

**Analysis of opportunities and challenges
in the cardiovascular medical device industry
in India**

Dissertation Submitted to



IIHMR University, Jaipur

for the partial fulfilment for the

award of the degree of Master of

Business Administration (MBA) in

Hospital and Healthcare Management by

Dr Shipra Sharma

Under the guidance and supervision of

Dr Deepti Sharma

Associate Professor, IIHMR University, Jaipur

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Analysis of opportunities and challenges in the cardiovascular medical device industry in India** is the Bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published and unpublished work of others has been duly acknowledged in the text.

(signature)

Shipra Sharma

Date:



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22nd May 2023
Hyderabad

To

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Dear **Ms. Sharma**

Internship Experience Letter

This letter also certifies that **Ms. Shipra Sharma** is doing internship with Orbees Business Solutions Pvt Ltd from **21st February 2023 to till date** and her role is Intern – Senior Analyst

We wish her all the best for her future endeavors.

For Orbees Business Solutions Pvt. Ltd

Rakesh Valluru
Sr. Manager - Operations



31st May, 2023

TO WHOMSOEVER IT MAY CONCERN

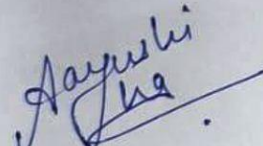
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This is to certify that, **Ms. Shipra Sharma** in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management) from the IIHMR University, Jaipur, has successfully completed her internship at **Adani Hospitals Mundra Pvt. Ltd. (AHMPL)** from **12th April 2023 to 31st May 2023**.

She is committed, responsible and hard working. She exhibited good interpersonal skills and had a high level of acceptance among colleagues at various levels.

We wish her all the best for her future endeavors.

For, Adani Hospitals Mundra Pvt. Ltd.


HR Department



CERTIFICATE

This is to certify that dissertation titled **Analysis of opportunities and challenges in the cardiovascular medical device industry in India** is a record of the research work undertaken by Shipra Sharma in partial fulfilment of the requirements for the award of the degree of MBA (Hospital and Healthcare) from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide

IIHMR University, Jaipur

Date

School Dean

IIHMR University, Jaipur

Date

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ABSTRACT

Background

Cardiovascular diseases are a major factor in the high rates of mortality worldwide, with the most common conditions being ischemic heart disease and stroke. Cardiovascular diseases are the leading cause of death worldwide, causing significant loss of health in India as well as rising costs of the healthcare systems. When it comes to India, the medical device industry—which includes the cardiovascular medical device sector—is crucial and essential. The market's growth indicates that this category will develop and expand soon. The cardiovascular medical device industry in India has distinct possibilities and challenges. The study aims to identify those opportunities and challenges to examine the future of the industry in India.

Objectives

- To find out the opportunities and challenges in the cardiovascular medical device industry in India
- To assess the growth and potential of India's market for cardiovascular medical devices.
- To examine current market developments in the cardiovascular device sector and to identify the major players along with products of this industry in India.

Methodology

This research is exploratory and descriptive in nature. It comprises researching and evaluating the criteria that can be recognised as opportunities and problems in the cardiovascular medical device business by looking at a variety of journals, research articles, published papers, government websites and data, news items, and other internet sources. The influence of the expansion of the cardiovascular medical device business will be evaluated by analysing the secondary data that was gathered through rigorous study with each parameter.

Result

After analysing all the parameters that were taken as opportunities and challenges, the study found out that the India's ageing population, which revealed that senior folks (those 60 and over) are multiplying fast in India, cardiovascular illnesses are becoming more prevalent in India, and at the moment, India is responsible for a significant portion of the world's CVD mortality, the number of cardiovascular illnesses is rising as a result of the

daily rise in risk factors, the Indian government is also supporting the sector with several initiatives and legislation. Many of them are primarily concentrating on laying the groundwork for domestic production, a better and more patient-centred approach to cardiac care is being made possible through several collaborations and partnerships, as well as developing technology, the numerous risk factors for cardiovascular illnesses were mostly unknown to Indians. Only one in four people were aware of what causes a stroke, and even fewer were aware of the risk factors, The lack of professionals to utilise the goods on patients will provide a difficulty for the cardiovascular medical device business as a result of the labour crisis, Pacemakers, stents, and cardiac catheters are examples of medical devices that people with lower incomes and those living below the poverty line cannot buy. Their yearly salary prevents them from being able to purchase these things, let alone pay for the operation and hospital costs.

Conclusion

Given the opportunities and difficulties found in this study, it can be said that the cardiovascular industry in India will have a bright future in the years to come. However, the difficulties must also be overcome if this industry is to reach its full potential.

CHAPTER 1 – INTRODUCTION

The world's top cause of mortality is cardiovascular disease. These diseases have concurred major loss of health globally along with increasing costs of the health systems. Cardiovascular diseases are a large contributor in the high rates of mortality globally with conditions such as ischemic heart disease and stroke being the most prevalent. CVDs are increasing at an alarming rate and are a large contributor in the non-communicable diseases worldwide. The cases of cardiovascular diseases showed a rise to 523 million along with an increase in the deaths at 18.6 million in 2019. This shows the upward trend in the prevalence of the cardiovascular diseases at a global level. A lot of countries including countries in the central and southern Asia will also be seeing a remarkable rise in the cases of CVDs as the population seems to be increasing and aging. Ischemic heart disease accounted for 49% while ischemic stroke of 17% among the causes of CVD deaths globally. There are several risk factors that account for the prevalence of CVDS and some of them are: high body mass index, cigarette use, high LDL cholesterol, high systolic blood pressure, and risky diet, kidney dysfunction, alcohol usage, low physical activities and few others. Diabetes plays a major role when it comes to the risk factors for the aging population. A high risk of developing diabetic cardiomyopathy is also prevalent. These risk factors have been divided into 3 categories that are, metabolic risks, environmental/occupational risks and behavioural risks. Hypertension is known to be a major risk factor that contributes to majority of stroke and acute myocardial infarction cases. Physical inactivity in aging population also contributes to the high risk of developing CVDS. Any activity that involves one hundred and fifty minutes per week May 30 percent lessen the chance of getting ischemic heart disease. Family history plays a vital role as a person having a family history of CVDS is two times more likely than someone who doesn't to develop the illness. A huge part of the global prevalence of CVDs is found in India. According to the WHO, India accounts for one-fifth of the deaths caused by CVDs globally. India has seen an increase in the life expectancy and along with that, an increase in the non-communicable diseases has also been seen. The four main types of NCDS are the cardiovascular diseases, cancers, chronic respiratory diseases and diabetes. The highest number of deaths are observed with CVDS globally accounting for 17.9 million annually. Out of all the diseases, non-communicable diseases comprise of 53%

of the total deaths and CVDS account for 24% which is a major contributor in terms of mortality in India. According to reports, Indians have the most coronary artery disease rate which leads to a high mortality rate. India is also known to have the highest rates when it comes to ST- elevation myocardial infarction and acute coronary syndrome. The mortality rate is of 20-50% in Indians that is influenced by coronary artery diseases, which is more than any other population in the world. According to a report by WHO, the age adjusted mortality rates due to CVD are higher for men than for women. Each year, more than 10.5 million fatalities are reported in India and 16% of them are of women due to CVDS. Even though women tend to develop heart diseases later in their life, roughly ten years after men, they have a higher chance of developing CVDS and more likely to get a heart attack as well. This clearly indicates that women are more risk prone to heart diseases than compared to men and more than 35% of heart attacks might go unreported in females. the urban aging population seems to suffer more from the CVDS as compared to the rural aging population with the risk factors being more inclined towards the urban population. The healthcare sector in India is expected to develop quickly and reach \$280 billion by 2025. amongst all the medical devices markets in in the world, India is in the top twenty markets. In Asia, India stands fourth after Japan, China and Korea when it comes to medical devices. The sector, which is presently worth \$5.2 billion, is projected to expand and reach \$50 billion by 2025. medical devices market is largely influenced by imports accounting for about 70-75%. the Indian market for medical devices is highly regulated and both the manufacturing and monitoring is regulated. The Since there were certain loopholes in the 1940 Drugs and Cosmetics Act, the Central Drug Standard Control Organisation published the Indian Medical Devices Rule, 2017 to ensure that the rules are adhered to. keeping update with the requirements of this industry, the medical devices rule, 2017 underwent a few amendments and were modified as part of the 2020 medical devices amendment regulations, which became effective in April 2020. These regulations ensure adherence to the categorization, registration, regulations, manufacture, import requirements, sales, labelling, and post-market requirements, if applicable, as well as any other needs. medical device rule (MDR) 2017 is to make medical device regulations in India as professional and ethical as possible. Under which, categories have been made for Depending on the level of danger, the classification of medical devices that is associated with them and they are Classes A and B are minimal danger, Class C is

