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Review Article

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Utilization patterns of cardiovascular drugs across public and private sector in Tamil Nadu

Authors names and affiliations-

Corresponding Author:

Herratdeep Singh¹, MPH

1.Indian Institute of Public Health Delhi

Contact Number: +91-9779741099

mail Address: herrat1313@gmail.com

Co-Author:

Rajesh Nair², PhD Health Psychology

2.Public Health Foundation of India, Gurugram, Haryana.

Contact Number: +91-9818885803

Email Address: rajesh.nair@phfi.org

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ABSTRACT

India is experiencing the increase in the burden of cardiovascular diseases. In the year 2016, cardiovascular diseases alone contributed to 28.1%(95% UI 26.5–29.1) of the mortality and 14.1% (12.9–15.3) of the DALYs (Disability adjusted life years).In the year 2013, WHO developed the targets for prevention and control of NCDs (Non-Communicable Diseases). A secondary data analysis was done. Passbook data was used for utilization of cardiovascular drugs for public sector and IMS sales audit data for utilization in private sector. The WHO ATC/DDD methodology was used to assess the utilization of cardiovascular drugs, expressed in form of DIDs (DDDs (defined daily dose) per 1000 inhabitants per day). Overall utilization of oralcardiovascular drugs in Tamil Nadu was 50.36 DIDs. Utilization of injectables was 3.45 DIDs. Utilization of oral cardiovascular drugs in private sector was four times the utilization of oral drugs in public sector.

KEYWORDS

ATC/DDD Methodology, Cardiovascular drugs, India, Tamil Nadu, Utilization

What We Already Know

- Very few drug utilization researches for cardiovascular drugs are available for South-east Asia region in comparison to utilization studies conducted on antibiotics.
- If any cardiovascular drugs utilization study was available, it was at level of a single health facility level or at a district level but not at a large scale.
- The studies available for South-east Asia region are mainly for antihypertensive drugs usage and very fewer studies cover entire segment of cardiovascular drugs.

What This Article Adds

- This study compares the utilization of cardiovascular drugs among both public and private sector of Tamil Nadu. Such kind of comparison is not done before as per the literature review.
- This utilization research presents the case of entire Tamil Nadu state of India which shows that the study outcome represents large scale population.

INTRODUCTION:

Burden of Cardiovascular Diseases

According to the Global Burden of Disease report (2016), prevalence of cardiovascular diseases in thousands was 469454 **95%UI (462582-474872)** and incidence was 54120 **95%UI (51965-56447)**. Years lived with disability (YLD) in thousands was 33482 **95%UI (24477-43376)** and percentage change between 2006 and 2016 was **29.4%**. All age disability adjusted life years (DALYs) of cardiovascular diseases in thousands was 353121**95%UI (341794.5-364965.3)** and percentage change from 2006 is **9.8%**. In India, most deaths according to global burden of disease report 2016 was caused due to ischemic heart disease (**53%** increase from 2005) and cerebrovascular disease was 4th most common cause of death(**25%** increase from 2005), both of which are cardiovascular diseases. From the top ten causes of disability adjusted life years (DALYs) in India, ischemic heart disease leads the list with cerebrovascular diseases ranked fifth.

Global Action Plan:

World Health Organization's Global Action Plan (for the prevention and control of non communicable diseases, 2013-2020)emphasizes that in order to address the prevention and control of non communicable diseases, one should strive for strengthening and orienting health systems via people focussed primary health care and universal health coverage.

Evidence based strategies:

Adopt evidence driven nation-based strategies to improve access to affordable medicines (for example, inclusion of relevant medicines in national essential medicines lists, separate dispensing and prescribing, and exemption of medicines that are needed for essential non communicable disease interventions from all forms of taxation),

promote good procurement systems and use of safe, efficacious, quality and affordable medicines, including generics and making the life-saving technologies and essential medicines available for proper management of diseases. Policies around essential medicines are extremely important in promoting health and achieving sustainable development.¹

Indian Scenario:

India face various barriers to access to medicines like less public health expenditure, weak supply chain management systems, no check on prices, a strong product patent regime and so on. As per the 8 states report on access to medicines(2012), in order to provide the households with financial risk protection, increasing the public spending on medicines is essential. As out of pocket expenditure on healthcare spending is leading to impoverishment of population living closer to the poverty line and poor cannot even access healthcare services because of this. An effective procurement and supply chain management systems ensures proper utilization of funds.

