, and the mean MPR of OBs was 7.4 (95% CI: 0.1–14.7). Among the OBs, hydrochlorothiazide (25.3), amlodipine (16.4), and methyldopa (5.6) had the highest MPRs. In contrast, four of the 13 LPGs had an MPR higher than 2.5 with a mean MPR of LPGs being 3.7 times (95% CI: 1.1–6.3) higher than the IRP. The highest MPRs among the LPGs were noted for digoxin and hydrochlorothiazide (both 12.6), enalapril (6.9), and methyldopa (3.8).

There was noticeable price variability for both the OBs and LPGs among the surveyed pharmacies (**Table 2**). The mean of high-to-low price ratio exceeded 4 for both OBs and LPGs. The preidentified OBs were manufactured in a range of 1 to 5 countries, whereas the LPGs were manufactured in a range of 1 to 9 countries by up to 12 manufacturers. The median prices of OBs were higher than the median prices of their equivalent LPGs, with a mean ratio of 2.9.

As shown in **Table 1**, the mean affordability levels of OBs and LPGs were significantly different ( $p < 0.025$ ): 2.9 days (95% CI: 1.7–4.1) and 1.5 days (95% CI: 0.7–2.3), respectively. This affordability gap was also reflected at the drug class level (**Fig. 1**). None of the drug classes with OB type were affordable for the lowest-paid government worker, whereas six drug classes with LPG type were affordable. The affordable LPG classes were angiotensin II receptor blockers, beta-blockers, cardiac glycoside, K<sup>+</sup> channel blocker, NSAIDs, and statins. The individual drug analysis (**Table 1**) showed that the cost of a 1-month course treatment of nine LPGs and only one OB was affordable for the lowest-paid unskilled government workers. According to our definition, the remaining medications were not affordable. Treatment courses with OBs of methyldopa (5.6 days' wage), verapamil (5 days), and spironolactone (3.6 days) were among the top three least affordable OBs. Among the LPGs, glyceryl trinitrate (5.6 days), methyldopa (3.8 days), and verapamil (3.3 days) were ranked lowest in terms of affordability.

The relationships between availability/affordability with the other variables are presented in **Table 3**. The percentage of the drug availability showed a significant negative correlation with the number of days' wages ( $\rho = -0.42$ ,  $p < 0.04$ ). Conversely, availability was positively correlated with supply-side factors, showing a moderate positive relationship with both the number of manufacturing countries ( $\rho = 0.51$ ,  $p < 0.002$ ) and the number of competing manufacturers ( $\rho = 0.50$ ,  $p < 0.002$ ). Furthermore, the number of days' wages was positively correlated with the median unit price ( $\rho = 0.59$ ,  $p < 0.002$ ).

**Table 1** Availability, median price ratio to international reference prices and affordability of the surveyed medications<sup>a</sup>

Medication <sup>b</sup>		Availability <sup>c</sup>		MPR <sup>d</sup> (local/IRP)		Affordability <sup>e</sup>	
		OB	LPG	OB	LPG	OB	LPG
Acetylsalicylic acid 75 mg		0.0	98.5	–	1	–	0.1
Amiodarone HCL 200 mg		49.5	10.1	2.4	1.5	1.4	0.9
Amlodipine 5 mg		76.5	96.5	16.4	2.1	2	0.3
Bisoprolol 5 mg		88.5	89.0	0.2	0.6	2.9	0.6
Clopidogrel 75 mg		88.0	90.5	3.3	1.5	2.6	1.2
Digoxin 250 mcg		0.0	66.5	–	12.6	–	1
Enalapril 5 mg		0.0	89.5	–	6.9	–	1.1
Furosemide 20 mg		0.0	88.0	–	–	–	0.5
Glycerol trinitrate 0.5 mg		1.0	42.0	–	0.9	–	5.6
Hydralazine HCL 25 mg		0.0	0.5	–	–	–	–
Hydrochlorothiazide 25 mg		53.0	8.5	25.3	12.6	0.8	0.4
Isosorbide mononitrate 20 mg		0.5	9.5	–	0.7	–	1.8
Losartan 50 mg		10.5	44.0	–	–	2.5	0.8
Methyldopa 250 mg		10.5	49.0	5.6	3.8	5.6	3.8
Simvastatin 10 mg		0.5	91.5	–	–	–	1
Spironolactone 25 mg		55.0	76.5	3.8	2.5	3.6	2.3
Verapamil HCL 40 mg		2.0	11.0	2.3	1.5	5	3.3
Mean		25.6	55.9	7.4	3.7	2.9	1.5
95% CI	Lower limit	8	37.6	0.1	1.1	1.7	0.7
	Upper limit	43	75.5	14.7	6.3	4.1	2.3
p-Value <sup>f</sup>		0.007*		0.191		0.025*	