moderately high risk, and Class D is severe risk. Regulation compliance must be tracked strictly and for that the Indian government had also approved India's materiovigilance scheme. India acting as a hub for manufacturing of medical devices has placed it on the map for the emerging markets for the key global players of the market for medical devices. Since imports constitute most of the Indian medical device industry, it is observed that 80% of the patent applications for the medical devices are made by foreign companies. only 17% of the patent filing is done by the local companies that are manufacturing in India which makes it a very small number in comparison to the foreign companies. USA leads with a share of about 41% with other countries such as Japan, Europe, Germany and many more. India is growing in the field of the medical industry annually by 8% but is still showing less patent filing than compared to other countries. Medical Devices used for local anaesthesia include injections, medical syringes, tubes, canulas of all kinds, infusion tubes, inhalers, pumping devices, catheters, blood collection kits, and inhalers. have been imported but devices of cardiology have seen the most patent filings in India which is then followed by the orthopaedic implants. the cardiovascular devices frequently used are drug eluting stents, heart valves, The class D category of devices includes a wide range of items, such as bioabsorbable vascular scaffold systems, over-the-wire thrombectomy sets, cardiac pacemakers, cardiac portable monitors, and many more. the Indian government is making a lot of initiatives and advancements in the field of medical devices and various opportunities such as the increase in the demand, opportunities in export, policy support from the government and increased investments. along with that the ageing population is also increasing which will directly influence the growth of cardiovascular medical device industry and with the increase in the population on India will also add to it. According to estimates, the ageing number of India will succeed to 19% till the year 2050. the rising number of medical facilities will create a demand for medical devices in Indian market and various government schemes such as Production linked incentive (PLI) scheme for medical devices. Medical devices parks are also being built and will aid a lot in the development of the industry. the government of India is coming up with a lot of initiatives and policies in this industry such as a medical device made in India campaign industry was recognized as a focus sector. The Central Drugs Standard Control Organisation (CDSCO) and the Ministry of Health and Family Welfare conducted several programmes, including re-examination system for export

labelling, clinical evaluation, strict state license authority rules and easy access to worldwide regulatory authorities. with all the opportunities present in the industry, there are a few challenges and gaps as well that need to be addressed. Some of the challenges include a shortage of cardiologists in India, especially interventional cardiologists. among other gaps in this sector, a lack of adequate infrastructure remains as one of the main concerns. A proper thorough training to every professional comes from an adequate infrastructure which in India is an issue a patients deserve a high quality and evidence-based treatments. Another challenge is where the rural population is not given access to such degree of care that the urban population can. This scenario also adds to the gaps that need to be filled and mor number of secondary and quaternary health centres should be provided to the rural population. there are a few more opportunities and challenges that will be mentioned later in this study.

This study aims to recognize the opportunities and challenges that are present in the cardiovascular medical devices industry. As it is a booming industry, these parameters will help us to navigate the way forward and know the current as well as the future market trends of this industry in India. Medical devices as a whole is a large market, and this study will be covering the current trends of the industry focusing more on one of its subcategories such as the cardiovascular devices segment. In this industry, the foreign companies have dominated the Indian market and the local players are a few. This study will also aim in identifying the major players in this industry as well the Indian local manufactures in the market. The current trends will include the market share, the best-selling products and the growth and impact of the industry in the country. The medical device industry has potential to expand more in India and for that all the parameters need to be assessed. Along with the market trends, the disease burden will also be assessed in this study. In India, one of the leading cause of deaths is cardiovascular diseases and the research also seeks to evaluate the weight of the growth and potential of the cardiovascular medical device industry.

OBJECTIVES –

1. To find out the opportunities and challenges in the cardiovascular medical device industry in India.
2. To assess the growth and potential of India's market for cardiovascular medical devices.
3. To examine current market developments in the cardiovascular device sector and to identify the major players along with products of this industry in India.

CHAPTER 2 – REVIEW OF LITERATURE

- A. Sreenivas Kumar, Nakul Sinha (2020) conducted a study which stated that cardiovascular diseases are a big burden in India and account for a huge number of deaths in India. It is said to be the leading causes of deaths accounting for over 2.8 million deaths in India and the cause of premature deaths. A lot of risk factors are involved in the development of CVDS and some of them are use of tobacco, unhealthy diet, hypertension, diabetes, physical inactivity and many more. Other conditions may include poverty, poor living conditions and air pollution. Management can be done through lifestyle changes, medications and if required surgical interventions. India faces several challenges such as shortage of healthcare professionals, inadequate infrastructure and limited services in the rural areas. CVD is a significant burden in India and improving the risk factors along with developing a good infrastructure will be beneficial.
- Prabhakaran D, Jeemon P, P Sharma et al (2018) conducted a study which states that India's biggest cause of mortality is now CVDS. accounting for more than 28% of deaths annually. The prevalence of stroke has also increased in some states of India. The risk factors have drastically increased leading to the disease burden and the study emphasises on the need for targeted interventions which can be based on specific risk factors. It also highlighted that there is an urgent need for the country's risk factors for cardiovascular disease prevention and treatment.
- Vaduganathan M, Mensah G, Turco J et al (2022) conducted a study which states that the risk factors influence the cardiovascular diseases and the lower- and middle-income countries suffer the most. The study also states that there is a need for an increased research efforts so that the causes and risk factors leading to cardiovascular diseases are better understood. That way, the development of prevention and necessary approaches can take place for better treatment options. The study also shows how there is an urgent need globally to address the issue of cardiovascular diseases and addressing of the risk factors involved with it. By promoting a good and healthy lifestyle, with an increase to the access to healthcare

even in low- and middle-income countries, the burden can be greatly managed and reduced.

- Roth G, Mensah G, Jonson C et al (2020) conducted a study which stated that cardiovascular diseases are the leading cause of deaths worldwide and accounting for 523 million (DALYS) are disability-adjusted life years as of 2019. The research also revealed that the prevalence of CVD is highest in the low- and middle-income countries than compared to the high-income countries. The study found that the biggest risk factor is systolic blood pressure and that it has contributed a lot in the increasing of the burden of the disease between 1990 to 2019. It also stated the risk factors influencing the burden country wise like dietary causes being the risk factor in central Asia and systolic blood pressure in sub-Saharan Africa. The study states the importance and urgency of addressing these issues in order to curb the disease burden that is caused by the cardiovascular diseases worldwide.
- Ngan Thi do, Konnie Bellingham, Paul N Newton et al (2021) conducted a study aimed to investigate the quality of all the medical products that are used for cardiovascular diseases and also identify the gaps that are present in the global cardiac management. The study also stated that the quality of medical products including devices and drugs did not meet the quality standards criteria globally. It also highlighted the reasons for the drop in quality such as inefficient regulatory systems, a weak supply chain management and limited access to quality assurance management. The impact of low-quality products on mortality and morbidity has been observed and trust on health systems reduced along with increase in health care expenditure. The study called for actions to be taken on globally to improve the quality standards for products related to cardiovascular disease and bring improvement in regulatory systems and quality. By improving the quality standards of care, the burden of cardiovascular diseases can be reduced.
- Manu M, Anand G (2022) conducted a study which reviewed the medical device regulations in India and revealed that the regulations concerned with the medical devices in India were found to be inadequate, lacked clarity and transparency

which could lead to confusion among the users of the devices. The study also found out that the regulation system of India is fragmented, and many authorities are responsible for the regulations. The study also compared the regulatory system with the one in EU and found many differences such as difference in comprehensive and transparency. In EU, the device regulation is done by a hierarchical system of authorities, and it is clear and free from confusion. The EU system has a well-defined process for the approval and monitoring of all the medical devices. The study proposed recommendations such as creating a single body for the regulations to ensure adequate quality and patient safety and how a connected robust regulatory system can help generate jobs and employment in the sector of medical devices in India. An increased investment from the government to enable innovations in this field may also prove beneficial. The study aimed to suggest various ways to improve the current state of medical devices regulations and as an industry.

- Markan S, Verma Y (2017) conducted a study which revealed the patent filings of medical devices in India. The study also showed that there has been a significant increase in the patent filing of medical devices in India which has increased by 86% from 2014 to 2018. The study also highlighted the growing areas such as diagnostics and monitoring devices followed by surgical instruments and implants. Cardiology devices were found to have the highest patent filings given that the cardiac disease burden of the country is a lot. The study also emphasised how the industry needs a more effective regulation. Effective policies need to be made to encourage the innovations in the medical device industry. This may include more focus on investments on innovation, research and development, and improvement in the regulatory body networks. This study also showed that the Indian medical device industry is heavily influenced by imports as the country's major devices are import which accounts for about 70-75%. Among the importers, In India, the US has the most patent applications. Among other countries, UK, Germany, Italy and Japan are also contributors in the Indian medical device industry.

- Kalaiselvan V, Tripathi S, Prakash J (2020) conducted a study which stated that the MvPI collected data on all the adverse events that were related to the medical devices and take actions to prevent the harm to the patients. The MvPI plays a significant part in ensuring the medical devices including failures or device defects if any. It also identifies the issues that occur with the adverse effects. The MvPI has also made many recalls on certain devices which has led to the building of trust with the public and users of these devices. The program has helped in bringing several policy changes which ultimately help in improving the regulations of the medical devices in India. It has also helped in enabling the guidelines through which quality standards can be maintained. The materiovigilance program in India aims to safety and quality standards of the Indian medical equipment. It is an essential plan that has allowed to identify the key important areas as well as ensure the safety of the public using these devices.
- Bansal M, Kasliwar R (2016) conducted a study which aimed to evaluate the accuracy of the World Health Organisation (WHO) risk prediction charts. This study evaluated the cardiovascular risk in south Asians and propose an alternative algorithm for evaluating the risk factors. The study also shows that the WHO had underestimated the risk of cardiovascular diseases in Asia by only accounting the data from the western Asia and not evaluating the unique risk factors present in the south Asians. The proposed algorithm for the cardiovascular risk prediction takes in account all the unique risk factors that are presented in the south Asians as well. It includes various factors such as body mass index, glucose levels, family history and a few more. The study also stated how the new program enabled new interventions and recommendations to reduce the risk factors. By targeting the risk factors and implanting new ways to lower them, India can easily reduce its burden of cardiovascular diseases.
- Do N, Bellingham K, Newton P et al (2021) conducted a study that reviews the adverse effects and treatment failures that can be seen due to the poor quality of cardiovascular medical devices which possess a significant gap in the cardiac care on a global level. The study also states that the poor quality of cardiac care devices

is not only found in the low-income countries but also in the high-income countries as there is a huge gap persisting in the supply chain as well as a lack of an efficient regulatory system for this industry. The study suggests a few solutions to address the gaps in this industry such as spreading awareness amongst the users and the healthcare professionals about the quality of devices, improving quality standards and investing more in research to develop more cost effective, efficient and safe devices to the patients. The authors of the study also highlight the importance of organisations such as WHO and IMPACT as these organisations can help in setting of standards that are required and can also address the regulatory bodies.