The case of Tamil Nadu:

As per the study 'The India State Level Disease Burden Initiative', about 86% of the total mortality in the state of Tamil Nadu is seen in the age group of 40 and above where approximately 40% of the mortality is caused because of cardiovascular diseases. Ischaemic heart disease is the leading cause for Years of life lost (YLL) among the population of Tamil Nadu. Tamil Nadu is ranked 3rd in the prevalence of cardiovascular diseases in India.

Research on cardiovascular drugs utilization: WHO South-east Asia Region

A study done with the aim of investigating the antihypertensive use among the hypertensive patients in college of South Delhi in 2007.² Combination therapy was used more commonly than monotherapy (54.6% vs 45.4). With respect to overall utilization pattern, diuretics (42.2%) were the most frequently prescribed class, beta- blockers (41.2%) ranked second followed by calcium channel blockers (39.1%), ACE inhibitors (26.0%), angiotensin II receptor blockers (23.4%) and α 1- blocker (9.4%).²

A study on utilization of antihypertensives was done in Kasturba Medical College, Manipal where, the therapeutic class which was most prescribed was calcium channel blockers (72.3%) and the most prescribed drug was Amlodipine (55.6%), prescription of diuretics was (9%) and the utilization of Angiotensin 2 blockers/ ACE inhibitors was (41.4%) in patients with diabetes. Combination therapy was mostly prescribed than the monotherapy (51.5% v/s 48.8%).³

Study on utilization of antihypertensive agents was done in urban primary health care centres of South India. 72.5% of generics and 92% of essential drugs were prescribed. The Beta blockers were commonly prescribed to the patients followed by calcium channel blockers.⁴

A drug utilization study was conducted among geriatric in patients of tertiary hospital of India where utilization of Antiplatelet drugs (93%), H2 blockers (77.22%), vasodilators (55%), anti-emetics (67.6%), and hypolipidaemic drugs (52%).⁵

A study was conducted in Pakistan on general practitioners approach to hypertension, describing trends in practice. The use of sedatives alone (23.8%) or in combination with antihypertensive agents as first-line for lowering BP was reported by 45.0%. Thiazide diuretics were rarely prescribed (4.2%). Sublingual antihypertensive agents were prescribed by 68.7% (67.1% to 70.3%) of practitioners for treating very high levels of BP.⁶

A study was conducted in Bangladesh where prescription patterns of Antihypertensives in Preeclampsia was assessed, where among the antihypertensive drugs, most commonly preferred drugs in mild to moderate hypertension by clinicians are alpha methyl dopa, labetalol and nifedipine.⁷

Gaps in Research:

Very few drug utilization researches have been done in South-east region or across world for cardiovascular drugs unlike research on antibiotics and if any research was performed, it was confined to single health facility or at district level but not at a larger scale. We didn't come across any study of drug utilization of cardiovascular drugs that compared both public and private sector of any state in India or elsewhere. So we purposively thought of taking a high CVDs burden state in India to carry out our research among both public and private sector of Tamil Nadu.

Objectives:-

1. To study the overall utilisation of CVD drugs in the Indian state of Tamil Nadu.
2. To make a comparative assessment of the utilisation patterns for cardiovascular drugs in the public and private sector in Tamil Nadu.

METHODS

Data Source for Private Sector-

The data around the drug utilization of cardiovascular drugs in private sector of Tamil Nadu was extracted from sales audit data from IMS health. The pharmaceutical sales data collected from 5600 stockists across India is extrapolated to reflect the sales in the entire country as well as specific states. The data organizes pharmaceuticals based on anatomical therapeutic chemical (ATC) classification system into four levels. There are 23 categories or groups of drugs under the cardiovascular drugs group. There are 389 drugs that falls under these 23 categories of drugs out of which 160 are plain (generics) and 229 are combinations.

Data Source for Public Sector-

The state essential drug list (SEDL) of Tamil Nadu, which is the basis of procurement, comprises of 305 formulations, from these we considered only the cardiovascular drugs for our analysis of utilization.⁸ Total number of cardiovascular drugs procured by Tamil Nadu Medical Services Corporation as per essential drugs list are 28.⁸

Sales were used as a **proxy** of **utilization** in the **private** sector and **passbook data** was used as a **proxy** for **utilization** in the **public** sector.