Abbreviations: CI, confidence interval; IRP, international reference price; LPG, lowest-priced generic; MPR, median price ratio; OB, originator brand.

<sup>a</sup>“–” = absence of the IRP or medication was available in fewer than four pharmacies.

<sup>b</sup>All medications are in tablet form.

<sup>c</sup>Availability is the proportion of pharmacies that stocked the medication at the time of data collection.

<sup>d</sup>MPR is the ratio between local median price to the adjusted IRP price.

<sup>e</sup>Affordability refers to a day's wage of lowest-paid government employees needed to pay for a month's supply of medication.

<sup>f</sup>Mann–Whitney U test (the estimate is statistically significant if  $p$ -value < 0.05).

The multilevel mixed-effects regression was used to model the possible factors influencing the unit price of drugs. The Null Model indicated that 37% of the total variance in the price occurred between different drugs. The introduction of fixed effects significantly reduced this variance to 8%, demonstrating that the selected fixed effects accounted for 29% of the variability between drug prices. As shown in **Table 4**, the drug price was significantly higher for OBs compared with LPGs ( $\beta=0.98$ , 95% CI: 0.94–1.0,  $p < 0.001$ ). Price was also significantly associated with specific drug classes compared with the reference class (NSAIDs); P2Y12 inhibitors ( $\beta=1.1$ ,  $p < 0.035$ ) and vasodilators ( $\beta=1.7$ ,  $p < 0.003$ ) showing significantly higher prices. Price also varied by region of drug origin, being significantly higher for products from Africa ( $\beta=0.38$ ,  $p < 0.001$ ) and Asia ( $\beta=0.48$ ,  $p < 0.001$ ) compared with North America. The presence of an import sticker and the remaining drug classes did not show a statistically significant influence on the drug unit price.

## Discussion

CVD medications are required for long-term treatment to prevent, control, and manage CVDs. However, their utilization level remains low, especially in LMICs.<sup>8</sup> Our findings demonstrate that the availability of both OBs and LPGs was below the WHO target for noncommunicable diseases. Furthermore, most available products lacked an official import sticker and were unaffordable for unskilled government employees. Moreover, all LPGs were less expensive than the OBs. However, two key issues were identified with their prices: high MPR and significant variation across the pharmacies. The availability was affected by supply-side factors, whereas the affordability was mainly determined by the product prices. The unit price was significantly affected by the product type, specific drug classes, and the geographic region of drug origin.

The mean availability of both OBs (very low at 25.6%) and LPGs (fairly high at 55.9%) did not meet the WHO