CHAPTER 3 – METHODOLOGY

This study is a descriptive exploratory study. It involves the study of various journals, research articles, published papers, government websites and data, news articles and other online sources to explore and assess about the parameters that can be identified as opportunities and challenges in the cardiovascular medical device industry. The secondary data that is obtained from thorough research will then be analysed with each parameter to determine the impact of the growth of the cardiovascular medical device industry. The analysis for each parameter will be from secondary sources that are authentic and will be shown along with the parameters.

The current market trends of the medical device industry will also be studied in order to obtain a clear picture of the opportunities and challenges that are present in the market. The current market trends will include the market size, growth in terms of CAGR, India's position in medical devices in the world, import and export of medical devices, major companies both international and local, cardiovascular devices that are used, government initiatives, policies and regulations.

The parameters on which the opportunities and challenges will be assessed are –

1. Burden of cardiovascular diseases in India.
2. Aging population of India.
3. Risk factors associated with cardiovascular diseases.
4. Government initiatives and policies.
5. Collaborations, partnerships and emerging technologies.
6. Awareness of Indian population on cardiovascular diseases.
7. Healthcare workers in India.
8. Medical infrastructure.
9. Affordability.

Duration of the study is of 3 months and the tools that will be used are secondary data and MS Excel.

Research question

What are the opportunities and challenges faced by the Indian market for cardiovascular medical devices, and how are they affecting its future?

Materials and methods:

- Type of study – Descriptive exploratory study
- Type of data – Secondary
- Research instruments – Research papers, publications, journals, government websites, news articles etc
- Duration of study – 3 Months
- Tools for analysis – Secondary data and MS Excel
- Data collection procedure – It will be based on the secondary data obtained from the above-mentioned sources.

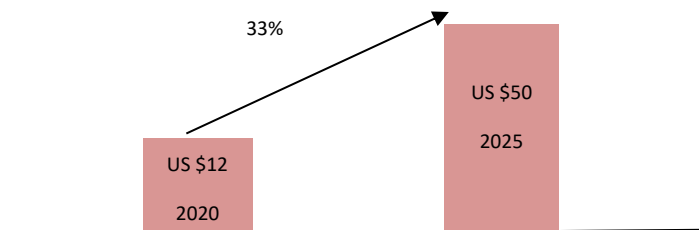
CHAPTER 4 – ANALYSIS AND FINDINGS

In this part of the chapter, the descriptive analysis will be divided into three parts such as

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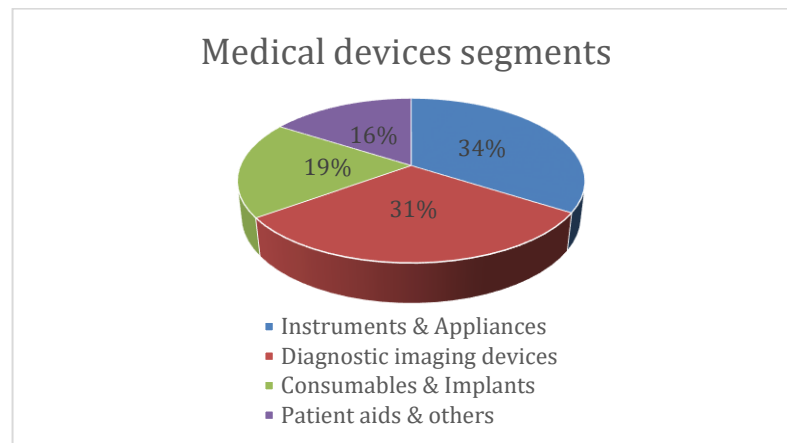
1. Assessing of the market trends of the medical device industry and the cardiovascular device segment.
2. Analysis of the parameters that can be identified as the opportunities present in the cardiovascular device industry.
3. Analysis of the parameters that can be identified as the challenges that are faced in the cardiovascular device industry.

1. Assessing of the market trends of the medical device industry and the cardiovascular device segment – Total market share – India's medical equipment industry is estimated to be worth \$12 billion USD and to have a CAGR of 33% till the year 2025. it is expected to reach US \$50 by the year 2025.



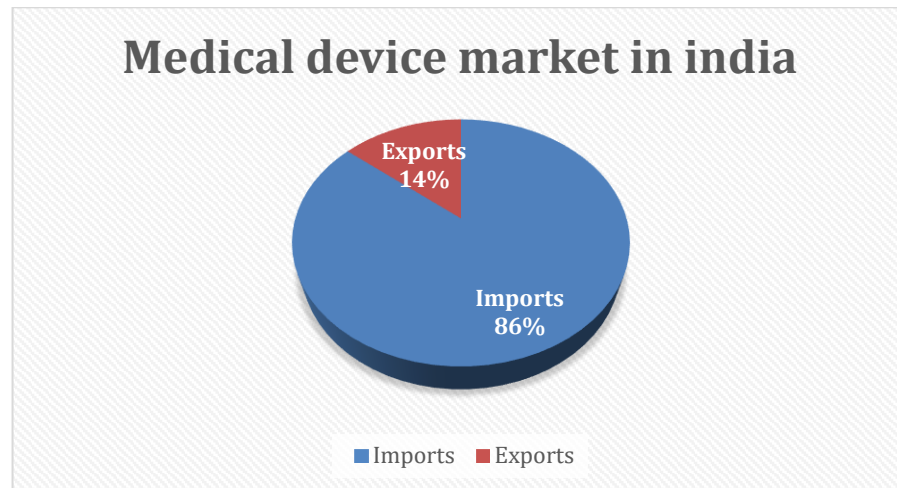
Graph 1: Increase in market size by 2050.

- After Japan, China, and South Korea, India has the fourth-largest market in Asia for medical devices.
- India is one of the top 20 nations globally in the medical equipment sector.
- The device distribution has been segmented into various segments such as – Diagnostics, Instruments and appliances, diagnostic imaging devices, consumables and implants and patient aids. The largest market share is covered by appliances.



Graph 2: components of medical equipment in India

- Presently, according to estimates, India imports 86% of all the medical devices. India largely depends on imports whereas the export figures are less. India is largely dependent on gadgets such as PCR technology, medical imaging instruments, ultrasound exams, and cancer diagnoses.
- The export sector is estimated to show a growth of 51% and reach US \$10 billion by the year 2025. Some of the key exporters will be the US, Germany, China, Brazil and many more.



Graph 3: Import and export of devices in India.

- Some of the major global companies in the medical device industry and the suppliers to India are Boston Scientific, GE Healthcare, Johnson & Johnson, Medtronic, Philips, TransAsia, 3M, Siemens Healthineers, Stryker, Polymed, SMT, Baxter, Abbott etc.

- The startup ecosystem is flourishing in India as over 250 organisations are working on new innovations for addressing important needs. Some of the startups are Sattva MedTech, Consure medical, BeatO, Forus health, Indolabs etc
- CDSCO, the Central Drugs Standard Control Organisation, observed that the maximum number of patent filing of medical devices was done in cardiology and the data suggests that the foreign manufacturers are bringing in their medical devices with cardiology devices on top.
- The Indian cardiovascular market for medical devices is anticipated to expand at a CAGR of 6.6% till 2028.
- Some of the major devices used in cardiology are –
 - i) Diagnostic & Monitoring equipment, such as an electrocardiogram and remote heart monitoring.
 - ii) Therapeutic and surgical tools - tools for controlling cardiac rhythm, catheters, grafts, heart valves and stents.

2. Analysis of the parameters that can be identified as opportunities and challenges in the cardiovascular medical device industry in India.
Among the various opportunities and challenges present in this industry, some of the will be analysed further in the study.

- Aging population in India

In the world today, India has the second-largest senior population after China & the elderly population is growing on average three times faster than India's overall population each year. India, one of the two superpowers in terms of population, is dealing with a demographic change. Rising lifespan and declining fertility are two factors that support this. this has led to the population of over 60 years of age going dramatically up. This change comes up with a wide range of problems such as health, economic, social challenges. it is estimated that the aging population of India will see a double increase by 19% till the year 2050.