Both the passbook as well as IMS data was used for the year **2012**. Our study provides the utilization of cardiovascular drugs for the year **2012**.

Classification system of drugs followed by IMS is different from classification which was followed in this research which is **WHO ATC classification**.⁹

Classification of drugs: ATC (Anatomical, Therapeutic and Chemical) classification-

The ATC classification is recommended by WHO in order to present the drug utilization statistics for comparisons across world. The ATC classification system categorizes drugs into different groups based on the organ or system on which they act and according to their therapeutic, pharmacological and chemical properties.⁹ Drugs are classified in groups at five different levels.

Medicinal products are classified on basis of main indication of a particular active constituent, providing a single code for a formulation. In some circumstances, formulations can be given multiple ATC codes when they are available in different forms with different therapeutic uses.⁹

Assessment of utilization patterns: DDD (Defined Daily Dose) methodology

To assess the utilization patterns of cardiovascular drugs, **DDD methodology** was used. The DDD is defined as the assumed average maintenance dose consumed per day for a medication used for its core indication in adults. The DDD can be a dose that is not prescribed quiet often as it is an average of two or more frequently used sizes of dose.⁹

In this research DDDs per 1000 inhabitants per day (**DDD presentation**) of findings was used. The formula for the same is- [Amount of drug sold in one year(mg) divided by (DDD into 365 days into number of inhabitants)] whole multiplied by 1000 inhabitants. (Drug Utilization Studies, Methods and Uses, WHO European Series No. 45)

Sales data presented in DDDs per 1000 inhabitants per day may give us a **rough estimation of the proportion of population treated by a particular drug or a drug group**. For example, 20 DDDs per 1000 inhabitants per day indicates that 2% of the population on average might receive a certain drug or group of drugs on daily basis. It is essential to consider the size of the population as it is used as the denominator.

Inclusion Criteria: 1. All cardiovascular drugs which were provided with DDDs by WHO were included in the study.

2. If DDDs were not available for drugs and if we were able to give DDDs to such drugs following WHO's guidelines were included.

Exclusion Criteria: 1. No drugs other than cardiovascular drugs were considered for assessing utilization patterns.
2. The formulations for which strengths were not given have to be excluded from analysis of utilization patterns as DDDs computation was not possible.

DDDs Computation:

For combination products used for treatment of hypertension, DDDs are provided based on average no. of dosing intervals per day. The fixed dose combinations for which DDDs computed was 1 Tablet, the same unit is also given to strength of such fixed dose combinations.

DIDs (defined daily doses per 1000 population per day) calculation:

For the calculation of DIDs, population of Tamil Nadu was taken as 73,221,042.¹⁰

Ethical Consideration: Our study was not based on primary data therefore our study was exempted from ethical clearance.

RESULTS:

Description of Public Sector Data:

In passbook data, there were 30,191 entries for all the formulations which were differentiated on the basis of formulation name and their mode of administration and ultimately analyzed at all levels of ATC classification and ranked as per their DIDs in descending order.

Description of Private Sector Data

There were total of 5337 entries. When analyzed, the formulations were separately considered based on mode of administration, the units of strengths and the DDDs. Only formulations that had similar units for both strengths and DDDs were considered. Unit similarity was essential to carry out the analysis.

Overall utilization of oral cardiovascular drugs, Tamil Nadu 2012:

Overall utilization of oral cardiovascular drugs for 2012 for Tamil Nadu was **50.36DIDs**, utilization in public sector was 10.02 DIDs and utilization in private sector was 40.33 DIDs (24.74 DIDs of Plain formulations and 15.59 DIDs of fixed dose combinations.) “INSERT TABLE 1 HERE”

Overall utilization of cardiovascular drugs injectables, Tamil Nadu 2012:

Overall utilization of injectable cardiovascular drugs for the year 2012 was 3.45 DIDs where utilization in public sector was 2.48 DIDs and utilization in private sector was 0.97 DIDs. “INSERT TABLE 2 HERE”

Comparative assessment of utilization of oral and injectable cardiovascular drugs at 3rd level of ATC classification:

The utilization of oral cardiovascular drugs across both the sectors is found to be highest in Selective calcium channel blockers, Beta blocking agents, Angiotensin 2Antagonists. In public sector the highest utilized therapeutic classes of drugs are Beta blocking agents, Selective calcium channel blockers and Ace Inhibitors. In the private sector the highest utilized therapeutic classes Selective calcium channel blockers, Lipid modifying agents and Angiotension 2 Antagonists. “INSERT TABLE 3 HERE”

The utilization of injectable cardiovascular drugs across both the sectors is found to be highest in therapeutic classes namely Antithrombotic agents, High ceiling diuretics and Cardiac stimulants. The similar trend is seen across both public and private sector. “INSERT TABLE 4 HERE”

Utilization of cardiovascular drugs across public and private sector of Tamil Nadu:

The highest utilized individual cardiovascular drugs in Public sector of Tamil Nadu are Atenolol, Amlodipine and Enalapril. “INSERT GRAPH 1 HERE”

The highest utilized individual cardiovascular drugs in Private sector of Tamil Nadu are Rosuvastatin, Olmesartan and Acenocoumarol. “INSERT GRAPH 2 HERE”

DISCUSSION:

This research was focussed at assessing the utilization patterns of Cardio-vascular drugs in the Indian state of Tamil Nadu. In this research, an assessment and comparison of both public and private sector utilization was done, in order to assess whether certain drug or category of drug is utilized in exceptionally high quantities in both sectors or to assess the similarities or dissimilarities in the utilization of cardiovascular drugs across public and private sectors of Tamil Nadu.

DIDs is the parameter based on which the comparison of utilization of various cardiovascular drugs was done. As DIDs gives us the idea about the amount of drug utilized per capita in a certain population.

The overall cardiovascular drugs utilization in Tamil Nadu in year 2012 was found out to be 53.81 DIDs and the only study which assessed the utilization of entire segment of cardiovascular drugs was of Croatia where utilization for year 2005 was found to be 363 DIDs^[11] and in other study of Croatia, utilization of Calcium channel blockers (CCBs) was found to be 80 DIDs^[11] whereas utilization of CCBs in Tamil Nadu was 8 DIDs

Utilization of lipid lowering agents in Tamil Nadu was 5.25 DIDs for year 2012. Utilization of lipid lowering agents was also assessed for five nations namely Australia, Italy, Sweden, Norway and Finland in the year 1994 which was found out to be 11.9, 6.7, 5.6, 4.9 and 4 respectively.^[12]

Utilization of antithrombotic agents in Tamil Nadu in year 2012 was 2.58 DIDs and the utilization of antithrombotic agents in Denmark in 2014 was 96 DIDs.^[13]

Utilization of antiarrhythmic agents in Tamil Nadu was found out to be 0.09 DIDs. A study showed that for the year 2011, utilization of antiarrhythmic drugs for Italy was 7.2 DIDs and for Sweden was 1.2 DIDs.^[14]

There were few studies on utilization of cardiovascular drugs in the South-east Asia region where four were from India^[2,3,4,5], one from Pakistan^[6] and one from Bangladesh.^[7] The studies from South-east Asia didn't use the DDD methodology for assessing the utilization and because of this, these studies are not comparable with our research.

Facts and the way forward:

As DIDs gave us the estimate of the proportion of population which has utilized the cardiovascular drugs, for Tamil Nadu that proportion is 5.4%. 4/5th of the total drug consumption was seen in private sector. About 30% of the utilized cardiovascular drugs were fixed dose combinations. The patients suffering from cardiovascular diseases are more dependent on private sector despite of having a robust drugs procurement and distribution systems in the State. It is also seen that the health seeking behaviour of the patients in Tamil Nadu is more inclined towards private sector. Tamil Nadu Medical Services Corporation doesn't procure fixed dose combinations at all.

Every year a huge chunk of population is pushed below the poverty line due to increased out of pocket expenditure on medicines. More utilization of drugs from private sector means that it will have more burden on the pocket of an individual as the price charged by private sector is more when compared to drugs provided in public health facilities.

As health is one's Fundamental Right, therefore availability, accessibility and affordability of essential medicines at free or reasonable prices is necessary. To earn the confidence of population, health services delivery in public sector should be according to the established gold standards. Only this could lead a change in health seeking behaviour of a population which will ultimately ease their financial burden. In order to improve the utilization of drugs in public sector, availability of commonly prescribed drugs is important. Commonly prescribed drugs must be included in the State's essential drugs list so that their prices are capped. Fixed dose combinations should also be procured so that if physicians feel necessary, they don't hesitate to prescribe them.