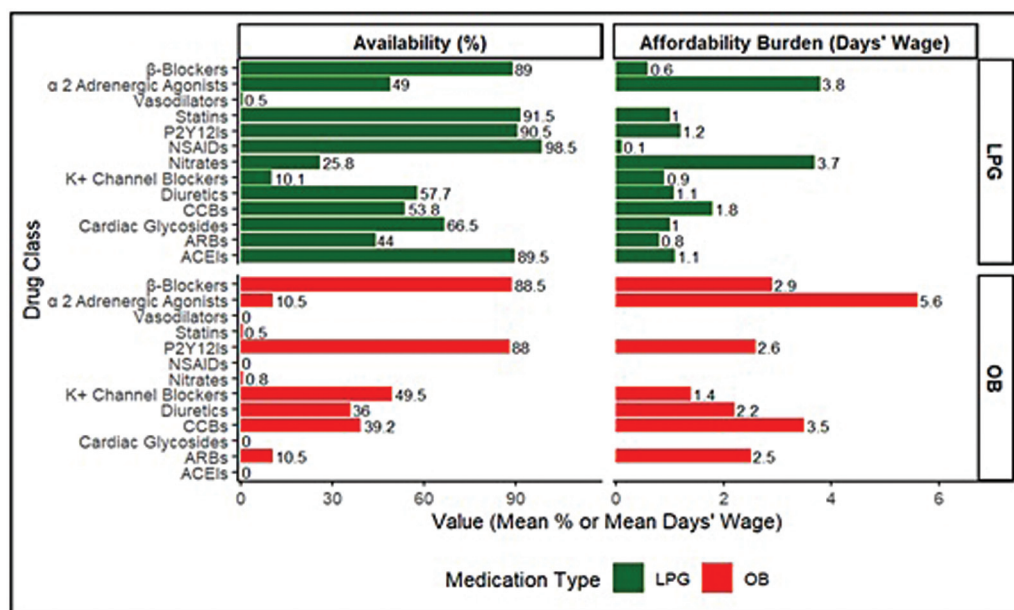


Fig. 1 The availability and the affordability levels according to drug class and type.

Table 2 Price variation for each medication and between originator brand/lowest-priced generic among the surveyed community pharmacies<sup>a</sup>

Medication <sup>b</sup>	Number of manufacturing countries		Number of manufacturers <sup>d</sup>	High to low		MPR <sup>c</sup>
	OB	LPG		OB	LPG	
Acetylsalicylic acid 75 mg	0	2	3	–	10	–
Amiodarone HCL 200 mg	3	4	6	3.1	5.4	1.6
Amlodipine 5 mg	4	3	4	8	3.7	7.8
Bisoprolol 5 mg	2	4	8	5	6.4	4.8
Clopidogrel 75 mg	1	4	8	4.5	4.3	2.1
Digoxin 250 mcg	0	1	2	–	3.5	–
Enalapril 5 mg	0	9	11	–	2.8	–
Furosemide 20 mg	0	1	2	–	3.3	–
Glyceril Trinitrate 0.5 mg	2	1	1	–	1.4	–
Hydralazine HCL 25 mg	0	1	1	–	–	–
Hydrochlorothiazide 25 mg	1	4	4	2.6	3.8	2
Isosorbide mononitrate 20 mg	1	3	4	–	9.5	–
Losartan 50 mg	1	3	4	2.7	5.8	3.2
Methyldopa 250 mg	4	9	12	2.4	5	1.5
Simvastatin 10 mg	0	2	4	–	3	–
Spironolactone 25 mg	5	3	4	6.7	4.4	1.6
Verapamil HCL 40 mg	3	3	6	3	3.4	1.5
Mean	1.6	3.4	4.9	4.2	4.7	2.9

Abbreviations: LPG, lowest-priced generic; MPR, median price ratio; OB, originator brand.

<sup>a</sup>“–” = medication was available in fewer than four pharmacies.

<sup>b</sup>All medications are in tablet form.

<sup>c</sup>MPR is the ratio between median prices of OBs and median prices of LPGs.

<sup>d</sup>The manufacturers for OBs are already preidentified refer to Supplementary File S1.

**Table 3** Factors associated with the availability and affordability of surveyed medications

Factor	Availability		Days' wage	
	$\rho$	<i>p</i> -Value	$\rho$	<i>p</i> -Value
Days' wage	-0.42	<b>0.04</b>	1.00	
Availability	1.00		-0.42	<b>0.04</b>
MPR ratio	-0.13	0.58	-0.03	0.90
High-to-low ratio	0.18	0.38	-0.25	0.23
Median unit price	-0.28	0.18	0.59	<b>0.002</b>
No. of manufacturing countries	0.51	<b>0.002</b>	0.10	0.64
No. of manufacturers	0.50	<b>0.002</b>	-0.36	0.08

Abbreviation: MPR, median price ratio.