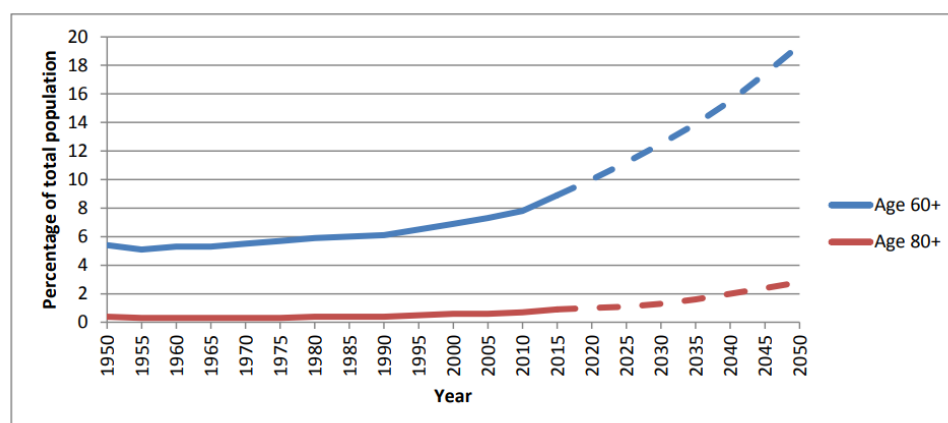
Table 1 shows Indian age-related indicators trends from 1950 to 2050.

	1950	1975	2000	2025	2050
elderly population (those 60 and older)	5.4	5.7	6.9	11	19.5
Adults who are 45 years of age and older	16.2	16.3	18.4	28.6	40
Most senior citizens (75 years and older)	0.9	0.9	1.3	2.3	5.2

Source: Longitudinal Aging Study in India, 2020

The percentage of the elderly individuals (those over 60) is expected growth, double by 19.5% in the year 2050. By 2025, this number is anticipated to reach 319 million.

Graph 4: Showing the number of older Indians growing rapidly



Source: Facts, Concerns, and Options Regarding India's Ageing Population

Table 2: Showing countries with the highest populations of 60 years adults

2015		2050	
Country	Adults 60+ (thousands)	Country	Adults 60+ (thousands)
1. China	209,240	1. China	491,533
2. India	116,553	2. India	330,043
3. United States	66,545	3. United States	108,326
4. Japan	41,873	4. Brazil	69,882
5. Russian Federation	28,730	5. Indonesia	61,896

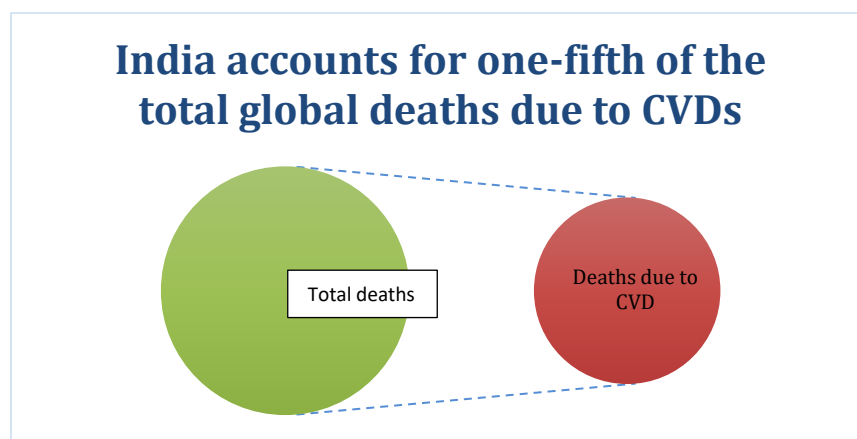
Source: Facts, Concerns, and Options Regarding India's Ageing Population

The most important factor to consider a person's cardiovascular health is by the age of the person. By 2030, approximately, 20% of the global population will be 65 years old and above and about 40% of them will be at a risk of developing cardiovascular diseases and death due to the same. The heart is significantly impacted by ageing, which increases the risk of cardiovascular disorders such as hypertension, myocardial infarction, atherosclerosis, and stroke. Numerous pathologic changes, including as hypertrophy, altered left ventricular diastolic function, and decreased LV systolic reverse capacity, are indicative of ageing heart tissues.

- Cardiovascular disease burden in India

In India, cardiovascular disorders are the main cause of mortality. They account for more than 17.7 million deaths annually and India's deaths contribute to one fifth of it. According to the findings of the global burden of disease research, India has an age-standardised CVD mortality rate of roughly 272 per 100,000 people, which is much higher than the global average of 235. as India's population is growing so are the non-communicable diseases (NCDS). Cardiovascular diseases are the non-communicable diseases and increase with age. According to reports, India possesses one of the highest rates of cardiovascular disease worldwide.

Fig 7: Showing total number of deaths out of which one fifth is due to CVD in India.



Graph 5: Indian burden of CVD

The annual number of deaths as a result of CVD has elevated to 4.7 million in 2020 from 2.26 million in the 90's. (20) coronary heart diseases have shown a drastic increase in number in both rural and urban fronts. The incidence in rural India, the prevalence of

heart disease has climbed from 1.6% to 7.4%, whereas it has increased from 1% to 13.2% in urban areas. India may pay a high price in the years to come in terms of years of healthy working life than any other country due to fatalities from cardiovascular diseases. Out of all the deaths that occur in India, 60% are due to Non communicable diseases and 43.4% is accounted for deaths by CVD. Comparing mortality from 1990 to 2016, cardiovascular disorders in India were responsible for 28% of all fatalities and 14% of all disability-adjusted life years (DALYS). Acute coronary syndrome and ST elevation myocardial infarction are now most common in India. Asian Indians appear to have greater rates of death from cardiovascular illnesses population by 20-50% which is remarkably higher than of the other population worldwide.

- Risk elements connected to cardiovascular diseases.

Common risk factors include obesity, smoking, diabetes mellitus, hypertension, and linked with the increase in cardiovascular diseases in India. in a cross-sectional study conducted in 2002, revealed that The risk factors for cardiovascular disease with the highest frequency were hypertension (36%), cigarette use (23%), obesity (63%), hypercholesterolemia (39%) and diabetes mellitus– 12.2% leading to CVD.

Table 3: Risk factors contributing to cardiovascular diseases.

Diabetes Mellitus	12%
HTN	36%
High cholesterol	39%
Tobacco	23%
Obesity	63%

When it comes to tobacco usage, it has been observed that the prevalence of current tobacco usage in males in India i.e., 23.6% have found to be higher than the global prevalence that is of 22%. Tobacco usage remains one of the modifiable and reversible risk factors that attributes to cardiovascular diseases. In India, one of every 10 people have a raised level of blood glucose. India accounted for 73+ million cases of diabetes worldwide in 2017 which has been the highest in the world so far. According to WHO,

there are above 77 million people in India who are diabetic and 25 million are prediabetics. Adults with diabetes are two to three folds at risk of heart attacks and strokes. the increase in sedentary lifestyles, urbanisation, globalisation, unhealthy diets, overweight and obesity has been linked to increase in diabetes. one in every four individuals, India's blood pressure has grown levels and accounts for 10.8% deaths in India. This load is anticipated to increase twice Approximately 213.5 million by 2025, up from 118 million in 2000. According to estimates, 16% of the cardiovascular diseases and 29% of strokes are caused due to hypertension. Urban Indians have a higher body mass index (BMI) than that of rural Indians and Obesity in the abdomen area is concerning. Asian adults with BMI over 21kg/m were associated with developing diabetes, ischemic heart disease, stroke and cancers. dietary habits and exercise contribute to the cardiovascular diseases as the diet of an average Indian contains more carbohydrates, fats like milk and ghee their regular meals. Because of their reliance on coconut oil, Keralans have India's highest rates of cardiovascular disease. In India, less than 10% of the population is physically active every day, and every second individual is inactive, according to the ICMR INDIAB survey.

- Awareness in the Indian population regarding cardiovascular diseases

As cardiovascular diseases remain of all the factors, as the leading killer globally, it becomes an important public health concern. it is 80% of the entire burden of CVD is thought to be preventable. Prevention can be defined- the actions performed to obliterate, destroy, and lessen the effects of an illness. WHO noted that cardiovascular diseases have no boundary, and it is also a major problem in not only developing countries but also in developed countries. some individuals are a greater risk of developing CVDs and the factors that are linked to an increase in the cardiovascular diseases are family history, age, sex, smoking, alcohol, abnormal lipid profiles, high blood pressure, physical inactivity and obesity in a study conducted the awareness regarding the risk factors that are associated with cardiovascular diseases among the adult population. The study concluded that half of the participants were fairly aware of the cardiovascular risk factors. Smoking, alcohol consumption, high blood pressure, obesity and hyperlipidaemia. Majority of the individuals were unaware of the association of the risk factors such as age and family history with cardiovascular diseases. Only a few participants knew that male diabetics

area higher risk of developing it. In another stud. 76.2% Participants claimed that heart attacks are caused by stress. Heart attacks are ascribed to diabetes, high cholesterol, and hypertension by 47%, 32.9%, and 35.6% of people, respectively. According to the research conducted, there was There a lack of knowledge about cardiovascular risk factors among all myocardial infarction patients' families. a survey conducted by the Cleveland clinic in 2022 on Indian public awareness on the risk factors of cardiovascular diseases states that only 43% Indians identified obesity as a risk factor. 28% was given to sedentary lifestyle, 51% to smoking and vaping, 58% to stress, 55% to high blood pressure, 38% to no physical exercise and 14% to poor dental hygiene. The survey showed that there is need of awareness in the Indian population regarding the cardiovascular diseases and risk factors. only one in four Indians is aware of stroke and its risk factors as said by the national survey. 77% of Indians were not aware of the risk factors associated with stroke. This shows the poor level of awareness amongst Indians.