Limitations:

Data of drug utilization when presented as DDDs doesn't give the real picture of use but only the rough estimate of consumption. The research had taken the sales values as a proxy for utilization, actual utilization could not be attained using the sales data. No research was found for South-east Asia where utilization of cardiovascular drugs was assessed using same methodology that we used which had resisted us from doing a comparison of our study.

It was also difficult to compare the study with available literature because Indian state of Tamil Nadu was not comparable with the countries as they differ completely with respect to the disease profile, population size and characteristics.

Strengths:

This research is a first attempt of its kind where two sector i.e. public and private sectors are compared in any Indian state or where utilization of cardiovascular drugs is assessed at a state wide level. All the formulations irrespective of any specific therapeutic class that falls under Cardiac segment were analysed or considered unlike the researches already conducted in the past in the world, as generally the studies were focussed at a single therapeutic segments or a part of that segments and not the complete Cardiac drugs.

CONCLUSION

This study has addressed the overall utilization of cardiovascular drugs in the Indian state of Tamil Nadu for the year 2012, where a comparison of public and private sector drug utilization was also done. The findings suggested that the overall utilization of oral drugs was 50.36 DIDs and in private sector it was four times the utilization of oral drugs in public sector whereas in case of injectables, the utilization was about 2.5 times higher in public sector when compared to private sector and in total it was 3.45 DIDs. The therapeutic classes with highest utilization were beta blockers, calcium channel blockers and ACE inhibitors in public sector whereas in private sector the therapeutic classes with highest utilization were Calcium channel blockers, lipid lowering agents and angiotensin 2 antagonists. For injectables, the classes with highest utilization in both public and private sectors were same namely, antithrombotic agents, high-ceiling diuretics and cardiac stimulants.

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TABLES AND GRAPHS

Utilization Parameters	DID	DDD	Volumes
Oral Drugs(Public)	10.02	267815839	632590898
Plain Oral Drugs (Private)	24.74	661240844	974918733
Fixed Dose Combinations(Private)	15.59	416742672	416742672
Overall Consumption of CVD Drugs	50.36	1345799355	2024252303

Table 1:Overall utilization of Oral Cardiovascular drugs

Utilization Parameters	DID	DDD	Volumes
Injectables (Public)	2.48	66306114.2	1636373
Injectables (Private)	0.97	25980794.3	9906147
Overall Consumption of Injectables	3.45	92286908.4	11542520

Table 2:Overall utilization of cardiovascular drugs injectables

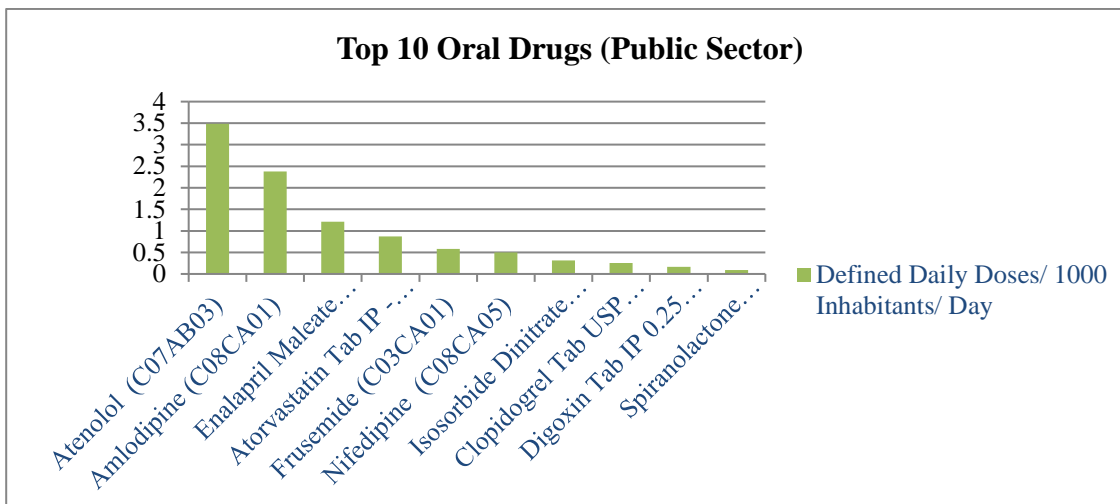
	Comparison (Oral Drugs)	Private Sector	Public Sector	
S No.	3rd Level Of Cardiovascular	DIDs	DIDs Consumed	DIDs Across