**Table 4** Factors associated with the unit price of 17 medications among 200 community pharmacies

Characteristic	Beta	95% CI	<i>p</i> -Value
Type			
LPG	-	-	-
OB	0.98	0.94, 1.0	<b>&lt;0.001</b>
Drug Class			
NSAIDs	-	-	-
ACEIs	0.33	-0.60, 1.3	0.4
ARBs	0.6	-0.33, 1.5	0.15
Beta-blockers	0.14	-0.79, 1.1	0.7
Cardiac Glycosides	0.63	-0.30, 1.6	0.13
CCBs	0.25	-0.55, 1.1	0.4
Diuretics	0.04	-0.72, 0.80	0.9
K <sup>+</sup> Channel Blocker	0.29	-0.64, 1.2	0.4
Nitrates	0.4	-0.40, 1.2	0.2
P2Y12 inhibitors	1.1	0.13, 2.0	<b>0.035</b>
Statins	0.16	-0.76, 1.1	0.6
Vasodilators	1.7	0.69, 2.7	<b>0.003</b>
$\alpha$ 2 Adrenergic Agonist	0.51	-0.42, 1.4	0.2
Region			
North America	-	-	-
Africa	0.38	0.15, 0.61	<b>0.001</b>
Asia	0.48	0.23, 0.73	<b>&lt;0.001</b>
Europe	0.21	-0.01, 0.43	0.065
Import sticker			
No	-	-	-
Yes	0.05	-0.02, 0.12	0.13

Abbreviations: ACEIs, angiotensin-converting enzyme inhibitors; ARBs, angiotensin II receptor blockers; CCBs, calcium channel blockers; CI, confidence interval; LPG, lowest-priced generic; NSAIDs, nonsteroidal anti-inflammatory drugs; OB, originator brand.

recommendations (>80%).<sup>12</sup> Therefore, Libyan patients with CVDs in Tripoli may encounter challenges in obtaining their prescribed medications. In our study, five OBs were completely unavailable, which is likely due to these drugs have been off-patent for a long time (e.g., statins' patent

expired in mid-2000s<sup>8</sup>), the availability of generics, and the health authority efforts to support generic use. The fairly high availability of LPGs suggests that patients who seek those medications are likely to obtain them. Given the need for long-term care for patients with CVDs, access to LPG

medications may boost patient compliance and improve clinical outcomes at a lower cost than OBs. This suggests that legislative support for LPGs can improve availability to exceed 80% and enhance patient access to their required medications.

In a cross-country comparison, our finding, the availability of generics was higher than OBs is consistent with the observed patterns in the other studies conducted in Lebanon,<sup>14</sup> Zambia,<sup>15</sup> China,<sup>16</sup> Pakistan,<sup>17</sup> and 53 developing countries.<sup>8</sup> However, their exact values are different from ours. The availability of OBs in this study was lower than that reported in Pakistan (30%),<sup>17</sup> and LMICs (46%),<sup>8</sup> China (47.4%),<sup>16</sup> Qatar (64.8%),<sup>14</sup> and Lebanon (69.8%).<sup>14</sup> However it was higher than in the Central province of Zambia (0%).<sup>15</sup> The availability of the LPGs is lower than that reported in Lebanon (58.6%),<sup>14</sup> 53 developing countries (67%),<sup>8</sup> and China (70.2%).<sup>16</sup> However, it was higher than that reported in Qatar (29.6%),<sup>14</sup> Pakistan (34.9%),<sup>17</sup> Central province of Zambia (46.7%),<sup>15</sup> and Cameroon (49.2%).<sup>18</sup>