- Government initiatives and policies for medical devices industry

Government has taken many initiatives to encourage the medical device industry in the country. The Production Linked Incentive Scheme (PLI) for promoting domestic manufacturing gives a financial boost to substantial investments in local manufacturing and medical device sectors including cancer care, radiology, and imaging etc. the scheme is set to create global champions out of India and boost the Make in India, make for the world mandate. Another initiative that is taken by the government is the promotion of the medical device's amusement parks. This initiative aims to strengthen the infrastructure and develop a base for the manufacture of medical devices in India. It will help to promote an ecosystem for the medical devices in the domestic market. The cost of manufacturing will reduce with this step and lead to better accessibility and affordability. The amusement parks made in India will also help to smoothen the supply chain and help with better fulfilling of demands. his program's overall financial cost is Rs. 400 crore, and the programme is valid till the year 2025. The amusement parks will be made in Uttar Pradesh, Himachal Pradesh, Tamil Nadu and Madhya Pradesh. Under the scheme, the central and state government will partner to develop the medical parks for better development and performance of the sector. the National medical device policy, 2023 was approved in April 2023. It is a scheme that is brought in to facilitate access,

affordability, quality and innovation. The policy is made to extend the vision of making the medical device sector of India reach from 11 billion to 50 billion by the year 2025 and achieve 10-12% of the share in the total global market share. This policy creates a road map for quality improvement of medical devices to achieve quality standards, affordability, accessibility, security, research and innovation. Other strategies that have been adopted to facilitate guidance in the medical device sector are regulatory streamlining which will involve the single window clearance system for licensing of medical devices. An enabling infrastructure for the medical device's amusement parks. Facilitation of R&D and innovation in the MedTech sector of India aiming at developing MedTech hub and centres for better growth. Attracting private partnerships and investments through the private firms, collaborations and public private partnerships (PPP) Lastly, creating awareness and brand positioning is also one of the schemes thought of by the government which will be dealing with various market issues.

- Collaborations, partnerships and emerging technologies in the cardiovascular medical device market

The Indian market for cardiovascular devices is anticipated to expand at the rate of 5% from the year from 2022 until 2030. Given that cardiovascular disorders are one of the top causes of mortality in India, both the public and private sectors appear to be lacking in the necessary infrastructure and competence. A few of the collaborations in the cardiovascular device industry are a memorandum of understanding between IIT Guwahati and through research and digitalization, Sri Sathya Sai Heart Hospital in Ahmedabad hopes to progress the field of cardiac care, particularly in India's paediatric cardiac care sector. Mayo Clinic and Max Healthcare formed a cooperation. In this partnership, Max healthcare will try to utilise the education, research programs and expertise in clinical sector for better treatment outcomes for cardiovascular health in India. Another partnership recently observed was with Tricog health services and four Governments of the various states and healthcare organisations like Redcliffe Labs, Max Healthcare, Apollo Hospitals, Fortis, Manipal Hospitals, and Apollo Hospitals. This initiative will help millions of people with remote cardiac solutions. Wipro GE healthcare has partnered providing end-to-end revolutionary interventional cardiac care solutions in partnership with Boston Scientific. GE healthcare as a strong imaging system such as the

catheterization labs, related software and support diagnostics for the cardiac unit. This collaboration will help in decreasing the disease burden of the country by availing easier access to the public. remote cardiac monitoring devices are gaining popularity as it is an easy and conventional way of monitoring patient's heart activities. Such a partnership enabling the remote monitoring took place when AliveCor introduced a personal ECG machine, KardiaMobile 6L. owing to accessibility challenges due to the pandemic, the portable technology-based device proves to be helpful for cardiac patients. It was estimated that it will be able to help over 260 million of heart patients without visiting the hospital. It is a device that can detect the three most common arrhythmias in the heart. The device gives a facility of generating an ECG within 30 seconds. Medtronic India in 2021 launched the Arctic front cardiac cryoablation catheter system which was approved by the CDCSO for the treatment of atrial defibrillation in India. Siemens healthineers launched corindus Corpath GRX robotic system for coronary and peripheral vascular interventions in India.

- Healthcare providers and medical infrastructure in India

A 2011 study conducted stated that India has roughly 20,000 health care workers for 10,000 people. The allopathic doctors comprised of 31% of the workforce, 30% are both nurses and midwives, 11% were pharmacists, 9% comprised of Ayush practitioners and 9% were others. In India's rural statistics for 2015, there are roughly 10.4% unfilled auxiliary midwife positions, 27% of doctor's posts are vacant in the PHCs. the number of qualified doctors is not sufficient for the Indian healthcare systems as the requirements are increasing.

Below is the table that summaries the data and numbers of the Healthcare providers and medical infrastructure of India in comparison with four other countries.

Table 4: Indicators of countries in comparison with India

Countries	Population (million)	Doctors (per 1000)	Nurses (per 1000)	No. of Cardiologists	Hosp Beds (per 1000)	Total Hospitals
U. S	336.6	2.6	15.7	14,415	2.9	13,944
Japan	125.3	2.5	11.9	14,529	1.3	8200
Australia	26.3	4.1	13.1	1600	3.8	1354
Germany	84.3	4.4	14.2	3293	8	1887
India	141.9	0.7	1.7	5500	0.5	69,000

Source: World Bank 2018

The table shows countries such as U.S, Japan, Australia, Germany in comparison with India. The data is taken from the world bank and government websites of the respective countries. The healthcare providers in the table included the number of doctors per 1000 population, number of nurses per 1000 population and total number cardiologists in the country. The medical infrastructure included the number of beds per 1000 population and the total number of hospitals in the country. With the above analysis, it is clearly seen that India has the largest number of populations among all the countries and the healthcare providers are at the lowest in comparison with other countries. This shows the shortage of healthcare providers in India. Along with that, the medical infrastructure shows the low number of beds and hospital facilities.

- Affordability

Affordability of the heart devices in India may be concerning. Among the various heart conditions, the most common one's coronary heart disease, stroke, rheumatic heart disease, and hypertension are all prevalent in India.

Private players are the dominant ones when it comes to the medical industry but the lack of regulations in the private sector and the costs and quality of services provided is also variable. The public medical sector is the first choice someone who cannot afford the private sector's expenses but due to the unreliability and indifferent quality of services, it turns out to a difficult choice to make even though the costing is quite low at public settings. The government expenditure increased from 2% to 5-6% which is a good initiative in terms of the health infrastructure, personal and services the country needs.

Cardiovascular treatment is expensive and below, an analysis of the costing of a cardiac care pathway of a patient along with pricing of the commonly used cardiovascular medical devices will be shown.

PCP Process	Costs (in Rs)	Average costs (in Rs)
Cardiologist Fee	1000-1500	1250
Cost of diagnostic tests		
Angiography	7000-20000	13500
Electrocardiogram	150-300	225
Holter monitoring ECG	2000	2000
Echocardiogram	2000-4000	3000
Stress test	1000-4500	2750
Cardiac MRI	8000-15000	11500
Medicine cost (avg 10 tablets)		
Blood thinners	30-40	35
Statins	35-350	192
Beta blockers	20-40	30
ACE Inhibitors	40-90	65
Calcium channel blockers	75-150	112.5
Diuretics	35-150	92.5
Medical procedures cost		
Angioplasty	2.5-4 lakh	325000
Dual Chamber Pacemaker	3 lakhs	300000
Bypass surgery	4-5 lakh	450000
Valve replacement	5-6 lakh	550000
Post surgery follow up cost		
Blood tests	1000	1000
Echocardiogram (annual)	2000-4000	3000

With the above given information, it can fairly be observed that the entire patient care pathway of a cardiac patient is expensive and medical procedures that involve

angioplasty, pacemakers, bypass surgery and valve replacements are expensive procedures. Some of the most used cardiovascular medical devices in India and their pricing is listed below.

Table 5: Prices of cardiovascular devices in Indian market

Cardiovascular Device	Costs (in Rs)
Balloon Valvopathy Catheters	15,000-30,000
Catheters used in Ablation Procedures	15,000-75,000
Pacemakers	60,000-1,00,000
Defibrillators	2,00,000-5,00,000
Bi ventricular Pacemakers	2,50,000-7,00,000

Source: Indian guidelines for the reuse of cardiovascular catheters and devices

The Indian population is divided into four categories based on their annual income. The four segments include the lower middle class, lower middle class, upper middle class, and high class. Based on these income groups, an analysis will be done where the average income of all the groups in India will be compared with the costing of the most used cardiovascular devices in India.

Table 6: Population distribution in India based on Income groups

Population segment	Average annual Income (in Rs)
High Income	>30lakhs
Upper middle income	5-30 Lakhs
Lower middle income	1.25-5 Lakhs
Low income	1.25 Lakhs
Poor (BPL)	27,000

Source: People Research on People Indian Economy (PRICE)

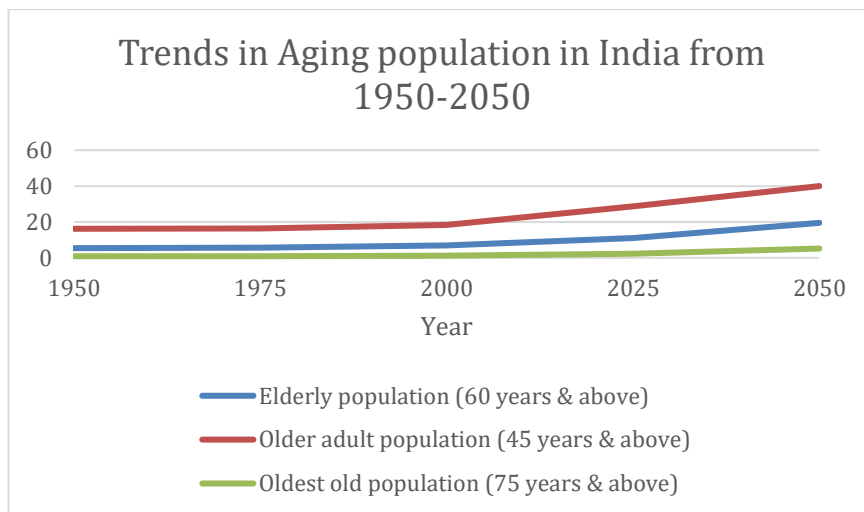
The poor and low-income groups comprise of 50% of the total population distribution, the upper middle and lower middle-income groups constitute 40% and the high-income group is of 10%.