	Drugs	Consumed		Classes
1	C08C- Selective Calcium Channel Blockers Having Vascular Effects	4.86	2.88	7.74
2	C10A- Lipid Modifying Agents, Plain	4.38	0.87	5.25
3	C09C- Angiotensin 2 Antagonists, Plain	4.04	0.01	4.05
4	C07A- Beta Blocking Agents	3.43	3.54	6.97
5	C09A- Ace Inhibitors, Plain	2.33	1.21	3.54
6	B01A- Antithrombotic Agents	2.3	0.28	2.58
7	C03C- High-Ceiling Diuretics	1.27	0.58	1.85
8	C01D- Vasodilators Used In Cardiac Diseases	0.57	0.31	0.88
9	C01A- Cardiac Glycosides	0.45	0.16	0.61
10	C01E- Other Cardiac Preparations	0.43	0	0.43
11	C02C- Antiadrenergic Agents, Peripherally Acting	0.32	0.01	0.33
12	Others	0.8	0.14	0.94
	Total	25.21	10.01	

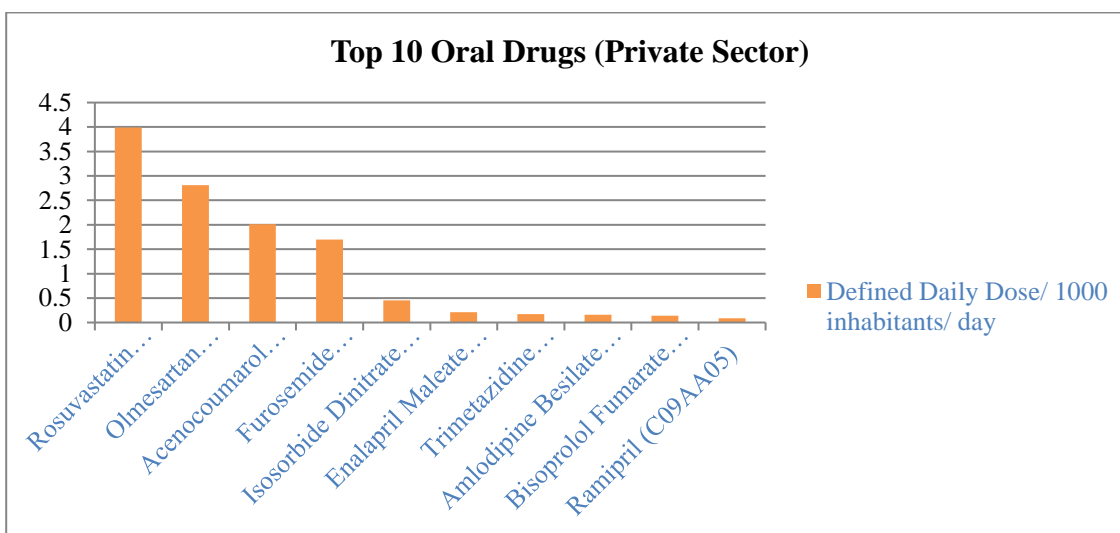
Table 3: Comparative assessment of utilization of oral cardiovascular drugs in public and private sector of Tamil Nadu

	Comparison (Injectables)	Private Sector	Public Sector	
S No.	3rd Level Of Cardiovascular Drugs	DIDs Consumed	DIDs Consumed	DIDs Across Classes
1	B01A- Antithrombotic Agents	0.89	2.47	3.36
2	C03C- High-Ceiling Diuretics	0.05	0.01	0.06
3	C01C- Cardiac Stimulants Excluding Glycosides	0.03	0.0002	0.0302
	Total	0.97	2.48	

Table 4: Comparative assessment of utilization of injectable cardiovascular drugs in public and private sector of Tamil Nadu



Graph1: Top 10 utilized oral cardiovascular drugs (Public Sector)



Graph2: Top 10 utilized oral cardiovascular drugs (Private Sector)