Most available OBs (87%) and almost all available LPGs (99%) lack the importer sticker on their packages, which creates a difficulty for tracking the sources of these items. The vast majority of CVD medications could have entered into the market through unofficial channels without any official record or regulatory check. This situation increases the likelihood of substandard and counterfeit products in the Libyan market. In such cases, the effectiveness and safety of using these medications cannot be guaranteed. However, the absence of this sticker should not be regarded as a definitive proof that the available medications are a result of illegal importation status or are of low quality. This is supported by a previous study, which reported that various brands of atenolol and furosemide sampled from the Libyan market met the physical and chemical quality assessment standards.<sup>19</sup> The current situation is likely a result of the parallel market phenomenon<sup>20</sup> or importers' noncompliance with the import regulations.

The local prices were much higher than the IRPs for both OBs (7.4 times) and LPGs (3.4 times). Both values exceeded the cutoff point (2.5) set by the WHO for private sector.<sup>12</sup> For the LPGs, this indicates that some of generic drugs' prices were still too high, specifically hydrochlorothiazide, digoxin, and enalapril. This suggests that the applied add-on costs (e.g., markups, taxes, distribution costs) by the private wholesalers/retailers to the manufacturer's price for both drug categories are high. This highlights an inefficient supply system in the private sector that should be studied to determine the possible causes. Although the difference in MPR between OBs and LPGs was not statistically significant, the consistently lower values for LPGs suggest a trend toward potential cost savings for patients if the LPGs were supported. Our findings are consistent with studies conducted in China (OBs = 14.6, LPGs = 3.4),<sup>16</sup> developing countries (OBs = 98.9, LPGs = 26.1),<sup>8</sup> Zambia (mean values were not computed),<sup>15</sup> Lebanon (OBs = 12.3, LPGs = 5.8),<sup>14</sup> and Qatar (OBs = 21.6, LPGs = 26.5),<sup>14</sup> and differ from a study conducted in Pakistan (OBs = 2.7, LPGs = 1),<sup>17</sup> where at least the LPGs were imported efficiently without adding excessive extra costs.

The cross-country difference is expected due to several factors, including country-specific factors (medicine prices, inflation rate, procurement systems, currency strength, price control policies), IRPs, and the study year.

Prices were not consistent across pharmacies for both OBs and LPGs. The price inconsistency for LPGs could result from collecting prices of products from multiple manufacturers; this variation was also noticed for the preidentified single manufacturer OBs, which might be partially attributed to the fact that these products are manufactured in multiple countries. This inconsistency could result from a lack of import control or price reduction policies and the existence of a parallel market. Because all pharmaceutical products are imported and procured in USD with no local manufacturing activities,<sup>15</sup> the prices are determined by external market forces (mainly the LD–USD exchange rate). Limiting the number of acceptable manufacturers and controlling prices by imposing a price cap and a limit on markup values would reduce these price discrepancies between pharmacies, diminish physicians' confusion during prescribing, and protect consumers from excessively high prices. Moreover, for all medications, OBs were dispensed at higher prices than LPGs. This emphasizes that the generic products are cheaper than the OB products. However, the small magnitude of difference (MPR OB/LPG, ► **Table 2**) in some formulations like verapamil (1.5 times) suggests generic prices were possibly raised with a higher markup value to nearly match the price of its corresponding OB. Again, the lack of a price control policy contributes to this manipulation.

On average, both OBs (2.9 days) and LPGs (1.5 days) were not affordable (>1 day<sup>12</sup>). For all surveyed medicines, the LPGs were more affordable than the OBs. The number of required dayworks was significantly associated with the median price, as the median price increase the medication becomes less affordable. The unaffordability of medications is a barrier for good medication adherence and better cardiovascular treatment outcomes, as it is associated with an increase in the risk of mortality by 20%.<sup>7</sup> To improve the situation, strategies like a strong supportive drug policy for generics, an establishment of local production, a price control and reduction through limit markup value, and a negotiation to obtain better prices need to be implemented.<sup>8,21</sup> Compared with the other studies, our affordability level of OBs is close to that reported in China (2.5 days),<sup>16</sup> but lower than values reported in Pakistan (6.4 days),<sup>17</sup> and 53 developing countries (6 days).<sup>8</sup> In contrast, our affordability level of LPGs is higher than in China (0.84 days),<sup>16</sup> but lower than in Pakistan (2.2 days),<sup>17</sup> and 53 developing countries (1.8 days).<sup>8</sup>