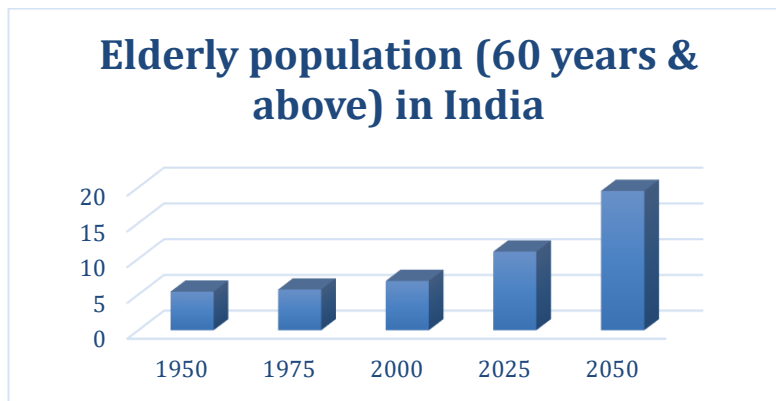
Most of the share of the income distribution is consists of the poor and low-income groups. The affordability is a matter of concern as most of the cardiovascular devices are expensive and not easy to afford by the 50% of the country's population. The average price of a pacemaker in India Rs 80,000. Now, that is a concern for a person who is below the poverty line and earning only Rs 27,000 per year. The economic condition of the country does affect the cardiovascular medical device segment.

CHAPTER 5 – RESULT

The above analysis of various parameters gives us information on the opportunities and challenges that are faced by the cardiovascular device industry. The various parameters that were analysed through secondary data are: the ageing population in India, the growing disease burden of cardiovascular diseases, the risks factors leading to cardiovascular diseases, awareness among the public regarding the cardiovascular diseases, government initiatives and policies in the industry, industry collaborations, partnerships and emerging new technologies in the cardiovascular industry, medical infrastructure, healthcare providers and affordability of the cardiovascular treatments and devices by the Indian public. All the parameters will be covered one by one in the study ahead.

1. Aging population of India

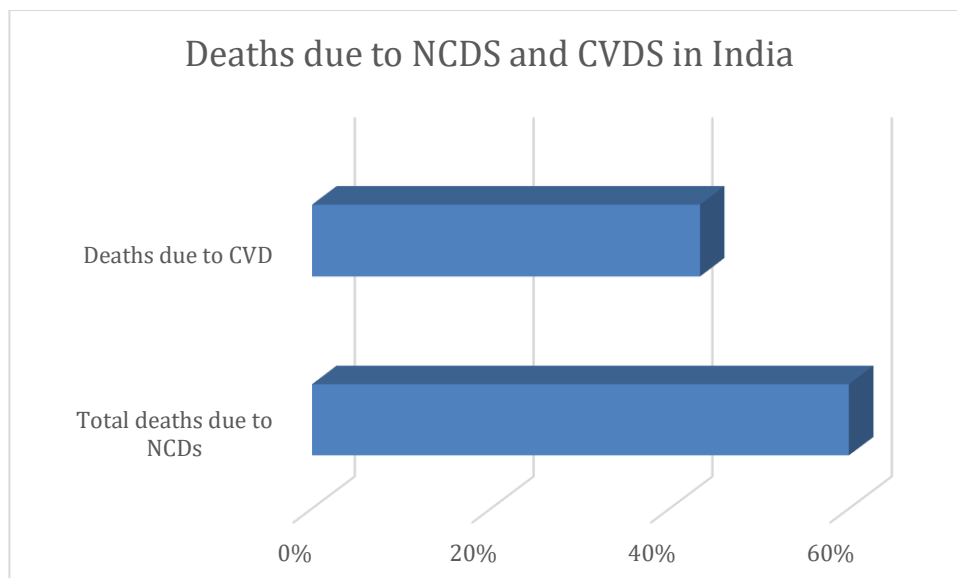




Graph 6 and 7: showing increasing aging trends in India

- As seen from the data from the Longitudinal Aging Study of India, it is clearly stated that the aging population is increasing in India. The increase in individuals of the age 60 years and above is exponentially doubling with 19.5% till the year 2050.
- With the increase in the aging population, the increase in cardiovascular diseases will also be prevalent as aging changes the heart vasculature and makes it more prone to cardiovascular diseases.

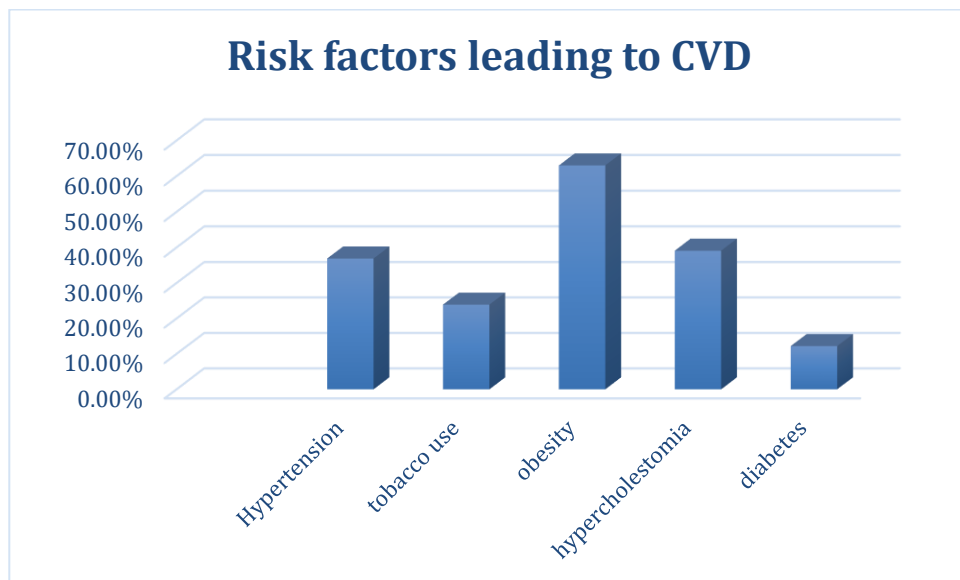
2. Cardiovascular disease burden in India



Graph 8: showing the NCDS and CVDS deaths in India

- India contributes to one-fifth of the total deaths due to cardiovascular diseases in the world.
- Out of the total deaths non-communicable diseases (NCDs) make about 60% of all illnesses in India. Among the 60% fatalities, 43% of deaths are due to cardiovascular diseases. These figures show that the cardiovascular disease burden is of great significance in India.
- There has been a significant spike in the number of deaths because of cardiovascular diseases from 1990 to 2020. The deaths due to cardiovascular diseases have been observed more in the urban settings than rural.

3. Risk factors associated with cardiovascular diseases.

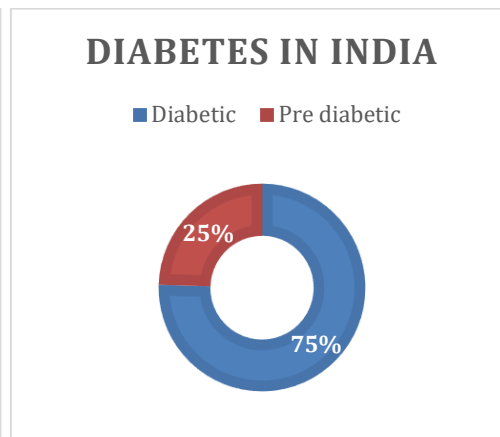


Graph 9: showing the risk factors leading to cardiovascular diseases

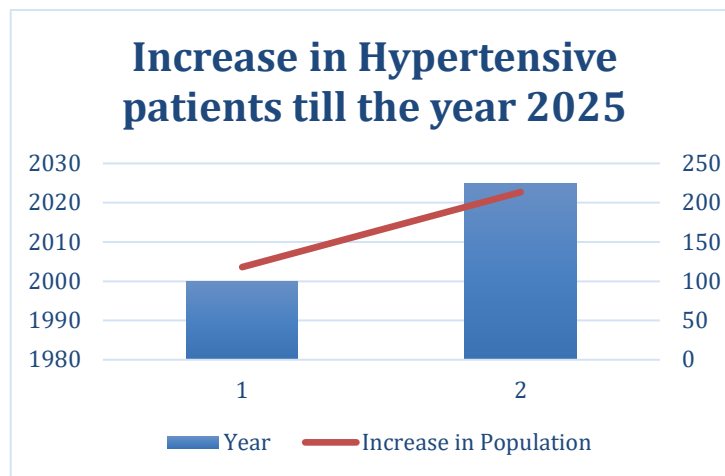
- Hypertension, Tobacco use, Obesity, Hypercholesterolemia and diabetes were identified as the major risk factors that lead to cardiovascular diseases in India. With Obesity being at the top as the largest risk factor.



Graph 10



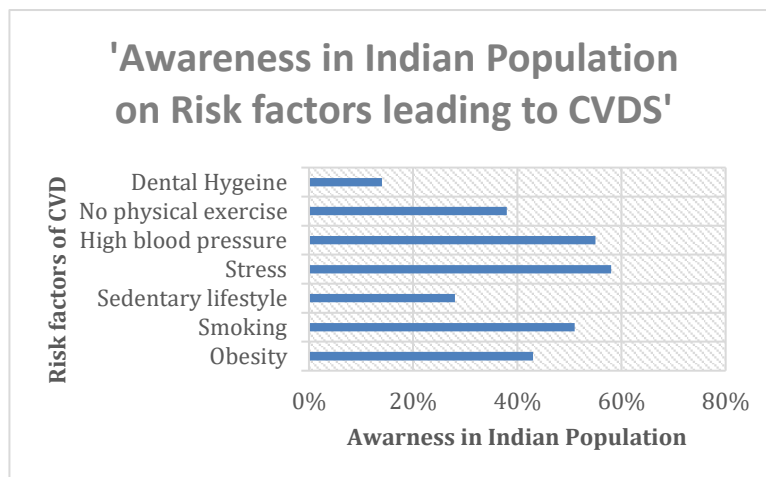
Graph 11



Graph 10, 11 and 12: showing the increasing trends in tobacco usage, diabetic population and Hypertension.

- With tobacco usage being at 23.6% in India, it surpasses the global usage which is at 22% which shows that tobacco usage is very prevalent in India.
- The population affected with diabetes in India is at 77 million while the prediabetics are at 25 million.
- Hypertension in India is increasing at an alarming rate with an increase in the hypertensive individuals at 213.5 million by the year 2025.
- India only has 10% of the population physically active regularly.

4. Awareness in the Indian population of cardiovascular diseases



Graph 13: showing the awareness in Indian population on CVD

- Only 51% of Indians identified smoking as a risk factor to cardiovascular diseases.
- Only 58% and 55% of Indians identified stress and hypertension respectively as risk factors.
- 43% identified stress and 28% identified sedentary lifestyle as a risk factors.
- Only 38% Indians identified not exercising as a risk factor.

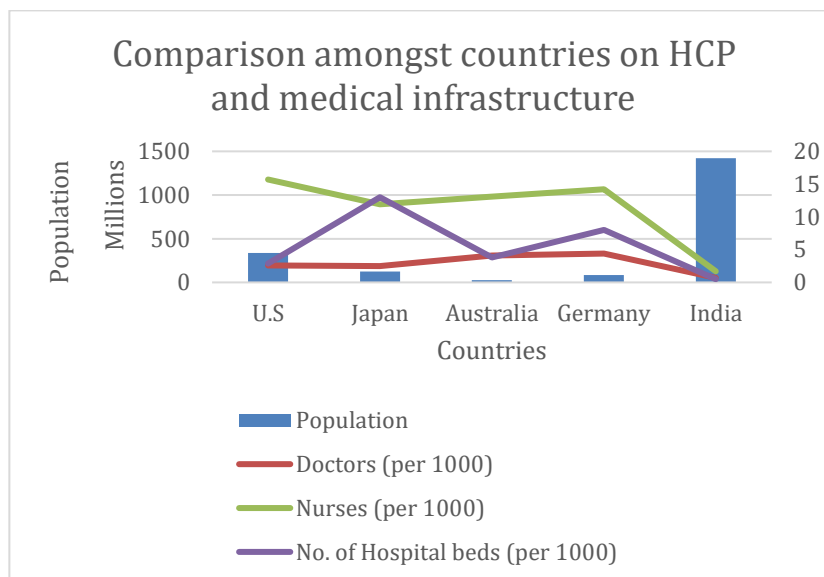
5. Government initiatives and policies

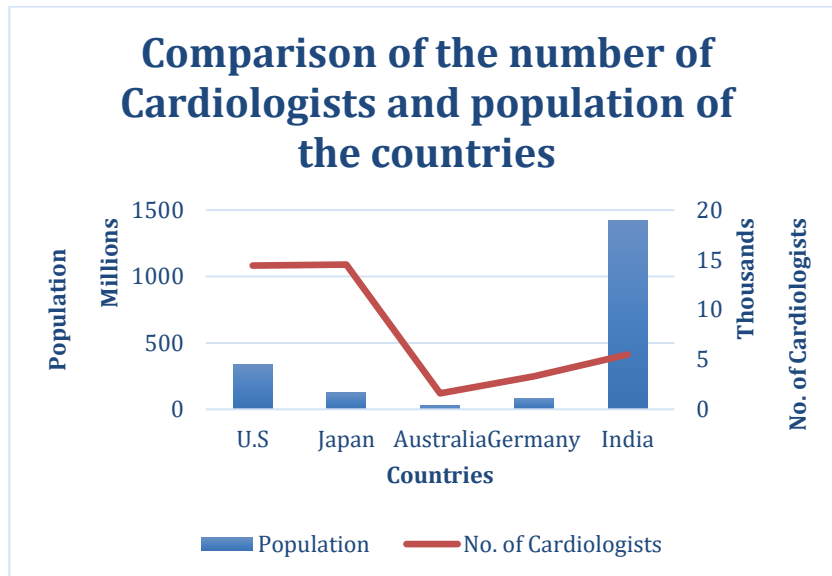
- Government of India launched the Production Linked Incentive Scheme (PLI) for promoting domestic manufacturing gives a financial boost to domestic manufacturing. Another initiative that is taken by the government is the promotion of the medical device's amusement parks.
- The National medical device policy, 2023 was approved in April 2023 and it is a scheme that is brought in to facilitate access, affordability, quality and innovation.

6. Collaborations, partnerships and emerging technologies

- A memorandum of understanding between IIT Guwahati and Ahmedabad's Sri Sathya Sai Heart Hospital will improve in the field of cardiac treatment.
- Max healthcare made a partnership with Mayo clinic for cardiac health care.
- Partnership with Tricog health services and Four state governments as well as healthcare organisations including Redcliffe Labs, Max Healthcare, Apollo Hospitals, Fortis, Manipal Hospitals, and Apollo Hospitals. This initiative will help millions of people with remote cardiac solutions.
- Wipro GE healthcare has partnered with Boston Scientific to offer complete, cutting-edge solutions for interventional cardiac care.
- Partnership enabling the remote monitoring took place when AliveCor introduced a personal ECG machine, Kardiamobile 6L.
- Medtronic India in 2021 launched the Arctic front cardiac cryoablation catheter system which was approved by the CDCSO for the treatment of atrial defibrillation in India.
- Siemens healthineers launched corindus Corpath GRX robotic system for coronary and peripheral vascular interventions in India.

7. Healthcare providers and medical infrastructure

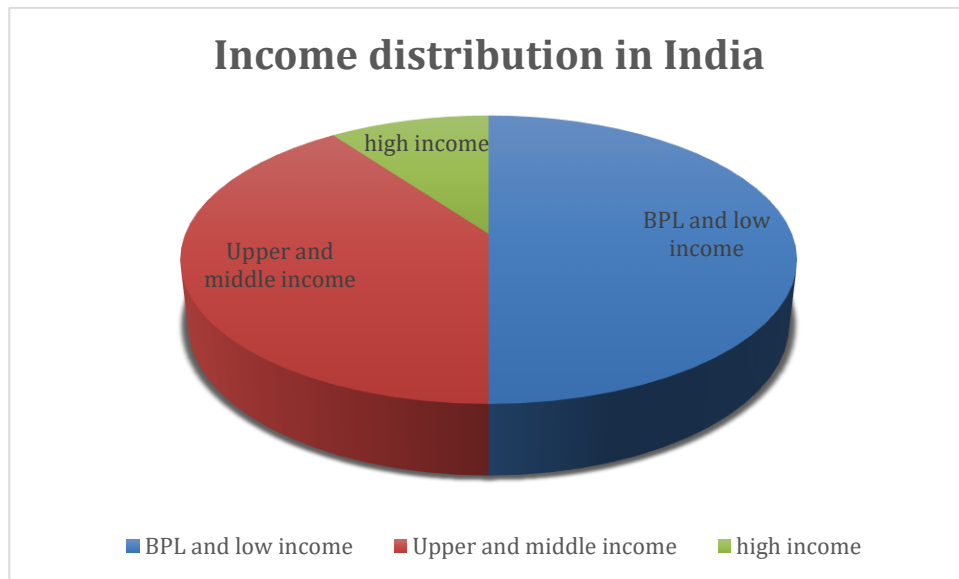




Graph 14 and 15: showing the number of health care providers and medical infrastructure in India

- A comparison was made between India and other countries such as U.S, Japan, Australia and Germany.
- The results showed that in comparison to the population that India has, the number of Hospital beds were significantly less which was found at 0.5% per 1,000 people.
- The quantity of physicians and nurses who represent the healthcare providers was also significantly less than other countries which were found at 0.7 per 1000 and 1.7 per 1000 population.
- The number of cardiologists were more in number compared to the other countries yet for a population like India, they were less.
- In total India has 5,500 cardiologists.