The findings revealed that dependence on diverse sources of supply for a medication (the number of manufacturers and number of manufacturing countries) makes the drug more reliably stocked in pharmacies. When a drug is sourced from many manufactures and multiple global locations, the local supply is protected from disruption (e.g., regulatory delays, production issues) in any single country, resulting in more consistent stock levels at the community level. This supports the principle of supply chain resilience.<sup>22</sup> This diversity

introduces suitable competition which, if properly controlled, can be used as a useful strategy for reducing medications prices and improving the affordability. Conversely, the availability level was negatively correlated with the number of days' wages. This indicates that expensive medications had low availability. This may reflect a low pharmacist willingness to stock expensive medications in community pharmacies. For a pharmacy owner, stocking expensive medications carries financial risks, which include tying up a significant part of the pharmacy's working budget<sup>23,24</sup> and increasing the risk of inventory write-offs due to product expiration, especially if they have lower and unpredictable demand.<sup>24</sup>

The multivariable analysis revealed that the unit price was significantly influenced by the medication type (-OB/LPG), the geographic region of the manufacturing country, and certain drug classes. Compared with the LPG as reference category, the OB status was associated with a higher unit price. Counter to the general assumption that African and Asian products are cheaper, the model suggests that the North American-sourced medications available in the private community pharmacies were the least expensive. Both African-manufactured drugs and Asian-manufactured drugs showed a significant positive association with price compared with North American manufactured ones. This finding warrants further investigation to determine the reasons, which may guide policymakers in deciding the best drug origin region. While most drug classes did not show a unit price significantly different from the reference category (NSAIDs), Vasodilators and P2Y12 inhibitors emerged as significant cost drivers. These two classes were inherently the most expensive groups among the studied medications. Their higher cost should be considered by the institutional procurement agencies and formulary committees to prioritize affordability within these specialized drug classes. Lastly, the presence or absence of an import sticker did not affect the final consumer price.

## Limitations

The findings of this study should be interpreted with caution for several reasons. First, the data were collected at a particular time point, and therefore, the situation may differ at another time point. Second, the study was conducted in one Libyan city, so the results might not apply to the whole country. Third, the focus was on specific strengths and dosage forms, but some medications are available in other dosage forms and concentrations. Consequently, our findings might underestimate the availability level. Fourth, affordability was based on the cost of medications and excluded other costs such as medical consultations and diagnostic procedures. Moreover, it does not reflect the situation for unemployed patients. Despite these limitations, this study provides useful insights about access to cardiovascular medications in Libya. Fifth, although the fixed effects successfully reduced the between-drug variance by 29 percentage points, a large residual variance (63%) remains unexplained at the observation level. This suggests that future studies should

incorporate microlevel variables, such as the size and location of the pharmacy, competition density, purchase quantity, and inventory cost.

## Conclusion

In Tripoli, the availability of CVD medications is lower than the WHO target. A positive finding is that the availability of generic products is better than that of the OB products. However, a major concern is that most of the products available in the market lack the importer information, raising questions about their source, quality, and safety. Also, higher prices compared with the international prices and wide price variations indicate an inefficient drug supply system. The cost of a 1-month treatment for all brands and a few generics places a high economic burden on the lowest-paid government workers. To increase access to CVD medications, government regulations and related drug price policies should be established and improved. Policymakers should therefore focus on supply-side measures (increasing generic competition, diversifying sourcing, and prudent selection of manufacturing regions) in the private sector to prevent drug shortages and significantly reduce the patient's financial burden.

## Conflict of Interest

None declared.

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