8. Affordability



Graph 16: showing the income distribution in India

- The population is divided into the income groups such as the high-income groups that have an income of >30 lakhs, upper- and middle-income groups that have an income of 5 to 30 lakhs and 1.25 to 5 lakh respectively. The lower income group has an income of 1.25 lakh per annum and the below the poverty line earns only Rs 27,000.
- The BPL and lower income groups constitute 50% of the total earning groups whereas the upper and middle groups make up 40% and the high-income groups are only 10% in India.
- Cardiovascular devices such as pacemakers, stents, defibrillators, catheters that are commonly used for treating cardiovascular conditions are at the prices mentioned below.

Cardiovascular Device	Costs (in Rs)
Balloon Valvopathy Catheters	15,000-30,000
Catheters used in Ablation Procedures	15,000-75,000
Pacemakers	60,000-1,00,000
Defibrillators	2,00,000-5,00,000
Bi ventricular Pacemakers	2,50,000-7,00,000

- Individuals under the BPL and low-income groups will not be able to afford these devices at these prices. And this group consist of 50% of the total population, affordability remains a concern.

CHAPTER 6 – DISCUSSION

India's medical device market has a lot of promise. India now has a \$12 billion market share for medical devices, and by 2025, that market share is anticipated to increase to \$50 billion, with the CAGR of 33%. India is among the top 20 countries worldwide in the medical device industry. Currently India imports 86% of the total devices and the local players are not many. The export sector is expected to show growth in the coming years of 51% and the key exporters will be countries like U.S, Germany, China, Brazil. The Indian cardiovascular medical device CAGR for the market is predicted to be 6.6%. The CDCSO has witnessed that the maximum number of foreign patents have been filed for the cardiology devices in India. The cardiovascular medical device industry has its own opportunities and challenges in India. Some of the opportunities that this study aimed to identify were the aging population of India, the cardiovascular disease burden, increase in risk factors leading to CVD, the new government support policies and initiatives, collaborations, partnerships and emerging technologies in the industry. Few of the challenges identified in the cardiovascular medical device industry were low awareness level of the Indian population regarding the cardiovascular diseases and their risk factors, shortage of health care providers such as the doctors, nurses and cardiologists in India, the medical infrastructure not being fully adequate such as the number of beds in the hospitals and affordability issues.

The cardiovascular industry is surely going to reach heights in the coming future looking at the figures, but a few challenges also need to be addressed. The opportunities will enable the growth of this sector. The aging population of India is showing an upward trend. It is estimated that the aging population of India will see a rise of 19%, the proportion of seniors (those 60 years and older) will reach 319 million by the year 2050. The most important factor to consider is the age in a person when it comes to cardiovascular health. Aging has a significant impact on the heart vascular function that leads to hypertension, myocardial infarction and stroke. Cardiovascular diseases burden in India is said to be the highest and the leading cause of deaths. The cardiovascular diseases account for more than 17.7 million deaths annually and India contributes to one fifth of the total deaths in the world due to cardiovascular diseases. With the yearly

frequency of CVDs rising in India, the burden has kept on increasing. The incidence is on a rise in both rural and urban setting so of India. The prevalence of acute coronary syndrome and myocardial infarction is greatest in India. With such an increasing burden of the cardiovascular diseases in India, it acts as an opportunity for the cardiovascular medical device industry for future growth. The rise of the risk factors associated with cardiovascular disease shows an upward trend in India. Risk factors such as hypertension, tobacco usage, sedentary lifestyle, obesity, diabetes and hypercholesterolemia are leading to cardiovascular diseases. Tobacco usage is one of the highest in India and it remains as the most modifiable risk factor. India has plenty of diabetic and prediabetic individuals and it is shown that adults who are diabetic have a two- to three-fold higher risk of cardiovascular disease development. One in every four individuals in India, an increased level of blood pressure is seen which accounts for 10% of deaths in India. The prevalence of hypertension in India is alarmingly rising, which is contributing to an increase in strokes. A higher BMI is connected to the emergence of cardiovascular conditions like ischemic heart disease and stroke. Government is taking a lot of initiatives in the sector of medical devices. Few policies have also been introduced. The Production Linked Scheme (PLI) is for the promotion of domestic products and manufacturers so that a financial boost can be provided, and large investments can be attracted. Make in India, make in the world mandate has been popularised and is being taken forward the medical device industry as well. Amusement parks for the medical devices are also being introduced in states such as Madhya Pradesh, Tamil Nadu, Himachal Pradesh, and Uttar Pradesh. These amusement parks will enable strengthening of the infrastructure and will also develop a base for medical devices in India. Since majority of the products are imported, the accessibility and affordability is will also increase with these government initiatives for the people in India. Various collaborations and partnerships in the cardiovascular medical device industry are seen as the private front is more dominant in this industry. Collaborations between big chain hospitals and foreign companies are taking place to make cardiac care better in India in terms of research and treatment outcomes. Innovative interventional cardiac care solutions and strong imaging systems such as catheterisation labs and software are being brought into India through these partnerships which will eventually help the industry to flourish more. Along with all these opportunities, the cardiovascular medical device industry has a fair share of its challenges

as well. The awareness of the Indian population related to cardiovascular diseases was less. Very few Indians knew about the risk factors that lead to cardiovascular diseases. Other risk factors include stress, a sedentary lifestyle, and physical inactivity. Risk factors including smoking, hypertension, and obesity have also been discovered were known to few individuals. One of the biggest challenges in India is faced on the health care providers and medical infrastructure front. When compared to other countries, India stands far below when it comes to the manpower of the medical industry. The shortage leads to less expertise and manpower inadequacy. The doctors and nurse's ratio stands far below per 1000 population India compared to other countries. The number of cardiologists and in specific interventional cardiologists also stands short of the required. With the population like our country, the medical manpower is on the lower side. The number of beds per 1000 population also seems to be lower than the required standards. Another challenge faced by the cardiovascular device industry is the affordability. India is a country with varying income groups. It is divided in groups such as the below the poverty, low income, upper and lower middle income and high-income groups. The below the poverty and low-income groups form most of the distribution in the population. The income being so low of these groups shows that the average costing of a medical device e.g., a pacemaker at Rs 60,000 to 1 lakh cannot be affordable to most of the population. Other commonly used cardiovascular medical products such as stents, catheters, defibrillators are also at the prices that are non-affordable to most of the households in the country. The high income and upper and lower middle-income groups will be able to afford the devices. Affordability stands as a challenge in this sector, and this is mainly due to the imported devices. The prices at which most of the medical device products are sold need to be lowered for these income groups to be able to afford them. The market share of cardiovascular medical devices is both opportunities and challenges and their impact on the future growth of the industry.

CHAPTER 7 – CONCLUSION

The medical device business is expanding quickly, and during the past few years, it has exhibited expansion in India. According to predictions, the medical device industry will develop more rapidly in the next years due to technological improvements. The medical device business, which includes the cardiovascular medical device sector, is an important and integral part when it comes to India. The market growth shows an increase and expansion of this segment in the coming future. India's market for cardiovascular medical devices offers unique potential and difficulties. Some of the most important opportunities that this study could identify were, the aging population of India which showed that the number of older adults (60 years and above) are increasing exponentially in India which provides with an opportunity to this industry as with the increasing age, the heart vasculature tends to deteriorate causing cardiovascular diseases. Another opportunity identified was the increasing burden of cardiovascular diseases in India. Currently, India accounts for a vast number of deaths due to CVD globally. One fifth of the deaths that occur worldwide, are in India. Annually, many people die from cardiovascular diseases like coronary artery disease and stroke in India. The increasing burden acts as an opportunity for the cardiovascular medical device industry. The prevalence of risk factors including smoking, being sedentary, being overweight, having high blood pressure, diabetes, and hypercholesterolemia is a major influence to the increase of cardiovascular diseases in India. Hypertension and diabetes are posing a great risk to growth of these diseases and acting as major threats to the individuals predisposed to them. The increase in the risk factors on a day-to-day basis is increasing the number of cardiovascular diseases. The government of India is also taking many initiatives and implementing several policies for the industry. A lot of them are focusing mainly on building the foundation for local manufacturing as most of the cardiovascular devices are imported and that causes a concern when it comes to affordability and accessibility to the patients. Many collaborations and partnerships along with emerging technologies are also taking up which is enabling a better and more patient centric cardiac care approach. These partnerships are helping India gather more information, use more of research tools and technologies to bring advancements in the cardiac care. Along with the opportunities are the challenges that were identified and analysed. Few of the major challenges were the

awareness level in the Indian public regarding the cardiovascular diseases and their risk factors. Very few Indians were aware of the various risk factors that are related to cardiovascular diseases. Only one in four individuals knew about stroke and very few knew about the risk factors associated with it. Another challenge is the shortage of health care providers in India. There are very few doctors and nurses per 1000 population in India. The manpower shortage will lead to a challenge in the cardiovascular medical device industry as experts will not be available to use the products on patients. The number of cardiologists is also less than compared to the requirements of the country. The medical infrastructure also seems inadequate with the ratio of beds to 1,000 people. The figure is below the accepted standards and will lead to a challenge in the future. Lastly, the challenge that was identified was affordability. The Indian population is divided into income groups. The lower income groups and the below the poverty line individuals are not able to afford medical devices such as pacemakers, stents and cardiac catheters. Their annual income does not let them avail these products, let alone the process of the procedure and hospital expenses. Affordability will remain a challenge for the low-income groups in this sector.

With all the opportunities and challenges identified in this study, it can be said that the opportunities will pave the road for the cardiovascular industry in India in the coming few years, but the challenges also need to be addressed to gain the maximum and full potential of this industry in the future.

CHAPTER 8 - REFERENCES

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